Wound failure in laparotomy: new insights

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Wound Failure in Laparotomy: New insights

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Wondfalen van de laparotomie: nieuwe inzichten

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Chapter 1

Introduction and outline of the thesis

Wound failure is a common complication of abdominal surgery. Its clinical presentation can vary from superficial wound dehiscence to burst abdomen with intraabdominal organs protruding through the wound. In long term, incisional hernia can be considered a representation of abdominal wound failure.

The abdominal wall

The abdomen is the space between the diaphragm and the pelvic musculature. Abdominal organs are retained within the abdominal space and protected from external trauma by the abdominal wall. The abdominal wall consists of various tissue layers. Solidity of the abdominal wall is partly based on the different muscle fibre directions. The rectus abdominis muscle (or 'straight muscle') consists of two vertical parts, separated by the linea alba, this is a layer of connective tissue. Function includes bending of the thorax and lifting of the pelvis. The transverse abdominis muscles (or 'horizontal muscles') have horizontally directed muscle fibers and are located laterally to the rectus abdominis muscles. These muscles are separated from the internal organs by the posterior rectus fascia, the fascia transversalis and the peritoneum. The posterior rectus fascia only extends to the semicircular line of Douglas caudally. The transverse abdominis muscles are covered by the internal oblique abdominal muscles and the external oblique abdominal muscles, which can pull the ribs downwards, and bend and rotate the vertebral column. Finally, the abdominal muscles are covered by subcutaneous fat tissue and skin.

In case of incisional hernia, a defect in the fascia exists through which abdominal contents (eg, intestines or omentum), covered by peritoneum, can protrude. The skin however, generally remains intact and a swelling may be noticed especially in case of raised intraabdominal pressure, for instance during coughing, sneezing, or straining of the abdominal wall. In case of burst abdomen, an acute herniation presents at the level of the fascia in an earlier phase of the postoperative period. As the skin and subcutaneous tissue may not yet have healed, the abdominal wall defect could allow for evisceration to occur, ie, presence of abdominal contents outside the intraabdominal space.

Risk factors for burst abdomen

The incidence of burst abdomen in most recent studiese varies between 0.2-3.5%.[1-6] Several studies have been performed to identify risk factors for this complication, but in only a minority of studies multivariate analyses were used.[7-13]

Patient related risk factors

Most frequently identified patient related risk factors include age [9, 11, 12, 14-18], malignancy [10, 12, 14], use of corticosteroids [11-15], chronic obstructive pulmonary disease [7, 12, 19, 20], sepsis or systemic infection [7, 10, 12, 15, 17], uremia [12, 14], hypoalbuminemia or hypoproteinemia [10, 12, 14, 15, 17, 19, 21, 22], anemia [10, 18, 19, 22, 23], ascites [12, 15], gender [9, 10, 16, 18, 24], jaundice.[10] Smoking has been investigated by Abbas et al, who found a significant association between smoking and burst abdomen in a case-control study which included 52 patients with burst abdomen and 104 control patients.[25] These results were not confirmed in a retrospective case-control study performed by Kenig et al. [13] Against common belief, neither diabetes mellitus or obesity have been identified as risk factors for burst abdomen in the vast majority of studies.[7, 8, 11-15, 19]

Operation related risk factors

Emergency surgery has been stated a risk factor by many authors [7-9, 14, 15, 17, 19, 26], as well as hemodynamic instability [8, 12, 15], indication for surgery [14, 16], degree of wound contamination [7, 18, 24], and operating time. [7, 22]

Postoperative period risk factors

Wound infection has been identified as a risk factor for burst abdomen by most authors. [7-10, 12, 13, 15, 17, 18, 21, 22, 27] Nausea or vomiting, abdominal distension, prolonged postoperative ileus, increased intraabdominal pressure, increased coughing, pneumonia, and wound hematoma were identified as risk factors for burst abdomen in a few studies. [7, 14, 17, 19, 21, 22]

Surgical risk factors

Type of incision

Various authors have attempted to investigate whether the type of incision is a risk factor for burst abdomen. (Table 1)

Table 1: Studies in which type of incision was investigated as risk factor for incidence of burst abdomen

Author	Year	Level of evidence	Trans-verse	Median	Upper median	Lower median	Gridiron/ oblique	Para-median	Lateral paramedian	Sub-costal
Brown[28]	2005	1a	X	X[1]						
Gislason[9]	1995	1b	X	X						
García-Valdecasas[29]	1988	1b		X						X
Ellis[30b]	1984	1b		X				X		
Ellis[30b]	1984	1b	X					X		
Grantcharov[31]	2001	2[a]	X	X*						
Seiler[32]	2009	1b	X	X						
Inaba[33]	2004	1b	X		X					
Proske[34]	2005	1b	X	X						
Cox[35]	1986	2b		X					X	
Armstrong[10]	1984	2b	X	X				X		X
Richards[36]	1983	2b		X	X		X			
Stone[37b]	1983	2b	X	X						
Greenall[38]	1980	2b	X	X						
Irvin[39]	1978	2b		X				X		X
Halasz[40]	1968	2b	X	X*				X		
Hendrix[41]	2000	3b	X			X				
Waldhausen[17]	2000	4	X	X*						
Cöl[21]	1998	4		X	X	X		X		X
Mäkela[19]	1995	4			X	X				
Riou[12]	1992	4	X	X						X
Stone[37b]	1983	4	X	X						
Keill[18]	1973	4	X	X*				X*		
Campbell[a]	1972	4	X	X*			X			

*significant risk factor for burst abdomen

[a] Trend towards lower incidence was found (CDT 5.1 OR (fixed) 95% CI 0.55 [0.25-1.20]).

[b] multiple cohorts of patients displayed in multiple rows

The studies by Waldhausen and Campbell were performed in pediatric surgical patients.[1, 17] Although no randomized studies have been performed, pediatric surgeons generally prefer transverse incisions over median incisions.[1, 17] Riou et al and Gislason et al did not find a significant difference between transverse and median incisions.[9, 12] These authors were among the few authors who performed multivariate analyses, which increased the reliability of their results. Cöl et al investigated five types of (combinations of) incisions, but both the patient and control group consisted of only 40 patients each.[21] Richards et al and Greenall and all did not report which statistical methods were used for their analyses.[36, 38] Hendrix et al did not find a significant difference in occurrence of AWD between patients with lower vertical incisions and Pfannenstiel incisions for gynaecological surgery in a retrospective case-control study.[41]

From the previously mentioned studies could be concluded that the preference for a type of incision might be relevant if a choice is to be made between a transverse and a median incision. In theory, healing of median incisions could be considered more challenging than, eg, transverse incisions due to the anatomy of the abdominal wall. The transverse muscle fibers are oriented perpendicularly to median incisions and activation of these muscles results in increased tension at the site of the sutured tissue. Retraction of the abdominal muscles and fascia is a frequently observed phenomenon in open abdomen treatment, which eventually hinders tension free closure of the abdominal wall. Also, the vascular supply of the fibrous linea alba is assumed to be poor compared to abdominal muscles.[2]

The review by Burger et al also contained on overview of the type of incision as risk factor for incisional hernia formation including randomized and retrospective studies published before 2002.[2] Based on the high incidence of incisional hernia found for midline incisions, it was suggested that unilateral transverse incisions should be preferred for small unilateral operations, and that lateral paramedian incisions should be used for most major laparatomies. According to Burger et al, midline incisions should be reserved for emergency surgery and other procedures which require unlimited access to the abdominal cavity.[2]

The Cochrane Review by Brown et al, published in 2005 and updated in February 2011, included randomized controlled studies only.[28] Results from retrospective and prospective studies published from 2001 onwards with regard to type of incision as risk factor for incisional hernia are summarized in Table 2.

Table 2: Type of incision as risk factor for occurrence of incisional hernia

Author	Year	Level of evidence	Transverse	Median	Upper median	Pfannenstiel	Subcostal
Brown[28a]	2005	1a	X	X*			
Halm[42]	2009	1b	X		X*		
Seiler[32]	2009	1b	X	X			
Fassiadis[43]	2005	1b	X	X*			
Salonia[44]	2005	1b		X		X	
Inaba [33]	2004	1b	X		X		
García-Valdecasas[29]	1988	1b		X			X
Grantcharov[31]	2001	2a	X	X*			
Lee[45b]	2012	2b	X*	X*		X	
deSouza[46b]	2011	2b		X*		X	

[a] Systematic review updated Feb 2011
[b] study on type of hand-assistance and/or specimen extraction incision for laparoscopy vs laparotomy
* significant risk factor for incisional hernia

Halm et al published a multicenter trial in which 150 patients who underwent open cholecystectomy were randomized between transverse and midline incisions. This trial showed that a significant reduction of incisional hernia formation is possible (from 14.5% to 1.7%) by using transverse instead of midline incisions.[42] Further, both surgeons and patients have reported higher satisfaction with scar cosmesis with transverse incisions compared to median incisions.[42] In some trials no differences in incisional hernia rate were found between median and transverse incisions.[32, 38]

Although Pfannenstiel incisions were not associated with a lower incidence of AWD compared to lower midline incisions by Hendrix et al, low rates of incisional hernia of up to 3.5% have been reported in other studies on patients with Pfannenstiel incisions.[41, 47] At a mean follow-up of 17.5 months, DeSouza et al found no incisional hernia formation in a series of 139 patients who received Pfannenstiel incisions for specimen extraction and/or hand-assistance for laparoscopic colorectal procedures.[46] Comparable results were found by Lee et al, with no incisional hernia formation in patients with Pfannenstiel incisions after a mean length of follow-up of 37 months.[45] In Pfannenstiel incisions, after incision of the rectus sheath and laterally through the fascias of the internal and external oblique and transverse abdominis muscles, the anterior fascia and linea alba can be separated in the midline from the pubic bone to umbilicus, with division of the posterior rectus fascia above the linea arcuata. Although uncommonly used, lateral paramedian incisions have also been associated with a low incidence of incisional hernia as well described in the aforementioned review by Burger et al.[2]

Type of suture material

Many types of suture material with different material properties are currently available. Most relevant properties include knot reliability, tensile strength, degree of tissue response and duration of absorbability. Wissing et al published a randomized multicenter trial in which four techniques were compared for closure of the fascia after midline laparotomy: interrupted closure with polyglactin, continuous closure with polydioxanone-s, and continuous closure with nylon.[48] The incidence of wound dehiscence in this trial was 2.3% without statistically significant differences between the four groups. At one year, a significant difference was found in the incidence of incisional hernia between nylon and continuous polyglactin (10.3% vs. 20.6%), comparisons with other techniques were not statistically significant.[48] A meta-analysis by Van 't Riet, in which fifteen studies with a total of 6566 patients were analysed, showed that closure of the abdominal wall with quickly absorbable suture material in a continuous fashion showed poorer results compared to slowly absorbable and non-absorbable suture materials. Non-absorbable

material resulted in more wound pain and wound sinus formation than slowly absorbable material.[49] Retention sutures have been applied in the past, with the majority of studies of poor quality. A protective effect of retention sutures against burst abdomen has been postulated by some [16, 50] and negated by others.[9, 18, 40]

Type of suture method

Sutures can be applied in a continuous fashion or as interrupted stitches. Hoer et al found differences in wound collagen and vascular structures between different suturing methods in rat experiments. Continuously sutured polypropylene sutures were associated with increased tissue vascularity and decreased inflammatory response.[51] No statistical differences were found between continuous and interrupted sutures in the incidence of burst abdomen.[18-20, 48, 52-54]

Since suturing continuously is quicker and easier, this method is preferred by most surgeons. In the past, closure of the abdominal wall in layers was frequently performed. This technique has been replaced by the mass closure technique, which involves suturing several layers at once. The latter is assumed to result into better wound healing than layered closure.[14, 53, 55] Increases in intraabdominal pressure lead to more tissue tension, and thereby, decreased vascularisation, if only one layer is enclosed by the suture. This division of tension is also relevant on suture level. In case of a relatively short suture, the SL:WL ratio is low. If the wound length increases, such as during postoperative paralytic ileus, less stretching of the suture ('creep') and tissue can occur if the suture is relatively short.[56] Tension on the fascia edges will occur and lead to less vascularisation and, thus, a status of ischemia and impaired wound healing. Jenkins reported a series of five surgical patients with ileus. He found an increase in wound length of up to 30%.[56] Israelsson and colleagues have performed extensive research on the topic of SL:WL ratio. Both clinical and experimental studies by this research group showed that an SL:WL ratio below four is associated with a significantly increased risk of impaired fascia healing.[57, 58] He argued that the SL:WL ratio depends on the width of the sutured tissue (fascia), the distance between the sutures and the suture tension.[59] All these variables appear to be relevant.

Surgical site infection

Postoperative wound infection is the most frequent complication of abdominal surgery and has proven of great significance in the etiology of burst abdomen.[7-10, 12, 14, 15, 18, 21, 22] Bacterial presence in wounds causes activation and influx of neutrophils and levels of degradative matrix metallo proteinases are increased. Bacterial endotoxin release leads to collagenase production and collagen fiber degradation. It has been observed in patients

with burst abdomen that collagen synthesis is exceeded by collagen degradation. This negatively affects tissue breaking strength, causing sutures to tear through fascial edges. [60, 61] Follow-up of wound status for early and adequate drainage of infected tissue, therefore, appears important. Some authors reported that a history of wound infection is a risk factor for surgical site infection (SSI) following subsequent hernia repair with or without mesh [62, 63], whereas others did not find a significant correlation.[64, 65]

Clinical presentation

Wound failure can result into a variety of clinical presentations, depending on the cause, timing and severity.

Superficial dehiscence

Superficial dehiscence of the top layers (skin and subcutaneous tissue) of the abdominal wall is most common. Dehiscence can occur either spontaneously or deliberate opening of the wound in case of superficial infection. This type of dehiscence often closes by secondary healing.

Fascial dehiscence

If a defect presents at the level of the fascia, a more serious complication has occurred. A fascial defect can be accompanied by evisceration of abdominal contents, with or without dehiscence of the overlying skin. The incidence has mostly been reported at 3-5%, although higher rates of up to 7% have been reported in specific populations.[9, 20, 66-68] The presentation of burst abdomen is typically around the eigtht postoperative day.[1, 3, 69] Production of serosanguineous wound exudate prior to dehiscence has been reported in 23-84 % of cases.[12, 18, 69-73] Therefore, clinical detection of serosanguineous wound exudate sometimes results in opening of the superficial wound to check for the presence of fascial defects.

Treatment of acute wound failure

Several options are available for treatment of acute fascial defects. In case of evisceration, prompt surgical treatment is necessary to reduce herniated organs into the intraabdominal space. If possible, the abdominal wall is closed with primary suture, mesh and/or relaxing incisions. In case of high intraabdominal pressure, closure is not advised since this could lead to pulmonary complications or recurrence of burst abdomen (reburst). In these cases, closure with mesh must can be performed, with or without approximation of overlying skin. Decrease in intraabdominal pressure over time can sometimes allow for secondary closure of the abdominal wall. Conservative management with or without negative

pressure therapy is a viable option in patients whose general health status does not allow for immediated surgery, small fascial defects, high risk of iatrogenic intestinal perforations due to adhesions, or considerable bowel edema.[74, 75] Since the mortality rate in burst abdomen patients has been reported between 4-35% in recent studies, it has proven difficult to perform long term outcome studies.[6, 9, 15, 19, 21, 41, 72, 76-79, 81-83]

Outline of the problem

Burst abdomen is associated with significant morbidity, eg, prolonged admission with subsequent reoperations and need for intensive wound care during and after inhopitalisation.[6, 84] Mortality rates of up to 40% have frequently been reported.[9, 67, 68, 81, 83] As few reports have included results of recurrent fascial dehiscence (reburst), it remains uncertain whether an independent correlation exists between number of rebursts and mortality. Also, fascial dehiscence has been associated with unsatisfactory cosmetic results, and incisional hernia formation in 4-70% of survivors.[9, 67, 77, 81] The latter can negatively affect body image and physical functioning. There is a wide range in health-care associated costs, which can increase dramatically in individual cases. With an incidence of up to a maximum of 7%, burst abdomen is not the most frequent complication of general surgery, but certainly one of the most serious complications.[9, 20, 66-68]

Aim of the thesis

Most published studies in the field of burst abdomen have been retrospective and only included a low number of patients. Our intention was to analyse risk factors for burst abdomen, to identify aberrant wound healing dynamics in burst abdomen patients, review treatment options for burst abdomen and investigate long term outcomes.

First, it was attempted to identify patient related, operation related and postoperative risk factors for burst abdomen. The first study, performed in adults, was a single center case-control study which included 363 patients with burst abdomen and 1089 control patients operated between January 1985 and December 2005. Putative relevant patient-related, operation-related, and postoperative variables were evaluated in univariate analysis and subsequently entered in multivariate stepwise logistic regression models to delineate major independent predictors of abdominal wound dehiscence. A risk model was developed, which was validated in a population of patients who had undergone operation between January and December 2006. Next, risk factors for burst abdomen in children were investigated in a multicenter case-control study. Multivariate analyses were performed to identify major independent risk factors for burst abdomen in the pediatric surgery population.

In order to investigate which clinical patient- and wound related variables are predictive for abdominal wound dehiscence, a prospective study was designed and performed in our university hospital. Patients underwent daily wound inspection and photography from the second postoperative day up to three weeks postoperatively or until discharge if earlier, and were invited for follow-up 30 days after surgery. Univariate and multivariate analysis was performed to compare patient- and wound-related clinical aspects between patients without events, superficial SSI, deep SSI, organ/space SSI and abdominal wound dehiscence.

A high number of SSI was found in this prospective study. The impression, however, existed that many SSI remained unrecognized. Photographs and clinical data from patients included in this study were used to investigate the inter and intra observer agreement amongst surgeons in diagnosis of superficial infection of laparotomy wounds. Further, we compared the incidence of SSI as registered by our surgeons using different methods with the incidence measured in the prospective study. We assessed the reliability of the surgeons' registration systems and identified risk factors for missing registrations.

Patients from our prospective study were invited for clinical follow-up to investigate the incidence of incisional hernia as a long term presentation of wound failure. Patients were asked to complete questionnaires on health-related quality of life and body image. These data were compared in analyses for patients with and without incisional hernia. Next, a separate follow-up study was performed in patients with burst abdomen from the prospective patient cohort in order to identify the long term impact of burst abdomen on health-related quality of life, body image, incidence of incisional hernia, and costs.

Treatment options for burst abdomen were reviewed in a study in which studies were included that reported on at least one surgical outcome (recurrence, mortality, or incisional hernia rate) of at least 10 patients with burst abdomen. All identified treatment options were discussed in detail and supported by reviewed literature. The quality of included studies, however, was poor since all studies were non-randomized and of retrospective design. In general, treatment of burst abdomen was associated with unsatisfactory surgical outcome.

Finally, we focussed on prevention of burst abdomen by concentrating on suturing techniques. Thirty-eight porcine abdominal walls were randomized between closure of midline incisions with double-loop polydioxanone using large stitches with large suture distances (1cm each) and small stitches with small suture distances (0.5 cm). Abdominal

walls were fixed on a tensile testing machine and tensile force was increased at a constant rate until dehiscence or maximum tensile force was reached. The effects of suture technique and SL:WL ratio on tensile force were compared in analyses. Millbourn et al published a randomized controlled study in which the incidence of burst abdomen, surgical site infection, and incisional hernia were compared between abdominal wall closure with small bites and large bites.[57] This study raised additional questions from our perspective, based on our previously mentioned experimental study and clinical experience, and were published in a letter to the editor.

With increasing evidence for the use of small bites to improve healing of the abdominal wall, a multicenter randomized controlled trial was designed. In preparation for this study, practical aspects of the small bites technique were investigated in Sundsvall Hospital, Sweden. Personnel were interviewed with respect to their experiences with the introduction and compliance to the new technique. A number of laparatomy closures were timed in Sundsvall Hospital, and compared to eighteen closure procedures in Erasmus University Medical Center. Also, achieved SL:WL ratios were measured.

In the designed trial, the effects of small stitches on the incidence of incisional hernia in midline incisions (STITCH trial) are evaluated in 576 patients who are randomized between small bites and large bites. Main outcomes of this trial include incidence of incisional hernia, postoperative complications including burst abdomen, direct and indirect costs and quality of life. Currently, the inclusion of this trial has been completed and final results will provide evidence to support the preference for either a continuous suture technique with many small tissue bites in the aponeurosis only or for the commonly used large bites technique for closure of the abdominal wall.

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Chapter 2

Abdominal Wound Dehiscence in Adults: Development and Validation of a Risk Model

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Abstract

Background: Several studies have been performed to identify risk factors for abdominal wound dehiscence. No risk model had yet been developed for the general surgical population. The objective of the present study was to identify independent risk factors for abdominal wound dehiscence and to develop a risk model to recognize high-risk patients. Identification of high-risk patients offers opportunities for intervention strategies.

Methods: Medical registers from January 1985 to December 2005 were searched. Patients who had primarily undergone appendectomies or nonsurgical (e.g., urological) operations were excluded. Each patient with abdominal wound dehiscence was matched with three controls by systematic random sampling. Putative relevant patient-related, operation-related, and postoperative variables were evaluated in univariate analysis and subsequently entered in multivariate stepwise logistic regression models to delineate major independent predictors of abdominal wound dehiscence. A risk model was developed, which was validated in a population of patients who had undergone operation between January and December 2006.

Results: A total of 363 cases and 1,089 controls were analyzed. Major independent risk factors were age, gender, chronic pulmonary disease, ascites, jaundice, anemia, emergency surgery, type of surgery, postoperative coughing, and wound infection. In the validation population, risk scores were significantly higher ($P < 0.001$) for patients with abdominal wound dehiscence ($n = 19$) compared to those without ($n = 677$). Resulting scores ranged from 0 to 8.5, and the risk for abdominal wound dehiscence over this range increased exponentially from 0.02% to 70.1%.

Conclusions: The validated risk model shows high predictive value for abdominal wound dehiscence and may help to identify patients at increased risk.

Introduction

Abdominal wound dehiscence (burst abdomen, fascial dehiscence) is a severe postoperative complication, with mortality rates reported as high as 45%.[1–3] The incidence, as described in the literature, ranges from 0.4% to 3.5%.[4–17] Abdominal wound dehiscence can result in evisceration, requiring immediate treatment. Prolonged hospital stay, high incidence of incisional hernia, and subsequent reoperations underline the severity of this complication.

Despite advances in perioperative care and suture materials, incidence and mortality rates in regard to abdominal wound dehiscence have not significantly changed over the past decades. This may be attributable to increasing incidences of risk factors within patient populations outweighing the benefits of technical achievements. Several mainly retrospective studies have been performed to identify risk factors for this complication, often presenting conflicting results. Unfortunately, multivariate analysis has only been performed in a minority of studies and in general on small numbers of patients.[4–7, 10, 15]

The goal of the underlying study was to evaluate possible risk factors for abdominal wound dehiscence and to design a risk model based on independent risk factors. This model can be used to assess the risk for individual patients, and it may prove useful for prevention strategies in clinical studies, e.g., development of alternative closure techniques, in high-risk patients.

Materials and methods

All medical registers and operation records of adult patients from our academic teaching hospital dating from January 1985 to December 2005 were used for a computer-generated search of the keywords dehiscence, wound dehiscence, fascial dehiscence, and *Platzbauch* (widely used German term for abdominal wound dehiscence). Patients who had primarily undergone laparoscopic surgery, abdominal surgery in other wards (e.g., gynecology, urology), appendectomy, and umbilical and inguinal hernia surgery were excluded. Likewise, identified patients were excluded if insufficient evidence of fascial dehiscence (e.g., serous wound exudate production without confirmed fascial dehiscence) was found in clinical records.

For each case three suitable controls were randomly selected from a group of patients who had undergone open abdominal surgery as close as possible in time. For patients who had undergone operation on weekends and holidays, controls were selected from patients who had been operated between Sunday midnight and Friday midnight. This approach was chosen to avoid excessive inclusion of emergency operations in the control

group, thereby ensuring that the control group is as representative for the "average" surgical population as possible. Controls were not matched according to age, sex, and type of surgery because these characteristics had been reported as risk factors in other studies and we intended to evaluate these factors as well. Moreover, patients who had undergone open abdomen treatment were excluded.

Patient and operation-related preoperative, perioperative, and postoperative variables and in-hospital mortality were recorded for all cases and controls by examining patient charts, operation records, laboratory and culture results, and discharge letters. Postoperative coughing was defined as coughing documented by doctors in the patient charts before the diagnosis of abdominal wound dehiscence, or before discharge in patients without abdominal wound dehiscence. Wound infection was defined as documented pus production, "infection" or "abscess" of the operative site prior to the diagnosis of abdominal wound dehiscence, or opening of the operative site on suspicion of infection without presence of negative wound cultures within 30 days after surgery. On the condition that at least 85% of data were complete, patients were compared with controls using the chi-square test or the Mann–Whitney *U*-test for categorical or continuous data, respectively. Subsequently, multivariate stepwise logistic regression with backwards elimination was used to identify major independent predictors of abdominal wound dehiscence. The resulting regression coefficients for the major risk factors were used as weights for these variables to calculate a risk score for abdominal wound dehiscence.

All patients who had undergone open abdominal surgery between January and December 2006 were reviewed to validate the risk model. Medical registers were used to record the presence of risk factors for each patient, after which total scores were calculated and compared for patients with and without abdominal wound dehiscence. Patients were excluded for validation of the risk model if data on risk factors were absent. The goodness-of-fit of the risk model was assessed with the Hosmer and Lemeshow test. The predictive value of the risk model was assessed by plotting the sensitivity versus the fraction false-positives for all possible cut-off levels in a receiving operating characteristic curve (ROC curve). An area under the curve of 0.90 or greater is generally considered to denote high predictive value; *P* values (two-sided) <0.05 were considered significant in all analyses.

Results

From January 1985 to December 2005, 429,906 operative procedures were performed at the department of surgery. The incidence of abdominal wound dehiscence did not show significant changes during the study period, and a total of 363 cases of abdominal wound dehiscence were identified and compared to 1,089 selected controls. Mean presentation

of abdominal wound dehiscence was at postoperative day 9 (range: 0–32 days), with 90% of all cases presenting before the 15th postoperative day. Hospital stay was significantly longer ($p<0.001$) for patients with abdominal wound dehiscence, with a median of 36 days, versus 16 days in the control group. In-hospital mortality for the two groups was 22% and 9%, respectively ($p<0.001$). Sixty-one patients were treated conservatively and 302 were treated operatively. Of these 302 patients, 29 developed recurrences of abdominal wound dehiscence within 30 days of reoperation (9.3%), and 6 of them developed second recurrences. Women were treated conservatively more often than men ($p=0.03$). Conservatively treated patients were comparable with operatively treated patients in terms of hospital stay (median 33 days versus 37 days [$p=0.339$]), age ($p=0.379$), mortality ($p=0.408$), and comorbidity (all $p>0.05$).

In most cases, tearing of sutures through the fascia was reported to be the cause of the dehiscence (29%). Other reported causes were infection (9%), broken suture (8%), fascial necrosis (6%), and loose knots (4%). However, in 44% of all patients no explanation was recorded for abdominal wound dehiscence. Data were incomplete in more than 15% of subjects for smoking, body mass index (BMI), American Society of Anesthesiologists (ASA) class, hemodynamic instability, type of incision, and type of closure (such as continuous versus interrupted or type of suture used), or preoperative protein and albumin levels, which prevented us from entering these factors in univariate analysis.

The results of the univariate analyses are shown in Table 1. In the abdominal wound dehiscence group, the following variables were significantly more prevalent compared to the control group: old age, male gender, hypertension, chronic pulmonary disease, ascites, anemia, jaundice, corticosteroid use, sepsis, emergency surgery, postoperative coughing, wound infection (all $p<0.001$), uremia ($p=0.013$), and operative time ($p=0.003$). Also, type of surgery differed between cases and controls. The subcategories “spleen” and “adrenal gland” were combined into the category “other” in view of the small group numbers. The variables diabetes mellitus, previous laparotomy, and postoperative vomiting were not found to be significant risk factors.

Table 1 Characteristics of the two groups in the study

Variable	Abdominal wound dehiscence (*n* = 363)	Control group (*n* = 1,089)	*P*value
Age, years	65 ± 14.1 (19–91)	57 ± 16.0 (18–95)	<0.001
<40	8% (28)	21% (230)	
40–49	11% (39)	16% (173)	
50–59	20% (71)	21% (232)	
60–69	28% (102)	24% (256)	
>70	34% (123)	18% (198)	
Gender			<0.001
Male	75% (272)	56% (604)	
Female	25% (91)	45% (485)	
Previous laparotomy	46% (165)	50% (540)	0.173
Hypertension	46% (168)	31% (332)	<0.001
Diabetes mellitus	9% (33)	9% (101)	0.917
Chronic pulmonary disease	29% (104)	12% (129)	<0.001
Corticosteroid use	30% (109)	18% (200)	<0.001
Malignancy			<0.001
Local disease	34% (122)	20% (221)	
Metastases	13% (46)	19% (204)	
Ascites	23% (84)	5% (59)	<0.001
Jaundice	15% (54)	8% (307)	<0.001
Anemia	61% (223)	35% (377)	<0.001
Uremia	31% (112)	23% (245)	0.013
Sepsis	20% (72)	8% (83)	<0.001
Emergency surgery	46% (165)	26% (285)	<0.001
Type of surgery			<0.001
Abdominal wall	21% (76)	27% (296)	
Gallbladder/bile duct	5% (19)	7% (79)	
Esophagus	9% (32)	6% (61)	
Gastroduodenal	8% (28)	5% (50)	
Small bowel	7% (26)	8% (90)	
Large bowel	27% (98)	19% (203)	
Vascular	15% (54)	10% (107)	
Kidney	2% (7)	7% (71)	
Liver	4% (13)	5% (56)	
Pancreas	2% (6)	5% (51)	
Adrenal gland	0% (0)	1% (9)	
Spleen	1% (4)	2% (16)	
Operative time (min)	207 ± 134 (30–755)	180 ± 126 (25–735)	0.003
<150 min	32% (117)	39% (425)	0.024
≥150 min	68% (246)	61% (664)	
Coughing	17% (46)	4% (36)	<0.001
Vomiting	3% (6)	3% (33)	0.662
Wound infection	52% (188)	11% (121)	<0.001

Data are presented as percentages, with numbers in parentheses, or as mean ± SD (range)

All variables that were significant in univariate analyses were entered in a multivariate stepwise logistic regression to determine which variables were significant independent risk factors (Table 2). In the evaluation of type of surgery, we expected the subcategory "abdominal wall" (including only "clean" operations, i.e., incisional hernia repair and exploratory laparotomy without further intervention) to be associated with the lowest risk of developing abdominal wound dehiscence. Therefore, this category was used as the reference category. For the variable "age," the reference category was patients under the age of 40 years. Adjusted for the significant risk factors, none of the other variables, including operative time, corticosteroid use, and sepsis, had significant effects.

Table 2 Results of multivariate logistic regression analysis

Variable	Regression coefficient	Odds ratio (OR)	95% Confidence Interval for OR		*P*value
			Lower limit	Upper limit	
Age category (years)[a]					0.002[b]
40–49	0.43	1.54	0.81	2.93	0.192
50–59	0.89	2.44	1.37	4.34	0.002
60–69	0.89	2.43	1.39	4.26	0.002
>70	1.09	2.96	1.67	5.25	<0.001
Male gender	0.72	2.05	1.44	2.90	<0.001
Chronic pulmonary disease	0.72	2.05	1.39	3.01	<0.001
Ascites	1.49	4.43	2.68	7.33	<0.001
Anemia	0.72	2.05	1.48	2.84	<0.001
Jaundice	0.56	1.75	1.02	3.00	0.042
Emergency surgery	0.59	1.80	1.27	2.55	0.001
Type of surgery[c]					<0.001[b]
Gallbladder/bile duct	0.70	2.02	0.93	4.37	0.075
Esophagus	1.45	4.28	2.21	8.28	<0.001
Gastroduodenum	1.38	3.97	2.05	7.69	<0.001
Small bowel	0.94	2.55	1.32	4.90	0.005
Large bowel	1.38	3.97	2.45	6.45	<0.001
Vascular	1.25	3.50	2.01	6.09	<0.001
Kidney	–0.11	0.90	0.35	2.27	0.819
Liver	0.11	1.12	0.46	2.74	0.804
Pancreas	–0.41	0.66	0.23	1.91	0.446
Other[d]	0.30	1.35	0.53	1.71	0.669
Coughing	1.42	4.15	2.49	6.91	<0.001
Wound infection	1.86	6.43	4.56	9.06	<0.001

[a]Reference category age <40 years
[b]Overall *P* value
[c]Reference category abdominal wall
[d]Spleen or adrenal gland

Based on these findings, a risk model for abdominal wound dehiscence was developed. Because none of the surgery subcategories "liver," "kidney," or "pancreas" had proven significant risk factors, and because the effects of these variables did not significantly differ from one another (p=0.81), regression coefficients were recalculated after combining these factors with "spleen" and "adrenal gland" in the category "other." For the subcategory "gallbladder and bile duct" a strong trend toward significance was found and led to the inclusion of this factor in the risk model. The risk scores, weighing the various factors by using the resulting regression coefficients in the logistic regression analysis, are shown in Table 3. If risk factors are absent (such as in a female patient or when another type of surgery is performed), no points are given. A higher value of the score predicts a higher risk.

Table 3 Risk score for abdominal wound dehiscence

Variable	Risk score
Age category, years	
40–49	0.4
50–59	0.9
60–69	0.9
>70	1.1
Male gender	0.7
Chronic pulmonary disease	0.7
Ascites	1.5
Jaundice	0.5
Anemia	0.7
Emergency surgery	0.6
Type of surgery	
Gallbladder/bile duct	0.7
Esophagus	1.5
Gastroduodenum	1.4
Small bowel	0.9
Large bowel	1.4
Vascular	1.3
Coughing	1.4
Wound infection	1.9

Theoretical score (min–max): 0–10.6

Validation of the risk model

A total of 863 patients underwent open abdominal surgery between January and December 2006. Medical registers were used to record the presence of identified risk factors and abdominal wound dehiscence for every individual. In 177 cases, including 3 cases of abdominal wound dehiscence, data on one or more major risk factors were

missing, leaving 686 cases for validation of the risk model. The incidence of abdominal wound dehiscence in this group was 2.8% (19/686). Characteristics of the two groups are displayed in Table 4.

Table 4 Characteristics of the validation population

Variable	Abdominal wound dehiscence (*n* = 19)	No abdominal wound dehiscence (*n* = 667)
Age, years	66 ± 9.6 (42–79)	58 ± 15.7 (18–99)
<40	0% (0)	17% (111)
40–49	11% (2)	16% (106)
50–59	11% (2)	23% (155)
60–69	37% (7)	23% (156)
>70	42% (8)	21% (139)
Male	58% (11)	56% (373)
Female	42% (8)	44% (294)
Chronic pulmonary disease	16% (3)	14% (96)
Ascites	26% (5)	9% (57)
Jaundice	5% (1)	5% (35)
Anemia	79% (15)	38% (255)
Emergency surgery	47% (9)	37% (248)
Abdominal wall	5% (1)	13% (84)
Gallbladder/bile duct	0% (0)	6% (38)
Gastroduodenum	16% (3)	7% (44)
Small bowel	5% (1)	8% (50)
Large bowel	37% (7)	19% (127)
Vascular	11% (2)	6% (41)
Esophagus	5% (1)	8% (56)
Adrenal gland	0% (0)	0% (0)
Kidney	11% (2)	19% (124)
Liver	5% (1)	11% (72)
Pancreas	5% (1)	4% (24)
Spleen	0% (0)	1% (6)
Coughing	32% (6)	11% (75)
Wound infection	90% (17)	17% (112)

Data are presented as percentages, with numbers between parentheses, or as mean ± SD (range)

Calculation of risk scores for all 686 patients revealed significantly higher scores in the abdominal wound dehiscence group (p<0.001). Median scores were 5.7 in the abdominal wound dehiscence group (range: 2.8–8.5) and 2.9 in the control group (range: 0–7.6). Logistic regression analysis of abdominal wound dehiscence in relation to the calculated risk scores showed that an increase of the risk score by one point is associated with an increase of the risk of abdominal wound dehiscence of 2.96 (p<0.001). The fit of the model was good, as shown by the Hosmer and Lemeshow test (p=0.79). The area under the curve

in the ROC plot was 0.91, showing a high predictive value of the risk score. The absolute risk of developing abdominal wound dehiscence in relation to the risk score is shown in Fig. 1, and the mean probability per risk score category is featured in Table 5.

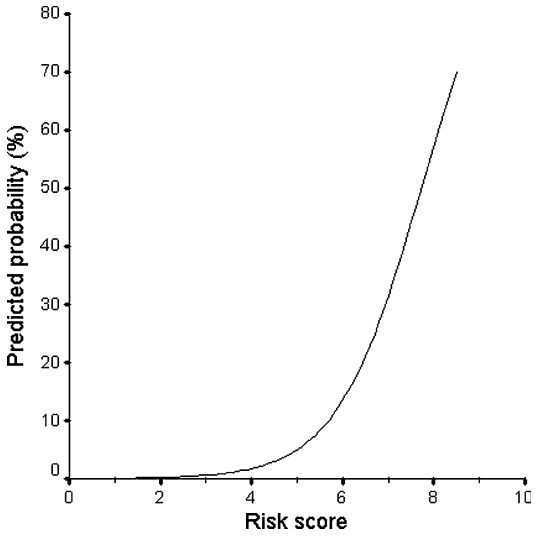

Fig. 1 Predicted probability (%) of developing abdominal wound dehiscence according to risk score

Table 5 Absolute risk of abdominal wound dehiscence in the validation population by risk score

Risk score	Total no. of patients	%	Abdominal wound dehiscence		Mean probability[b] (%)
			Number	%	
0–2	188	27.4	0	0.0	0.1
2–4	329	48.0	2	0.6	0.7
4–6	138	20.1	8	5.8	5.5
6–8	29	4.2	7	24.1	26.2
>8	2	0.3	2	100	66.5
Total	686	100	19	2.8	

[a]Observed percentages within risk score groups
[b]Mean values of individual calculated probabilities according to risk score within risk score group

The calculation of the probability of abdominal wound dehiscence for an individual surgical patient is performed in two steps. First, the total risk score is calculated by adding the weights of the various variables shown in Table 3. In the second step, the probability of developing abdominal wound dehiscence, *P*, is calculated according to the logistic formula: $P = e^x/(1 + e^x) * 100\%$,
where 'e^x' represents the exponential function and '*x*' represents '−8.37 + (1.085 * calculated total risk score)'.

For example, the risk score for a 67-year-old man who undergoes an elective reconstruction of the abdominal aorta and is known to have a history of chronic pulmonary disease is 0.9 (score for age 60–69 years) + 0.7 (score for male gender) + 1.3 (score for vascular surgery) + 0.7 (score for chronic pulmonary disease), for a total of 3.6. The probability, *P*, of this patient's developing abdominal wound dehiscence is:

$$e^{(-8.37+(1.085*3.6))}/1+e^{(-8.37+(1.085*3.6))} * 100\% = 1.1\%.$$

An emergency repair in a similar patient with a ruptured aneurysm and subsequent anemia results in a total score of 4.9 (i.e., subtotal of 3.6 points + 0.6 emergency + 0.7 anemia). Thus, the absolute risk rises to 4.5%.

Discussion

In recent years, surgical therapy has become increasingly adjusted to individual patients based on their specific risk profiles. The goal of this strategy is to affect treatment outcomes positively. Furthermore, informed consent issues are gaining more attention from patient organizations, lawyers, and doctors in the light of juridical procedures. Before obtaining informed consent, patients should be fully informed about complications that can be expected to occur. Thus, preoperative risk assessment and information on absolute risk is important for both patients and doctors.
We have developed a risk model based on a large group of patients with abdominal wound dehiscence and compared possible risk factors with a large control group, all from a single academic teaching hospital. A risk model was designed based on the relative weights of the various risk factors. The model was validated in a separate population and demonstrated high predictive value for abdominal wound dehiscence, supporting the hypothesis that the variables identified as risk factors are actual risk factors. Calculation of the absolute risk, *P*, for a particular patient is performed by adding the weights of the various risk factors. The resulting risk score is subsequently entered into the given formula

to obtain the absolute risk for that patient. The probability can also be deduced more easily from Fig. 1 by tracing the percentage that corresponds with the calculated risk score. This figure also shows that the probability of developing abdominal wound dehiscence increases exponentially with higher scores and more risk factors.

Although the risk model has shown high predictive value for abdominal wound dehiscence, the relative weight of the risk factors may differ slightly in reality. Our method of control group selection could have induced a bias concerning the relative weight of the factor "emergency surgery." For patients with abdominal wound dehiscence who were primarily treated during weekends and holidays, control patients were selected from patients operated on the following workdays. Therefore, the effect of emergency surgery might have been overestimated in our study. It has been reported though, to be a highly significant factor in other studies.[4–6,9, 11, 13, 16] Patients who undergo emergency surgery are generally in worse condition and nutritional state, and the chance of contamination of the surgical field is higher than in elective surgery. Moreover, the performance of the surgeon might be affected at night, which could lead to suboptimal closure of the abdomen at the end of the operation.

Old age is another independent risk factor for abdominal wound dehiscence. Age has also been reported as a risk factor in other studies.[6, 8–10, 12, 13, 15] The explanation for this might lie in deterioration of the tissue repair mechanism in the elderly. Especially during the first few days of the wound healing process, the immune system plays a key role. Functional changes adversely affect the influx of cells and compounds that are essential for tissue repair.[18] Anemia is a risk factor that is related to increased perioperative stress, blood transfusions, and decreased tissue oxygenation, all of which can affect the immune system and the wound healing process.[19, 20]

One of the interesting risk factors found in this study, is gender. In previous studies, males have been reported to have a higher risk of developing abdominal wound dehiscence.[6–8, 12] The reason for this disadvantage is not entirely clear. One of the possible confounders may be smoking. Because most smokers from the studied generations tended to be male, the effect of gender may be confounded with the effect of smoking on tissue repair. Unfortunately, smoking has thus far not been investigated as an independent risk factor for abdominal wound dehiscence. Because of the lack of sufficient data, this factor could not be investigated in the present study either. Another explanation may be that men build up higher abdominal wall tension than females. An increase in intra-abdominal pressure results in higher strain on the wound edges, causing the sutures to cut through the muscles and fascia. This explanation may also apply to ascites and coughing, causing increment in intra-abdominal pressure.

In the present study, wound infection proved to be the risk factor with the highest relative weight. Its importance has been confirmed by virtually every study on this topic.[4–7, 9, 12–15] Continued presence of bacteria causes influx and activation of neutrophils and increases in levels of degradative matrix metalloproteinases (MMPs). In the absence of sufficient tissue inhibitors of MMPs, wound degradation will occur.[21] The release of endotoxins by bacteria leads to the production of collagenase, which degrades collagen fibers.[22] Infection thereby causes a prolongation of the inflammatory phase and negatively affects deposition of collagen and fibroblast activity. In wounds of patients with abdominal wound dehiscence, it has been observed that degradation of collagen exceeds the synthesis of collagen, which adversely affects breaking strength.[23] Adequate tissue breaking strength is necessary, however, to provide support for the sutures that hold the wound edges together. Low breaking strength can therefore amount to abdominal wound dehiscence, especially in the presence of increased intra-abdominal pressure and abnormal inflammatory response.[18] Primary repair can be difficult or impossible when tissue has low breaking strength, creating the need for the use of mesh or acceptance of the high risk of recurrent abdominal wound dehiscence.

Risk factors that did not have independent effects in our evaluation included hypertension, uremia, and corticosteroid use, although these factors have been described as risk factors by a number of authors.[9, 13,15, 24] The latter can be explained by the more frequent use of corticosteroids in lung disease patients, which applied to both cases and controls in our study. We found no significant effect on the occurrence of abdominal wound dehiscence for diabetes mellitus and previous laparotomy. Malignancy, sepsis, and postoperative vomiting have been identified as risk factors by several authors, but no significant effects were found in the present study.[7, 9, 11, 13–15] This was surprising because it was suspected that the presence of scar tissue, microvascular changes due to hypertension and diabetes, poor tissue perfusion, and poor overall condition of the patient, associated with sepsis and malignancy, would be risk factors. Jaundice, on the other hand, was found to be an independent risk factor. This has not been confirmed by other studies.[7,11–15] Most important, Armstrong investigated jaundice in relation to hematocrit and albumin levels and malignancy.[7] Jaundice was significant in univariate analysis but not in multivariate analysis in that study. The conclusion of that study was that wound healing is affected in jaundiced patients due to the association with low hematocrit and albumin levels and malignancy (i.e., poor nutritional status) and not to raised bilirubin levels. Low protein and albumin levels and deficiencies of several vitamins and minerals such as vitamins A, B_1, B_2, B_6, C and zinc and copper have been associated with poor wound repair.[18] Data on preoperative albumin levels were available for 83% of patients with abdominal wound dehiscence and 56% of controls. Albumin levels were below 35 g/l in 63% of patients with

abdominal wound dehiscence and 34% of controls, which was significantly less ($p<0.001$) and suggestive of an association between low albumin levels and development of abdominal wound dehiscence.

Additional investigation is needed to determine the value of the underlying risk score in other settings. Also, studies are needed to evaluate other possible factors for which limited retrospective data are available, such as nutritional state. The consequences of the score are also limited by the inclusion of risk factors that occur in the postoperative phase, such as coughing and wound infection. Still, because the model has been shown to be highly predictive, it can be used to identify patients at risk. Preventive measures, e.g., the use of mesh and special suture techniques and materials, aimed at decreasing tension on the wound edges, can be investigated and used in these patient groups. Tohme et al., for example, reported the results of a retrospective study on the preventive use of polyglactin 910 mesh versus retention sutures in patients with at least one suspected risk factor for abdominal wound dehiscence.[25] These factors included malnutrition with loss of over 10% of body weight, obesity, cirrhosis, and/or ascites, neoplastic diseases, immune depression due to corticosteroid use or chemotherapy, chronic respiratory insufficiency, repeated intervention, and diffuse or local peritonitis. Although the incidence of abdominal wound dehiscence was significantly lower in the polyglactin 910 mesh group (0/66 versus 14/226 patients, $p<0.05$), no stratification was made for the predicted risk of abdominal wound dehiscence, which hampers the interpretation and extrapolation of the results of this study. The same holds true for other future studies on closure technique with abdominal wound dehiscence as study outcome. The necessity of good surgical technique is underlined by the fact that broken sutures and loose knots accounted for 12% of the cases of abdominal wound dehiscence in these series. We therefore hope that the results of this study will lead to better, evidence-based treatment options for abdominal wound dehiscence and, eventually, a lower incidence of this severe complication.

In conclusion, various putative risk factors for abdominal wound dehiscence were investigated in the thus far largest study in the general surgical population. Important risk factors for abdominal wound dehiscence have been identified in this case-control study, including age, gender, chronic pulmonary disease, ascites, jaundice, anemia, emergency surgery, type of surgery, coughing, and wound infection. On the basis of these data, we were able to develop a risk score for abdominal wound dehiscence. This score can be entered into a formula to calculate the probability of developing abdominal wound dehiscence for individual patients. High-risk patients, for instance with scores of 6 or higher without counting postoperative factors such as coughing and wound infection, have a probability of developing abdominal wound dehiscence of more than 13.5%. This type of patient would be interesting to include in future intervention studies that could involve

preventive wound closing with such reinforcements as (biologic) mesh. Furthermore, utmost efforts should be made to consider minimally invasive surgery, also if other centers need to be involved for this indication. The risk model has shown high predictive value for the occurrence of this severe complication in the validation analyses. From the results of this study, we can also conclude that a number of risk factors for abdominal wound dehiscence can be mitigated during the perioperative period. This implies that the risk of developing abdominal wound dehiscence can be reduced by preventing pneumonia and wound infection, and by applying optimal surgical technique in every patient.

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Chapter 3

Risk Factors for Abdominal Wound Dehiscence in Children: A Case-Control Study

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Abstract

Background: In the limited literature concerning abdominal wound dehiscence after laparotomy in children, reported incidences range between 0.2–1.2% with associated mortality rates of 8–45%. The goal of this retrospective case-control study was to identify major risk factors for abdominal wound dehiscence in the pediatric population.

Methods: Patients younger than aged 18 years who developed abdominal wound dehiscence in three pediatric surgical centers during the period 1985–2005 were identified. For each patient with abdominal wound dehiscence, four controls were selected by systematic random sampling. Patients with (a history of) open abdomen treatment or abdominal wound dehiscence were excluded as control subjects. Putative relevant patient-related, operation-related, and postoperative variables for both cases and control subjects were evaluated in univariate analyses and subsequently entered in multivariate stepwise logistic regression models to identify major independent predictors of abdominal wound dehiscence.

Results: A total number of 63 patients with abdominal wound dehiscence and 252 control subjects were analyzed. Mean presentation of abdominal wound dehiscence was at postoperative day 5 (range, 1–15) and overall mortality was 11%. Hospital stay was significantly longer ($p<0.001$) in the case group (median, 42 vs. 10 days). Major independent risk factors for abdominal wound dehiscence were younger than aged 1 year, wound infection, median incision, and emergency surgery. Incisional hernia was reported in 12% of the patients with abdominal wound dehiscence versus 3% in the control group ($p=0.001$).

Conclusions: Abdominal wound dehiscence is a serious complication with high morbidity and mortality. Median incisions should be avoided whenever possible.

Introduction

Abdominal wound dehiscence is a severe complication of abdominal surgery in children. Its sudden presentation and requirement of surgical repair in the majority of cases underline the stressful character of this complication for both patients and parents. Literature on risk factors for abdominal wound dehiscence in children is limited (Table 1). Reported incidences range from 0.4–1.2%, with mortality rates reported as high as 45%.[1–5] Until now, only relatively small case series, series without control groups, or without multivariate logistic regression analyses have been reported, which complicates interpretation of the results of these studies.[1–5]

Table 1 Literature concerning abdominal wound dehiscence in children

Author	Year of publication	No. of patients	Incidence (%)	Mortality (%)	Statistical analyses
Gross and Furguson[1]	1953	75	0.9	45.3	NR
Campbell and Swenson[2]	1972	26	0.97	19.2	NR
Gruessner et al.[3]	1986	21	1.17	14.3	NR
Waldhausen and Davies[4]	2000	12	0.43	8.3	Univariate
Çigdem et al.[5]	2006	27	0.8	34.5	Univariate
Van Ramshorst[a]	2009	63	0.6	11.1	Multivariate

NR not reported
[a]Current series

In the study by Waldhausen and Davies, vertical incision was reported as a risk factor (compared with transverse incision).[4] Based on the characteristics of his population, he concluded that abdominal wound dehiscence is more frequent in young children (younger than aged 1 year). Age (younger than 1 month) and median incision also have been reported as risk factors by Çigdem et al.[5] The outcomes of these reports should be considered relative due to the minority of variables studied. This case-control study was designed to evaluate a substantial number of possible risk factors for abdominal wound dehiscence in children through univariate analyses and multivariate stepwise logistic regression.

Materials and methods

All patient charts, office notes, and operation records of patients younger than aged 18 years from three pediatric surgical centers who had been treated between January 1985 through December 2005 were found by use of a computer-generated search, using the keywords "dehiscence," "wound dehiscence," "fascial dehiscence," and "Platzbauch."

Patients who primarily underwent laparoscopic surgery, abdominal surgery in other departments (e.g., pediatric urology), umbilical, and inguinal hernia surgery were excluded. Identified patients were excluded if insufficient evidence of abdominal wound dehiscence was found in the patient charts.

For each case, four control patients at the same center who had been operated in the same week were selected. If the number of controls was too small during that week, patients from the succeeding week(s) were selected as controls as well. Controls were not matched according to age or type of surgery, because these variables were considered putative risk factors and we intended to assess their effects. Patients with (a history of) open abdomen treatment or abdominal wound dehiscence were excluded as control subjects.

The following variables were collected for all cases and controls: age, sex, weight, body mass index, duration of pregnancy (in case of neonates), anemia, hypoalbuminemia, hypoproteinemia, uremia, diabetes mellitus, malignancy, jaundice, pulmonary disease, use of corticosteroids, (parental) smoking, sepsis, ascites, previous laparotomy, type of surgery, indication for surgery, duration of surgery, emergency or elective operation, hemodynamic instability, ASA-classification, type of incision, method of closure, suture material used, day of presentation, cause of abdominal wound dehiscence, postoperative coughing/vomiting/wound infection, hospital stay, in-hospital mortality, and incisional hernia.

On the condition that at least 85% of data were complete, patients with abdominal wound dehiscence were compared with controls using the χ^2 or Mann Whitney *U* test for categorical or continuous data, respectively. Subsequently, all factors that were significant in univariate analyses were entered in multivariate stepwise logistic regression with backwards elimination to identify major independent predictors of abdominal wound dehiscence. Odds ratios (OR) and regression coefficients were calculated for all variables. $P < 0.05$ was considered significant.

Results

A total of 63 patients with abdominal wound dehiscence and 252 control subjects were analyzed. The incidence of abdominal wound dehiscence could be calculated from hospital records for one of the pediatric surgical centers and was found to be 0.6% (12/1,942 patients). The mean presentation of abdominal wound dehiscence was at postoperative day 5 (range 1–15). In most cases, tearing of sutures through the fascia was reported to be the cause of the dehiscence (29%). Other reported causes were infection (13%) or a combination of infection and fascial tearing (3%), broken sutures (10%), and loose knots (5%). In the remaining 26 patients, no explanation was recorded.

Hospital stay was significantly longer ($p<0.001$) for patients with abdominal wound dehiscence with a median of 42 days versus 10 days for controls. In-hospital mortality was 11% and 6%, respectively ($p=0.151$). Patients who died in the hospital were significantly younger ($p=0.021$) and suffered more frequently from necrotizing enterocolitis compared with survivors (23% vs. 4%, $p<0.001$). No recurrences of abdominal wound dehiscence were found. One patient developed abdominal wound dehiscence twice after laparotomies in separate hospital admissions 1 year apart. In 13% of the patients with abdominal wound dehiscence (7/56 survivors), incisional hernia was reported in medical records after the initial admission compared with 3% (6/237 survivors) in the control group ($p=0.001$).

Data were incomplete in more than 15% of patients for preoperative protein and albumin levels, uraemia, duration of pregnancy, (birth) weight, (parental) smoking, body mass index, hemodynamic instability, ASA-classification, type of suture, and suture technique, which prevented us from entering these factors in univariate analyses. The techniques of fascial closure (running vs. interrupted, multilayered vs. mass-closure) could not be extracted from original operation records in 40% of patients with abdominal wound dehiscence and in 43% of patients in the control group.

The results of the univariate analyses are shown in Table 2. The distributions of the following variables differed significantly between patients with and without abdominal wound dehiscence: age, anemia, jaundice, malignancy, type of incision, type of surgery, emergency surgery, necrotizing enterocolitis, hypertrophic pyloric stenosis, and wound infection. The variables sex, previous laparotomy, diabetes mellitus, pulmonary disease, corticosteroid use, sepsis, ascites, duration of operation, postoperative coughing, and vomiting, were not found to be significant risk factors.

All factors that were significant in univariate analyses were subsequently entered in multivariate stepwise logistic regression with backwards elimination to determine which variables were significant independent risk factors (Table 3). In the evaluation of "type of surgery," the subgroup "abdominal wall" was expected to be associated with the lowest risk of abdominal wound dehiscence, including "clean" procedures, e.g., incisional hernia repairs and exploratory laparotomies. Therefore, this category was chosen as reference category. For the variable "age", the reference category consisted of children older than 1 year in view of group sizes. There was no significant difference between children younger than aged 6 weeks compared with those aged between 6 weeks and 1 year. In view of small group sizes, incisions other than median incisions (McBurney, transverse, and semilunar incisions) were combined to form one category to assess the effects of median incisions.

Table 2 Results of univariate analyses

Variable	No. of patients (%)				*P*value
	Abdominal wound dehiscence group (*n* = 63)		Control group (*n* = 252)		
Age (year) median ± SD, range	0.2 ± 3.9	(2–17.4 days)	1.1 ± 5.5	(0–17.7 days)	<0.001[a]
0–6 weeks	19	30%	52	21%	
6 weeks–1 year	35	56%	71	28%	
>1 year	9	14%	129	51%	
Male/female ratio	38/25	60%/40%	142/110	56%/44%	0.569
Diabetes mellitus	0	0%	2	1%	0.639
Pulmonary disease	11	18%	31	12%	0.281
Corticosteroid use	3	5%	12	5%	0.649
Malignancy	1	2%	25	10%	0.032
Ascites	5	8%	15	6%	0.563
Previous laparotomy	10	16%	61	24%	0.157
Anemia	19	30%	75	30%	0.829
Jaundice	13	21%	14	6%	<0.001
Sepsis	9	14%	17	7%	0.052
Necrotizing enterocolitis	9	14%	7	3%	<0.001
Hypertrophic pyloric stenosis	16	25%	25	10%	0.001
Emergency surgery	42	67%	124	50%	0.013
Type of surgery					0.015[a]
Abdominal wall	13	21%	65	26%	
Stomach-pylorus	16	25%	29	12%	
Small bowel	14	22%	29	12%	
Large bowel	16	25%	94	37%	
Gall bladder/bile duct/liver	3	5%	12	5%	
Kidney/adrenal gland	1	2%	20	8%	
Other[b]	0	0%	3	1%	
Type of incision					0.002[a]
Transverse	36	57%	101	40%	
Midline	15	24%	38	15%	
Semilunar (umbilical)	5	8%	14	6%	
Subcostal	2	3%	14	6%	
McBurney	0	0%	50	20%	
Lumbotomy	0	0%	2	1%	
Unknown	5	8%	33	13%	
Operation time (min), median ± SD	65 ± 103	(20–600)	75 ± 83	(15–550)	0.665
Coughing	3	5%	7	3%	0.425
Vomiting	5	8%	17	7%	0.782
Wound infection	15	24%	18	7%	<0.001

[a]Overall *p* value
[b]Other: 2 splenectomies, 1 vascular procedure

Table 3 Results of multivariate stepwise logistic regression analyses

Risk factor	Odds ratio (OR)	95% CI for OR Lower limit	Upper limit	*P*value
Age up to 1 year[a]	9.5	4.03	22.36	<0.001
Wound infection	3.7	1.46	9.17	0.006
Median incision[b]	2.9	1.29	6.74	0.01
Emergency surgery	2.8	1.37	5.54	0.01

[a]Reference category age over 1 year
[b]reference category other types of incisions (McBurney, transverse, etc.)

In multivariate analyses age up to 1 year, wound infection, median incision, and emergency surgery proved independent risk factors. Adjusted for these significant risk factors, none of the other variables had significant effects.

Discussion

We have been able to investigate the second-largest population of pediatric patients with abdominal wound dehiscence reported in literature so far, covering a period of 20 years. The substantial size of the control group has enabled thorough analyses of variables to identify major independent risk factors for abdominal wound dehiscence. The severity of this complication is illustrated by the associated morbidity and mortality as described in this article.

In this study, wound infections were found in 24% of patients with abdominal wound dehiscence and in 7% of patients in the control group. Although these rates may seem to be high, similar data have been reported in literature. In previous studies on abdominal wound dehiscence, Campbell et al. reported that a deep wound infection preceded 23% of the dehisced wounds.[2] Finally, Çigdem et al. observed significant wound infection before development of abdominal evisceration in 27.5%.[5] Sharma and Sharma reported an overall wound infection rate of 5.43% in a series of 1,325 consecutive patients operated in a general pediatric surgery unit.[6] In these series, wound infection rates were 12.39% in children undergoing colonic surgery and rates of 13.75% in neonates.

Very young age has been associated with suboptimal wound healing in many studies. Impaired or immature wound healing and higher risks to develop wound infection explain the increased risk of developing abdominal wound dehiscence in children younger than aged 1 year.[6–10] Necrotizing enterocolitis is highly prevalent in this age group and is without exception combined with poor clinical condition and emergency surgery, which again negatively influence wound healing. Decreased breaking strengths of abdominal incisions, combined with increased abdominal pressure due to ileus or mechanical ventilation put a patient at risk for abdominal wound dehiscence.

Median incisions, in these series of patients, can be associated with an increased risk for abdominal wound dehiscence. Although there have been some reports of median incisions as a risk factor for abdominal wound dehiscence,[2, 4, 11, 12] a number of authors have not been able to confirm this in previous studies.[13–17] However, transverse incisions are preferred to median incisions by the majority of pediatric surgeons, largely because of the strong association between median incisions and incisional hernia in the literature. Aforementioned variables also have been reported as risk factors in adult patient series. Apparently, similar mechanisms are responsible for the development of abdominal wound dehiscence in both children and adults. Although the surgical technical aspect of abdominal wound dehiscence has not been the focus of this report, the importance of technique should not be ignored. In adults, the use of slowly resorbable suture material in a continuous suturing method has been accepted as the "gold standard".[18, 19] In pediatric surgery, however, multifilament material, such as polyglactin is still widely used. Possibly, the use of slowly resorbable suture material has less support among pediatric surgeons due to the low incidence of incisional hernia in the pediatric population. The influence of, for example, suture length to wound length ratio and tissue bite size on tissue breaking strength and the development of incisional hernia and abdominal wound dehiscence has not yet been investigated in children. For patients (both children and adults) with increased risks to develop abdominal wound dehiscence, these factors deserve more attention in future research and clinical practice.

We have studied a large number of putative risk factors for abdominal wound dehiscence in a large population of pediatric patients. For the first time, multivariate regression analyses were performed to identify major independent risk factors. Abdominal wound dehiscence has proven a serious complication, associated with high morbidity and mortality. Risk factors for abdominal wound dehiscence include patient age younger than 1 year, wound infection, median incision, and emergency surgery. Two of these factors can be mitigated by pediatric surgeons: wound infection and median incision. In view of this, measures against wound infection ought to be stimulated and median incisions should be avoided whenever possible to prevent abdominal wound dehiscence.

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Chapter 4

A 1,000 laparotomy prospective cohort study on abdominal wound dehiscence: high morbidity might be improved

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Abstract

Background: Patient-related and wound-related variables were studied to identify variables predictive for abdominal wound dehiscence (AWD) and surgical site infections (SSI).

Methods: Patients who underwent open abdominal surgery in an academic teaching hospital were included in an observational study conducted between May 2007-January 2009. Wounds were inspected daily for AWD and superficial, deep, and organ/space SSI. Follow-up after discharge was performed 30 days postoperatively. Univariate and multivariate analyses were performed to identify variables predictive of AWD and SSI.

Results: In total, 914 patients with 8,825 days of in hospital observations were included in analyses and categorized as no event (n=662, 72.4%), AWD (n=36, 3.9%), superficial (n=163, 17.8%), deep (n=23, 2.5%), or organ/space SSI (n=30, 3.3%). Patients with AWD showed the highest rates of postoperative mechanical ventilation, productive and non-productive cough, emesis, and nasogastric tube use before clinical diagnosis of AWD. Wound edge separation, amounts of exudate and wound slough, and wound malodour rates were significantly increased, whereas significantly less wound granulation was found in patients before development of AWD compared to all other patient categories. No significant differences were found for wound temperature or pain. Length of stay was doubled in patients with AWD (24 vs 12 days, $p<0.0001$). Thirty-day mortality and in hospital mortality were 14% and 17%, respectively.

Conclusion: Patients with AWD showed a distinct wound healing pattern before clinical manifestation of AWD. Wound edge separation, presence of slough, malodour or increased amounts of exudate should be included in structured assessment of abdominal wounds to decrease morbidity.

Introduction

Abdominal wound dehiscence (AWD), or burst abdomen, is a serious complication of open abdominal surgery, with a reported incidence varying between 0.4-3.5%.[1-14] Abdominal wound dehiscence is associated with significant morbidity, eg, prolonged admission with subsequent reoperations and need for intensive wound care during and after hospitalisation.[15, 16] Mortality rates vary between 4 and 35% in more recent studies.[3, 6, 8, 11, 17-23] Abdominal surgery is necessary in presence of evisceration and/or intraabdominal abscesses that cannot be drained radiologically. Also, fascial dehiscence has been associated with unsatisfactory cosmetic results, and incisional hernia formation in up to 70% of survivors.[3, 16, 18, 21, 24] The latter can negatively affect body image and physical functioning.[25] AWD has been associated with several patient and surgery related risk factors, such as age, anemia, ascites, chronic pulmonary disease, emergency surgery, jaundice, male gender, postoperative coughing, type of surgery, and wound infection.[17] Few wound related risk factors for abdominal wound dehiscence other than wound infection have been reported in literature. The goal of this study was to prospectively study clinical patient-related and wound-related variables in order to investigate the predictive value of several putative risk factors for AWD, such as induration (healing ridge), wound temperature, and amount of exudate.

Methods

The study was designed as a prospective observational cohort study and was conducted at a 1200-bed academic teaching hospital. Inclusion criteria included minimum age of 18 years and open abdominal surgery or converted laparoscopic procedure. Exclusion criteria were laparoscopic surgery, inguinal/umbilical hernia and day surgery, thus obtaining a study population that could be subjected to repetitious, daily in-hospital surveillance, with an estimated high risk of developing AWD and/or SSI. Approval for the study was obtained from the hospital's medical ethical committee. Informed consent was obtained from all study participants or from family members in case of patient incompetence.

Primary outcomes were incidence of AWD, defined as clinically observed dehiscence of the fascia of the abdominal wall incision with or without superficial dehiscence and/or evisceration, and surgical site infection (SSI) using the Centers for Disease Control and Prevention (CDC) definitions for superficial, deep, and organ/space infection.[26]
Five groups of patients were discerned for analysis: no event, or one of the following events: AWD, superficial SSI, deep SSI, or organ/space SSI. All other patients with SSI were

classified according to the severest type of infection (organ/space SSI, followed by deep SSI and superficial SSI), or were classified as AWD. Data collected after occurrence of events (AWD, superficial, deep or organ/space infection) were censored.
Secondary outcome was wound pain -described as mean pain throughout the previous 24 hours- as measured with visual analogue scale completed by the patient (score 0-100 on horizontal line indicating no pain- worst imaginable pain) from the second postoperative day on.

The following patient and surgery-related data were documented: age, gender, body mass index (BMI), comorbidity (chronic obstructive pulmonary disease, diabetes mellitus), preoperative albumin and total protein levels (measured within 5 days before surgery), preoperative hemoglobin levels (measured within 48 hours before surgery) oral systemic corticosteroid use, smoking, American Society of Anaesthesiologists (ASA) score, operation time, type of surgery, emergency surgery, and National Research Council wound contamination class. Data on length of hospital stay, reoperation within 30 days after primary surgery, 30-day and in hospital mortality were collected prospectively.

Daily observations
Abdominal wounds were examined on a daily basis (including weekends and holidays) by two research fellows from postoperative day 2 until 21 days in hospital or until discharge, if earlier. This observation period was chosen because the majority of SSI have been reported to present within 21 days postoperatively.[27,28] Research fellows were medical students in the 4th-6th year of training who participated in the study for a minimum period of five months, supervised daily by the first author (GHvR). All participants of this team observed wounds independently from the surgeon involved in the operation. At least once a week inspection rounds were performed with the supervisor. In addition, wound photographs were taken for review and discussion, if necessary.

A standard protocol was followed for wound examination (see also Table 1 for wound variables and subscores). Measurement bands were used for measurements of maximum tissue induration (mm) and maximum wound edge separation (mm) at skin level. Wound slough/necrosis type and exudate type were classified according to the most prevalent type present in the wound. Surfaces of wound slough/necrosis and granulation/epithelialisation were estimated. Findings from previous wound bandage changes were taken into account for the classification of exudate amount. Wound edge colour was classified according to colour in rest and response to touch. Wound and skin temperatures were measured in ºC (1 decimal) with DermaTemp DT-1001 LT infrared thermographic

scanners (Exergen Corporation). Wound temperature was measured in the middle of the wound in case of uncomplicated healing or at the most representative site in case of suspected infection. If bilateral temperature measurements were available for skin temperature (at 1, 3, and 5 cm from wound edges), mean temperature was calculated and used for analysis. If a single measurement was available, eg, in presence of ostomy, this measurement was used. Presence of wound malodour was determined by both researchers. In case of doubt, consensus was reached with or without supervisor(s).

Examinations were not planned on the first postoperative day to avoid break in sterility by early bandage removal.[29] Likewise, patients who underwent reoperations were not reexamined for a period of 24 hours following reoperation, data for these postoperative days were scored as missing data. Several wound variable scores were derived from a previously published Pressure Sore Status Tool.[30] Clinical data were collected on a daily basis by questioning and examining patients with regard to emesis, presence of nasogastric tubes, mechanical ventilation, productive and non-productive coughing. Nurses' and doctors' notes were reviewed for wound description, wound treatment, and indications for and use of antibiotics. If transferred (eg, Intensive Care Unit, dialysis), patients were examined in these respective departments.

Follow-up

After 21 days of clinical observation or at discharge if earlier, patients were given hard copy diaries for wound problems and VAS-scores for wound pain until postoperative day 30. Follow-up was performed at the outpatient clinic on postoperative day 30 (allowing for minor deviations for planning reasons), or alternatively by telephone or letter. In case of (re-) admission on postoperative day 30, follow-up was performed in hospital. Patient charts, discharge letters, wound photographs, and culture results were reviewed by the first author (GHvR) after a minimum period of three months after discharge for verification of events.

Table 1: Daily collected wound characteristics and measurements

Wound variable	Score	
Maximum tissue induration (mm)	0.	≥5 mm
	1.	3-4 mm
	2.	1-2 mm
	3.	0 mm
Maximum wound edge separation (mm)		… mm
Wound slough/necrosis type	0.	none visible
	1.	white/greynonviable tissue
	2.	loosely adherent yellow slough
	3.	adheren, soft, black eschar
	4.	firmly adherent, hard, black eschar
Wound slough/necrosis amount	0.	None visible
	1.	<25% of wound bed covered
	2.	25 to 50% of wound covered
	3.	>50% and <75% of wound covered
	4.	75 to 100% of wound covered
Granulation/epithelialisation	0.	Skin intact
	1.	75 to 100% of wound filled &/or tissue overgrowth
	2.	25 to 75% of wound filled
	3.	<25% of wound filled
	4.	no granulation or epitheliasation present
Exudate type	0.	none or bloody
	1.	serosanguineous: thin, watery, pale red/pink
	2.	serous: thin, watery, clear
	3.	purulent: thin or thick, opaque, tan/yellow
	4.	foul purulent: thick, opaque, yellow/green with odor
Exudate amount	0.	none (tissue is dry)
	1.	scant (non measurable amount)
	2.	small (exudate spread over wound, gauzes 25% wet)
	3.	moderate (exudate irregularly spread over wound, gauzes >25 and <75% wet)
	4.	large (large amount, widespread, gauzes >75% wet)
Wound edge colour	0.	pink or normal for ethnic group
	1.	bright red and/or blanches to touch
	2.	white or gray pallor or hypopigmented
	3.	dark red or purple and/or nonblanchable
	4.	black or hyperpigmented
Temperature (°C)	Wound	
	1 cm from wound edge (left/right)	
	3 cm from wound edge (left/right)	
	5 cm from wound edge (left/right)	
Wound maladour	Yes/no	

Statistical analysis

A total number of 1000 patients were to be recruited, based on the hypothesis that 3% of patients would develop AWD and 10% would develop SSI, allowing for sufficient group sizes to compare patient groups. Patients were included in analyses if at least two consecutive observations were recorded. Bonferroni adjustments were made to assess whether effects were unique for patients with AWD or attributable to other types of infections. Comparisons between baseline variables and endpoints were performed with chi-square test for groups, with Mann Whitney U test for continuous variables. The associations and patterns of potential wound related factors measured postoperatively and the occurrence of events were analysed with repeated measurement analysis. The models included patient random-effects for intercept and slope over time. To study development of the potential wound related factors just prior to the event the analyses above were repeated with reversed time. Reversed time is defined as time since occurrence of the event and for patients without events as last follow-up visit. Additionally, mean rates of patients with cough, productive cough, emesis and mechanical ventilation in the postoperative period were compared between outcomes with one-way analysis of variance. The Kaplan-Meier method was used to calculate survival and log-rank tests used for comparisons. P values <0.05 were considered statistically significant.

Results

Between May 2007 and January 2009, 1,000 of 1,459 eligible patients were included, 459 patients did not give informed consent as shown in the study flow chart. (Figure 1) Thirty-three patients did not fulfill inclusion criteria (eg, cancelled operation); another 53 patients were not evaluated due to less than two observation days, leaving 914 patients. Thirty-day follow-up was completed in 792/914 patients (86.6%): 620/792 patients were evaluated at the out patient clinic or in hospital (67.8%), 159/792 patients by telephone (17.4%), and 13/792 patients by email or letter (1.4%). Thirty-day mortality rate was 3.4% (n=31). In the remaining 92 patients 30-day follow-up was not completed despite repeated attempts (10.1%). All 914 patients with 8,825 days of in hospital observations were evaluated in analyses.

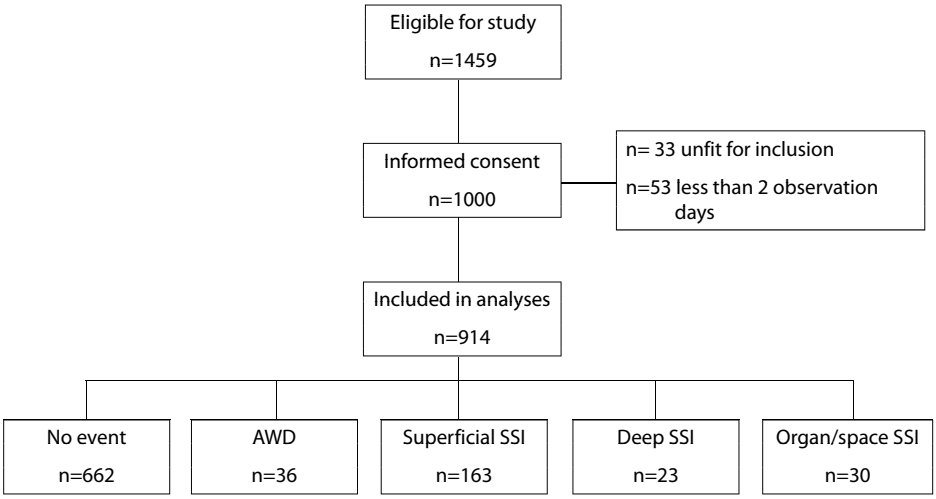

Figure 1: Study flow chart

Primary outcome

Several groups were discerned for analysis: patients without events from day 2 to day 30 (n=662, 72.4%), and 252 (27.6%) patients with events: AWD (n=36, 3.9%), superficial SSI (n=163, 17.8%), deep SSI (without AWD, n=23, 2.5%), or organ/space SSI (n=30, 3.3%).

Mean presentation of AWD was on postoperative day 10 (IQR 7-14 days). In table 2, baseline and clinical characteristics of the study subpopulations are shown according to the patient groups analyzed as severest SSI or AWD. All 36 patients with AWD met CDC criteria for classification as deep SSI. In total, 16 patients with AWD did not develop additional superficial or organ/space SSI, 17 patients developed superficial SSI (47%), and 5 patients developed organ/space SSI (14%, 2/5 developed superficial and organ/space SSI).

Univariate analyses were performed to allow for comparison of patients with AWD (n=36) and all patients without AWD (n=878). No significant differences were found for age (p=0.103), gender (p=0.233), body mass index (p=0.439), smoking (p=0.675), systemic corticosteroid use (p=1.000), diabetes mellitus (p=0.923), chronic lung disease (p=0.220), radiotherapy within last 3 months (p=1.000), chemotherapy within last 3 months (p=0.164), emergency surgery (p=1.000), ascites (p=1.000), ASA class (p=0.109), and type of incision (p=0.094). Operation time of the index operation was significantly longer in patients with AWD (median 334 min, IQR 154-463 min) compared to patients without AWD (median 216, IQR 162-348 min, p=0.014). Data with regard to preoperative hemoglobin, albumin and total protein levels were not available for at least 85% of patients, and therefore not analyzed.

Length of stay was significantly longer in patients with AWD (median 24 days, IQR 14-33 days) compared to patients without AWD (median 12 days, IQR 8-18 days), p<0.001. Readmission within 30 days was significantly more common in patients with AWD (n=5, 14%) compared to patients without AWD (n=78, 9%), p=0.004. Thirty-day mortality and in hospital mortality were higher in patients with AWD compared to patients without AWD (30-day mortality n=5 (14%) vs. n=26 (3%), p=0.002; and n=6 (17%) vs. n=41 (5%), p=0.008.

Wound-related variables and association with AWD

Associations and patterns of potential wound related variables measured postoperatively were analysed for all patient subgroups (no event, superficial, deep, organ/space SSI and AWD). Data from patients without events were used as reference data for computing differences in slope (Δ slope) and p-values. Results from the forward time and reversed time analysis are displayed in Table 3 and Table 4, respectively.

Wound pain

Mean initial VAS scores on postoperative day 2 were significantly lower for patients with AWD (21 se 4.4, p=0.0209) compared to other patient categories. Declining wound pain levels were found for all patient categories. Wound pain levels showed less decline in patients with superficial SSI (Δ slope 0.70, p=0.0009), organ/space infections (Δ slope 1.01, p=0.0399) and AWD (Δ slope 1.94, p<0.0001), compared to patients without events (slope –1.99 se 0.1).

Wound temperature

In patients with superficial SSI, deep SSI and organ/space SSI, mean wound temperatures were lower at time of events in reversed time analyses compared to patients without events (31.4ºC). Statistical significance was reached for superficial SSI (31.0ºC, Δ slope 0.03, p=0.01028); but not for deep SSI (30.4ºC, Δ slope 0.07, p=0.1501), AWD (30.7ºC, Δ slope 0.02, p=0.6577), or organ/space SSI (30.9 ºC, Δ slope 0.05, p=0.405).

Skin temperature

Baseline postoperative temperature measurements at 1 cm from wound edge were higher than wound temperatures, ranging between 31.5ºC for patients with organ/space SSI to 32.0ºC for patients without events. Skin temperature levels declined over time without significant differences between patient categories. No clinically relevant differences were found between patient categories for skin temperature at 3 and 5 cm from wound edge (see supplementary table 2).

Table 2: Population characteristics and clinical data for the subpopulations of patients analyzed as no event, patients with abdominal wound dehiscence (AWD), and patients with superficial, deep, and organ/space surgical site infections (SSI)

Variable	No event n=662		AWD n=36		Superficial SSI n=163		Deep SSI n=23		Organ/space SSI n=30	
Age (median yrs, IQR)*	58	(48-67)	62	(53-71)	60	(49-66)	52	(47-62)	60	(45-65)
Male gender	413	(62)	26	(72)	106	(65)	14	(61)	15	(50)
BMI (median, IQR)	24.8	(22.3-27.9)	24.9	(23.5-29.2)	26.5	(23.8-29.8)	25.0	(21.7-30.2)	24.9	(22.4-28.4)
Smoking	284	(43)	16	(44)	68	(42)	5	(22)	2	(7)
Sigarettes/day (median, IQR)	0	(0-10)	0	(0-20)	0	(0-10)	0	(0-0)	0	(0-0)
Alcohol units (median/week, IQR)	0	(0-7)	0	(0-4)	0	(0-7)	0	(0-5)	0	(0-6)
Systemic corticosteroids	76	(12)	4	(11)	24	(15)	6	(26)	7	(23)
Diabetes mellitus	77	(12)	4	(11)	28	(17)	5	(22)	5	(17)
Chronic lung disease	54	(8)	6	(17)	20	(12)	3	(13)	3	(10)
Radiotherapy <3 months	12	(2)	0	(0)	2	(1)	0	(0)	1	(3)
Chemotherapy < 3 months	44	(7)	0	(0)	16	(10)	1	(4)	0	(0)
Emergency surgery	141	(21)	8	(22)	40	(25)	4	(17)	13	(43)
Ascites	13	(2)	1	(3)	12	(7)	0	(0)	4	(13)
Asa class										
I	81	(12)	1	(3)	16	(10)	1	(4)	2	(7)
II	287	(43)	17	(47)	80	(49)	15	(65)	12	(40)
III	277	(42)	15	(42)	63	(39)	7	(30)	16	(53)
IV	17	(3)	3	(8)	3	(2)	-	-	-	-
V	-	-	-	-	1	(1)	-	-	-	-
Contamination degree										
Clean	134	(20)	3	(8)	26	(16)	-	-	1	(3)
clean-contaminated	482	(73)	27	(75)	121	(74)	16	(70)	20	(67)
contaminated-dirty	19	(3)	1	(3)	5	(3)	3	(13)	1	(3)
Dirty	27	(4)	5	(14)	11	(7)	4	(17)	8	(27)
Operation time (median, min, IQR)	209	(160-318)	334	(154-463)	252	(180-387)	248	(196-447)	225	(141-406)
Type of incision										
Median	303	(46)	24	(67)	85	(52)	11	(48)	16	(53)
Subcostal	127	(19)	7	(20)	42	(26)	2	(9)	4	(13)

Transverse	41	(6)	2	(6)	11	(7)	5	(22)	3	(10)
Lower oblique	181	(27)	3	(6)	22	(14)	5	(22)	5	(17)
Other#	10	(2)	-	(8)	3	(2)	-	-	2	(7)
Type of surgery										
Abdominal wall	49	(7)	1	(3)	6	(4)	2	(9)	1	(3)
Gastoduodenum	25	(4)	-	-	5	(3)	-	-	1	(3)
Gall bladder/bile duct	30	(5)	1	(3)	6	(4)	-	-	-	-
Liver	92	(14)	5	(14)	22	(14)	2	(9)	4	(13)
Other^	25	(4)	1	(3)	9	(6)	-	-	2	(7)
Small bowel	30	(5)	5	(14)	15	(9)	4	(17)	2	(7)
Kidney	178	(27)	3	(8)	22	(4)	5	(22)	5	(17)
Vascular	47	(7)	2	(6)	6	(4)	1	(4)	1	(3)
Esophagus	71	(11)	9	(25)	24	(15)	1	(4)	-	-
Large bowel	70	(11)	6	(17)	28	(17)	4	(17)	11	(37)
Pancreas	45	(7)	3	(8)	20	(12)	4	(17)	3	(10)
Length of stay (median, days, IQR)	11	(7-15)	24	(14-33)	14	(11-21)	28	(11-58)	30	(16-53)
Readmission<30 days	51	(8)	5	(14)	20	(12)	4	(17)	3	(10)
30-day mortality	19	(3)	5	(14)	5	(3)	0	(0)	2	(7)
In hospital mortality	30	(5)	6	(17)	5	(3)	0	(0)	6	(20)

BMI: body mass index (kg/m^2)
* Values present mean ± standard deviation and range
# Includes McBurney, lumbotomy, Pfannenstiel, thoracoabdominal incision
^ Includes, eg, splenectomy, adrenal gland resection

Tympanic temperature

All patient groups showed mean tympanic temperatures ranging between 37.2°C for patients without events to 37.5°C for patients with deep SSI and AWD. In reversed time analysis, all patients showed decreasing temperature levels towards events.

Cough (non-productive)

On postoperative day 2, cough was reported by 70% of patients with AWD (p=0.0809), 69% of superficial SSI (p=0.0018), 59% of patients without events (reference), 52% of deep SSI (ns), and 42% of patients with organ/space SSI (p=0.0269). Over time, significantly increasing rates of reported cough were found for patients with organ/space SSI (Δ slope 0.05, p=0.0026). In reversed time analysis, patients with AWD and organ/space SSI demonstrated the highest rates of non-productive cough (58% and 65%, respectively) of all patient categories (both p<0.0001).

Cough (productive)

At baseline, highest rates of productive cough were identified in patients with superficial SSI (48%, p=0.0002) and AWD (54%, p=0.004), compared to 38% of patients without events (reference). At time of event, patients with AWD showed the highest rate of productive cough (46%, p<0.0001). In total, 60/914 patients received antibiotics for indication of pneumonia (6.6%) during the observation period. Cough was reported by 45/60 with pneumonia (75%) compared to 59/854 patients without pneumonia (6.9%, p<0.001). Productive cough was reported by 38/60 patients (63%) with pneumonia compared to 42/854 patients without pneumonia (4.9%, p<0.001).

Emesis and nasogastric tube use

On the second postoperative day, highest rates of emesis were reported by patients with AWD (25% vs 13% of patients without events, p=0.0024). On the second postoperative day, nasogastric tubes were present in 48% of patients with deep SSI (p<0.0001), 41% of patients with AWD (p<0.0001), 27% of patients with superficial SSI (p<0.0001), and 28% of patients with organ/space SSI (p=0.0287), compared to 15% of patients without events. Patients with AWD showed the highest rates of nasogastric tube use over time. At time of event, nasogastric tubes were used by 42% of patients with AWD (p<0.0001), 30% of patients with deep SSI (p=0.0001), 27% of patients with organ/space SSI (p=0.0003), 17% of patients with superficial SSI (p<0.0001) and 4% of patients without events (reference category).

Mechanical ventilation

At baseline, 11.5% of patients with AWD were mechanically ventilated (p=0.0007), 1.6% of patients with deep SSI (p=0.4299), 3.8% of patients without events (reference), 7.2% superficial SSI (p=0.0025), and 7.4% of patients with organ/space SSI (p=0.2225). All patient categories showed decreasing proportions of patients on mechanical ventilation, except for patients with organ/space SSI, who showed an increase over time (Δ slope 0.012, p=0.0989). Reversed time analysis showed that mechanical ventilation was used in 14.9% of organ/space SSI (p<0.0001), 10.5% of AWD (p=0.0002), 8% of superficial SSI (p<0.001), 3.1% of deep SSI (p=0.8987) and 3.4% of patients without events (reference) at time of events.

Mean rates of patients suffering from cough, productive cough, emesis, or on mechanical ventilation are displayed for each patient category in Figure 2.

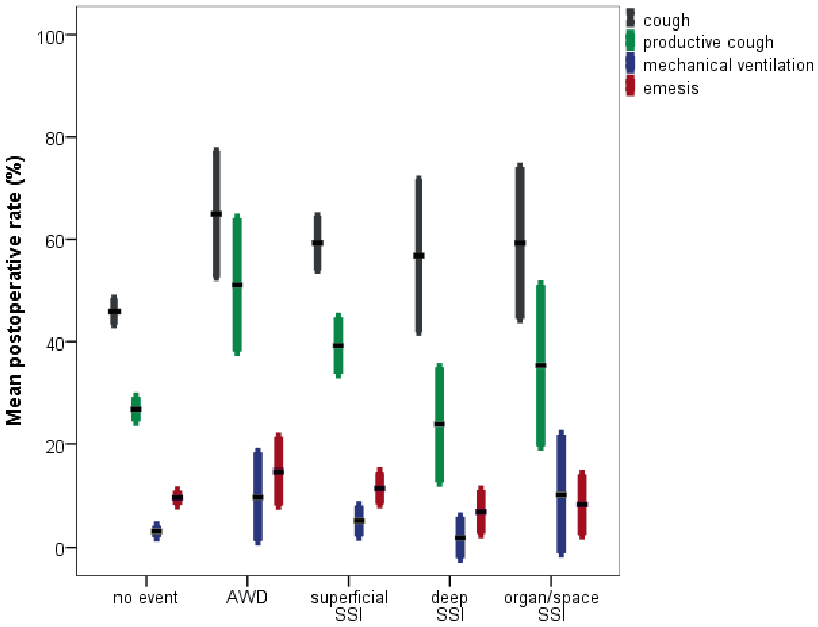

Figure 2: Mean postoperative rates of patients with cough, productive cough, emesis and mechanical ventilation in the postoperative period

Table 3: Forward time analysis

Variable		No infection n=662	AWD n=36	Superficial SSI n=163	Deep SSI n=23	Organ/space SSI n=30
Wound pain	Intercept	31.59 (0.99)	21.18 (4.39)	29.72 (1.97)	30.95 (5.31)	30.19 (4.74)
	Slope	-1.99 (0.10)	-0.05 (0.48)	-1.29 (0.18)	-1,10 (0.52)	-0.98 (0.48)
	Δ slope	-	1.94	0.70	0.89	1.01
	p-value	-	<0.001	0.0009	0.0918	0.0399
Wound temperature	Intercept	31.45 (0.08)	31.0 (0.36)	31.4 (0.16)	31.4 (0.44)	30.85 (0.44)
	Slope	-0.02 (0.01)	-0.04 (0.04)	-0.05 (0.02)	-0.10 (0.05)	0.0003 (0.06)
	Δ slope	-	-0.02	-0.03	-0.09	0.02
	p-value	-	0.635	0.1125	0.1148	0.7501
Skin temperature 1 cm	Intercept	32.0 (0.08)	31.7 (0.37)	32.0 (0.17)	32.05 (0.46)	31.5 (0.45)
	Slope	-0.03 (0.01)	-0.05 (0.04)	-0.04 (0.02)	-0.12 (0.06)	-0.004 (0.06)
	Δ slope	-	-0.01	-0.01	-0.08	0.03
	p-value	-	0.75	0.6419	0.1475	0.6346
Tympanic temperature	Intercept	37.2 (0.02)	37.5 (0.11)	37.3 (0.05)	37.5 (0.13)	37.4 (0.13)
	Slope	-0.01 (0.003)	-0.01 (0.01)	-0.01 (0.006)	-0.03 (0.02)	-0.04 (0.02)
	Δ slope	-	0.004	0.003	-0.01	-0.03
	p-value	-	0.7855	0.7145	0.5145	0.1789
Coughing	Intercept	0.59 (0.01)	0.70 (0.06)	0.69 (0.03)	0.52 (0.08)	0.42 (0.08)
	Slope	-0.02 (0.003)	-0.01 (0.01)	-0.02 (0.006)	0.01 (0.02)	0.03 (0.02)
	Δ slope	-	0.01	0.005	0.03	0.05
	p-value	-	0.4388	0.4581	0.0528	0.0026
Coughing (productive)	Intercept	0.38 (0.01)	0.54 (0.06)	0.48 (0.03)	0.33 (0.07)	0.26 (0.07)
	Slope	-0.02 (0.002)	-0.01 (0.01)	-0.02 (0.005)	-0.01 (0.01)	0.009 (0.02)
	Δ slope	-	0.01	0.004	0.004	0.03
	p-value	-	0.4144	0.5315	0.7859	0.0832
Emesis	Intercept	0.129 (0.01)	0.245 (0.04)	0.155 (0.02)	0.141 (0.05)	0.071 (0.05)
	Slope	-0.006 (0.001)	-0.02 (0.006)	-0.006 (0.003)	-0.009 (0.007)	0.005 (0.008)
	Δ slope	-	-0.01	0.0001	-0.003	0.01
	p-value	-	0.0382	0.9618	0.7011	0.1377
Nasogastric tube	Intercept	0.18 (0.01)	0.42 (0.06)	0.32 (0.03)	0.48 (0.07)	0.33 (0.07)
	Slope	-0.02 (0.002)	-0.006 (0.008)	-0.02 (0.004)	-0.03 (0.01)	-0.03 (0.01)
	Δ slope	-	0.01	-0.007	-0.02	-0.01
	p-value	-	0.2467	0.0654	0.0741	0.3412

Mechanical ventilation	Intercept	0.038 (0.005)	0.115 (0.02)	0.072 (0.01)	0.0157 (0.03)	0.074 (0.03)
	Slope	-0002 (0.001)	-0.003 (0.005)	-0.004 (0.002)	0.001 (0.007)	0.01 (0.007)
	Δ slope	-	-0.001	-0.002	0.003	0.012
	p-value	-	0.8012	0.4746	0.6549	0.0989
Amount of exudate	Intercept	0.80 (0.02)	0.79 (0.12)	0.88 (0.05)	0.34 (0.16)	1.33 (0.15)
	Slope	-0.06 (0.006)	0.22 (0.03)	0.04 (0.01)	0.13 (0.04)	0.02 (0.04)
	Δ slope	-	0.29	0.10	0.19	0.08
	p-value	-	<0.001	<0.001	<0.001	0.0272
Type of exudate	Intercept	0.38 (0.02)	0.32 (0.08)	0.44 (0.04)	0.20 (0.11)	0.66 (0.10)
	Slope	-0.02 (0.003)	0.12 (0.02)	0.04 (0.008)	0.07 (0.02)	-0.004 (0.02)
	Δ slope	-	0.14	0.06	0.09	0.02
	p-value	-	<0.0001	<0.0001	<0.0001	0.3871
Wound maladour	Intercept	0.003 (0.002)	-0.003 (0.008)	0.007 (0.004)	-0.008 (0.01)	0.006 (0.01)
	Slope	0.0003 (0.0004)	0.02 (0.002)	0.002 (0.001)	0.01 (0.003)	0.0006 (0.003)
	Δ slope	-	0.002	0.002	0.01	0.0004
	p-value	-	<0.0001	0.0633	<0.0001	0.8934
Wound slough/necrosis amount	Intercept	0.04 (0.01)	-0.14 (0.05)	-0.04 (0.02)	0.14 (0.07)	0.17 (0.07)
	Slope	0.004 (0.003)	0.11 (0.01)	0.06 (0.006)	0.05 (0.02)	0.04 (0.02)
	Δ slope	-	0.11	0.06	0.04	0.04
	p-value	-	<0.0001	<0.0001	0.0099	0.0576
Wound edge separation	Intercept	0.64 (0.14)	-6.21 (0.61)	1.17 (0.32)	2.10 (0.86)	2.13 (1.00)
	Slope	0.02 (0.05)	3.07 (0.19)	0.50 (0.10)	0.61 (0.27)	1.18 (0.32)
	Δ slope	-	3.05	0.48	0.59	1.16
	p-value	-	<0.0001	<0.0001	0.0308	0.0003
Granulation/ Epithelialisation	Intercept	0.15 (0.02)	0.32 (0.07)	0.22 (0.03)	0.42 (0.09)	0.61 (0.09)
	Slope	-0.0007 (0.006)	0.23 (0.03)	0.13 (0.01)	0.12 (0.04)	0.10 (0.04)
	Δ slope	-	0.23	0.13	0.12	0.10
	p-value	-	<0.0001	<0.0001	0.0021	0.0172
Induration	Intercept	0.83 (0.01)	0.62 (0.05)	0.82 (0.02)	0.85 (0.06)	0.82 (0.07)
	Slope	0.02 (0.003)	0.02 (0.01)	0.02 (0.006)	0.02 (0.02)	0.01 (0.02)
	Δ slope	-	-0.004	-0.0004	-0.007	-0.008
	p-value	-	0.7657	0.9514	0.6673	0.6596

* compared to patients without events (reference category)

Table 4: Reversed time analysis

Variable		No infection n=662	AWD n=36	Superficial SSI n=163	Deep SSI n=23	Organ/space SSI N=30
Wound pain	Intercept	13.43 (0.77)	18.86 (3.66)	19.01 (1.61)	26.02 (4.37	24.20 (4.64)
	Slope	1.91 (0.11)	0.07 (0.51)	0.61 (0.23)	0.59 (0.58)	0.17 (0.70)
	Δ slope	-	-1.84	-1.29	-1.32	-1.74
	p-value	-	0.0004	<0.0001	0.0266	0.0148
Wound temperature	Intercept	31.4 (0.07)	30.7 (0.32)	31.0 (0.15)	30.4 (0.42)	30.9 (0.39)
	Slope	0.01 (0.01)	0.03 (0.04)	0.04 (0.02)	0.08 (0.05)	0.06 (0.06)
	Δ slope	-	0.02	0.03	0.07	0.05
	p-value	-	0.6577	0.1028	0.1501	0.405
Skin temperature 1 cm	Intercept	31.7 (0.07)	31.3 (0.32)	31.6 (0.15)	31.0 (0.43)	31.4 (0.39)
	Slope	0.02 (0.01)	0.03 (0.04)	0.03 (0.02)	0.10 (0.05)	0.04 (0.06)
	Δ slope	-	0.002	0.005	0.07	0.02
	p-value	-	0.9698	0.8146	0.17	0.7588
Tympanic temperature	Intercept	37.1 (0.02)	37.4 (0.10)	37.3 (0.05)	37.4 (0.13)	37.4 (0.12)
	Slope	-0.009 (0.003)	-0.01 (0.01)	-0.003 (0.006)	-0.008 (0.02)	-0.006 (0.02)
	Δ slope	-	-0.004	0.006	0.001	0.003
	p-value	-	0.7357	0.3539	0.9445	0.8866
Coughing	Intercept	0.390 (0.01)	0.580 (0.05)	0.510 (0.02)	0.58 (0.07)	0.653 (0.06)
	Slope	0.02 (0.003)	0.01 (0.01)	0.02 (0.005	0.002 (0.01)	-0.02 (0.02)
	Δ slope	-	-0.006	-0.001	-0.02	-0.03
	p-value	-	0.5958	0.8527	0.2589	0.0331
Coughing (productive)	Intercept	0.200 (0.01)	0.457 (0.04)	0.329 (0.02)	0.098 (0.06)	0.292 (0.06)
	Slope	0.01 (0.003)	0.008 (0.01)	0.01 (0.006)	0.02 (0.01)	-0.002 (0.02)
	Δ slope	-	-0.006	-0.0009	0.008	-0.02
	p-value	-	0.5882	0.8726	0.5245	0.3088
Emesis	Intercept	0.069 (0.006)	0.101 (0.03)	0.111 (0.01)	0.034 (0.04)	0.085 (0.04)
	Slope	0.005 (0.001)	0.005 (0.006)	0.001 (0.003)	0.009 (0.007)	-0.0003 (0.008)
	Δ slope	-	-0.0002	-0.004	0.004	-0.005
	p-value	-	0.9765	0.2543	0.5521	0.5176
Nasogastric tube	Intercept	0.04 (0.01)	0.42 (0.05)	0.17 (0.02)	0.30 (0.07)	0.27 (0.06)
	Slope	-0.019 (0.002)	-0.002 (0.008)	-0.019 (0.004)	-0.011 (0.01)	-0.005 (0.01)
	Δ slope	-	0.017	-0.0003	0.008	0.01
	p-value	-	0.0353	0.9512	0.4229	0.2495

Mechanical ventilation	Intercept	0.034 (0.004)	0.105 (0.02)	0.080 (0.01)	0.031 (0.03)	0.149 (0.02)
	Slope	-0.002 (0.001)	0.001 (0.005)	-0.004 (0.002)	-0.0003 (0.006)	-0.005 (0.007)
	Δ slope	-	0.003	-0.003	0.001	-0.003
	p-value	-	0.5794	0.2917	0.8336	0.6669
Amount of exudate	Intercept	0.19 (0.02)	2.94 (0.09)	1.22 (0.04)	1.72 (0.13)	1.31 (0.12)
	Slope	0.06 (0.006)	-0.19 (0.03)	-0.04 (0.01)	-0.11 (0.03)	0.01 (0.04)
	Δ slope	-	0.25	0.10	0.17	0.05
	p-value	-	<0.0001	<0.0001	<0.0001	0.1737
Type of exudate	Intercept	0.14 (0.01)	1.53 (0.06)	0.81 (0.03)	1.05 (0.09)	0.71 (0.08)
	Slope	0.02 (0.003)	0.10 (0.01)	0.04 (0.007)	0.07	0.02
	Δ slope		-0.12	0.06	0.09	0.04
	p-value		<0.0001	<0.0001	<0.0001	0.0472
Wound maladour	Intercept	0.005 (0.003)	0.11 (0.01)	0.02 (0.006)	0.08 (0.02)	0.01 (0.02)
	Slope	0.0002 (0.0006)	0.008 (0.001)	0.001 (0.0006)	0.005 (0.002)	0.0006 (0.001)
	Δ slope	-	-0.001	-0.0007	-0.002	-0.001
	p-value	-	<0.0001	0.1016	0.0035	0.7673
Wound slough/necrosis amount	Intercept	0.08 (0.01)	0.94 (0.04)	0.46 (0.03)	0.60 (0.06)	0.34 (0.06)
	Slope	0.003 (0.002)	0.08 (0.009)	0.04 (0.004)	0.04 (0.01)	0.005 (0.01)
	Δ slope	-	0.08	0.04	0.04	0.002
	p-value	-	<0.0001	<0.0001	0.0007	0.8564
Wound edge separation	Intercept	0.21 (0.02)	3.68 (0.09)	1.54 (0.05)	1.57 (0.13)	1.82 (0.14)
	Slope	0.004 (0.008)	-0.33 (0.03)	-0.15 (0.02)	-0.14 (0.04)	-0.05 (0.05)
	Δ slope	-	0.34	0.16	0.14	0.05
	p-value	-	<0.0001	<0.0001	0.0008	0.313
Granulation/ Epithelialisation	Intercept	0.15 (0.02)	2.18 (0.08)	1.09 (0.04)	1.43 (0.11)	1.04 (0.10)
	Slope	0.0002 (0.005)	0.18 (0.02)	0.11 (0.01)	0.11 (0.02)	0.04 (0.03)
	Δ slope	-	0.11	0.11	0.04	0.18
	p-value	-	<0.0001	<0.0001	<0.0001	0.1564
Induration	Intercept	0.99 (0.01)	0.64 (0.05)	0.95 (0.03)	0.96 (0.07)	0.89 (0.07)
	Slope	0.02 (0.003)	-0.004 (0.01)	0.014 (0.006)	0.009 (0.01)	0.009 (0.02)
	Δ slope	-	-0.012	-0.003	-0.007	-0.008
	p-value	-	0.0945	0.6499	0.5895	0.6467

Direction of slopes was calculated from preceding days towards events
Δ slope = difference in slope compared to patients without events
p-values compared to patients without events

Amount of wound exudate

In patients without events, significant decreasing amounts of wound exudate were found over time (slope –0.06 se 0.006, p<0.001). After 5 days, 49% of all non-infected wounds did not produce any exudate and all non-infected wounds were completely dry after 12.8 days.

Patients with AWD showed the highest increase in wound exudate amount over time compared to patients without events (Δ slope 0.29, p<0.0001), followed by deep (Δ slope 0.19, p<0.0001), superficial (Δ slope 0.06, p<0.0001), and organ/space SSI (Δ slope 0.08, p=0.0272). At time of event, wound exudate amount and increase over time were highest for patients with AWD (intercept 2.94, Δ slope 0.25). Mean wound exudate amount intercept scores were 1.72 for patients with deep SSI, 1.31 for organ/space SSI, and 0.18 for patients without events.

Type of exudate

At time of event, highest scores for type of exudate were found for patients with AWD, implicating a higher proportion of patients with purulent wound exudate. The highest proportion of patients with serosanguineous wound exudate compared to other types of exudate was found in patients with organ/space SSI.

Wound slough/necrosis amount

Significant increases in amount of wound slough/necrosis were found over time for patients with AWD (Δ slope 0.11, p<0.0001), superficial SSI (Δ0.06, p<0.0001), and deep SSI (Δ slope 0.04, p=0.0099), with a trend towards significance for organ/space SSI (Δ slope 0.04, p=0.0576). The highest mean score was found for patients with AWD at time of event (0.94, score 0= none, score 1=<25% of wound covered, p<0.0001). No clinically relevant differences were found between patient categories for type of wound slough/necrosis (see supplementary table 2).

Wound edge separation

AWD showed most progression in wound edge separation (measured at skin level) compared to patients without events (Δ slope 3.05, p<0.001). In reversed time analysis, mean wound edge separation was 25 mm in patients with AWD (p<0.0001), compared to 0.9 mm for patients without events (reference), 6.3 mm for superficial SSI (p<0.0001), 6.1 for deep SSI (p<0.0001), and 10.0 for organ/space SSI (p<0.0001) at time of events. No clinically relevant differences were found between patient categories for wound edge colour (see supplementary table 2).

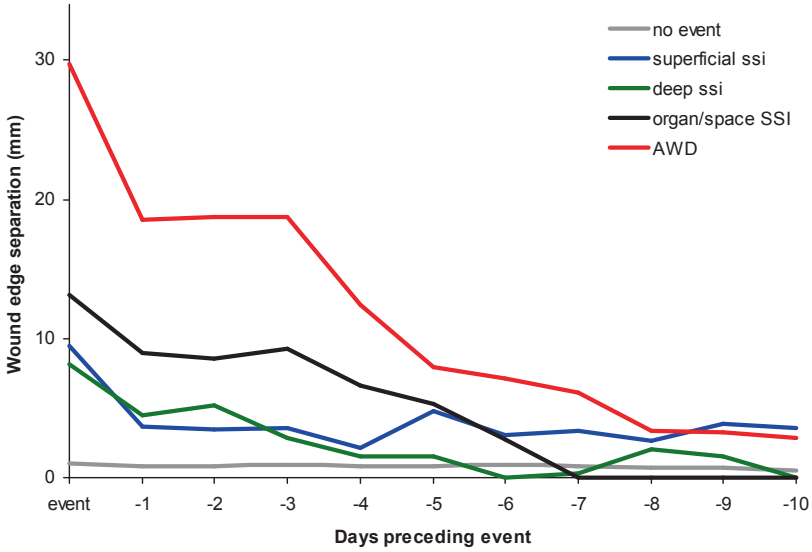

Figure 3: Wound edge separation in mm for patients with and without events.
Wound edge separation is shown for patients without events (no event), superficial surgical site infections (superficial SSI), deep surgical site infections (deep SSI), organ/space surgical site infections (organ/space SSI) and abdominal wound dehiscence (AWD). Events are displayed at day 0, and values for days preceding the events are displayed along the x-axis.

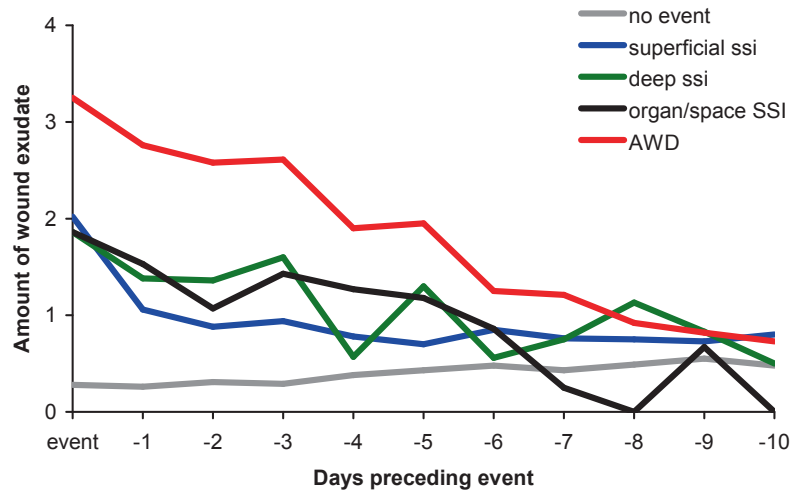

Figure 4: Amount of wound exudate score for patients with and without events.
Scores are displayed for patients without events (no event), superficial surgical site infections (superficial SSI), deep surgical site infections (deep SSI), organ/space surgical site infections (organ/space SSI) and abdominal wound dehiscence (AWD). Scores for amount of wound exudate are 0 none (dry tissue); 1 scant (non measurable amount); 2 small (gauzes 25% wet); 3 moderate (gauzes >25% and <75% wet) ; 4 large (gauzes >75% wet)
Events are displayed at day 0, and values for days preceding the events are displayed further along the x-axis.

Granulation/epithelialisation
Significantly lower degrees of granulation/epithelialisation were found for patients towards events compared to patients without events (all p<0.0001). The lowest degree of granulation/epithelialisation was found in patients with AWD (Δ slope 0.18, p<0.001).

Induration
At baseline, patients with AWD showed significantly greater palpatory ridges compared to patients without events (p<0.0001), but this difference was not clinically relevant (Δ score - 0.21). All patients showed decreasing palpatory ridges over time.

Wound maladour
Rates of wound maladour significantly increased over time in patients with deep SSI and AWD compared to patients without events (p<0.0001), with a trend towards significance for patients with superficial SSI (Δ slope 0.002, p=0.0633). In reversed time analysis, wound malodour at time of event was found in 10.6% of patients with AWD (Δ score 0.10, p<0.0001), 7.7% of deep SSI (Δ score 0.07, p<0.0001), 2% of superficial SSI (Δ score 0.02, p=0.0296), 1% of organ/space SSI (Δ score 0.005, p=0.763) and 0.5% of patients without events (reference category).

Bonferroni correction was applied to adjust for multiple testing (supplementary Table 1).

Discussion

Prospective longitudinal studies on clinical aspects of wound healing with regard to normal and complicated human abdominal wound healing remain scarce. This prospective observational study on wound healing after laparotomy is the first to have performed daily, consecutive wound observations on a large number of patients. Also, this study cohort is one of the very few prospective cohorts including patients with AWD. With adequate 30-day follow-up and review of hospital records, it is highly probable that most patients with AWD and SSI were identified. In our study, 27.6% of patients developed events (superficial SSI, deep SSI, organ/space SSI and/or AWD). This high percentage of 27.6% is in consistency with percentages found in other prospective studies.[31, 32] In our study, risk factors for AWD were analysed at patient and at wound level.

Previously published studies on risk factors for AWD included our study in adults [17] and the study by Webster et al.[1] In both studies multivariate analyses were included. Our previous study, which included 363 patients with AWD and 1089 control patients, revealed the

following independent risk factors for AWD: age, gender, emergency surgery, chronic pulmonary disease, jaundice, anemia, ascites, type of surgery, postoperative coughing, and postoperative wound infection.[17] Obesity was not identified as a risk factor for AWD in this study or in the former study, consistent with other reports.[2, 3, 8, 9] In the current study, no significant effects were found in univariate analyses for any of the tested variables with exception of operation time, which was also identified as a risk factor for wound dehiscence by others [1, 33] In this study, smoking could not be identified as a risk factor for AWD, nor was the amount of cigarettes consumed per day of influence. Similar results were found by Kenig et al.[34] Smoking was identified as a risk factor in one previously published case-control study, but this effect could be based on a type I error.[35]

Several risk factors for AWD related to abdominal wound healing have been reported in literature. Pareira and Serkes described wound healing of laparotomy patients of a single clinic during a six-year period. In his study, absent or partial 'healing ridges', i.e. induration of the wound edges, were observed in patients who developed AWD. Healing ridges were never absent in normally healed patients, and partial healing ridges were only found in a small proportion of normally healed patients.[36] In our study, no clinically detectable differences were found for degree of induration between patients with AWD and patients without AWD.

Production of large amounts of serosanguineous wound exudate has been reported to occur in 23-84% of patients with AWD.[9, 12, 23, 37-40] In most of these publications, no clear descriptions of follow-up, study methods or statistical analysis were given. Our study results confirm that increase in wound exudate is significantly correlated with occurrence of AWD, more so than with SSI. Reported increase in amount of wound exudate, equal to or exceeding 25% of gauze surface, necessitates wound examination as this is a symptom of surgical site infection or AWD. In uncomplicated wound healing, no or scant amounts of wound exudate are found with a decreasing trend over time.

Perioperative hypothermia has been associated with an increased risk of developing SSI.[41] These negative effects on wound healing have been extrapolated to low wound temperature, but the evidence for this extrapolation is of low quality.[42-44] In our study, tympanic temperature measurements in all patient categories decreased over time with few variations. Low wound temperature has been suggested to be associated with delayed epithelial recovery, reduced collagen production and reduced presence of inflammatory cells.[45] As wound temperature has been reported to depend on core temperature, environmental temperature and presence of wound bandages, these factors may influence wound healing. The threshold for fibroblast activity has been reported to be at 33 °C in in vitro studies.[45, 46] Room temperature was not measured in our study, and showed little variation in the study by McGuiness et al.[45] In our study, gauzes were

removed prior to wound temperature measurements in case of open wounds. If adherent, minimal amounts of normal room-temperature saline solution were added to allow for painless removal of bandages but the wounds were not cleansed. Adding normal saline solution might have influenced wound temperature measurements, as full cleansing of wounds with saline has been reported to cause an average drop in wound temperature of 2.7°C.[45] In our study, wound temperatures were lower at time of the events in patients with superficial SSI (31.0°C), deep SSI (30.4°C) and AWD (30.7°C) compared to patients without events (31.4°C). However, the small differences in wound and skin temperatures over time lacked clinical relevance.

Mean VAS scores for wound pain on postoperative day 2 were below 32 in all patient categories, thereby demonstrating adequate pain management. Initial VAS scores for patients with AWD were significantly lower than for patients from other categories. All patient categories showed declining wound pain levels over time, and none of the patient categories showed an increase in VAS scores towards the events. The latter is not easily explained, as wound pain has always been considered to be one of the symptoms of wound infection.

Cough has been described as a risk factor by several other authors, but has not been studied prospectively.[1, 8, 10, 11, 17, 47] Patients with AWD were among the patients with the highest percentages of (non-)productive cough on the 2nd postoperative day and this is a clear difference with patients with deep SSI without AWD. During coughing, forces are exerted on the abdominal wall which can create (localized) disruption of the abdominal wall, and may eventually lead to AWD or incisional hernia. Coughing showed high correlation with antibiotic treatment for pneumonia. Pneumonia was also described as a risk factor for AWD by others.[1, 34] The use of mechanical ventilation, which results in increased intraabdominal pressure, was significantly more frequent in patients with AWD compared to other patient categories. Meena et al recently described significantly higher intraabdominal pressure values in patients with wound dehiscence compared to patients without wound dehiscence.[34]

Postoperative nausea or emesis was identified as a significant risk factor in (univariate) analyses by Cöl et al.[11] Likewise, Mäkela et al found significant effects for vomiting and prolonged intestinal paralysis in their case-control study.[8] Both studies included small numbers of patients with AWD. No significant effects were found for emesis in our aforementioned study on risk factors for AWD.[17] Keill et al performed a case-control study in which causes of increased intraabdominal pressure (defined as distension, ascites, vomiting, and hiccups) were scored retrospectively, and no significant effects were found.[9] Underscoring of emesis may have been more common in retrospective studies, especially if only doctors' notes were reviewed. In this prospective study, emesis and use

of nasogastric tube were scored daily and both nurses' and doctors' notes were reviewed. High rates of emesis and nasogastric tube use were reported in patients with AWD (25% and 41%, respectively) and stayed high at time of events (10.1% and 42%, respectively). Our study results imply important roles for mechanical factors in the pathophysiological mechanism of AWD, which stresses the need for optimal abdominal wall closure technique. Tissue tensile strength is decreased in presence of infection. Wound malodour has been associated with infection caused by anaerobe bacteria.[48] A significant increase in the rate of patients with wound maladour was found in patients with superficial SSI (2%), deep SSI (7.7%), and AWD (10.6%) compared to patients without SSI (0.5%). Patients with infections showed increasing amounts of wound slough/necrosis over time. The mean wound slough/necrosis score was highest in the group of patients with AWD, representing a wound bed surface covered with slough/necrosis under 25%. Increased amounts of wound slough/necrosis were also found for patients with superficial SSI and deep SSI.

In patients with AWD, wound edge separation at skin level was clearly increased (at 25 mm) at the time of event compared to other patient groups, and showed the lowest degree of granulation/epithelialisation. Therefore, wound malodour, lack of granulation tissue, presence of wound slough/necrosis, wound edge separation and increasing wound exudate necessitate regular wound examination for AWD. Retraction at level of the fascia can result in ventral hernia formation. Early diagnosis of dehiscence and wound exploration may show limitation of fascial retraction. This might improve outcome of suture closure with or without mesh augmentation of the abdominal wall, resulting in less cases of rebursts and frequently reported incisional hernia of up to 70%.[16] If closure is not possible, negative pressure wound therapy in combination with mesh-mediated fascial traction resulted in a high percentage of initial successful closure by reduction of fascial retraction in a study by Acosta et al.[49] Furthermore, at 1-year follow-up, few small incisional hernias were found.[50]

In our study, AWD was associated with high morbidity, i.e. doubling of hospital stay (24 vs. 12 days) and considerable thirty-day and in hospital mortality rates (14 and 17%, respectively). Our study results have shown that structured assessment of abdominal wounds should include the following: 1) degree of wound edge separation, 2) amount of wound exudate, 3) presence of wound slough/necrosis, 4) presence of wound malodour, and 5) degree of granulation/epithelialisation. Incorporation of these aforementioned items in a wound checklist deserves future evaluation, as early diagnosis and treatment might be most promising in decreasing the high morbidity associated with AWD.

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Supplementary Table 1: Bonferroni-adjusted comparisons between AWD, superficial SSI, deep SSI, organ/space SSI and reference category no event

Variable		Mean difference*	SE	*P*value	95% CI	
					lower	upper
Coughing	AWD	-0.191	0.06	0.018	-0.362	-0.019
	Superficial	-0.134	0.03	<0.001	-0.218	-0.050
	Deep	-0.109	0.07	1.000	-0.317	0.099
	Organ/space	-0.134	0.07	0.641	-0.338	0.069
Coughing (productive)	AWD	-0.243	0.06	<0.001	-0.405	-0.081
	Superficial	-0.123	0.03	<0.001	-0.204	-0.045
	Deep	0.029	0.07	1.000	-0.168	0.227
	Organ/space	-0.852	0.07	1.000	-0.278	0.108
Emesis	AWD	-0.051	0.03	1.000	-0.143	0.042
	Superficial	-0.018	0.02	1.000	-0.064	0.027
	Deep	0.027	0.04	1.000	-0.085	0.139
	Organ/space	0.013	0.04	1.000	-0.097	0.123
Mechanical ventilation	AWD	-0.067	0.01	0.196	-0.147	0.014
	Superficial	-0.021	0.03	1.000	-0.060	0.019
	Deep	0.012	0.03	1.000	-0.085	0.109
	Organ/space	-0.072	0.03	0.338	-0.167	0.023
Necrotic wound type	AWD	-0.528	0.08	<0.001	-0.750	0.306
	Superficial	-0.242	0.04	<0.001	-0.351	-0.132
	Deep	-0.548	0.10	<0.001	-0.818	-0.279
	Organ/space	-0.40	0.09	<0.001	-0.662	-0.134
Necrotic wound amount	AWD	-0.428	0.06	<0.001	-0.610	-0.246
	Superficial	-0.183	0.03	<0.001	-0.273	-0.093
	Deep	-0.375	0.08	<0.001	-0.596	-0.154
	Organ/space	-0.271	0.08	0.004	-0.488	-0.055
Exudate type	AWD	-0.740	0.09	<0.001	-0.987	-0.493
	Superficial	-0.402	0.04	<0.001	-0.524	-0.280
	Deep	-0.440	0.11	<0.001	-0.741	-0.140
	Organ/space	-0.545	0.10	<0.001	-0.838	-0.251
Exudate amount	AWD	-1.531	0.14	<0.001	-1.918	-1.144
	Superficial	-0.632	0.07	<0.001	-0.823	-0.441
	Deep	-0.699	0.17	<0.001	-1.169	-0.229
	Organ/space	-0.987	0.16	<0.001	-1.447	-0.527
Wound edge separation	AWD	-10.14	0.10	<0.001	-12.949	-7.324
	Superficial	-2.690	0.54	<0.001	-4.213	-1.167
	Deep	-5.476	1.24	<0.001	-8.975	-1.978
	Organ/space	-6.254	1.35	<0.001	-10.056	-2.453
Wound edge colour	AWD	-0.232	0.10	0.200	-0.512	0.048
	Superficial	-0.067	0.05	1.000	-0.205	0.072
	Deep	-0.134	0.12	1.000	-0.474	0.206
	Organ/space	-0.054	0.12	1.000	-0.386	0.279
Nasogastric tube	AWD	-0.207	0.04	<0.001	-0.320	-0.095
	Superficial	-0.087	0.02	<0.001	-0.144	-0.029
	Deep	-0.211	0.05	<0.001	-0.350	-0.072
	Organ/space	-0.152	0.04	0.005	-0.274	-0.030
Wound malodour	AWD	-0.073	0.01	<0.001	-0.103	-0.043
	Superficial	-0.019	0.01	0.005	-0.034	-0.004
	Deep	-0.039	0.01	0.033	-0.076	-0.002
	Organ/space	-0.029	0.01	0.111	-0.062	0.003
Granulation/epithelialisation	AWD	-1.413	0.11	<0.001	-1.623	-1.203
	Superficial	-0.650	0.06	<0.001	-0.757	-0.542
	Deep	-0.848	0.13	<0.001	-1.108	-0.588
	Organ/space	-0.803	0.12	<0.001	-1.032	-0.575
Induration	AWD	-0.187	0.06	.027	-0.363	-0.012
	Superficial	-0.052	0.03	1.000	-0.140	0.037
	Deep	0.001	0.08	1.000	-0.214	0.215
	Organ/space	-0.015	0.07	1.000	-0.204	0.174

* compared to patients without events (reference category)

Supplementary Table 2:

Variable		No infection n=662	AWD n=36	Superficial SSI n=163	Deep SSI n=23	Organ/space SSI n=30
Skin temperature 3 cm	Intercept	32.1 (0.08)	31.8 (0.36)	32.0 (0.17)	32.3 (0.45)	31.6 (0.45)
	Slope	-0.04 (0.01)	-0.05 (0.04)	-0.05 (0.02)	-0.13 (0.06)	0.03 (0.06)
	Δ slope	-	-0.009	-0.006	-0.09	0.07
	p-value	-	0.849	0.7945	0.1321	0.2282
Reversed time analysis	Intercept	31.7 (0.07)	31.4 (0.32)	31.6 (0.15)	31.1 (0.42)	31.7 (0.39)
	Slope	0.03 (0.01)	0.03 (0.04)	0.03 (0.02)	0.09 (0.05)	0.01 (0.06)
	Δ slope	-	-0.004	0.0001	0.06	-0.03
	p-value	-	0.9182	0.9966	0.245	0.6626
Skin temperature 5 cm	Intercept	32.0 (0.08)	31.9 (0.37)	32.0 (0.17)	32.2 (0.48)	31.6 (0.44)
	Slope	-0.05 (0.01)	-0.08 (0.04)	-0.07 (0.02)	-0.11 (0.06)	0.02 (0.06)
	Δ slope	-	-0.03	-0.01	-0.05	0.07
	p-value	-	0.5368	0.5361	0.3685	0.2229
Reversed time analysis	Intercept	31.6 (0.07)	31.2 (0.32)	31.4 (0.15)	31.1 (0.46)	31.7 (0.39)
	Slope	0.04 (0.01)	0.05 (0.04)	0.05 (0.02)	0.07 (0.05)	0.02 (0.06)
	Δ slope	-	0.01	0.002	0.03	-0.02
	p-value	-	0.7868	0.9417	0.5842	0.7126
Wound slough/necrosis type	Intercept	0.04 (0.01)	-0.16 (0.06)	-0.04 (0.03)	0.21 (0.08)	0.16 (0.08)
	Slope	0.006 (0.004)	0.14 (0.02)	0.08 (0.008)	0.07 (0.02)	0.07 (0.02)
	Δ slope	-	0.13	0.07	0.07	0.07
	p-value	-	<0.0001	<0.0001	0.0026	0.0056
Reversed time analysis	Intercept	0.10 (0.01)	1.19 (0.06)	0.62 (0.03)	0.89 (0.08)	0.57 (0.07)
	Slope	0.01	0.06	0.03	0.08	0.07
	Δ slope	-	0.10	0.05	0.06	0.02
	p-value	-	<0.0001	<0.0001	<0.0001	0.3071
Wound edge colour	Intercept	1.15 (0.02)	1.11 (0.09)	1.04 (0.04)	1.01 (0.11)	1.38 (0.11)
	Slope	-0.02 (0.004)	0.02 (0.02)	0.01 (0.01)	0.01 (0.02)	-0.06 (0.03)
	Δ slope	-	0.04	0.03	0.03	-0.04
	p-value	-	0.0535	0.0016	0.1893	0.1677
Reversed time analysis	Intercept	0.90 (0.01)	1.28 (0.07)	1.14 (0.03)	1.19 (0.10)	1.01 (0.09)
	Slope	0.02 (0.004)	-0.02 (0.02)	-0.01 (0.009)	-0.02 (0.02)	0.02 (0.03)
	Δ slope	-	-0.04	-0.03	-0.04	-0.006
	p-value	-	0.0289	0.0003	0.092	0.8235

For reversed time analyses, direction of slopes was calculated from preceding days towards events
Δ slope = difference in slope compared to patients without events
p-values compared to patients without events

Chapter 5

Long-Term Outcome Study in Patients with Abdominal Wound Dehiscence: a Comparative Study on Quality of Life, Body Image, and Incisional Hernia

GH van Ramshorst, HH Eker, JA van der Voet, J Jeekel, JF Lange

Abstract

Objective: Long-term quality of life and body image of patients with abdominal wound dehiscence were assessed.

Methods: Thirty-seven patients with abdominal wound dehiscence from a prospectively followed cohort of 967 patients (2007–2009) were reviewed. Patients completed the Short Form 36 quality of life questionnaire and Body Image Questionnaire and participated in semi-structured telephone interviews. For each patient, four controls were matched by age and gender. Analyses were adjusted for age, gender, comorbidity, and follow-up length.

Results: Of the 37 patients with abdominal wound dehiscence, 23 were alive after a mean follow-up of 40 months (range 33–49 months). Nineteen patients developed incisional hernias (83 %). Patients with abdominal wound dehiscence reported significantly lower scores for physical and mental component summaries (p=0.038, p=0.013), general health (p=0.003), mental health (p=0.011), social functioning (p=0.002), and change (p=0.034). No differences were found for physical functioning (p=0.072), role physical (p=0.361), bodily pain (p=0.133), vitality (p=0.150), and role emotional (p=0.138). Patients with abdominal wound dehiscence reported lower body image scores (median 16.5 vs. 18, p=0.087), cosmetic scores (median 13 vs. 16, p=0.047), and total body image scores (median 30 vs. 34, p=0.042).

Conclusions: At long-term follow-up, patients with abdominal wound dehiscence demonstrated a high incidence of incisional hernia, low body image, and low quality of life.

Introduction

Abdominal wound dehiscence, or burst abdomen, is an acute hernia, a defect of the fascia occurring in the early postoperative period. It is a severe complication of open abdominal surgery, associated with high morbidity and mortality rates varying between 3 and 35 % in most studies.[1–10] No previous studies have investigated quality of life, body image, or costs in patients with abdominal wound dehiscence. Both conservative and operative management of abdominal wound dehiscence have been associated with a very high incidence of incisional hernia.[2] Van 't Riet et al. found an incidence of incisional hernia of 44 % at 1 year and a 10-year cumulative incidence of 69 % after various types of wound dehiscence repair, with abdominal aortic aneurysm and evisceration as significant independent risk factors for incisional hernia.[1] Also, the use of mesh in abdominal wound dehiscence repair can be complicated by mesh infection, enterocutaneous fistula formation, and mesh migration, especially in the presence of intra-abdominal infection.[3,11] Although various studies have studied the long-term impact of incisional hernia on quality of life and/or body image, no studies have focussed specifically on quality of life in patients with abdominal wound dehiscence.[12–14] Therefore, this study was intended to prospectively determine and compare the long-term health-related quality of life and body image between patients with abdominal wound dehiscence and a group of control patients from the original study cohort. In addition, rates of recurrence (reburst), incisional hernia, and costs were studied.

Materials and Methods

Between May 2007 and January 2009, 967 eligible patients who underwent open abdominal surgery at a university hospital were included in a prospective observational study which involved daily protocolled abdominal wound assessment.[14,15] Primary outcomes for this study included surgical site infection and abdominal wound dehiscence. Abdominal wound dehiscence was defined as a defect of the fascia of the abdominal wall incision during the postoperative period. The pre-estimated incidence of abdominal wound dehiscence in this cohort was 3%. Type of management (conservative or operative repair, with or without mesh) of abdominal wound dehiscence was left to the surgeon in charge. Inclusion criteria were age 18 years and over, open abdominal surgery, and converted laparoscopic abdominal surgery. Exclusion criteria were laparoscopic abdominal surgery and umbilical, inguinal, and day surgery. These patients were excluded due to the low incidence of abdominal wound dehiscence and the generally short hospital admission, which would have resulted in too few in-hospital observations. Study approval was

obtained from the Institutional Review Board, and all patients had given written informed consent.

From August to September 2011, all patients from the original study cohort who had developed abdominal wound dehiscence were reviewed for long-term follow-up. All in- and out-patient records, operation notes, and patient correspondence were reviewed for operation details, type of repair, in- and out-patient complications, incisional hernia, enterocutaneous fistula formation, mesh infection, and type of hernia repair. Presence of incisional hernia was obligatory verified by physical examination, either during follow-up by the authors or through patients' doctors. Deceased patients were identified through national administrative data and, thereafter, excluded from further follow-up. All remaining patients were subjected to semi-structured telephone interviews; questions included in this interview are shown in Table 1. Inquiries were made for surgical and general health issues, and collected data were verified.

Table 1: Telephone interview questions

No.	Question
1	Do you now have an incisional hernia?
2	Do you wear any type of supportive clothing, such as a corset, abdominal binder, or anything else?
3	Do you have any complaints, such as swelling or pain?
4	How did you experience the reoperation?
5	How was the cause of the abdominal wound dehiscence explained to you?
6	Did you consider the abdominal wound dehiscence a medical error or a complication?
7	Did you feel more insecure about the future due to the wound complications?
8	Did you receive wound care after discharge, and if so, how long/frequently?

All patients were requested to complete the Body Image Questionnaire (BIQ) and Short Form 36 (SF-36) questionnaire. The BIQ consists of a body image score and a cosmetic score and has been used in several studies.[16,17] The body image score and cosmetic score are awarded 5–20 points and 3–24 points, respectively. Adding both scores results in a total body image score, which can vary between 8 and 44 points, with higher scores signifying higher patient satisfaction. The SF-36 questionnaire consists of 36 items that comprise eight health domains including physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. Component summary scores are calculated for mental and physical health. Calculated scores range between 0 and 100 points, with higher scores signifying higher quality of life. Charlson Comorbidity Index (CCI) scores, as described by Charlson et al., were calculated for all patients to indicate severity of patients' health condition.[18] For this comorbidity score, one point is awarded for myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary

disease, connective tissue disease, ulcer disease, stroke or transient ischemic attack, and diabetes. Two points are awarded for hemiplegia, moderate or severe renal disease, diabetes with end-organ damage, any tumor, leukemia, and lymphoma. Three points are awarded for moderate to severe liver disease, and six points are awarded for metastatic solid tumor and AIDS.

Recurrence of dehiscence (reburst) was defined as division of all layers of the abdominal wall after previous repair for abdominal wound dehiscence. This included tearing of mesh after mesh repair, with resultant evisceration and need for subsequent (mesh) repair.

For each patient, four controls matched by age and gender were randomly selected from the original study cohort to compare the SF-36 questionnaire and Body Image Questionnaire responses. The assessor was not blinded as to whether patients were cases or controls. Thus, 92 patients were selected from a group of patients from the original study cohort, who were clinically evaluated for presence of incisional hernia. Of the 967 included patients, 374 patients gave informed consent and were examined at a separate follow-up, the results of which have been published previously.[14] The remaining 593 patients were deceased ($n = 176$), incompetent ($n = 1$), emigrated/untraceable ($n = 11$), nonresponders despite repeated attempts ($n = 244$), or refused participation ($n = 161$). Incisional hernia was defined as a palpable defect in the abdominal wall of the incision used for the operation performed during the initial study period, resulting in herniation of abdominal contents. All patients had completed the SF-36 questionnaire and Body Image Questionnaire after a median follow-up of 16 months after surgery (range 10–24 months). Abdominal wound dehiscence was an exclusion criterium for selection of controls.

Further, it was attempted to estimate abdominal wound dehiscence-related costs by calculating median hospital costs based on admission period (measured in days) and wound nurse care costs (measured in number of visits) by using standardized reference data for economic evaluations of the Dutch health-care system as described by Hakkaart-van Roijen et al.[19] Costs associated with the surgical procedure were based on published calculated costs of on-demand second look laparotomies in patients with peritonitis in The Netherlands, at €1,139 per procedure.[20]

Statistical Analyses

Differences between the patients with abdominal wound dehiscence and controls were analyzed in univariate analysis using the chi-square test or Mann–Whitney *U* test for categorical or continuous data, respectively. Multiple linear regression was used to evaluate the impact of abdominal wound dehiscence on questionnaire responses. Adjustments were made for the putative effects of age, gender, length of follow-up, and patient comorbidity (indicated by CCI) by using these factors as covariates in statistical analyses. *P* values <0.05 were considered statistically significant.

Results

In total, 37/967 patients developed abdominal wound dehiscence (3.8%) and 6/37 patients with abdominal wound dehiscence died in hospital (16%). At baseline, there was no significant difference in comorbidity (CCI) between patients with conservative treatment ($n = 19$, CCI mean 3.0 ± 2.1) and operative treatment ($n = 18$, CCI mean 2.9 ± 2.7; $p = 0.535$). All patients with evisceration ($n = 10$) were operated; mortality was high with four in-hospital deaths (and two deaths during follow-up). After a mean follow-up of 40 months (range 33–49 months), eight patients had died and were lost to follow-up. The remaining 23 patients all participated in this study (see Fig. 1). In total, 8/23 patients included (35%) were operated for abdominal wound dehiscence (four polydiaxonone loop, two polyglactin mesh, one composite mesh inlay, one component separation technique with bridging composite mesh) and 15 patients were treated conservatively (65%).

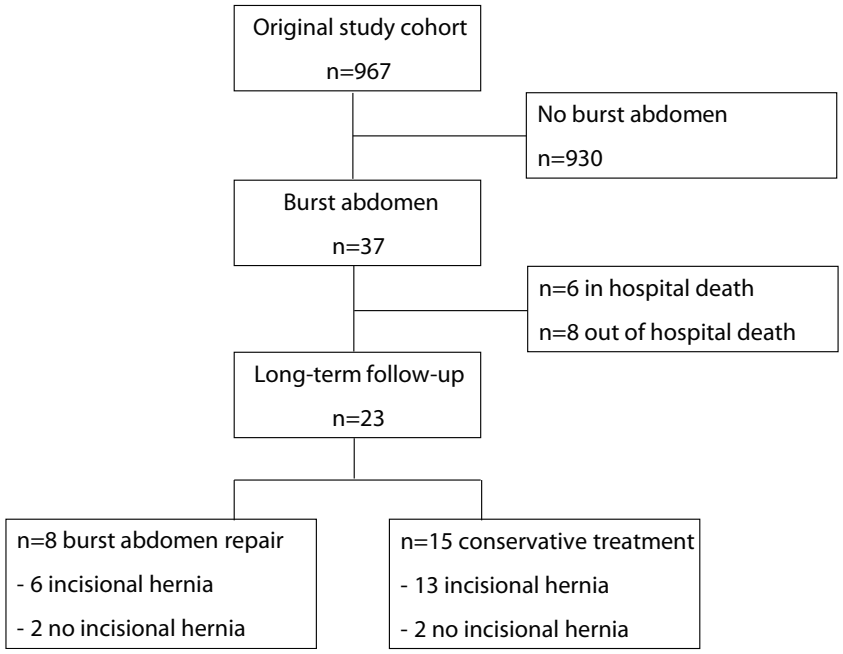

Fig. 1: Flow chart

All patients completed the questionnaires and telephone interviews. Baseline characteristics of patients with abdominal wound dehiscence and of the control group are displayed in Table 2. Incisional hernias were found in 19 of 23 patients (83%) at 40 months, 13/15 of whom had been treated conservatively for abdominal wound dehiscence and

6/8 had been operated for abdominal wound dehiscence (2/4 polydiaxonone loop, 4/4 mesh repairs). All 19 cases of incisional hernia were objectified by physical examination. Eight patients had undergone incisional hernia repair (42%), and during follow-up, two of the eight patients were operated again for incisional hernia recurrences.

Table 2: Baseline of patients with abdominal wound dehiscence and of the control group

Variable	Abdominal wound dehiscence (*n* = 23)	Control group (*n* = 92)	*P* value
Age in years (mean ± SD)	62 ± 15.2	61 ± 14.4	0.817
Gender: male/female	16/7	64/28	1.000
CCI score (mean ± SD)	3.3 ± 2.7	2.7 ± 2.7	0.230
BMI[a] (mean ± SD)	26.3 ± 3.6	25.3 ± 4.0	0.271
ASA class (*n*)[a]			0.189
I	4% (1)	12% (11)	
II	48% (11)	42% (39)	
III	40% (9)	45% (41)	
IV	9% (2)	1% (1)	
V	–	–	
Incisional hernia	83% (19)	20% (18)	<0.001
Follow-up in months (mean ± SD)	40 ± 5	17 ± 3	<0.001

BMI body mass index (in kilograms per square meter), *CCI* Charlson Comorbidity Index, *ASA* American Society of Anesthesiologists
[a]At time of initial surgery

In Table 3, the differences in the SF-36 questionnaire and BIQ results are shown for patients with and without abdominal wound dehiscence after adjustments for age, gender, CCI, and length of follow-up. The median length of follow-up was 17 months in the control group vs. 40 months in the abdominal wound dehiscence group (p<0.001). Patients with abdominal wound dehiscence did not report significantly lower body image scores than control patients (median 16.5 vs. 18, p=0.087). Patients with abdominal wound dehiscence reported significantly lower cosmetic scores (median 13 vs. 16, p=0.047) and total body image scores (median 30 vs. 34, p=0.042) compared with controls. Patients with abdominal wound dehiscence also reported significantly lower scores for SF-36 physical component summary (p=0.038) and mental component summary (p=0.013), as for subscores general health (p=0.003), mental health (p=0.011), social functioning (p=0.002), and change score (p=0.034). No significant differences were found for physical functioning (p=0.072), role physical (p=0.361), bodily pain (p=0.133), vitality (p=0.150), and role emotional score (p=0.138) (see also Fig. 2).

Table 3: Mean and standard deviation (SD) scores for Short Form 36 questionnaire and Body Image Questionnaire for patients with abdominal wound dehiscence and for the control group. Results have been adjusted for age, gender, length of follow-up, and Charlson Comorbidity Index (CCI) score

Questionnaire	Abdominal wound dehiscence (n = 23)	Control group (n = 92)	Mean difference (95% CI)[a]	*P*value
Body Image Questionnaire				
Body image score	15.2 (4.6)	16.5 (3.8)	−1.7 (−3.7 to 0.3)	0.087
Cosmetic score	12.4 (5.1)	15.0 (5.0)	−2.5 (−5.0 to −0.0)	0.047
Total body image score	27.6 (9.1)	31.5 (8.3)	−4.4 (−8.6 to −0.2)	0.042
Short Form 36 questionnaire				
Physical functioning	58.4 (33.3)	71.4 (22.0)	−11.0 (−22.9 to 1.0)	0.072
Role physical[b]	49.6 (43.5)	59.8 (42.1)	−9.9 (−31.4 to 11.5)	0.361
Bodily pain	67.9 (28.1)	75.9 (24.3)	−9.3 (−21.5 to 2.9)	0.133
General health	46.9 (26.6)	59.8 (23.0)	−11.6 (−23.1 to −0.6)	0.003
Vitality	54.7 (21.7)	62.4 (18.8)	−7.1 (−16.7 to 2.6)	0.150
Social functioning	64.9 (27.6)	82.3 (20.5)	−17.6 (−28.4 to −6.8)	0.002
Role emotional	74.7 (36.9)	75.7 (37.0)	−13.6 (−31.6 to 4.4)	0.138
Mental health	68.3 (25.5)	78.1 (15.3)	−11.6 (−20.5 to −2.7)	0.011
Change score	57.6 (35.0)	71.7 (25.7)	−14.4 (−27.7 to −1.1)	0.034
Physical component summary[b]	55.3 (22.9)	67.1 (19.2)	−10.6 (−20.7 to −0.6)	0.038
Mental component summary	62.9 (22.6)	73.0 (15.4)	−10.7 (−19.3 to −2.3)	0.013

[a]Mean difference between patients with abdominal wound dehiscence compared to the control group
[b] *n* = 22 available for abdominal wound dehiscence group

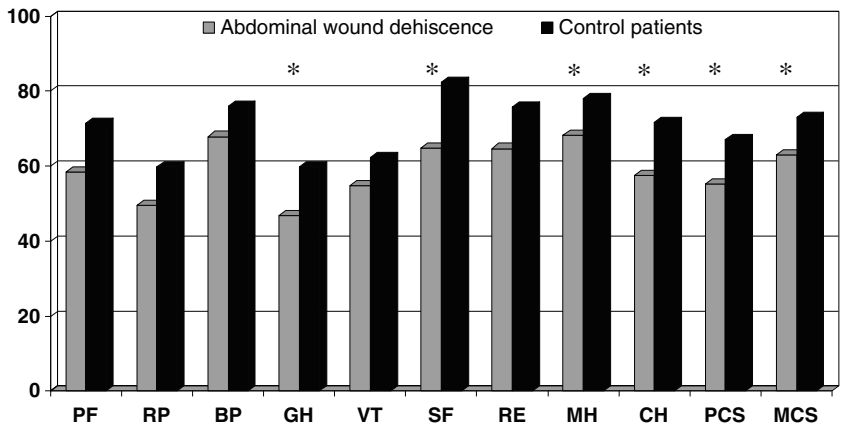

Fig. 2: Mean scores for Short Form 36 questionnaire for patients with abdominal wound dehiscence and for the control group. *$p < 0.05$, significant difference after adjustments for age, gender, length of follow-up, and Charlson Comorbidity Index score. PF physical functioning, RP role physical, BP bodily pain, GH general health, VT vitality score, SF social functioning, RE role emotional, MH mental health, CH change score, PCSphysical component summary, MCS mental component summary

Telephone Interviews

All patients participated in the telephone interviews and responded to all the questions. Of the 19 patients with confirmed incisional hernia, 15 self-reported swelling at the incisional site at the time of the interview. The other four patients had undergone incisional hernia repair and did not report any swelling. Four patients with incisional hernia reported use of custom-made corsets at the time of the interview. Six patients reported use of abdominal binders in the past; they had discontinued the use of binders after hernia repair ($n = 3$) or due to binder-related discomfort ($n = 3$). Out of 23 patients, nine (39%) reported abdominal wall pain and two patients reported back pain (9%). Enterocutaneous fistulas were present in two patients; one patient had undergone multiple excisions in the presence of polypropylene mesh, and the other patient was treated conservatively. Four out of eight patients who were reoperated for abdominal wound dehiscence had few or no recollections due to illness. The other four patients remembered feeling terrible, disappointed, ill-fated, or unprepared (all $n = 1$). Out of 23 patients, 12 (52%) stated that no explanation was ever given for the abdominal wound dehiscence; three patients stated that they had been too ill to remember whether or not any explanation was given, and eight patients were satisfied with explanations provided at the time (35%). A total of seven patients (30%) did not consider themselves competent enough to determine whether abdominal wound dehiscence was a complication or medical error. Sixteen patients stated that they considered abdominal wound dehiscence a complication of surgery, and not a medical error (70%). One patient, however, considered the resulting incisional hernia as a medical error. Six patients felt more insecure about their future due to the wound complications (26%); other patients did not report wound-related feelings of insecurity.

Median hospital stay was 11 days for control patients and 24.5 days for patients with abdominal wound dehiscence ($p < 0.001$). There was no significant difference in length of admission postdehiscence between patients with abdominal wound dehiscence who were treated conservatively and patients who were treated operatively (median 15 vs. 18 days, p=0.429). Hospital care costs (€575 per day for academic hospitals) were €6.325 for control patients and €14.088 for patients with abdominal wound dehiscence, in case of conservative treatment (additional costs €7.763).[19] In total, 10 repairs for abdominal wound dehiscence and/or recurrent dehiscence (rebursts) were performed in eight patients. The additional costs for abdominal wound dehiscence associated with relaparotomy procedures were €11,390 (10 × €1,139); an average of €1,424 per operated patient.[20]

Of all patients with abdominal wound dehiscence, five patients did not need specialized wound care. Four patients were discharged to a care hotel ($n=1$), nursing home ($n=2$), or to another hospital ($n=1$). Fourteen patients had received home (wound) care over a median period of 7.5 weeks (range 2–52 weeks), with a median of 67 visits (range 14–730). Application of the standard personal care nursing tariffs (€44 per visit) resulted in a median nurse cost of €2.948 per patient in this group of 14 patients. Most health insurance companies reimburse up to €200 for abdominal binders ($n=6$) and up to €500 for custom-made corsets ($n=4$), which results in a mean expense of €139 for abdominal support per patient (calculated as [6 × €200 + 4 × €500] / 23 patients). Direct wound costs (e.g., gauzes) and indirect costs (e.g., return to work) could not be calculated. In conclusion, health-care costs were €10.850 higher (€7.763 for hospital care, €2.948 for nurse wound care, and €139 for abdominal support) in patients with conservatively treated abdominal wound dehiscence compared to uncomplicated control patients. In addition, €1,424 was spent on surgical repairs in operated patients.

Discussion

This is one of few studies to report on long-term results in patients with abdominal wound dehiscence and the first to report on health-related quality of life in this vulnerable patient group. As mortality in this group of usually elderly patients is very high, especially in patients with evisceration, data have remained scarce.[15,21] The study was designed as a prospective single-center study, in which quality of life, body image, and incidence of incisional hernia were measured in patients with abdominal wound dehiscence.

The incidence of incisional hernia after abdominal wound dehiscence was extremely high at 83%, which is considerably higher than the 10–48% incidence of incisional hernia reported in the literature.[5,7,10,22] In two patients who were treated conservatively for abdominal wound dehiscence, no incisional hernias were found at physical examination. The fascial defects in these patients were small at original presentation and did not lead to clinically detectable incisional hernias. It cannot be excluded that these defects would have been detectable using ultrasonography or computed tomography. It would have been preferable if one of these methods had been used in these patients. The high incidence of incisional hernia could partly be explained by the high proportion of conservatively treated patients in our study. Also, length of follow-up in our study was longer than ever reported at a median follow-up of 40 months (range 33–49 months). Van 't Riet et al. concluded that a follow-up of at least 2 years appeared important because they diagnosed 31% of incisional hernias in patients with burst abdomen repair after more than 2 years postoperatively.*1* The incidence of incisional hernia in the group of control

patients was 20% at a median period of follow-up of 17 months, which is consistent with the data reported in the literature.

New study findings included data on health-related quality of life and body image of patients with abdominal wound dehiscence, which to our knowledge have not been reported previously. In this study, health-related quality of life was investigated with the SF-36 questionnaire and BIQ, submitted by all patients. Ninety-two patients from the original study cohort, who were matched by age and gender and had not developed abdominal wound dehiscence after open abdominal surgery, were randomly selected to serve as controls. In these analyses, adjustments were made for important confounders such as age, gender, comorbidity, and length of follow-up. Ideally, control patients would also have been matched on comorbidity and length of follow-up too to minimize the risk of bias, but the former was not possible in the chosen study setup because the number of cases with significant comorbidity was too low in the control group. SF-36 questionnaire results illustrated the frailty of the patient group with regard to both physical and mental elements. Patients with abdominal wound dehiscence reported significantly lower scores for cosmesis and total body image. Scores for physical component summary were significantly lower and physical functioning reached borderline significance, which could be explained by the negative effects on abdominal wall function caused by the high incidence of incisional hernia of 83% in patients with abdominal wound dehiscence.[23] Also, scores were significantly lower for the components mental health and mental component summary. These effects are not easily explained as adjustments were made for patient comorbidity and, therefore, may be based on the modest number of patients included in our study. As social functioning and change scores were also significantly lower in patients with abdominal wound dehiscence, it appeared that patients with abdominal wound dehiscence had become more socially incapacitated and isolated than control patients.

It was attempted to make an estimation of the direct costs associated with abdominal wound dehiscence by calculating costs for in-hospital stay and out-of-hospital wound nurse care. Health-care costs were €10.850 higher in patients with conservatively treated abdominal wound dehiscence compared to uncomplicated control patients, and for operated patients, an average of €1,424 per patient was spent on surgical repairs. Unfortunately, direct wound costs could not be calculated as wound gauze use was not recorded prospectively. Indirect costs related to return to work or loss of informal care provided by our patients could not be calculated. However, in view of the fact that many patients were already retired at the time of surgery, return to normal daily activities might have been a more relevant variable for this study. Also, it ought to be considered to include costs for incisional hernia repair as costs directly associated with abdominal wound dehiscence, as the incidence of incisional hernia was very high at 83%.

Interestingly, interviewed patients did not consider abdominal wound dehiscence a medical error but a complication of surgery. Besides many patient-related risk factors for abdominal wound dehiscence, technical risk factors may also include the suture length-to-wound length ratio, which has proven to be strongly associated with the occurrence of incisional hernia.[21,24–27] Use of small bites (short stitch lengths) with small intersuture distances and a suture length-to-wound length ratio of at least 4 is thought to be associated with a better division of pressure across the suture line, which would lead to a lower incidence of incisional hernia. Since at the time of this study, the suture length-to-wound length ratio was not standardly measured, it remains unsure whether this technical aspect was associated with cases of abdominal wound dehiscence. Application of the optimal suture technique might lead to a reduction of abdominal wound dehiscence, especially in high-risk patients. Harlaar et al. performed an experimental study in which tensile strengths were compared between long and short stitch lengths in porcine abdominal walls.[28] In the long stitch length group only, a slacking effect was observed with separation of fascia edges at suture intervals as tensile forces were increased. This effect, in vivo, might represent the incipient dehiscence. Use of small bites with small inter suture distances was compared with regular large bites with large intersuture distances in the "Suture Techniques to reduce the Incidence of The inCisional Hernia" trial (clinical trial identification no. NCT01132209), the inclusion of which was recently completed.[29] The trial was powered for occurrence of incisional hernia after 1 year and may also give an answer as to which of the two investigated techniques is more effective in preventing burst abdomen. The previously published randomized controlled trial by Millbourn et al. showed no significant difference between small and large bites in the occurrence of burst abdomen (secondary outcome, 1/381 long stitch length and 0/356 short stitch length, p=0.99).[27]

Preventive use of mesh is a concept that has not been studied extensively in patients at risk for abdominal wound dehiscence. Three French studies have compared the use of preventive polyglactin 910 mesh with other methods. Paye et al. published a series of patients in which two consecutive groups were compared: treatment with polyamide mesh glued to the skin vs. intraperitoneal polyglactine 910 mesh.[30] The latter was associated with a reduced rate of wound dehiscence (4 vs. 13%, p=0.02), but the study was not randomized and no adjustments were made for possible confounders. Gainant et al. performed a comparable randomized study in which 8/50 patients with polyamide mesh glued to the skin developed burst abdomen requiring surgery vs. 0/50 patients with intraperitoneal polyglactin 910 mesh (p<0.01).[31] Tohme et al. published a retrospective study on patients who were treated with extraperitoneal retention sutures ($n = 226$) or intraperitoneal polyglactin 910 mesh ($n = 66$).[32] The incidence of burst abdomen was

significantly lower in the polyglactin 910 mesh group (0/66 vs. 14/226 patients, p=0.02), but the patient groups were not comparable. In none of the aforementioned studies, stratification was performed for the estimated risk of burst abdomen. Risk estimation and stratification will be essential for future trials focussing on prevention of burst abdomen. Our previously published risk score will be helpful for this purpose by allowing calculation of individuals' probability of developing burst abdomen.[21] Variables included in the risk score are age, gender, chronic pulmonary disease, ascites, jaundice, anemia, emergency surgery, type of surgery, coughing, and wound infection.

The use of biological mesh could form a viable alternative for the use of polyglactin 910 mesh, which is completely absorbed in 90 days. Although more costly, biological mesh can be used in a contaminated environment and could offer support for a longer period of time compared to polyglactin 910 mesh. Reabsorption time also depends on the subtype of biological mesh (cross-linked or non-cross-linked). Although not yet studied as prevention of abdominal wound dehiscence, it was attempted to investigate the use of a cross-linked biological mesh for prevention of incisional hernia in patients with abdominal wound dehiscence. The international multicenter, randomized controlled trial "Repair of Challenging Abdominal Wall Defects: Strattice™ in Abdominal Wall Repair trial (StAR)" was terminated due to inclusion problems (clinical trial identification no. NCT01083472).[33] The termination of this trial illustrated that inclusion of ill patients with complications such as abdominal wound dehiscence in the acute setting remains challenging. Studies like these, however, are warranted to provide the surgical community with more evidence regarding the treatment of abdominal wound dehiscence. Future (randomized) studies should focus on determining short- and long-term benefits of operative treatment (primary suture, biological and synthetic mesh) compared to conservative approach.

Conclusion

Patients with abdominal wound dehiscence constitute a vulnerable patient group with high short- and long-term mortality rates. In this group of predominantly conservatively treated patients, the incidence of incisional hernia was high at 83% after a median follow-up of 40 months. Eight patients with incisional hernia (42%) underwent reoperations. Patients with abdominal wound dehiscence reported significantly lower body image and lower scores for both physical and mental quality of life components, compared to control patients. Conservative treatment of abdominal wound dehiscence is associated with disappointing results. Future studies should investigate success rates of mesh repair for abdominal wound dehiscence, compared to conservative approach.

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Chapter 6

Therapeutic Alternatives for Burst Abdomen

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Abstract

Burst abdomen is a postoperative complication associated with significant morbidity and mortality. The risk factors for burst abdomen are patient- and surgery-related. The management of this complication is a relatively unexplored area within the field of surgery. Relevant surgical outcomes include recurrence, mortality, and incisional hernia.

A total number of 27 studies are identified that reported on at least one surgical outcome (recurrence, mortality, or incisional hernia rate) of at least 10 patients with burst abdomen. None of the identified studies were designed prospectively, and only a minority of studies reported surgical outcomes of considerable numbers of patients with burst abdomen. Reported conservative management options included use of saline-soaked gauze dressings and negative pressure wound therapy. Operative management options included temporary closure options (open abdomen treatment), primary closure with various suture techniques, closure with application of relaxing incisions, use of synthetic (non-absorbable and absorbable) and biological meshes, and the use of tissue flaps.

The treatment of burst abdomen is associated with unsatisfactory surgical outcome. Randomized controlled clinical trials are needed to provide the surgical community with a greater level of evidence for the optimal treatment strategy for burst abdomen and the various subtypes.

Introduction

Burst abdomen is a serious complication of abdominal surgery and could be considered as an acute postoperative hernia. Reported incidence rates vary between 0.4% and 3.5%.[1–15] Despite advances in perioperative care, surgical techniques, and materials, the incidence of burst abdomen has remained unchanged over the past few decades.[16] In contrast to the large number of published articles to date on risk factors associated with burst abdomen, few reports exist on the surgical outcome of treated burst abdomen. In this chapter, the treatment options for burst abdomen and the surgical outcome will be discussed.

Etiology of Burst Abdomen

Burst abdomen usually occurs during the first two weeks after surgery.[2,17–21] In 23% to 84% of wounds, leakage of serosanguineous fluid is observed before dehiscence occurs.[9,12,19,22–24] Patient- and surgery-related factors may put a patient at increased risk of developing abdominal wound dehiscence. Patient-related variables that have frequently been reported as risk factors include age, male gender, anemia, chronic pulmonary disease, poor nutritional status, emergency surgery, and wound infection.[1–11,14,25] Infections of the operation site have been reported to be present in as many as 18% to 72% of patients with burst abdomen.[2,6,9,11,12,23–28] Tillou et al. reported a trauma series with a 71% intra-abdominal infection rate in patients with fascial dehiscence compared to 4.6% in patients without.[29] All fascial dehiscence patients with intra-abdominal infections required laparotomy (31%) or computed tomography (CT-)guided percutaneous drainage supporting routine evaluation for intra-abdominal infection in this patient group.[29] Graham et al. diagnosed intra-abdominal infections in 47 out of 90 patients (52%) operated upon for fascial dehiscence (32 patients with abscess, 15 with anastomotic leakage).[24] Fever and leucocytosis did not distinguish between patients with intra-abdominal infections compared to those without. The presence of intra-abdominal infection was associated with a significantly greater mortality rate of 44% versus 20% in patients without intra-abdominal infection.[24]

Surgical risk factors include the type of suture material and surgical technique.[17] Brown and Goodfellow found a trend toward a lower incidence of wound dehiscence with or without evisceration in transverse incisions compared to midline incisions in a systematic review.[30] Several studies have shown that absorbable fascial sutures are associated with an increased risk of developing an incisional hernia but found no association with burst abdomen.[31–34] One meta-analysis by Weiland et al. found a greater incidence of wound dehiscence if continuous absorbable closures or interrupted nonabsorbable closures were used, but these findings were not confirmed by two other meta-analyses by Rucinski

et al. and van 't Riet et al.[35–37] Weiland et al. also reported lower incidences of dehiscence and hernia if mass closures were used compared to layered closures.[35] A suture length to wound length (SL:WL) ratio of less than 4:1 has been associated with an increased incidence of incisional hernia, and may also expose patients to an increased risk of burst abdomen.[38–41] A definitive answer to the question of whether the SL:WL ratio is a relevant risk factor for burst abdomen can only be provided if these ratios are documented as part of the standard abdominal closure procedure.

Surgical outcome

The most frequent complications of burst abdomen include recurrence, mortality, and incisional hernia. Another complication is the occurrence of enterocutaneous fistula. Enterocutaneous fistula formation has only been reported incidentally after burst abdomen and will not be discussed in this chapter.[42,43]

Recurrence

The technical failure of surgical repair results in recurrences. Published recurrence rates vary between 0% and 35%.[2,18–20,22,42,44,45,50] The fascia, which has already been damaged during the initial (suture) repair and dehiscence thereafter, may be more prone to tearing after subsequent operative repair, especially in the presence of increased intra-abdominal pressure. Increases in intra-abdominal pressure can occur in the presence of abdominal distension as a result of bowel edema, mechanical obstruction, coughing, vomiting, or urinary retention.[42] Tensile and bursting strengths of fascia, subcutis, and skin are impaired in cases of infection, tissue necrosis, and poor nutritional status. A mesh repair can also result in recurrence: Our prospective data include four observations of patients with burst abdomen who underwent polyglactin mesh repair and developed recurrences due to tearing of the mesh (Fig. 1).

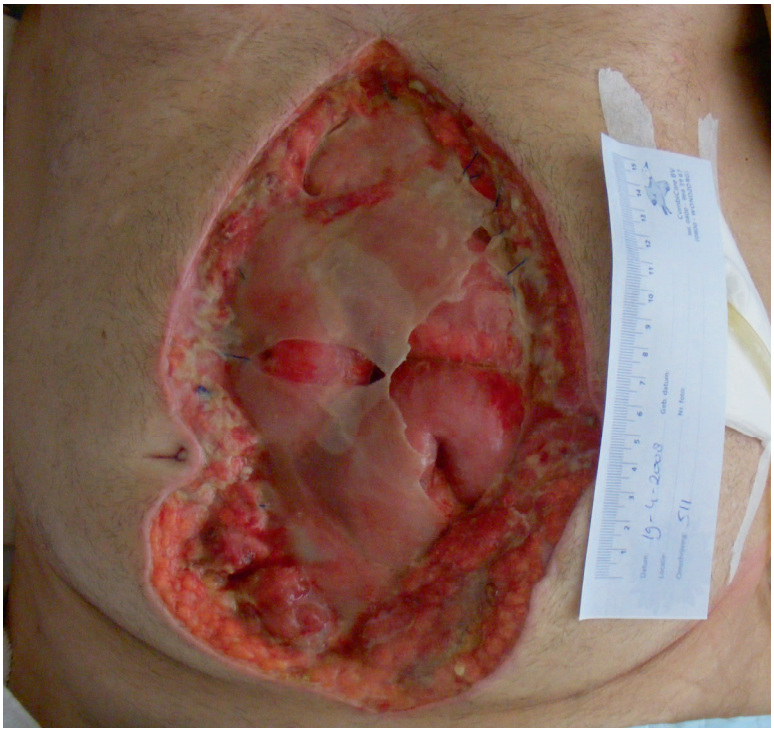

Figure 1. Example of repeat dehiscence by tearing of polyglactin mesh.

Mortality

Reported mortality rates of burst abdomen vary between 4% and 85% (Table 1). Cöl et al. reported a relation between the number of risk factors present for burst abdomen and the mortality rate.[11] Variables assigned as risk factors in this study included hypoproteinemia, nausea/vomiting, abdominal distension, wound infection, two or more drains, fever, an operation not performed by a senior surgeon, and wound closure of all layers with interrupted silk sutures. Mortality was found to be 30% for patients with seven risk factors and 58% for patients with eight risk factors. Madsen et al. reported the causes of death for 48 patients with burst abdomen, in order of frequency: cardiorespiratory insufficiency (n = 28), peritoneal sepsis (n = 7), primary disease (n = 5), complicating illness (n = 3), hemorrhage (n = 2), and unknown cause (n = 3).[22] White et al. reported the causes of death of 40 patients: malignant disease (n = 12), respiratory failure and pneumonia (n = 5), coronary occlusion (n = 4), renal failure (n = 3), pulmonary embolism (n = 3), peritonitis (n = 1), cardiovascular accident (n = 1), and hematemesis (n = 1).[20] Cardiac and respiratory complications were the most frequently reported causes of death in burst abdomen patients.

Table 1: Studies with reports of 10 or more patients with burst abdomen and surgical outcome

Author	Year	Type of study	No pt	Technique (number of patients and specific aspects)	Recurrence rate %	Mortality rate %	Incisional hernia rate %	Follow-up (range)
Reitamo[23]	1972	Retrospective	49	NR	10%	35%	10%	NR
Keill[9]	1973	Retrospective	47	21 through-and-through retention sutures 12 one-layer fascial closre with wire 10 wire fascial closure with retention sutures 2 conservative treatment 2 NR	11%	30%	NR	NR
Grace[48]	1976	Retrospective	103	96 resuture with or without tension sutures 7 conservative treatment	2.1%	20%	48%	NR
Sanders[75]	1977	Retrospective	11	NR	NR	18%	60%	NR (max 3 years)
Helmkamp[19]	1977	Retrospective	70	Single-layer through-and-through stainless steel or silver wire retention sutures	0%	3%	NR	NR
White[20]	1977	Retrospective	123	Resuture with deep tension sutures and a two-layer closure when possible	1.1%	24%	19%	NR
Haddad[26]	1980	Retrospective	70	NR	NR	5.7%	NR	NR
Stone[76]	1981	Retrospective	13	NR	NR	85%	NR	NR
Tohme[77]	1991	Retrospective	14	7 retention sutures 2 polyglactine mesh 5 conservative treatment	22%	29%	NR	NR
Riou[12]	1992	Retrospective	31	30 retention sutures 1 conservative treatment	NR	29%	NR	NR
Paye[77]	1992	Retrospective	17	9 repair 8 conservative treatment	22%	53%	NR	NR
Madsen[22]	1992	Retrospective	198	198 resuture with mass or retention sutures with non-absorbable braided or monofile sutures, often using a plastic bridge or polyvinylchloride tube	5.6%	24%	23%	NR
Wahl[2]	1992	Retrospective	30	27 resuture with interrupted sutures and two or three traction sutures 3 adapted wound edges, planned relaparotomies	11%	20%	NR	NR
Mäkelä[8]	1995	Retrospective	48	40 continuous sutures 8 interrupted sutures Type of suture: 39 polyglycolic acid 5 polyglyconate 4 polyglactin 910 28 cases additional steel-wire retention sutures	4%	10%	15%	NR
Gislason[3]	1995	Retrospective	14	11 resuture 3 conservative treatment	NR	14%	NR	NR
Graham[24]	1998	Retrospective	107	90 repair 17 conservative management	NR	35%	NR	NR
Cöl[11]	1998	Retrospective	40	30 repair 10 conservative treatment	0%	30%	NR	NR

McNeeley[49]	1998	Retrospective	36	11 polypropylene mesh 7 polyglactin mesh 18 NR	NR	5.6%	8%	6 months NR
Gislason[50]	1999	Retrospective	78	Type of suture: 18 polyglactin 17 polyglycolic acid 10 polyglyconate 2 polydioxanone 2 polyamide 29 NR Type of technique: 29 interrupted with retention sutures 8 continuous with retention sutures 9 interrupted 2 continuous 5 retention sutures alone 25 NR	1%	14%	43%	23 months (1-8 years)
Dare[55]	2000	Retrospective	14	13 interrupted nylon 1 sutures with tension sutures 1 conservative treatment	NR	14%	NR	NR
Hendrix[78]	2000	Retrospective	48	NR	NR	4%	NR	NR
Fleischer[18]	2000	Retrospective	38	Polyglyconate 1 sutures. Retention sutures or laparostoma with mesh on indication	8%	NR	27%	NR
Pavlidis[6]	2001	Retrospective	89	89 single layer closure Sterile tapes	NR	16%	NR	NR
Fackeldey[79]	2004	Retrospective	54	13 primary closure with nonresorbable suture (Prolene) 41 polyglactin mesh	NR	31.5%	NR	NR
Van 't Riet[44]	2004	Retrospective	168	Type of suture: 79 polyglactin 42 polydioxanone 9 polypropylene 9 polyglactin mesh 16 polypropylene mesh 1 polyester mesh 12 NR Type of technique: 70 interrupted 62 continuous 36 NR	9.5%	25%	44%†	37 months (3-146 months)
Heller[42]	2006	Retrospective	13	4 NPWT followed by no closure 4 NPWT followed by component separation 5 NPWT followed by delayed primary closure (including 3 polypropylene mesh repairs)	0%	NR	NR	6 months NR
Abbott[45]	2007	Retrospective	37	27 primary closure 7 polyglactin mesh 3 conservative treatment	35%	NR	19%	NR (3 months-8 years)

NR: not reported, * Including incisional hernia patients, † one-year incidence, NPWT: negative pressure wound therapy

Incisional Hernia

The development of an incisional hernia is a frequent, late complication of burst abdomen.[18,44,46,47] If burst abdomen is treated conservatively, an incisional hernia will develop in all cases. Reported incidences of incisional hernia vary between 6% and 48%, with a cumulative incidence of 69% after 10 years.[18,20,22,44,45,48–50] The high incidence of incisional hernia suggests that patients who develop burst abdomen are more prone to develop this late type of wound failure than the average patient population.

Search strategy

PubMed-Medline, EMBASE, and the Cochrane Library were searched for relevant publications and their references up to November 2009 using the keywords "abdominal wound dehiscence," "fascial dehiscence," "evisceration," and "burst abdomen." Searches were limited to studies in adults and elderly patients. Studies that reported on at least one surgical outcome (recurrence, mortality, incisional hernia) on 10 or more patients with burst abdomen are included in Table 1.

Results

A total number of 27 studies were identified. Data on applied techniques and the associated surgical outcomes were extracted (see Table 1). Treatment techniques for burst abdomen and the surgical outcomes associated with the applied techniques were incomplete in the majority of these reports. No prospective case series or randomized studies were found.

Conservative Management

Nonoperative management is a viable option for patients with small defects, in cases of a high risk of iatrogenic intestinal perforation due to vast adhesions, massive bowel edema, or if the general status of the patient does not allow for immediate surgery.[17] Wounds can be covered with saline-soaked gauze dressings. Regular gauze dressings are inexpensive in terms of direct material costs but will require frequent dressing changes.

The use of negative pressure wound therapy (NPWT) has been reported in 13 patients with fascial dehiscence by Heller et al. and resulted in definitive fascial closure in 9 out of these 13 patients.[42] Subramonia et al. applied NPWT in 9 patients with fascial dehiscence and 42 patients with either a laparostomy ($n = 10$) or more superficial types of abdominal wound dehiscences ($n = 32$).[43] The total group of patients showed a 29% mortality rate and 29% incisional hernia rate at a median follow-up of 8 months. No separate percentages were

reported for patients with fascial dehiscence. NPWT has been reported to promote the production of granulation tissue and the reduction of wound volume, and can be used if direct contact with intra-abdominal organs is prevented.[42] Adequate wound debridement usually precedes the placement of NPWT dressings. Granulated exposed bowel can heal either by secondary intention or by covering with split-thickness skin grafts, for instance, as part of a two-staged procedure or tissue flaps.[42,51] Virtually every conservatively managed patient who is denied operative repair will develop an incisional hernia.

Operative Management

A number of authors advocate debridement of necrotic and infected tissue, and exploration of the abdomen for the presence of intra-abdominal abscess formation, (infected) hematomas, intestinal (anastomotic) leakage, and obstruction.[17,18] It is unknown whether a local exploration of the dehisced fascia suffices in cases of small defects in the absence of clinical symptoms of infection or whether the entire fascia needs to be opened (and re-closed).

Primary Suture Closure

Primary closure can be performed using a mass closure technique with a slowly absorbable running monofilament suture. Generally, an SL:WL ratio of at least 4:1 is advised.[52] It is not known whether traditional tissue bites and suture distances of 1 cm should be used or small tissue bites with small suture distances of 0.5 cm, although use of the latter technique is supported by several clinical and experimental studies.[38,39,53,54] Primary closure without additional measures is possible in half of patients with abdominal wall rupture according to Fleischer et al.[18] Abbott et al. reported a 56% success rate associated with the primary closure of fascial dehiscence with or without retention sutures in 27 patients. [45] In selected patients, such as patients in whom technical failure has resulted in dehiscence rather than patient-related risk factors (e.g., slipped knots), primary suture repair may be successful.[17,45] If the fascia is easily torn during initial re-suturing, alternative closure methods can be considered. In cases of extensive debridement with the loss of abdominal wall tissue, primary closure has been reported to result in a 50% dehiscence rate.[47]

The use of retention sutures or modifications thereof has been reported in many studies with high rates of recurrence and incisional hernia (see Table 1).[2,8,9,12,19,20,22,48,50,55–57]

Retention sutures are reported to be very painful for patients and have frequently been associated with local complications and a need for early removal.[58] The available evidence is in disfavor of the use of retention sutures.[3,58,59]

Relaxing Incisions

Esmat reported the use of relaxing incisions in the transversus abdominis and internal oblique muscles (TI incision), an additional incision in the external oblique muscle (TIE incision), or also involving Scarpa's fascia (TIES incision).[21] Eight patients with burst abdomen underwent a total of 15 incisions (2 TI, 9 TIE, 4 TIES) in this study. The mortality rate was 12.5%, no recurrences occurred, and incisional hernias occurred at sites of TIES incisions only. Dietz et al. performed an inverting bilateral interrupted figure-of-eight suture (0 USP polypropylene) of the anterior and posterior rectus sheath in one patient, combined with relaxing incisions in the aponeuroses of the external oblique muscles and placement of a polypropylene mesh in sublay position.[60] No incisional hernia was diagnosed after 1 year of follow-up but numbness of the skin in the right lower abdomen was reported, which was possibly due to a lesion of (part of) the ilio-hypogastric nerve.[60] Relaxing incisions in the transversus abdominis and internal and external oblique muscles can be considered if primary closure cannot be performed tension-free.

Temporary Closure

Open abdomen treatment is an alternative option if tension-free closure cannot be performed. One study reported the temporary closure of the abdomen with a Bogota bag in one patient with burst abdomen, which enabled primary closure one month after placement.[61] There are no studies found to date that have compared the surgical outcomes of temporary closure with other methods of treatment for burst abdomen.

Synthetic Mesh

Synthetic mesh is often placed in inlay position fixated to both fascial edges. There is no evidence to support a preference for either an inlay, onlay, or sublay position in the repair of burst abdomen. Material options included absorbable meshes such as polyglactin and nonabsorbable meshes such as polypropylene. Polypropylene meshes have been associated with high complication rates in infected environments, especially in cases of placement in direct contact with intestines, leading to enterocutaneous fistula for mation and intestinal adhesions.[62–64] Van 't Riet et al. reviewed a group of 18 patients who had undergone abdominal wound dehiscence repair in the presence of intra-abdominal infection. All patients developed complications such as mesh infection (77%), enterocutaneous fistula formation (17%), or migration of mesh through the bowel (17%). Complications had led to mesh removal in 8 out of 18 patients (44%) and at a mean follow-up of 49 months, incisional hernia had developed in 63% of patients.[63]

Other complications of nonabsorbable meshes include bulging of the mesh, which can mimic the clinical presentation of incisional hernia, and mesh rejection. McNeeley et al. reported the use of nonabsorbable polypropylene mesh in 11 patients with fascial dehiscence (7 Marlex®, CR Bard, Murray Hill, NJ; 4 Prolene®, Ethicon, Somerville, NJ). In three out of seven patients who underwent Marlex® repair, grafts were removed and abdominal scars were revised. There were no reported observations of enterocutaneous fistula formation.[49] We are not aware of any reports to date on the use of composite nonabsorbable meshes in the acute treatment of abdominal burst. From a theoretical point of view, the use of this type of anti-adhesive meshes could be beneficial in terms of less adhesion formation than polypropylene mesh and lead to a lower incidence of incisional hernia compared to absorbable mesh.

Polyglactin mesh is 100% absorbable and can be used in the presence of infection. Repeated access to the abdomen is easily acquired by opening and subsequent closure of the mesh. However, the material can tear and thereby result in repeat evisceration and an indication for reoperation.[65] Covering the mesh with saline-soaked gauzes or NPWT is often used until granulation tissue is formed on the bowel and can be covered with split-thickness skin grafts. Removal of mesh due to rejection may be necessary at an outpatient clinic during the months following mesh repair. McNeeley et al. used polyglactin mesh in seven patients with fascial dehiscence, one of whom required mesh removal.[49] Moreover, the use of polyglactin mesh without direct contact between fascial edges inevitably resulted in incisional hernia over time. Abbott et al. reported a 100% success rate for primary polyglactin mesh repair in 7 out of 37 patients. Closure with polyglactin mesh required 12 subsequent operations (1.71 operations per case), compared to 39 operations in 27 patients (1.56 operations per case) for primary fascial repair.[45] Buck et al. reported the use of polyglycolic acid mesh (Dexon™, Mansfield, MA) in seven patients with wound dehiscence, all of whom developed incisional hernias.[66]

Biological Mesh

In recent years, various types of biological meshes have been developed and become commercially available. Biological meshes consist of cross-linked or non-cross-linked extracellular matrix without cellular components, derived from porcine dermis collagen, porcine small intestine submucosa, or cadaveric human dermis.[67] The high biological compatibility is generally seen as a great advantage in comparison with synthetic materials, especially in infected surgical fields.[68] Tissue ingrowth in the mesh will eventually create a new abdominal fascia, thereby preventing incisional hernia formation unless the mesh is degraded by collagenases in cases of (severe) infection. Few publications are available on

the use of biological mesh in burst abdomen patients. Bounovas reported the implantation of porcine dermal collagen under local anesthesia in one case of infected abdominal wound dehiscence after hysterectomy. After a follow-up period of 9 months, no incisional hernia occurred.[69] Chuo et al. described the use of a biological mesh, derived from porcine dermis, in combination with NPWT in a patient with abdominal dehiscence and exposed bowel.[70] One report has been published by Wotton et al. who described a case of a patient with burst abdomen in whom severe rejection of a biological mesh, derived from porcine dermis, occurred.[71] The limited number of studies published to date on this topic inhibits any substantiated advice on the use of a specific type of biological mesh (cross-linked versus non-cross -linked, human versus porcine) or on optimal mesh position.

Tissue Flaps

Tissue flaps have been used most frequently for delayed repair of abdominal wall defects, for instance, after abdominal wound dehiscence. However, Jeon et al. reported the use of a pedicled rectus femoris muscle flap for a completely eviscerated renal allograft in a 66-year-old man after development of a perigraft hematoma. The rectus femoris flap became dehiscent. After additional local tissue rearrangement and a perforator-based cutaneous advancement flap reconstruction, no incisional hernia occurred within the first two years after surgery.[72]

Closure of the Skin and Subcutaneous Tissue

Subcutaneous (multifilament) sutures initiate a foreign-body reaction and potential bacterial colonization. In a relatively clean environment, the skin can be closed with monofilament interrupted sutures or staples. If drainage of infected material through the wound is expected, the skin should be left open or approximated at intervals with staples or interrupted monofilament sutures to allow for sufficient drainage. Chendrasakhar described the bedside stapling of Vicryl mesh to the skin as a sole preventive measure against evisceration in two patients with abdominal wound dehiscence. Skin grafts were placed after ingrowth of the mesh with granulation tissue, thereby avoiding major surgery and accepting incisional hernia formation.[73]

Postoperative Period

Wound healing should be promoted by achieving adequate tissue perfusion and oxygenation and by creating an optimal wound environment. The nutritional status should be checked and optimized by resuming enteral feeding as soon as possible, preceded by administering total parenteral nutrition if necessary. Postoperative intestinal paralysis should be minimized to prevent abdominal hypertension and thereby stress

on the wound. Pulmonary inhalers and respiratory exercises under the guidance of a physiotherapist may assist in the prevention of pulmonary infection and frequent coughing, which can result in sudden peaks in intra-abdominal pressure. There is no evidence to support the use of restraining cotton sheets or abdominal binders to prevent burst abdomen, a further increase in the gap between both fascial edges, recurrences, or incisional hernia.

Treatment of Recurrence

Abbott et al. reported the largest series of treated recurrence patients ($n = 12$). Polyglactin mesh was used in two patients, both resulting in subsequent incisional hernia repair. Repeat fascial closure was performed in the remaining 10 patients, 3 of whom required additional operative interventions (70% success rate). Recurrence is often combined with additional damage to the fascia and adjacent tissues and is a relative contraindication for suture repair. Torn mesh can be repaired by sutures with or without bridging of the mesh or by applying two sheets of mesh in a double layer for extra support.

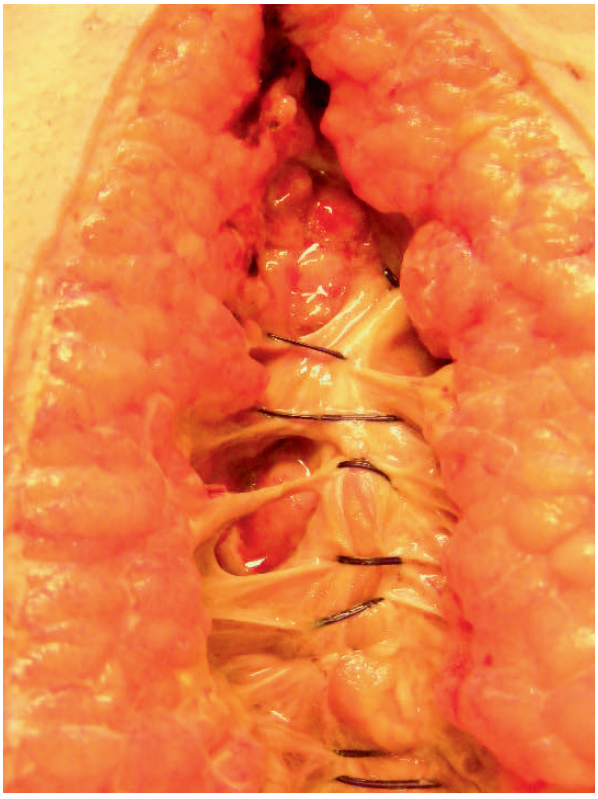

Figure 2: Example of patient with fascial necrosis, exposed abdominal content and concurrent intra abdominal infection

Discussion

The evidence regarding the management of burst abdomen is extremely poor. Our review of management options has revealed that none of the studies found in the literature to date were designed prospectively, and only a minority of studies have reported surgical outcomes of considerable numbers of patients. The level of evidence therefore does not exceed 2b (individual cohort studies). Any advice on the management of burst abdomen should therefore be interpreted with caution.

Based on the available evidence from case series, conservative management may be reserved for patients whose general health status does not allow for immediate surgery. In clean and clean-contaminated wounds, primary suture closure could be attempted (e.g., in case of failed suture technique), although this repair has been associated with considerable recurrence rates and the development of incisional hernia in a number of studies.[2,8,9,20,22,44,48,50] If intra-abdominal pressure (IAP) levels are high, primary suture repair will presumably be associated with an even worse surgical outcome. The high recurrence and incisional hernia rates following treatment of burst abdomen could be considered as a support of mesh repair, especially in these patients. In clean wounds, polypropylene or composite meshes could be used, depending on whether or not contact with abdominal contents can be avoided; intraperitoneal placement of polypropylene is associated with high complication rates after subsequent surgical interventions.[74] A biological mesh repair could be considered in clean-contaminated wounds as an alternative for a two-staged repair with temporary closure of the abdomen (with or without NPWT) or open abdomen treatment.

In contaminated-dirty wounds, treatment should be aimed at identifying the source of infection, for example, intra-abdominal abscess or anastomotic leakage. This type of patient is illustrated in Figure 2: Progressive necrosis of the fascia resulted in exposure of the abdominal content, and intra-abdominal infection was found at relaparotomy. We discourage primary suture repair in patients with obvious tissue (fascial) necrosis and considerable loss of the abdominal wall due to high reported rates of treatment failure.[47] Surgeons can choose open abdomen treatment (with or without NPWT) or closure of the abdomen with absorbable polyglactin or biological mesh repair. Due to lack of evidence, none of these techniques can be considered the method of first choice. Absorbable polyglactin meshes can be used to bridge abdominal wall defects but will eventually lead to incisional hernia formation.[44,45,66] Tension-free application allows for a certain safety window in cases of expansion of abdominal contents during the postoperative phase. Biological meshes have demonstrated high biocompatibility in infected fields and should be considered a closure option for burst abdomen. Closure with biological

mesh may be associated with a lower incidence of incisional hernia, but there are no case series of patients with burst abdomen available with long-term follow-up. Until evidence is available that the use of biological mesh results in improved surgical outcome in this patient group, its widespread use will be restrained by greater material costs.

Conclusions

Current surgical closure techniques are associated with unacceptably high rates of recurrences and incisional hernia. The overall lack of evidence to date on this topic mandates well-designed randomized controlled trials. Conservative and operative management options should be compared for short-term and long-term surgical outcomes to provide surgeons with a greater level of evidence regarding the optimal treatment strategy for burst abdomen. We propose that distinctions are made between treatment options for patients with clean and clean-contaminated wounds on one hand and patients with contaminated-dirty surgical sites on the other, and between patients with normal versus raised intra-abdominal pressure. A possibly relevant characteristic of affected patients in view of surgical outcome is the initial calculated risk of developing burst abdomen. The size of the defect and presence of evisceration should also be taken into consideration as presumed risk factors for the development of an incisional hernia.

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Chapter 7

Validity of Diagnosis of Superficial Infection of Laparotomy Wounds Using Digital Photography: Inter- and Intraobserver Agreement Among Surgeons

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ABSTRACT

Background. The use of digital photography to assess and document the wound healing process has become increasingly popular. One of the most common complications of wound healing is infection, but the validity of digital photography for the diagnosis of wound infection is unknown. We intended to measure the degree of inter and intra-observer agreement on the diagnosis of superficial wound infection using digital photography.

Methods. In a prospective, observational clinical study, abdominal wounds were photographed daily and signs of infection were documented in a standard manner. Four surgeons independently assessed photographs of 50 wounds opened for infection within hours after photography and 50 normally healed wounds. Wound pain scores, morning temperature, and post-operative day were noted. Surgeons recorded the presence of infection and treatment for each wound. Paired kappa (κ) values were calculated and intra-observer agreement was measured after 4–6 weeks.

Results. Mean specificity with regard to infection was 97% (94%–100%) and mean sensitivity was 42% (32%–48%). Paired κ-values with regard to wound infection were: 0.54, 0.67, 0.68, 0.63, 0.58, and 0.61. Agreement on treatment was present in 76 of 100 wounds (κ values: 0.15, 0.17, 0.20, 0.72, 0.63, 0.68). Kappa values for intra-observer agreement on infection were: 0.66, 0.43, 0.74, and 0.76 for surgeons A, B, C, and D, respectively.

Conclusion. Inter-and intra-observer agreement on the diagnosis of superficial infection with digital photography are moderate, but specificity is high. Physical examination findings should also be reported.

Recently, the use of digital photography has become increasingly popular and highlighted in literature for documentation and evaluation of wound healing progression in addition to its usefulness in telemedicine for diagnosis in dermatology and vascular surgery.[1–3] For chronic and burn wounds in particular, photography can be used to assess treatment results and support continuation or alteration of treatment strategy.[4] One of the most common complications of surgery is wound infection, as approximately 10% of all abdominal wounds are affected.[5,6] Although the validity of digital photography has been reported for a number of indications, its validity of diagnosing infection in surgical wounds remains unclear.[3]

The diagnosis of infection of the acute wound has been based on symptoms such as rubor, dolor, calor, tumor, and functio laesa, which have been around since the time of Hippocrates. Physicians diagnose wound infection based on subjective and objective criteria and experience. The international gold standard for diagnosis of surgical wound infection is represented by the criteria for surgical site infection (SSI) as defined by the Centers for Disease Control and Prevention (CDC).[7] According to the CDC, the surgeon's judgment is very important in the diagnosis of superficial SSI. In several studies where wound photography was used to assess healed lacerations and incisions, moderate to good inter- and intra-observer agreement was found on wound appearance scales.[8–10] Few reports exist on agreement among surgeons with regard to wound assessment. In the literature, kappa (κ) values for inter-observer agreement on infection vary between 0.08 and 1.00.[1,11,12] Unfortunately, neither the absolute numbers of infected wounds nor the levels of intra-observer agreement were reported in these studies.[1,11,12] The goal of the present study was to measure the degree of inter- and intra-observer agreement on the diagnosis of superficial infection of laparotomy wounds using digital photography thereby assessing its validity.

Materials and Methods

Between May 2007 and January 2009, 1000 patients were included in a prospective, observational clinical study on surgical wound healing. The Erasmus University Medical Center's ethics committee approved the research protocol. After informed consent was obtained, the abdominal wound was photographed on a daily basis (including weekends and holidays) until discharge or until the 21st postoperative day using a Fujifilm (Tokyo, Japan) Finepix S5700 digital camera (7.1 megapixels, 10x optical zoom) with standardized multi-auto focus and macrosettings. Each day, two photographs (resolution 3072 x 2304 pixels) were taken according to a standardized protocol. The first photo was of the entire abdomen from sternum to the pubic bone at a distance of approximately 40 cm. The second photo was a close-up photograph of the wound at a distance of approximately

20 cm. Photographs were loaded onto a personal computer and saved in Joint Photographic Expert Group (JPEG) format, coded for each patient, postoperative day, and number of sequence. Signs of infection were documented using a standard procedure and relevant data on wound infection were retrieved prospectively from hospital and nursing charts. Four gastrointestinal surgeons (A, B, C, D) with clinical experience ranging between 10–30 years independently assessed 100 randomly ordered sets of abdominal wound photographs. Each set consisted of one overview photograph and one close-up photograph. Fifty of these sets consisted of photographs of wounds that had been opened within hours on suspicion or presence of infection and had met the criteria for superficial SSI of the CDC.

According to the CDC, the following criteria have to be met for diagnosis of a superficial wound infection (SSI).[7] Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without laboratory confirmation from the superficial incision.
2. Organisms isolated from an aseptically obtained culture, fluid, or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by a surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Photographs of infected wounds were matched by postoperative day, type of incision, and skin color with 50 sets of photographs of wounds that had healed without complications, as verified by surveillance by means of outpatient clinic visits following discharge and review of hospital charts, discharge letters, and complication registration systems.

Surgeons were asked to read the CDC criteria for superficial SSI and to apply these criteria if possible before all sessions. Wound pain scores (visual analogue scale ranging from 0 = no pain to 100 = worst imaginable pain) of the current and previous day, morning temperature, and postoperative day were noted for each wound. All photographs were viewed on one laptop using standardized settings with the possibility to adjust the viewing screen (Toshiba A100 portable personal computer, 17-inch screen). Surgeons were requested to record for all wounds whether or not superficial infections were present and whether the wounds should be treated conservatively (ie, remain closed) or be opened (either partially or fully). Four to 6 weeks after the initial sessions, all photographs were placed in a different, random order and were re-evaluated in order to measure intra-observer agreement among all surgeons. Repeat evaluations took place in the same room at approximately the same time of day as the initial evaluations.

Statistical Analysis

Statistical analysis was performed by the first and fourth author (GHvR, WCJH) by calculating paired κ values with 95% confidence intervals (CI) calculated as 1.96 ± SE between all observers (A-B, A-C, A-D, B-C, B-D, C-D) for inter-observer agreement. For each observer intra-observer agreement was measured by calculating κ values (including 95% CI). In general, κ values of 0.80 or greater are considered to represent a good level of agreement.[13] Sensitivity and specificity was calculated for each observer.

Results

On average, abdominal wounds had been opened on the seventh postoperative day (range 3–15). Mean specificity with regard to wound infection was 97% (94%–100%) and mean sensitivity was 42% (32%–48%; Table 1). Paired κ values with regard to wound infection varied between 0.54 and 0.68 (Table 2). Agreement on treatment (conservative or opening of wound) was present in 76 of 100 wounds (κ values: 0.15, 0.17, 0.20, 0.72, 0.63, 0.68). The diagnosis of wound infection was unanimous in 12 of 50 cases; two examples of these cases are shown in Figures 1 and 2.

Table 1. Sensitivity and specificity for infected and noninfected wounds.

Surgeon	Infection present (n)	Sensitivity	Infection absent (n)	Specificity
A	24	48%	48	96%
B	16	32%	48	96%
C	22	44%	50	100%
D	21	42%	47	94%
Total	50	42% (mean)	50	97% (mean)

Table 2. Paired κ values for inter-observer agreement on wound infection and treatment.

Surgeons	Wound infection	95% CI lower–upper	Treatment	95% CI lower–upper
A–B	0.54	0.34–0.73	0.15	0.00–0.39
A–C	0.67	0.50–0.84	0.17	0.00–0.39
A–D	0.68	0.51–0.85	0.20	0.00–0.43
B–C	0.63	0.43–0.82	0.72	0.54–0.90
B–D	0.58	0.39–0.78	0.63	0.42–0.84
C–D	0.61	0.42–0.79	0.68	0.49–0.86

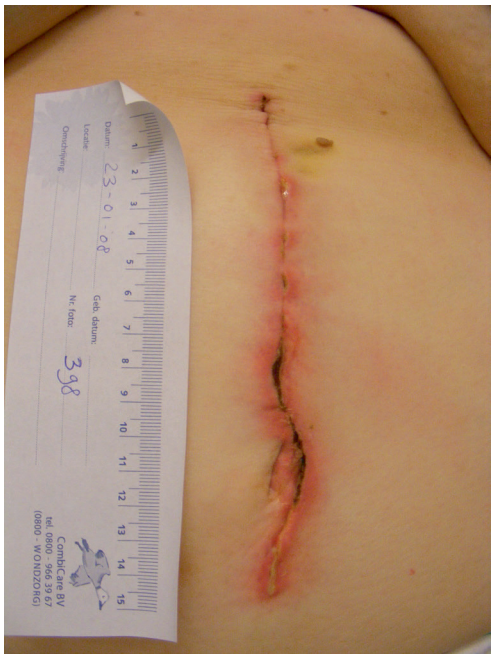

Figure 1. Upper midline wound on postoperative day 10 showing prominent erythema mostly along the caudal wound edges.

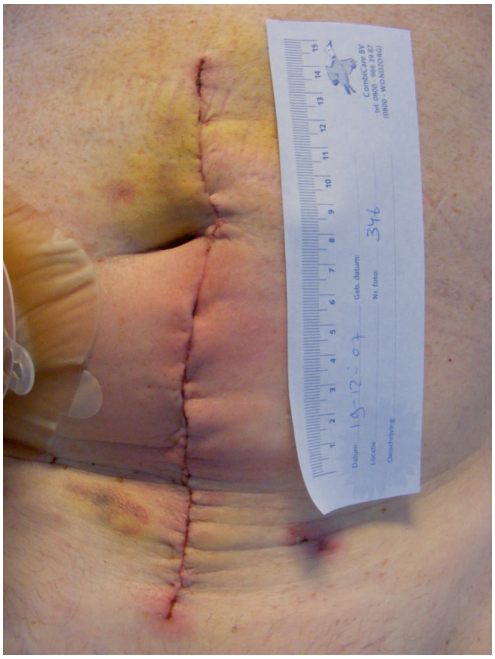

Figure 2. Lower midline wound on postoperative day 12 showing erythema in the middle of the wound and resolving hematoma along the cranial and caudal aspect of the wound.

In some cases, surgeons preferred not to open wounds in presence of infection. In 13 patients, symptoms of infection were considered minimal by one or more surgeons, and in five cases spontaneous drainage of pus was present and further opening of the wound was therefore not considered compulsory. Surgeon A was the only surgeon to report low morning temperature as a reason for not opening infected wounds. None of the additional information given on morning temperature or wound pain scores was significantly associated with wound infection in this group of patients (all $P > 0.05$).
Kappa values for intra-observer agreement varied between 0.43–0.76 for wound infection and 0.52–0.87 for wound treatment (Table 3).

Table 3. Kappa values for intra observer agreement on wound infection and treatment

Surgeon	Wound infection	95% CI lower -upper	Treatment	95% CI lower-upper
A	0.66	0.49 – 0.84	0.52	0.15 – 0.89
B	0.43	0.26 – 0.61	0.53	0.31 – 0.75
C	0.74	0.57 – 0.91	0.76	0.59 – 0.93
D	0.76	0.62 – 0.91	0.87	0.75 – 0.99

Discussion

Wound assessment is normally based on a combination of both subjective and objective information, visual and physical information, and experience. This study demonstrated that the inter-observer agreement regarding laparotomy wound infection is moderate among surgeons when using digital photography. The inter-observer agreement on the treatment of wound infection is also moderate and shows high variability among different surgeons. Moreover, the intra-observer agreement on wound infection and treatment differs among surgeons. This implies that wounds are possibly assessed and treated differently depending on which individual is supervising the patient's care. Infection rates, as collected in several national surveillance programs, might vary between hospitals partly as a result of differences in judgment among physicians.[14–18]

Standard protocols for the assessment of acute wounds such as ASEPSIS and the Southampton Wound Assessment Scale are time consuming and have yet to be implemented widely.[14,19,20] Therefore, wounds remain subject to the individual surgeon's or attending physician's experience. Two wound examples were rated as infected by two surgeons and as uninfected by the remaining two surgeons (Figures 3, 4). Mild erythema can be seen across the upper two-thirds of the wound (Figure 3). The contrast with the skin-colored lower third of the wound suggests that the erythema is a symptom of abnormal wound healing resulting in the diagnosis of wound infection by two of the four surgeons. A subcostal wound is shown with minimal bloody discharge from the cranial aspect of the wound (Figure 4). The minor dehiscence in combination with the discharge on postoperative day 5 suggests that the wound healing in this part of the wound shows less progression than the rest of the wound; however, the criteria for wound infection are not met by these symptoms alone. The two surgeons who rated the wounds as infected (Figures 3 and 4) also proposed to open the wounds—a sharp contrast with the two other surgeons.

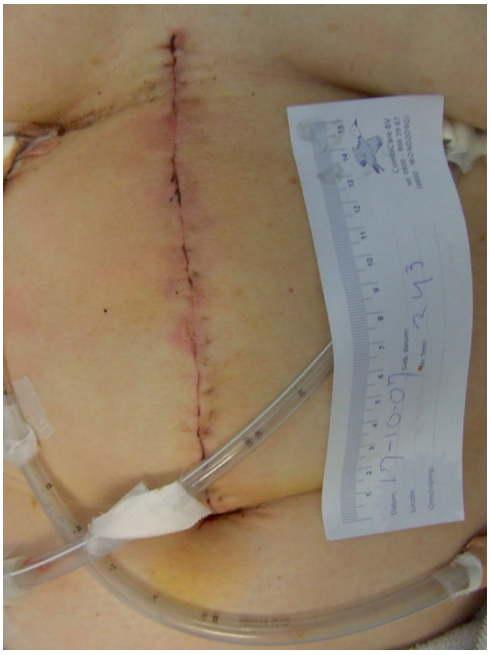

Figure 3. Upper midline wound on postoperative day 5 showing mild erythema across the upper two-thirds of the wound.

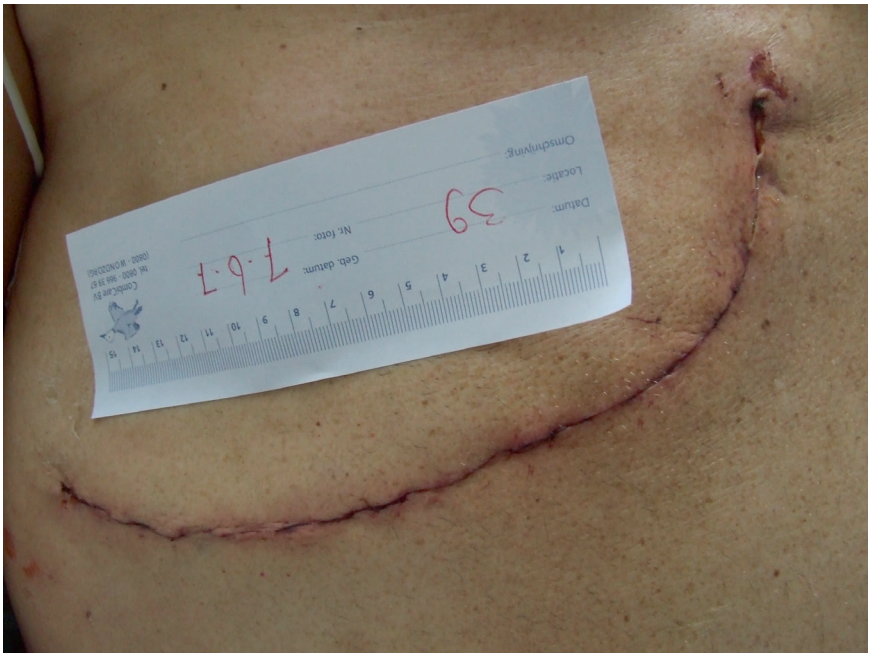

Figure 4. Subcostal wound on postoperative day 6 showing minor dehiscence and bloody discharge from the cranial aspect of the wound.

The predictive value of the criteria for wound infection used in the aforementioned protocols is unclear. The European Society for Wound Management reported the results of a Delphi approach in order to identify criteria for SSI in various types of wounds.[21] In the Delphi approach of the acute wound, 8–10 panel members were asked to list relevant clinical indicators of infection. Panel members were offered the opportunity to review scores for the most important criteria in view of the position of the group as a whole (the "group score"). Cellulitis and pus/abscess were considered the most important factors, followed by delayed healing, erythema with or without induration, hemo- or seropurulent exudate, malodor, and wound breakdown/enlargement. Assumed early signs of infection included increase of local skin temperature, edema, serous exudates with erythema, swelling with increase in exudate volume, and unexpected pain/tenderness.[21] The predictive value of these signs are yet unknown for acute wounds. Gardner et al[22] found positive predictive values of 1.00 for increasing pain and wound breakdown in chronic wounds. Sensitivity of classic signs of infection in chronic wounds showed large variability among different items: heat and purulent exudate 0.18, increasing pain 0.36, erythema 0.55, and edema 0.64.[22]

Moreover, from the few studies that exist on inter-observer agreement in wound assessment, it appears that κ values for many of the important variables in the Delphi approach were not high. Hollander et al[11] reported inter-observer concordances (κ values) of 0.51 for erythema, 0.39 for warmth, 0.38 for tenderness, and 1.00 for infection of 100 wounds registered in the emergency department by two independent physicians. Allami et al[12] reported inter-observer variations in the evaluation of 50 lower limb arthroplasty wounds between four observers. In this study, poor inter-observer agreement (κ values < 0.40) was reported for tenderness, localized swelling, redness, heat, and moderate agreement for pain (κ values 0.60–0.80), and good agreement (κ values 0.80–1.00) for clinical diagnosis of superficial SSI, purulent drainage, dehiscence, and fever. In a study by Wirthlin et al[1], agreement amongst surgeons in the "remote" assessment of digital photographs of 38 vascular surgery wounds, similar to the present study, proved lowest on the aspects cellulitis/infection and erythema (κ values of 0.08 and 0.28, respectively).[1] The mean κ value for inter-observer agreement on wound infection of 0.62 found in the present study may be fair considering the results of previous studies in which, presumably, fewer infected wounds were included.

In the present study, digital wound photographs were assessed with additional information available on wound pain—expressed as visual analogue scale scores—postoperative day, and morning temperature, which was thought to have been of additional value for the diagnosis of infection and to better simulate the clinical setting. The 2-dimensional aspect of digital photographs hampered assessment of swelling of the wound edges. Palpation

of the wound was an aspect that was considered an omission from the regular physical examination of wounds by the surgeons participating in this study. Palpation can provide valuable information in view of expression of wound pain and pus production during pressure exertion and elicit increased capillary refill. Digital photography, even with the provided additional information, seems adequate for diagnosis of "normal wound healing" (ie, no infection) in wounds based on a high specificity of 97%, but at a mean sensitivity of 42% not be sensitive enough to diagnose infections in all wounds. We recommend proper assessment of the entire wound and wound surroundings for erythema, dehiscence, and (purulent) discharge by physicians who are familiar with wound infection criteria to avoid diagnosis mistakes.

Besides the discussion on the use and validity of digital photography in wound assessment, it would appear that criteria for wound infection are not objective enough to establish uniformity in the diagnosis of wound infection. It may also be necessary for doctors to be educated more about present criteria for wound infection. In addition, more research is needed to evaluate the predictive value of wound characteristics for wound infection such as wound temperature and production of exudate, to be incorporated in a standardized wound appraisal tool. Structural assessment of wounds, combined with onsite registration of SSI and plenary discussion will undoubtedly result in more uniformity amongst surgeons and higher reliability of reported infections and infection rates.

Conclusion

Inter- and intra-observer agreement on the diagnosis of wound infection when using digital photography were both moderate, but specificity was very high. Findings of physical examination, palpation in particular, could present valuable information for electronic wound assessment. We recommend that these findings be documented in detail and presented in conjunction with digital wound photographs in the electronic assessment of infection in wounds. Furthermore, we believe more education is needed on wound assessment and criteria for wound infection, and that more data are needed on the predictive value of wound characteristics for infection.

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Chapter 8

Impact of incisional hernia on health-related quality of life and body image: a prospective cohort study

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Abstract

Background: We investigated the impact of incisional hernia (IH) on quality of life and body image.

Methods: Open abdominal surgery patients were included in a prospective cohort study performed between 2007 and 2009 in an academic hospital. Main outcomes were incidence of IH after approximately 12 months and Short-Form 36 and body image questionnaire results.

Results: There were 374 patients who were examined after a median follow-up period of 16 months (range, 10 –24 mo). Seventy-five patients had developed IH (20%); 63 (84%) were symptomatic. Adjusted for age, sex, and Charlson Comorbidity Index score, patients with IH reported significantly lower mean scores for components physical functioning (p=0.033), role physical (p=0.002), and physical component summary (p=0.010). A trend toward significance was found for general health (p=0.061). Patients with IH reported significantly lower mean cosmetic scores (p=0.002), and body image and total body image scores (both p=0.001).

Conclusions: Patients with IH reported lower mean scores on physical components of health-related quality of life and body image.

Introduction

Incisional hernia (IH) is a frequent complication of open abdominal surgery with an incidence ranging between 3% and 20%.[1–5] In subgroups, such as patients with obesity or abdominal aneurysms, incidences have been reported of up to 26% to 39%.[6–15] Few reports exist on the impact of IH on health-related quality of life, especially on groups of patients who have not been selected already for hernia repair.

Patients with IH can present with various symptoms such as pain, discomfort, limitation of daily activities, cosmetic complaints, skin problems, or incarceration with or without strangulation of the hernia content.[16–18] The natural course of incisional hernia and changes in the proportion of symptomatic patients over time are unknown. Most patients with IH undergo surgery electively, and a minority of patients present with acute incarcerations requiring emergency repair.[1] The absolute risk of incarceration in patients with IH is unknown but estimates as low as 1% are made in the literature.[18] However, reoperations for IH have been associated with recurrence rates of up to 63% for suture repair and up to 32% with mesh repair.[19–22] The purpose of this study was to investigate IH-associated symptomatology, health-related quality of life, and body image.

Materials and Methods

Between 2007 and 2009 a prospective cohort study was performed in which 967 eligible patients who underwent open abdominal surgery were included. Primary outcome for this study was surgical site infection according to the criteria as documented by the Centers for Disease Control and Prevention and abdominal wound dehiscence.[23] Approval for the study was obtained from the Institutional Review Board. Inclusion criteria included minimum age of 18 years, open abdominal surgery, or converted laparoscopic procedure. Exclusion criteria were laparoscopic surgery, inguinal/umbilical hernia, and day surgery. Informed consent was obtained from all study participants. Surgeons were asked to complete 2 questions: the first question was regarding fascia quality ("Was the fascia strong/easily torn/ infected?") and the second question was regarding the closure procedure ("Was fascia closure performed tension free/under tension/with mesh?") on the day of surgery. Abdominal wounds were inspected following our protocol on a daily basis (including weekends and holidays) by 2 research fellows from postoperative day 2 until discharge to observe for presence of surgical site infection and abdominal wound dehiscence. In the primary study, 30-day follow-up evaluation after discharge was completed in 827 of 967 patients (85.4%): 643 (77.9%) at the out-patient clinic, 170 (20.6%) by telephone, and 14 (1.7%) by letter/e-mail. In addition, patient charts, discharge letters,

electronic files, and registered wound complications were reviewed at least 3 months after discharge.

This follow-up study, which was not included in the original study design, was performed approximately 12 months after surgery between February 2009 and February 2010. The primary outcome of this study was the incidence of clinically detectable incisional hernia. The latter was defined as a palpable defect in the abdominal wall of the incision used for the surgery performed during the initial study period, resulting in herniation of abdominal contents. Secondary outcomes were health-related quality of life and cosmesis as measured with the Medical Outcomes Study Short Form 36 (SF-36) and body image (BIQ) questionnaires. Inclusion criteria for participation in the follow-up study included participation in the primary study, mental competence, and ability to complete the questionnaires. All 967 patients were invited for clinical evaluation after approximately 12 months after exclusion of deceased patients who were identified through national administrative data. All patients were requested to provide separate informed consent for this follow-up study. In each patient, the physical examination was performed by an independent physician in both a supine and erect position, in rest and during the Valsalva maneuver.

The SF-36 consists of 36 items that allow measurement of 8 health domains including physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. In addition, physical and mental health are scored with the SF-36 physical component summary and SF-36 mental component summary, respectively. SF-36 scores range from 0 to 100, with higher scores implicating a better quality of life.

The BIQ, previously described and used by Dunker et al, consists of a body image score and a cosmetic score.[24,25] For each item of the body image score, 1 to 4 points are awarded, resulting in a total score between 5 and 20. The cosmetic score ranges between 3 and 24 points. Again, higher scores represent higher satisfaction.

Four additional questions were added to the questionnaires, as follows: (1) "Do you find it bothersome if others, such as your partner or persons you are living with, see your abdomen nude?" (possible answers: not at all/a bit/quite a bit/yes, extremely); (2) "My body does not look as good as before my surgery" (possible answers: totally disagree/agree a little/quite agree/totally agree); (3) "Have you felt more inhibited to initiate/maintain sexual relation(s) since your surgery?" (possible answers: not at all/a bit/quite a bit/yes, extremely/not applicable); and (4) "Has there been a change in sexual activity in the period after your surgery?" (possible answers: much less active/a bit less active/equally active/a bit more active/much more active/not applicable).

Risk factors for IH were analyzed in univariate analysis using the chi-square test or the Mann–Whitney *U* test for categoric or continuous data, respectively. Multiple linear regression was used to evaluate the impact of IH on SF-36 and body image scores. Comorbidity was scored using the Charlson Comorbidity Index (CCI), a weighted score as described by Charlson et al.[26] One point was given for myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, connective tissue disease, ulcer disease, stroke or transient ischemic attack, and diabetes. Two points were given for hemiplegia, moderate or severe renal disease, diabetes with end organ damage, any tumor, leukemia, and lymphoma. Three points were given for moderate or severe liver disease and 6 points were given for a metastatic solid tumor and acquired immune deficiency syndrome. A higher CCI score indicates an increased severity of patient condition. Possible effects of age, sex, and comorbidity (represented by CCI) were taken into account by using these variables as covariates in the analyses. *P* values less than .05 were considered statistically significant.

Results

Of all 967 included patients, 374 patients provided informed consent and were examined. The remaining 593 patients were deceased (n=176), incompetent (n=1), emigrated/ untraceable (n=11), nonresponders despite repeated attempts (n=244), or refused participation (n=161). The median follow-up period was 16 months (range, 10 –24 mo). Seventy-five patients developed IH (20%); 63/75 (84%) were symptomatic and 51/75 (68%) considered these symptoms as complaints. The mean hernia defect size was 53.9 cm^2 (range, 1–504 cm^2). Symptoms reported by patients with IH included bulging (n=50), pain/discomfort (n=45), and cosmetic complaints (n=8). None of the patients reported episodes of incarceration or strangulation. Eight patients with IH were wearing supportive corsets. Eight patients underwent surgery for IH, 2 of whom had developed recurrences.
Baseline and clinical characteristics of patients at the time of the initial surgery were compared for patients with and without IH (Table 1). Risk factors for IH were body mass index (p=0.006) and surgical site infection (overall p<0.001).

Table 1 Patient and clinical characteristics for patients with and without IH at time of primary surgery

Variable	Patients with IH (n 75)	Patients without IH (n 299)	Total (n 374)	*P*value
Age, mean SD, y*	61 ± 12 (45–75)	56 ± 13 (36–72)	57 ± 13 (39–72)	0.006
50 y (%)	12 (12)	87 (88)	99	
50–64 y (%)	36 (22)	126 (78)	162	
65 y (%)	27 (24)	86 (76)	113	
Sex				0.003
Male (%)	58 (25)	175 (75)	233	
Female (%)	17 (12)	124 (88)	141	
Body mass index, kg/m^2, mean SD*	27.7 ± 4.6 (22–35)	25.5 ± 4.7 (20–31)	25.9 ± 4.8 (20–32)	0.001
20	3 (10)	27 (90)	30	
20–25	21 (14)	125 (86)	146	
25–30	27 (21)	99 (79)	126	
30	23 (37)	40 (63)	63	
Unknown	1 (11)	8 (89)	9	
ASA class				0.080
I (%)	4 (9)	42 (91)	46	
II (%)	38 (20)	148 (80)	186	
III (%)	31 (23)	106 (77)	137	
IV (%)	1 (25)	3 (75)	4	
V (%)	1 (100)	0 (0)	1	
Smoking	31 (21)	120 (79)	151	0.850
Comorbidity, mean SD†	3.4 ± (3.0)	2.6 ± 2.5	2.8 ± 2.6	0.032
Emergency surgery (%)	19 (23)	64 (77)	83	0.464
Type of surgery				0.162
Abdominal wall (%)	4 (15)	23 (85)	27	
Esophagus (%)	10 (24)	32 (76)	42	
Gastroduodenal (%)	1 (17)	5 (83)	6	
Pancreas (%)	6 (25)	18 (75)	24	
Small intestine (%)	8 (42)	11 (58)	19	
Colorectal (%)	8 (16)	43 (84)	51	
Kidney (%)	12 (13)	81 (87)	93	
Gall bladder/bile duct (%)	2 (11)	16 (89)	18	
Liver (%)	15 (28)	39 (72)	54	
Vascular (%)	7 (26)	20 (74)	27	
Other (%)	2 (15)	11 (85)	13	
Type of incision				0.185
Median (%)	42 (22)	148 (78)	190	
Subcostal (%)	15 (19)	64 (81)	79	
Transverse (%)	0 (0)	17 (100)	17	
Other (%)‡	18 (20)	70 (80)	88	
Surgical site infection				0.001
Superficial (%)	23 (28)	58 (72)	81	
Deep (%)	11 (48)	12 (52)	23	
Organ/space (%)	5 (38)	8 (62)	13	

ASA American Society of Anesthesiologists class. *Values present the range (10th–90th percentile).
†Charlson comorbidity Index score calculated at follow-up evaluation. ‡Includes gridiron and semilunar lower-abdominal incisions.

Surgeons' questionnaire answers were available in less than 85% of all patients and, therefore, not entered in univariate analysis. Surgeons' description of fascia closure were available for 83% (312 of 374) of patients and proved a significant risk factor for IH development (p=0.024). IH occurred in 18.5% (52 of 281) of patients with tension-free closures, 43% (9 of 21) of patients with closures under tension, and 15% (2 of 13) of patients with mesh closures.

Surgeons' description of fascia quality was available for 82.9% (310 of 374) of patients and was not a significant risk factor for IH development (p=0.584). IH occurred in 20% (59 of 294) of patients with strong fascia, 9% (1 of 11) of patients with easily torn fascia, and 25% (1 of 4) of patients with infected fascia.

Not allowing for the effects of age, sex, or comorbidity, patients with IH showed significantly lower scores for the SF-36 components physical functioning (p=0.012), role physical (p=0.002), and physical component summary (p=0.008) (Table 2). Patients with IH reported significantly lower scores on all components of the body image questionnaire (Table 3).

Table 2: Mean Short Form 36 scores and standard deviations (SD) for patients with and without incisional hernia (IH)

Short Form 36 component	Patients with IH			Patients without IH			*P*value
	N	Mean	SD	N	Mean	SD	
Physical functioning	73	64.5	23.8	289	71.6	24.0	0.012
Role physical	73	39.7	38.8	283	57.4	43.3	0.002
Bodily pain	73	68.6	25.5	287	72.7	26.0	0.152
General health perceptions	73	53.4	21.8	285	58.2	22.6	0.120
Vitality	72	60.5	17.7	286	59.1	21.2	0.956
Social functioning	73	74.0	23.7	287	75.8	24.9	0.371
Role emotional	72	68.1	42.0	282	71.7	39.9	0.523
Mental health	72	75.0	16.3	286	74.9	17.8	0.875
Change	73	76.0	24.5	289	73.0	27.2	0.502
Physical Component Summary	69	59.7	18.6	263	66.3	20.7	0.008
Mental Component Summary	67	69.5	14.4	271	70.0	17.9	0.493

Table 3: Mean Body Image questionnaire scores with standard deviations (SD) for patients with and without incisional hernia (IH)

Body Image Questionnaire	Patients with IH				Patients without IH				*P*value [a]
	N	Mean	SD	Scale	N	Mean	SD	Scale	
Are you less satisfied with your body since the operation?	73	2.9	1.1	1-4	289	3.2	0.9	1-4	0.011
Do you think the operation has damaged your body?	73	2.6	0.9	1-4	288	3.0	0.9	1-4	0.001
Do you feel less attractive as a result of your operation?	73	3.0	1.1	1-4	289	3.3	0.9	1-4	0.024
Do you feel less feminine/masculine as a result of your operation?	72	3.5	0.9	1-4	289	3.7	0.7	1-4	0.062
Is it difficult to look at yourself naked?	73	3.3	1.0	1-4	287	3.6	0.8	1-4	0.037
Body Image score (5-20)	72	15.3	4.0	5-20	286	16.8	3.5	5-20	0.002
On a scale of 1 to 7, how satisfied are you with your scar?	73	3.8	2.0	1-7	287	4.4	2.0	1-7	0.024
On a scale from 1 to 7, how would you describe your scar?	73	3.8	1.5	1-7	287	4.1	1.4	1-7	0.055
Could you score your own scar on a scale from 1 to 10?	72	6.0	2.2	1-10	285	6.6	2.1	1-10	0.021
Cosmetic Score (3-24)	72	13.6	5.0	3-24	282	15.1	4.9	3-24	0.023
Total Body Image Score (8-44)	71	28.8	7.8	8-44	280	31.8	7.7	8-44	0.002

[a]Mann-Whitney U test

Adjusted for age, sex, and comorbidity, patients with IH reported significantly lower scores on the SF-36 components physical functioning (p=0.033), role physical (p=0.004), and physical component summary (p=0.010) (Table 4). No significant differences were found for other SF-36 components, although a trend was found toward statistical significance for the general health component (p=0.061).

Adjusted for age, sex, and comorbidity, patients with IH reported significantly lower body image scores (p<0.001), cosmetic scores (p=0.002), and total body image scores (p<0.001) (Fig. 1). Median scar scores (scale, 1–10) were 6 for patients with IH and 7 for patients without IH (p=0.019). Length of follow-up evaluation did not significantly influence SF-36 or BIQ scores (all p>0.05). No differences were found for the SF-36 and BIQ between patients with IH who had undergone repeat surgeries and those who had not (p>0.05).

Table 4: Effects of incisional hernia on Short Form – 36 (SF-36) and Body Image Questionnaire components; data shown are differences between the hernia and non-hernia groups after adjustment for age, gender and Charlson Comorbidity Index (CCI) score

Questionnaire	Mean difference (95% CI)	*P*value
Physical functioning	-6.8 (-13.0 to –0.5)	0.033
Role physical	-16.4 (-27.5 to –5.2)	0.004
Bodily pain	-5.2 (-12.0 to 1.6)	0.135
General health	-5.6 (-11.4 to 0.3)	0.061
Physical Component Summary	-7.3 (-12.8 to –1.7)	0.010
Vitality	0.1 (-5.2 to 5.5)	0.961
Social functioning	-3.0 (-9.5 to 3.4)	0.353
Role emotional	-3.7 (-14.5 to 7.0)	0.498
Mental health	-0.6 (-5.2 to 4.0)	0.805
Mental Component Summary	-1.5 (-6.2 to 3.1)	0.515
Change score	3.7 (-3.3 to 10.7)	0.297
Body image score	-1.8 (-2.7 to -0.8)	<0.001
Cosmetic score	-2.0 (-3.3 to -0.7)	0.002
Total body image score	-3.8 (-5.8 to -1.8)	<0.001

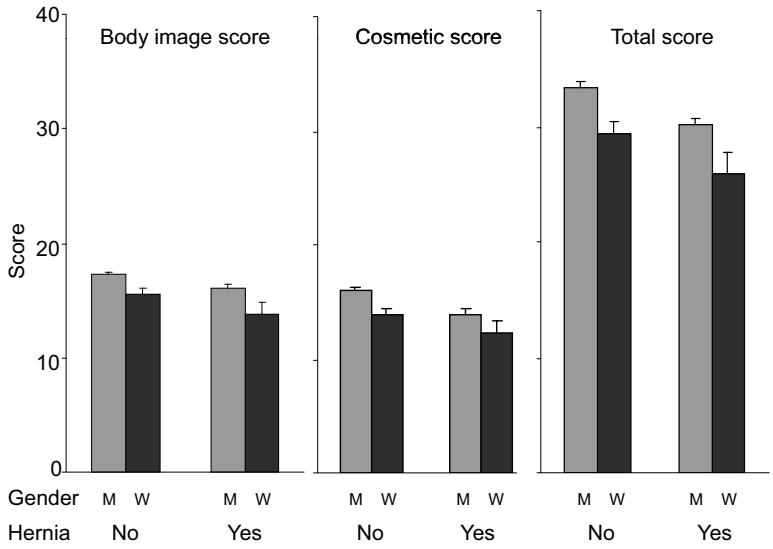

Figure 1 Data shown are age and Charlson Comorbidity Index score-adjusted mean values (with standard errors) for the body image score, cosmetic score, and total score according to presence of hernia and sex. The differences between the presence and absence of hernia are significant (all $p<0.002$). Also, women generally had lower mean scores (all $p<0.001$).

Patients with IH "quite agreed" or "totally agreed" significantly more often with the statement "My body does not look as good as before my surgery" than patients without IH (47% vs 31%; p=0.02). Although patients with IH did not report higher inhibition toward initiating or maintaining sexual relations since the primary surgery, patients with IH were significantly more often sexually inactive than patients without IH (45% vs 27%; p=0.004). Both these differences remained significant after adjustment for age, sex, and co-morbidity. No significant differences were found between patients with and without IH with regard to exposure of the abdomen in front of others (p=0.080).

After adjustment for age, sex, and comorbidity, patients with IH and complaints, as compared with patients with IH without complaints, reported significantly lower (ie, worse) mean scores for total body image score (difference, —4.6; p=0.020) and the SF-36 items of physical functioning (difference, —14.6; p=0.017), bodily pain (difference, —15.3; p=0.019), physical component summary (difference, —10.4; p=0.035), vitality (difference, —10.7; p=0.017), social functioning (difference, —15.7; p=0.007), and change score (difference, —15.7; p=0.009). No significant differences were identified between both groups for cosmetic score (borderline at p=0.053), body image score (borderline at p=0.056), and SF-36 items role physical (p=0.070), general health (p=0.757), role emotional (p=0.280), mental health (p=0.829), and mental component summary (p=0.125). The presence of bulging was correlated significantly with pain/discomfort (p=0.001).

Comments

Follow-up evaluation of a prospectively studied patient cohort revealed that IH occurrence has significant impact on health-related quality of life and body image. A high proportion of the patients with IH experienced complaints (68%), and the vast majority (84%) reported symptoms. These are high rates compared with the studies by Pollock and Evans and Hesselink et al, who reported complaints in 2 of 17 (12%) and 51 of 96 (53%) patients, respectively. [20,27] Body mass index and surgical site infection were risk factors for IH. After adjustment of the SF-36 results for age, sex, and comorbidity, mean physical component scores were significantly worse for patients with IH compared with patients without IH. After these adjustments, significance was lost for the component general health (p=0.061). Although patients with IH were significantly more often sexually inactive, it is unclear whether this was based on physical limitations or, for example, absence of a sexual partner. In patients with symptomatic IH, not only physical components (physical functioning, bodily pain, physical component summary), but also mental components (such as vitality and social functioning) proved worse than in patients with asymptomatic IH. A limitation of the current study was that SF-36 questionnaires were not issued at the time of inclusion

in the primary study, which inhibits comparison of preoperative and postoperative SF-36 outcomes. Also, postoperative quality of life may have been influenced by confounders in the association with IH for which no adjustments were made, such as severity of illness at inclusion or malnourishment.

Few reports exist on quality of life and SF-36 scores in particular of patients with IH. Thaler et al found significantly worse SF-36 scores in a nonrandomized study for the domains physical functioning, general health, social functioning, mental health, and mental component summary for 16 patients with IH compared with 83 patients without IH after laparoscopic or open colectomy.[28] Mussack et al compared SF-36 preoperative scores of 24 patients with IH who underwent laparoscopic hernia repair with 24 patients who underwent open hernia repair.[29] Their patients reported physical functioning and general health perception scores comparable with scores reported by patients with IH in our study. Our patients reported worse scores for role physical, but all other SF-36 scores were higher than the preoperative scores for the patients from the study by Mussack et al.[29]

Cheatham et al reported that patients with massive IH who await abdominal reconstruction experience significantly decreased physical, social, and emotional health.[30] As far as we are aware, no reports exist on the value of the SF-36 in the treatment decision process. A questionnaire among hernia specialists revealed that pain and limitations of daily activities were regarded as the most important indications for repair.[31]

Body image was impaired significantly in patients with IH, especially in patients with symptomatic IH. Body image has not been granted considerable attention by surgeons in the past, but eventually may harm patients' sense of self-worth. Results of the aforementioned questionnaire among hernia specialists confirmed that cosmetic complaints were regarded as the least important motive for surgical repair.[31] Cosmetic complaints were reported by 8 of 75 patients only, but this may present an underestimation in light of the low BIQ scores. In addition, the lack of improvement in cosmetic results after IH repair in a large proportion of patients is discouraging from a patient's perspective.[19]

Surgical site infection (or wound infection) is by far the most frequently reported risk factor for incisional hernia.[32–34] Although this correlation between surgical site infection and IH has been described by many, occurrence of surgical site infection seldom has been chosen as the primary outcome. In our primary study, however, surgical site infection was the primary outcome and therefore, very detailed and well-documented information was available on the incidence and degree of infection in this patient group. In 53% of patients surgical site infections had preceded the formation of incisional hernia compared with 26% in the patients without incisional hernia, comparable with the findings of Veljkovic et al.[34] Additional analysis concerning the impact of various degrees of infection on the occurrence of IH was possible as a result of the available, prospectively registered data. The infection percentage of 53% in our patients with IH was in the same range as published

by Bucknall et al, who found that 48% of their patients (41 of 84) had developed wound infections before IH formation. [35] Obesity has been reported as an independent risk factor by many investigators, especially if body mass index exceeded 30 kg/m^2. [2,9,32,35] In a series of gastric bypass patients published by Christou et al, IH occurred in 14% of patients without wound infection compared with 35% of patients with wound infection.[36] Besides the risk factors body mass index and surgical site infection, other variables such as closure method and the ratio of suture length to wound length, have been reported as relevant risk factors by other investigators.[32–35,37] Closure was almost without exception performed with slowly absorbable sutures in a continuous, mass-closure fashion; including the type of suture in the analysis therefore was considered irrelevant. It was note-worthy that the incidence of IH was significantly higher in patients in whom the fascia, according to the surgeon, was closed under tension. Unfortunately, the ratio of suture length to wound length was not measured in our study and therefore could not be included in the analysis. No significant differences were found for SF-36 or BIQ in the subgroup of patients with IH who had undergone surgery, including 2 patients who had developed recurrences, versus patients who had been treated conservatively. This may be a type 2 error owing to the small patient numbers. Also, differences might become detectable after a longer period of follow-up evaluation. Most patients present with IH within the first few years after surgery, but IH also can develop after longer periods, which warrants long-term follow-up evaluation of our patient population.[20,27,38–40] Long-term follow-up evaluation also may give us the opportunity to evaluate changes in quality-of-life scores after repair.

Patient follow-up evaluation was challenging in our study, as is the case for most quality-of-life studies. The high mortality rate in our patient group can be explained by the large proportion of oncologic patients (eg, pancreatic and esophageal cancer), causing significant drop-out at a median follow-up period of 16 months. We did not receive any reports on hernia-related deaths. Also, we considered physical examination essential to detect incisional hernia instead of, for instance, using a postal or telephone survey.

Because our hospital functioned as a tertiary referral center for a large proportion of our patients, many of them considered the transfer time too long and refused participation.

In general, minimally invasive surgery might be preferred to open abdominal surgery to prevent IH. If this is not an achievable option, the ratio of suture length to wound length and surgical site infection are the risk factors that can be influenced by surgeons most easily. Moreover, preventive use of mesh could be useful in high-risk patient groups (eg, obese and aortic aneurysm patients), and a randomized clinical trial on this topic currently is being conducted with our international trial group partners.

In conclusion, the vast majority of patients with IH in this cohort was symptomatic. Patients with IH experience a lower health-related quality of life on physical components and worse body image.

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Chapter 9

A Comparative Assessment of Surgeons' Tracking Methods for Surgical Site Infections

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Abstract

Background: The incidence of surgical site infections (SSI) is considered increasingly to be an indicator of quality of care. We conducted a study in which daily inspection of the surgical incision was performed by an independent, trained team to monitor the incidence of SSI using U.S. Centers for Disease Control and Prevention (CDC) definitions, as a gold-standard measure of care. In the department of surgery, two registration systems for SSI were used routinely by the surgeon: An electronic and a plenary tracking system. The results of the independent team were compared with the outcomes provided by two registration systems for SSI, so as to evaluate the reliability of these systems as a possible alternative for indicating quality of care.

Methods: The study was an incidence study conducted from May 2007 to January 2009 that included 1,000 adult patients scheduled to undergo open abdominal surgery in an academic teaching hospital. Surgical incisions were inspected daily to check for SSI according to definitions of health care-associated infections established by the CDC. Follow-up after discharge was done at the outpatient clinic of the hospital by telephone or letter in combination with patient diaries and reviews of patient charts, discharge letters, electronic files, and reported complications. Univariate and multivariable analyses were done to identify putative risk factors for missing registrations.

Results: Of the 1,000 patients in the study, 33 were not evaluated. Surgical site infections were diagnosed in 26.8% of the 967 remaining patients, of which 18.0% were superficial incisional infections, 5.4% were deep incisional infections, and 3.4% were organ/space infections. More than 60% of SSIs were unreported in either of the department's two tracking systems for such infections. For these two systems, independent major risk factors for missing registrations were (1) the lack of occurrence of an SSI, (2) transplantation surgery, and (3) admission to non-surgical departments.

Conclusions: Most SSIs were not tracked with the department's two systems. These systems proved poor alternatives to the gold-standard method of quantifying the incidence of Surgical Site Infection SSI and, therefore, the quality of care. Both protocolized wound assessment and on-site documentation are mandatory for realistic quantification of the incidence of SSI.

Background

Surgical site infections (SSIs) are the most frequent health care-associated infections among surgical patients, constituting 38% of all nosocomial infections in this group.[1] Surgical site infections are associated with high morbidity and high cost from increased durations of hospitalization, extra visits for ambulatory care, and higher readmission rates.[2–8] Tracking of surgical complications enables improvement of health care by identification of risk factors, risk groups, and specific interventions for complications.[9] Surgical site infections are considered increasingly to be indicators of quality of care. However, the extent of unreported infections remains unknown and depends on the methodology used to identify SSIs. We conducted a prospective incidence study of SSI to evaluate the reliability of the department's routine tracking systems as alternatives for measuring SSI incidence.

Methods

The study was designed as a prospective observational cohort study and was conducted at a 1,200-bed academic teaching hospital. Approval for the study was obtained from the local ethics committee. Inclusion criteria were a minimum age of 18 years and open abdominal surgery or a laparoscopic procedure that was converted intraoperatively to an open abdominal procedure. Exclusion criteria were laparoscopic surgery, inguinal/umbilical hernia repair, and day surgery. The inclusion/exclusion criteria were established for the purpose of providing a patient group that could be subjected to repetitious, daily in-hospital surveillance, with a high estimated risk of developing any of the three degrees of a superficial incisional, deep incisional, or organ/space SSI. Informed consent was obtained from all study participants. In addition to demographic data (age, gender, department of admission), the following data were documented: Body mass index, comorbidity (chronic obstructive pulmonary disease, diabetes mellitus), systemic corticosteroid use (oral, but not inhalation or dermal corticosteroid use), smoking, American Society of Anaesthesiologists score, duration of surgery, type of surgery, emergency surgery, transplantation surgery, National Research Council wound contamination class, and National Nosocomial Infection Risk Index. Data were also collected on duration of hospital stay, reoperation within 30 days after primary surgery, and in-hospital mortality.

Patients included in the study were subjected to the tracking method of daily surveillance, the primary outcome of which was the incidence of SSI according to the definitions of the U.S. Centers for Disease Control and Prevention (CDC).[10] Other endpoints included abdominal incision dehiscence and pain. However, these results will not be discussed in this paper. For each patient, data reported in the department's two routine tracking systems

were reviewed for the occurrences of SSIs in that particular system. In The Netherlands, national nosocomial infection tracking systems include the Dutch National Nosocomial Infection Surveillance System (Preventie Ziekenhuisinfecties door Surveillance (PREZIES), which is used mainly for prevalence studies. The definition of SSI used in PREZIES is based on the definition used by the CDC, with the additional obligatory presence of clinical symptoms; diagnosis of SSI by the surgeon alone was not sufficient for the determination of an SSI. Our study differed from PREZIES in that it did not require the presence of clinical symptoms in addition to the CDC definitions.

Daily surveillance tracking method ("gold-standard" method)

Abdominal incisions were inspected and photographed daily by two research fellows from postoperative day two onward (including weekends and holidays) to observe for the presence of SSIs. The research fellows were medical students in the fourth to sixth year of training who participated in the study for a minimum of five months, and were supervised daily by the first author (G.H.vR.). All participants in the inspection team tracked infections independently of the surgeon involved in the operation. On at least one occasion per week, inspection rounds were performed in conjunction with the supervisor. After 21 days of clinical observation or at discharge if it was earlier than 21 days, patients were given diaries in which to record problems with their incisions until postoperative day 30. This period was chosen because most SSIs have been reported to present within 21 days postoperatively.[1] Follow-up was done at the outpatient clinic on postoperative day 30, or alternatively by telephone or letter. Patient charts, discharge letters, wound photographs, and culture results were reviewed by the first author (G.H.vR.) after a minimum period of three months following discharge to verify the incidence of SSI. The surveillance team was impartial, and did not itself promote compliance with the electronic and plenary tracking systems, so as to preserve the validity of the sensitivities of the systems described below. Data collected by the surveillance team were not submitted to any national surveillance system.

Electronic tracking system

The electronic ward system was introduced at our institution in January 2007 and required residents to track in-hospital complications on a daily basis. Electronic record sheets allowed documentation of the absence or presence of complications and their severity. No application was included in the electronic system for alerting physicians to whether this sheet was missing at discharge. These data were not submitted to any national surveillance system.

Plenary tracking system

For several years, the plenary tracking system in our department consisted of a daily review of all patients discharged from surgical wards, which was part of the plenary morning report led by the head of the department. A few days after discharge, the occurrence of complications, including a short description and the severity of the most serious complication, were scored on hard copy discharge lists during the plenary report and filed for all patients. These data were not submitted to any national surveillance system. In addition to the scoring and filing of discharged patients' most serious complications, physicians were required to issue discharge letters for all patients, including those who died in-hospital.

Statistical analysis

A total of 1,000 patients were to be recruited for the study, based on the hypothesis that 10% of included patients would develop SSIs, thereby allowing group sizes sufficient for the comparison of patients with and without SSIs. Putative risk factors for registrations missing from the tracking systems were evaluated with univariate analysis, using the χ^2 test and Mann–Whitney U test for categorical and continuous data, respectively. Subsequently, variables that were significant in univariate analysis were entered in multivariable stepwise logistic regression analyses with backward elimination to identify major independent predictors of missing registrations. Cox regression analysis, with the occurrence of SSI as a time-dependent factor, was done to investigate the association between SSI and 30-day survival. The SPSS software system version 15 (SPSS, Chicago, IL) was used for all analyses. Two-sided values of $p<0.05$ were considered significant in all analyses.

Results

Between May 2007 and January 2009, 1,000 of 1,459 eligible patients were included in the study, with 459 patients not giving informed consent for participation. Thirty-three patients were not evaluated because of cancelled surgery or because they met the exclusion criteria for the study, leaving 967 patients whose data were available for analysis. Surgical procedures done on these patients included kidney transplantation (19.5%), and liver (13.8%), colorectal (13.0%), esophageal (11.5%), stomach–small intestinal (9.4%), pancreatic (8.3%), vascular (6.2%), and other (18.3%) procedures. Length of stay (10th–90th percentile) was 5–31 days for the study group as a whole, with a median hospital stay of 11 days (5–25 days) for patients without SSI and 16 days (8–51 days) for patients with SSI ($p<0.001$). Forty-five patients with SSI underwent reoperation (17.4%; of whom

27 had a diagnosis of SSI before or during reoperation and 18 patients had this diagnosis after reoperation), in contrast to 26 patients without SSI who underwent reoperation (p<0.001). In total, 41 patients (4.2%) died within 30 days after surgery (36 in the hospital, of whom 11 died after developing a SSI and 25 died without developing a SSI). Thirteen patients with a SSI died within 30 days after surgery versus 28 patients without a SSI who died within this period (5.0% vs. 2.9%, respectively). A survival analysis showed the hazard ratio for risk of death associated with SSI in the period of 30 days after surgery to be 2.7 (95% CI 1.3–5.5, p=0.006). Additional population characteristics of the study population are shown in Table 1.

Daily surveillance tracking method ("gold-standard" method)

Thirty-day follow-up was completed for 85.4% of the 967 patients whose data were available for analysis. Of these patients 643 (77.9%) had their follow-up completed at the outpatient clinic, 170 (20.6%) by telephone, and 14 (1.7%) by letter or e-mail. Data from the plenary and electronic tracking systems were reviewed for all 967 patients. The charts of 946 of the 967 patients (97.8%) were examined; 21 of the patients' charts (2.2%) were lost. Using the daily surveillance tracking method, SSIs were diagnosed in 259 of the 967 patients in the study (26.8%), with 174 of these being superficial incisional (18.0%), 52 being deep incisional (5.4%), and 33 being organ/space infections (3.4%) (Fig. 1).

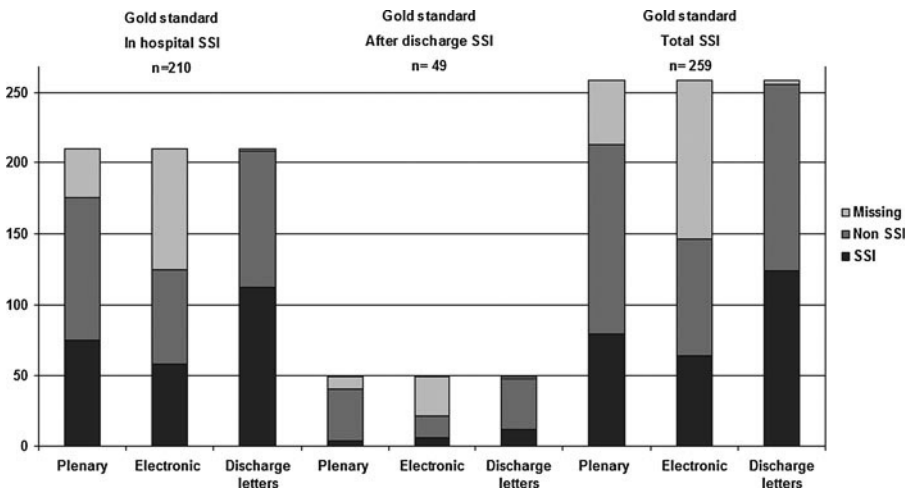

FIG. 1. Surgical site infections (SSI) according to gold standard were tracked as SSI, not tracked as SSI (non-SSI) or registrations were missing (missing). Bars demonstrate proportionate distribution by tracking method (plenary, electronic, and discharge letters) and timing of diagnosis.

Table 1: Population characteristics and clinical data for the total population (n=967) and subpopulations without surgical site infections (No SSI, n=708) and with surgical site infections (SSI, n=259) according to gold standard

Variable	Age (years)*	Gender f/m	BMI*	COPD	Diabetes mellitus	Systemic corticosteroids	Smoking	Emergency surgery	Operation time (min) *	NRC class				NNIS risk index†			
										Clean	Clean-contaminated	Contaminated	Dirty-infected	0	1	2	3
Total n=967	56.4 ± 14.4 (35.0-74.0)	363/604	25.7 ± 4.8 (20.1-31.6)	88 (9)	133 (14)	126 (13)	401 (42)	217 (22)	262 ± 131 (128-461)	171 (18)	710 (73)	30 (3)	56 (6)	165 (17)	593 (61)	196 (20)	13 (1)
SSI n=259	57.0 ± 13.6 (37.0-73.0)	95/164	26.6 ± 5.0 (20.6-33.7)	32 (12)	44 (17)	42 (16)	95 (37)	67 (26)	295 ± 147 (126-505)	31 (12)	188 (73)	11 (4)	29 (11)	22 (9)	160 (62)	70 (27)	7 (3)
No SSI N=708	56.1 ± 14.6 (34.9-74.0)	268/440	25.4 ± 4.7 (20.0-31.2)	56 (8)	89 (13)	84 (12)	306 (43)	150 (21)	250 ± 123 (129-431)	140 (20)	522 (74)	19 (3)	27 (4)	143 (20)	433 (61)	126 (18)	6 (1)
Overall SSI %	-	-	-	36	33	33	24	31	-	18	26	37	52	13	27	36	54
P-value	0.425	0.796	<0.001	0.046	0.098	0.094	0.077	0.148	<0.001	<0.001				<0.001			

BMI: body mass index
COPD: chronic obstructive pulmonary disease
NRC class: National Research Council (NRC) wound contamination class
*Values present mean ± standard deviation and range (10^{th}-90^{th} percentile) or numbers of patients (percentage)
† NNIS risk index: National Nosocomial Infection (NNIS) risk index was calculated by awarding 1 point for each of the following: (1) a patient with ASA class 3, 4, or 5, (2) an operation classified as contaminated or dirty-infected, and (3) an operations lasting over T hours, where T depends upon the operative procedure being performed.[11]

The median time of diagnosis of SSI was at postoperative day 9 (interquartile range 6–13 d). The majority of infections (81%) were diagnosed in the hospital. The median hospital stay increased with the severity of SSI, and was 14, 25, and 27 days for superficial incisional, deep incisional, and organ/space infections, respectively (p<0.001). Patients with a SSI were readmitted more than twice as often as patients without a SSI (15.1% vs. 7.4%, p=0.009). The mean number of ambulatory care visits within the three months after surgery was 1.9 for patients with a SSI versus 1.1 for patients without a SSI (p<0.001).

Electronic tracking system

Registrations of SSIs were entered in the electronic tracking system for 458 of the 967 patients whose data were analyzed (47.4%). Registrations were missing for 509 patients (52.6%), and no registrations of any complications were entered for these patients. SSIs were tracked according to the daily surveillance tracking method for 64 of 259 patients with SSIs (24.7%). In compliance with the electronic tracking method, infections diagnosed after discharge were tracked significantly less often than infections diagnosed while patients were in the hospital (6/49 vs. 58/210 patients; p<0.001). Deep incisional and organ/space infections were not reported more often than superficial incisional SSIs (p=0.488).

Plenary tracking system

Registrations in the plenary tracking system were available for 709 of the 967 patients (73.3%) whose data were analyzed, and were missing for the remaining 258 of 967 patients (26.7%). Of all patients with SSIs tracked with the daily surveillance tracking method (n=259), 79/259 patients (30.5%) were tracked with the plenary tracking system. In compliance with the plenary tracking method, infections diagnosed after discharge were tracked significantly less often than infections diagnosed while patients were in the hospital (4/49 vs. 75/210 patients; p=0.042). Deep incisional and organ/space infections were not reported more often than superficial incisional SSIs (p=0.097).

Discharge letters were available for 946 patients (97.8%), with letters missing for 21 patients (2.2%). Surgical site infections were reported in 40% of patients with superficial incisional infections (68/171), 70% of patients with deep incisional infections (37/53), and 61% of patients with organ/space infections (20/33). Deep incisional and organ/space infections were reported significantly more often than superficial incisional infections (p<0.001).

Missing registrations

In total, 40.2% of patients with SSIs were reported in the plenary or electronic tracking systems. For the total study population (n=967), registrations of SSIs were missing for 52.6% of patients in the electronic system and for 26.7% of patients in the plenary morning report. Patients with infections of which the records were missing from the plenary or electronic tracking systems (n=218) required readmission within 30 days in 14% of cases (n=30), reoperation following a diagnosis of SSI in 15% of cases (n=32), and use of antibiotics in 32% of cases (n=46); in the remaining 8% of cases (n=18) these unrecorded SSIs resulted in death. Table 2 shows the frequency of various putative risk factors for missing registrations of SSIs and the results of univariate analyses of these putative risk factors. Risk factors for missing SSI registrations in the plenary and electronic systems by univariate analysis were the lack of occurrence of an SSI, transplantation surgery, emergency surgery, and admission to a nonsurgical department. In-hospital mortality and length of hospital stay were not risk factors for missing SSI registrations. By multivariable analysis, no occurrence of SSI, transplantation surgery, or admission to a nonsurgical department proved to be a significant independent risk factor for missing SSI registration (Table 3).

Table 2: Results of univariate analyses of putative risk factors for missing registrations per tracking system

	Plenary system					**Electronic system**				
	Missing registration					***Missing registration***				
	Yes		***No***			***Yes***		***No***		
	n=258		***n=709***			***n=509***		***n=458***		
Variable	***n***	***%***	***n***	***%***	***P*value**	***n***	***%***	***n***	***%***	***P*value**
No occurrence of SSI	212	82.2	496	70.0	<0.001	396	77.8	312	68.1	0.001
Transplantation surgery	155	60.1	98	13.8	<0.001	195	38.3	58	12.7	<0.001
Emergency surgery	74	28.7	143	20.2	0.006	131	25.7	86	18.8	0.011
Admission to non-surgical department	46	17.8	58	8.2	<0.001	67	13.2	37	8.1	0.015
In hospital mortality	16	6.2	35	4.9	0.538	33	6.5	18	4.0	0.103
Length of stay (days) *	13	(6-30)	12	(5-32)	0.064	12	(5-29)	12	(5-34)	0.653

Values represent median and range (10^{th}-90^{th} percentile)

Table 3: Results of multivariate stepwise logistic regression analyses for missing registrations of surgical site infections (SSI) per tracking system

	Plenary system				*Electronic system*			
	Odds ratio	***95% C.I. for OR***			***Odds ratio***	***95% C.I. for OR***		
Risk factor	**(OR)**	**Lower limit**	**Upper limit**	***P*value**	**(OR)**	**Lower limit**	**Upper limit**	***P*value**
No occurrence of SSI	1.92	1.27	2.89	0.002	1.53	1.13	2.08	0.002
Transplantation surgery	14.35	9.91	20.8	<0.001	4.74	3.39	6.62	<0.001
Admission to non-surgical department	7.57	4.69	12.2	<0.001	1.72	1.72	4.11	<0.001

C.I.=confidence interval; OR-odds ratio; SSI= surgical site infection

Table 4 shows infection rates calculated for different combinations of the tracking systems investigated in the study. The infection rate for data from the plenary and electronic systems combined was 10.3% (100/967). After the addition of discharge-letter data, the infection rate was 16.9%, and sensitivity with the daily surveillance tracking method as a reference increased from 38.6% (100/259) to 61.8% (160/259). This rate remained significantly lower than that with the daily surveillance tracking method, for which the rate of SSI was 26.8% ($p<0.001$). A number of patients with opened incisions but with negative cultures and without other findings needed to fulfill the CDC criteria for SSI were diagnosed wrongly as having infected incisions in the electronic (n=2) and plenary systems (n=7). Specificities of the electronic and plenary system were 99.4% and 98.6%, respectively.

Table 4: Calculated infection rates per tracking method or combination of tracking methods for the population

Registration	**No. of patients with reported SSI**	**Infection rate***
Plenary tracking system only	79	8.2%
Electronic tracking system only	64	6.6%
Discharge letters only	128	13.5%
Plenary and electronic tracking systems combined	100	10.3%
Plenary and electronic tracking systems and discharge letters combined	160	16.9%
Study total according to gold standard	259	26.8%

* Infection rate calculated as number of patients with tracked surgical site infections (SSI) divided by the number of analyzed patients (n=946 for 'discharge letters only' and 'plenary and electronic systems and discharge letters combined' and n=967 for all others)

Discussion

The incidence of SSI in this study was 26.8%; SSIs were associated with substantial morbidity and with increased 30-day mortality. The majority of SSIs (61%) were not reported in any of the tracking systems used by surgeons. The substantial morbidity associated with missed SSIs suggests that a large proportion of these missed infections were relevant clinically. Methods of tracking complications of surgery and classification systems for such complications vary substantially in reports in the literature.[12–20] Tracking systems used by surgeons proved unreliable for monitoring the incidence of SSI, and this method of self-reporting therefore constitutes a poor indicator of quality of care. A self-reporting bias for surgeons and residents may partly explain the low sensitivity of the tracking systems for SSI, whereas such a bias was unlikely to exist for members of the team engaged in the tracking of SSI through the daily surveillance method. The sensitivity of the daily surveillance tracking method and the high rate of follow-up may also explain the high infection rate identified through this method, which was comparable to rates of SSI reported by other authors.[21,22] Furthermore, tracking by a specialized team cannot be exchanged for surgeons' tracking systems without a substantial loss of sensitivity. Comparison of these data with national data was possible because of a validation study of the PREZIES data that was conducted from 1999 to 2004. This latter study consisted of systematic retrospective chart review by the team that validated the PREZIES data and interviews with local infection-control professionals. In that study, a positive predictive value of 0.97 and negative predictive value of 0.99 were found, both of which were comparable with the findings in our study.[23]

Independent risk factors for missing registrations in our surgery department's systems included the lack of occurrence of SSI, transplantation surgery, and admission to a nonsurgical department. These risk factors most likely indicate non-compliance with registration on the part of surgeons and surgical residents in charge of patients admitted to the transplantation department and to non-surgical departments, which may not be generally true for other institutions.

Our routine electronic tracking system relied on the individual responsibility of the residents and supervising surgeons involved in performing surgery and detecting SSIs. A heavy workload may have hindered the reliability of medical records or electronic tracking by creating forgetfulness on the part of physicians or causing them to neglect the documentation of complications. Continuity of care can be endangered by frequent changes in staff shifts and compensatory leave, allowing a superficial incisional SSI to remain untracked. It might be useful to involve (trained) nurses or physician assistants in the tracking of SSIs, because nurses generally inspect incisions more often than do

physicians. One study reported good results of routine electronic (computer) tracking on a daily basis by nurses of deviations from the normal postoperative course of patients undergoing cardiac surgery, and specifically of tracking before discharge from the postoperative ward of a Swedish hospital, after which supervising physicians decided whether or not complications had occurred.[24] An additional weakness of our electronic system was its lack of alarm signals (e.g., flagging of patients) and supervision, which allowed missing registrations to remain unnoticed without consequences. However, we doubt whether patient safety would have been guaranteed through alarm signals and whether this would thereby have covered 100% of all patients, as the sensitivity of the self-reporting system was far lower than that of the tracking method used by the specialized team.

The plenary tracking system used during the morning report depended on the continuity of care in the surgery department. It was problematic that patients who had undergone surgery and were admitted to non-surgical wards in our local hospital and who were not registered primarily as surgical patients (e.g., through registration in urology, internal medicine, and other departments) were not featured on discharge lists. As a result, complications associated with various operations remained untracked. Furthermore, data kept in the tracking systems were not combined routinely or evaluated. Evaluation of any single self-reporting system revealed the reporting of a lower number of infections than were reported when all of the tracking systems were combined. Routine evaluation of the tracking systems or other types of exogenous inducements to complete missing SSI data might have helped to achieve higher compliance.

The results of this study have raised awareness of the underestimation of rates of SSI in the departments of general surgery and infection control at our hospital. Embedding the gold-standard surveillance approach (including patients' diaries and postdischarge follow-up) into routine practice has thus far proven challenging on financial and practical grounds, because this method is associated with an increased workload, and post-discharge surveillance of surgical patients has remained voluntary in the national surveillance system used in The Netherlands for nosocomial infections. Another way in which cost-effective surveillance can be conducted is through an electronic or automatic selection of patients for nosocomial infections. This system of automated selection will be validated against the time-consuming but very reliable system of direct surveillance. The automated selection of high-risk patients, which deserves increasing attention and will be a reality in the future, will provide information about rates of infection while at the same time leaving personnel free to provide the interventional care needed for treating infections.

The discharge letters issued for all patients who underwent surgery at our hospital were expected to be fairly complete in the description of complications such as SSI, and it was hoped that the efficacy of the electronic and plenary complication tracking systems could be easily determined from these data. However, our data illustrated that the review of discharge letters for the follow-up of patients with SSIs was of limited value because of its mediocre sensitivity, especially for superficial incisional SSIs. Considering that 19% of the SSIs in our patients were detected after discharge, and as many as 84% were found in previous studies to have been detected after discharge, depending on the patient population, post-discharge data ought to be included in audit meetings.[1] Infection rates reported in the literature, possibly as distinct from the rates reported in well-performed randomized controlled trials, will generally represent only a fraction of the true number of affected patients. It is notoriously difficult to achieve complete follow-up and documentation of SSIs even when charts are reviewed.[13,19] In many studies, follow-up after discharge is omitted or performed only through questionnaires administered by the surgeon. The relative percentage of SSIs detected after discharge depends strongly on the intensity of post-discharge surveillance, and can differ significantly in diffent countries even if comparable protocols and definitions are used in surveillance.[25] According to a report by the European Centre for Disease Prevention and Control, The Netherlands were, in 2007, among the countries with the highest percentages of infections diagnosed after discharge, at 58%.[26] Furthermore, the type of surgery proved relevant for the percentage of SSIs detected after discharge, with a relatively low percentage of SSIs reported for colon surgery (13%) in 2009, as compared with an overall rate of SSI of 48% in that same year.[27] Although follow-up of patients with implanted materials of non-human origin at one year after surgery is recommended by the CDC, it is often not done in studies with general-surgery patients. Implanted materials of non-human origin, such as mesh, are not used frequently in this patient group. The period of follow-up in our study was limited to 30 days.

Use of a self-reported incidence of infection as an indicator of quality of care is not advisable because of the low rate at which it can be documented (depending on the method used), and favors hospitals with the smallest rate of self-reported infection. Punishment of hospitals with high infection rates will promote a low documentation of infections and the alternative interpretation or use of definitions of infection, which does not contribute either to patient safety or to the development of a self-critical atmosphere for the documentation of hospital-acquired infections. Structural shortcomings in care may then be identified less easily. A better system for measuring patient safety is not comparing outcome data (e.g., SSI, depending on the case mix), but comparing process indicators for the prevention of infections, such as timely antibiotic prophylaxis. To truly

improve quality of care, a constructive approach to the problem of SSI is needed on the part of politicians and health insurers. In order to be able to compare hospital infection rates, uniform definitions must be used and surveillance for and prevention of SSI should be integrated into resident training programs. Lastly, comparing rates of infection requires accurate correction for case mix and large numbers of patients for adequate statistical power. The reliability of incidence rates of SSI depends on the quality of documentation of SSIs in both the inpatient and outpatient departments, which should involve the training of nurses and doctors in the protocol-governed, regularly supervised assessment of fresh surgical incisions as part of a continuous validation process.

Author Disclosure Statement

None of the authors has competing interests. Preliminary results of this study were presented at the Third Combined Meeting of the Surgical Infection Societies of North America and Europe (May 6–9, 2009, Chicago, IL) and received the European residents award for the best oral presentation at this meeting.

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Chapter 10

Small stitches with small suture distances increase laparotomy closure strength

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Abstract

Background: There is no conclusive evidence which size of suture stitches and suture distance should be used to prevent burst abdomen and incisional hernia.

Methods: Thirty-eight porcine abdominal walls were removed immediately after death and divided into 2 groups: A and B (N 19 each). Two suturing methods using double-loop polydioxanone were tested in 14-cm midline incisions: group A consisted of large stitches (1 cm) with a large suture distance (1 cm), and group B consisted of small stitches (.5 cm) with a small suture distance (.5 cm).

Results: The geometric mean tensile force in group B was significantly higher than in group A (787 N vs 534 N; p=0.006).

Conclusions: Small stitches with small suture distances achieve higher tensile forces than large stitches with large suture distances. Therefore, small stitches may be useful to prevent the development of a burst abdomen or an incisional hernia after midline incisions.

Background

Suture techniques for midline incisions have been the subject of investigation for a long period of time. Incidences of incisional hernia and burst abdomen after laparotomy are 2% to 20% and 1% to 3%, respectively. Although much is known about patient-related risk factors, technical risk factors such as suture techniques have not been investigated thoroughly.[1–4] Surgeons should take care to use optimal suture technique to avoid short- and long-term complications, especially in high-risk patients in whom incidences of incisional hernia are reported to be up to 35%.[5] The optimal suture technique should be easy to perform, quick, reliable, and give high long-lasting breaking strengths to improve wound healing.

For the prevention of incisional hernia, many clinical trials and meta-analyses have shown that a mass closure technique with simple running sutures is the best option to close a midline incision.[6–11] Such a technique also is easier to perform and quicker than layered techniques with interrupted sutures.

Furthermore, the use of long-lasting absorbable suture material compared with nonabsorbable suture material decreases postoperative pain and wound infection.[9–12]

Israelsson et al have argued that a suture length: wound length (SL:WL) ratio of 4 or more must be achieved because a lower ratio is associated with a 3-fold increase in the rate of incisional hernia.[13–15] It often is recommended to place continuous stitches more than 10 mm from the wound edge in combination with a long stitch length.[16–22] A long stitch is the result of a large stitch with the largest portion of fascia possible, aiming to increase tensile strength and to decrease the risk of facial dehiscence. However, long stitches have been associated with high rates of both wound infection and incisional hernia. [13,23,24]

Israelsson and his group performed experimental and clinical studies on the benefits of suture techniques of small stitches.[13–15,25–28] Small stitches are placed 4 to 6 mm from the wound edge and cut only through the aponeurosis and not through the rectus abdominis muscle. Because the small stitch is placed in the aponeurosis only, it also is possible to place more stitches in a single incision.

In daily practice, most surgeons use the large-stitch technique with large suture distances. With large stitches, the SL:WL ratio depends on the thickness of the abdominal wall including the muscles and the number of stitches. With small stitches, the SL:WL ratio is dependent mostly on the number of stitches. There is no proof of principle regarding which technique is the best option to close the abdominal wall to prevent incisional hernia and fascial dehiscence.

The aim of this study was to compare the large- and small-stitch techniques on tensile strength and type of dehiscence in a controlled laboratory setting by using porcine abdominal walls.

Materials and Methods

Thirty-eight porcine abdominal walls (Yorkshire pigs, 40 – 60 kg) were removed immediately after death and frozen at -20°C for at least 4 days (mean, 7 d).[29] After a defrosting period of 16 hours, fat and skin were removed, and a midline incision was made through the aponeurosis.

Two suturing methods using double-loop polydioxanone (PDS II 1.0 Ethicon, Johnson & Johnson, New Brunswick, NJ, USA), 240 cm) were tested in 14-cm midline incisions: group A: large stitches (1 cm) with a large suture distance (1 cm) with a total of 14 continuous stitches, and group B: small stitches (.5 cm) with a small suture distance (.5 cm) with a total of 28 continuous stitches. The techniques were used in alternate order and by 2 circulating investigators to avoid selection bias. To standardize the suture technique, the place of the stitch was measured with a ruler and marked with a needle (Braun sterican .5 mm 16 mm; B. Braun, Tuttlingen, Germany). The SL:WL ratios were calculated for all specimens.

Subsequently, abdominal walls were fixed on a tensile testing machine (Testometric, Rochdale, England) (Fig. 1).[30] Tensile force was increased at a constant rate of 10 mm/min. Each test was filmed (Sony Cyber-shot DSC-S700, Tokyo, Japan) and the type of dehiscence (eg, aponeurosis, lateral of sutures, site of fixation, or no dehiscence at maximum force) was recorded. The test setting is shown in Fig. 1.

Figure 1 Photograph of the test setting used. The sutured abdominal wall is fixed in the tensile testing machine and is pulled apart at a constant rate of 10 mm/min.

The force at the moment of the first drop resulting in dehiscence through the aponeurosis was considered the primary outcome. For experiments in which other types of dehiscence occurred it can be concluded that the true force to result in dehiscence through the aponeurosis will be greater than the recorded force (right-censored observation). To take account of such censored observations, STATA (College Station, TX, USA) software was used (procedure censored normal regression). Forces were transformed logarithmically in this analysis to obtain approximate normal distributions. The same method was used to evaluate the relation between the SL:WL ratio and the primary outcome. p values less than 0.05 were considered significant. Power calculations based on pilot data led to 2 groups of 19 abdominal walls each.

Results

In group A (large stitches; n = 19) and group B (small stitches, n = 19) there were, respectively, 14 and 7 experiments that resulted in dehiscence through the aponeurosis (p=0.049; Fisher exact test). In group A there were 5 experiments not resulting in dehiscence through the aponeurosis (3 on the fixation device, 2 lateral to the incision). In group B there were 12 experiments not resulting in dehiscence through the aponeurosis (8 on the fixation device, 3 lateral to the incision).

Analyzing the resulting forces of all 38 experiments, the tensile forces in group B were significantly higher than in group A with geometric mean tensile force able to create dehiscence through the aponeurosis of 534 N in group A and 787 N in group B (p=0.006). This corresponds to a 47% increase. Following the law of Laplace and assuming a mean abdominal diameter of 30 cm, a tensile force of 360 N represents the force created by the Valsalva maneuver.

Mean SL:WL ratios were 4.1 (range, 2.8 –5.1) in group A and 6.9 (range, 5.0 – 8.6) in group B. In group A, an increase in the SL:WL ratio was associated significantly with an increase in tensile strength (p<0.001), with each 1-point higher SL:WL ratio resulting in a 61% increase in of tensile force and a higher SL: WL ratio (Fig. 2). No significant relation was found in group B (p=0.102). None of the knots slipped and none of the sutures broke in any of the tests.

The type of dehiscence was very characteristic for group A compared with group B. During the experiments, large stitches were tearing through the muscle and the most tensile force was generated when the sutures were hanging on the aponeurosis while the wound edges were separated. This effect has been described before.[27] When stitches were placed in the aponeurosis the slacking effect was not observed (Fig. 3).

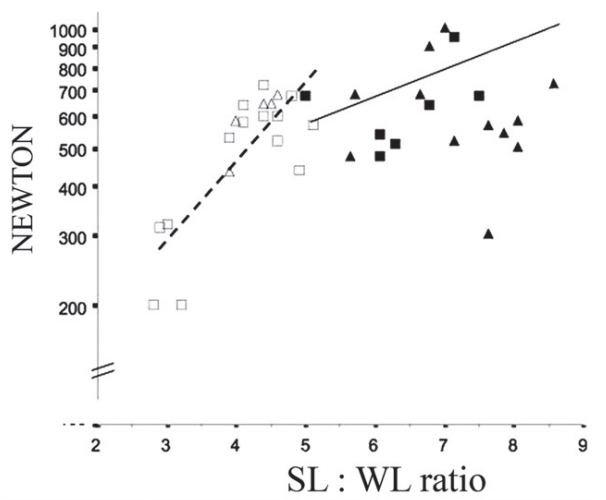

Figure 2 Scatter plot of tensile force versus the SL:WL ratio, with regression lines. Open and closed symbols represent tensile forces for group A (large stitches) and group B (small stitches), respectively. Triangles within each group represent forces that did not result in dehiscence through the aponeurosis (censored observations).

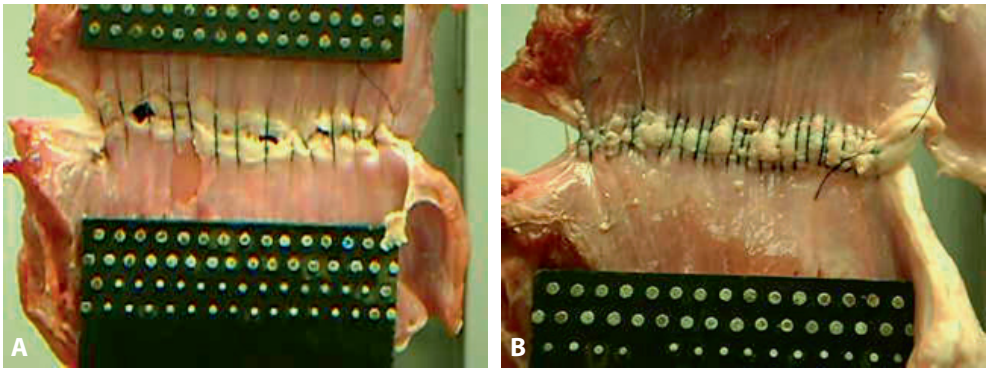

Figure 3 (A) Large-stitch group: slacking effect. Example of the slacking effect in the large-stitch group. Sutures first cut through the relatively weak tissue lateral to the aponeurosis, causing wound edges to separate. (B) Small-stitch group. In the small-stitch group, separation of wound edges was not observed. This possibly is owing to a better distribution of tensile forces, resulting in dehiscence far lateral from the aponeurosis.

Comments

This was an experimental study comparing large versus small tissue stitches with documented SL:WL ratios on breaking strength in a model anatomically comparable with human beings. A number of rat studies were performed on wound healing and bursting pressure in the past, but forces in small animals are hardly comparable with human physiology.

In the small-stitches group, more stitches resulted into a better division of tension over the abdominal wall. Furthermore, because of the achievement of high SL:WL ratios, tension was divided over a longer suture thread. In the large-stitch group, high SL:WL ratios were needed to create acceptable tensile strength and although standardized stitches of 1 cm were used, half of all SL:WL ratios were less than 4. In the large-stitch group, the ratio was dependent on stitch size, the thickness of the abdominal wall, and the extent of force used to haul the suture.

The SL:WL ratio of 4, as described by Jenkins, was based on a mathematic approach.[31] No specifications concerning the desired stitch size or anatomic location were described. Surgeons expect to always achieve a 4:1 ratio by taking 2-cm stitches of the abdominal wall with a continuous suture, and are reluctant to place stitches in the aponeurosis. Not only do surgeons fear that the aponeurosis is not strong enough to withstand tensile forces of the abdomen, the placement of many stitches in the aponeurosis also is assumed to inflict local necrosis. This study shows that the aponeurosis is strong enough to hold sutures. Furthermore, Cengiz et al have described the benefits of small stitches in several studies: better wound healing, no separation of wound edges, and less trauma to abdominal muscles.[26–28] These effects could not be established in this study because of the use of devitalized abdominal walls. However, no good alternatives are available to analyze and measure tensile forces and types of dehiscence in the clinical situation.

Our experiments show that the use of the small-stitch technique might have clinical advantages. Experience of the individual surgeon with this technique will influence the eventual result. In patients with midline laparotomy, using small stitches with small suture distances may prove the best strategy. Randomized clinical trials should be performed to provide convincing data to support a change of technique.

Conclusions

Small stitches with small suture distances achieve higher tensile forces than large stitches with large suture distances in our porcine in vitro model. Large stitches should be used only when high SL:WL ratios are achieved to attain acceptable tensile strengths. Small stitches with small suture distances are recommended to easily achieve high SL:WL ratios and higher tensile strengths. Therefore, small stitches may be useful to prevent the development of a burst abdomen or an incisional hernia after midline incisions in patients.

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Chapter 11

Closure of Midline Laparotomies by Means of Small Stitches: Practical Aspects of a New Technique

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** Both authors contributed equally to this manuscript*

Abstract

Purpose: Randomized studies support the closure of midline incisions with a suture length to wound length ratio (SL:WL) of more than four, accomplished with small tissue bites and short stitch intervals to decrease the risk of incisional hernia and wound infection. We investigated practical aspects of this technique possibly hampering the introduction of this technique.

Methods: Patient data, operative variables and SL:WL ratio were collected at two hospitals (SH and EMC). A structured implementation of the technique had been performed at SH but not at EMC. Personnel were interviewed by questionnaire.

Results: At each hospital 18 closures were analyzed. Closure time was significantly longer (p=0.023) at SH (median 18 minutes, range: 9-59) than at EMC (median 13 minutes, range: 5-23). SL:WL ratio of more than four was achieved in 8 of 18 cases at EMC and in all 18 cases at SH.

Conclusions: Calculation of SL:WL ratio is easily performed. Suturing with the small bite-short stitch interval technique of SH required five minutes extra, outweighing the morbidity of incisional hernia. Without a structured implementation to suture with an SL:WL ratio of more than four, a lower ratio is often achieved.

Introduction

The optimal method for wound closure is one associated with the lowest rates of complications, for example, wound infection, abdominal wound dehiscence, and incisional hernia. It should be technically simple, quick to perform, and well tolerated by patients.[1] A continuous suture technique is usually recommended because it is performed faster than an interrupted technique and produces similar rates of wound complications.[1–6] There are several technical variables associated with a continuous suture technique: suture length, wound length, number of stitches, stitch interval, tissue bite size, and tension on the suture.

The wound is in a dynamic state as postoperative abdominal distension may stretch the wound and increase the tension on the wound. A running suture compresses tissue enclosed by the suture with elongation of the wound. The shorter the suture, the more tissue compression and suture tension occur.[7] The suture length to wound length (SL:WL) ratio describes the relative length of the suture and is an independent risk factor for the development of incisional hernia.[8] In a prospective cohort study, incisional hernia occurred in 22% (70/326) of patients when the SL:WL ratio was less than four and in 9% (31/351) when the SL:WL ratio was more than four. During the second period of this study, an intervention was performed to urge surgeons to shorten stitch intervals in order to increase their personal SL:WL ratio to more than four. As a result of this intervention, the rate of incisional hernia dropped from 19% (68/363) to 11% (35/320).[8]

An SL:WL ratio of more than 4 can be achieved using large tissue bites or a higher number of small tissue bites. Experimental data show that on the condition that the SL:WL ratio is more than 4, wound bursting strength is higher with small tissue bites of 10 mm than with large tissue bites.[9,10] In clinical reports, small tissue bites have been associated with a lower risk of wound infection and incisional hernia compared with large tissue bites.[11–14] In a randomized controlled trial, wound infections occurred in 10% (35/343) of the patients in the long stitch group compared with 5% (17/326) of the patients in the short stitch group. Incidence of incisional hernia was also significantly lower in the short stitch group, 18% (49/272) compared with 6% (14/250).[14]

At Sundsvall Hospital (SH), Sweden, a suture technique for the closure of abdominal midline incisions is used with small tissue bites and short stitch intervals aiming for an SL:WL ratio of at least 4. At Erasmus University Medical Center (EMC), a large bite mass-closure technique is used without a structured implementation to suture with a specific SL:WL ratio. This study investigates differences in practical aspects of both techniques in preparation for future clinical implementation of the small bite suture technique.

Materials and methods

In March 2008, an independent investigator (BK) from EMC visited SH. During this period, all patients in the surgical department who underwent midline laparotomies with primary closure were included. The aponeurosis was closed using a continuous technique with a polydiaxanone USP 2/0 single suture mounted on a needle with a diameter of 20 mm. Small tissue bites were placed only in the aponeurosis (linea alba) with stitch intervals of approximately 5 mm. Surgeons were accustomed to suture with an SL:WL ratio of more than 4. If a lower ratio was achieved, protocol required removal of the suture and re-suturing of the aponeurosis. The SL:WL ratio was routinely measured and documented by the surgical nurses (Fig. 1).

The following data were collected: duration and type of surgery, time needed to close the aponeurosis, wound length, length of suture remnants for calculation of SL:WL ratio, age, and Body Mass Index (BMI) of patients. Available operating theatre personnel at SH were interviewed by questionnaire (Table I). The head of the department of surgery, the introducer of the technique, was not included in the interviews.

The measurements, with the exception of the questionnaire, were repeated at EMC during April through October 2008. Abdominal midline incisions were closed using a continuous technique with a polydiaxanone USP I double loop suture mounted on a needle with a diameter of 31 mm. Large tissue bites were used with a mass closure technique.

Statistical analysis was performed with SPSS™ (SPSS Inc, Chicago, IL). Chi-square test or Fisher's Exact Test when appropriate was used for categorical variables. Mann-Whitney U-Test was used for continuous variables. Anova was used to evaluate various factors simultaneously regarding closure time. In this analysis, the closure time was transformed logarithmically in order to obtain an approximate normal distribution. Differences were regarded significant at $p<0.05$.

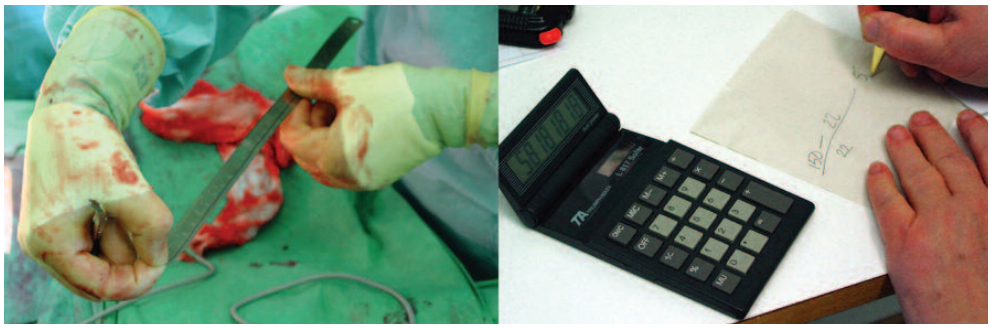

Figure 1. The suture length to wound length ratio is calculated by subtracting the measured length of suture remnants from the original suture length and dividing the result by the measured wound length.

Table I Questionnaire given to surgeons, residents, anesthesiologists, and surgical nurses at Sundsvall Hospital

Surgeons	• Have you used other suture techniques for closing abdominal midline incisions in the past? • If yes, were there any problems switching to this technique?
Residents	• Is the suture technique easy to learn? • Have you been taught methods other than this suture technique?
Anesthesiologists	• Are there problems with the anesthesia of patients when the abdominal midline incision has to be re-sutured because the SL:WL ratio was less than 4? If yes, what kind of problems did occur?
Surgical nurses	• Is it possible to combine the task to measure the SL:WL ratio with your other tasks without any problems? If not, what sort of problems do occur? • Is there increased delay of the operation schedule if an abdominal midline incision has to be re-sutured because the SL:WL ratio was less than 4?

Results

A total of 36 midline incisions were included (18 at SH, 18 at EMC). Patient-related variables were similar, but there was a difference in duration of surgery (Table II).

Time for closure of the aponeurosis was significantly longer at SH (median 18 minutes, range: 9–59) than at EMC (median 13 minutes, range: 5–23) (p=0.023). Simultaneous evaluation by Anova of closure time with regard to the factors of hospital, type of surgeon, BMI, type of surgery, and length of incision showed that hospital and length of incision were the most important factors (both p<0.001). Adjusted for incision length the closure time was on average prolonged by a factor of 1.7 (95% CI: 1.3 to 2.2). Surgeons at SH sutured a median of 1.2 cm (range 0.5–2.2) of aponeurosis per minute compared with a median of 2.1 cm (range 1.0–3.4) at EMC (p<0.01). An SL:WL ratio of more than four was achieved in all 18 midline closures at SH and in 8 out of 18 (p=0.001) at EMC (Fig. 2). A high SL:WL ratio correlated with a shorter length of aponeurosis being sutured per minute (correlation coefficient 0.53, p=0.001).

A total of 46 employees of SH were interviewed by questionnaire: 10 surgeons, 5 surgical residents, 11 anesthesiologists and 20 surgical nurses. Overall response rate was 91%. Only 3 out of 10 surgeons had ever used another suture technique besides the current practice at SH. Those who had experience with other suture techniques did not report any problems switching to the present technique. None of the residents had been taught any other suture technique, and all reported that the suture technique was easy to learn. Three anesthesiologists had experienced prolongation of anesthesia as a result of re-suturing the aponeurosis because an SL:WL ratio of more than 4 had not been achieved. The other 8 anesthesiologists had never experienced problems with the suture technique. Nineteen out of 20 surgical nurses responded that measuring and documenting the SL:WL ratio

was performed without problems. One surgical nurse responded to occasionally having forgotten to do the measurements. Six nurses (30%) had experienced at least once that a ratio of less than 4 had been achieved. This had resulted in delay of operating schedule due to re-suturing of the aponeurosis. All reported that ratios of less than 4 rarely occurred.

Table II Patient and operation characteristics at Sundsvall Hospital (SH) and Erasmus University Medical Centre (EMC)

Variable	SH (n = 18)		EMC (n = 18)		p
Age, mean years (SD)	62	(11)	60	(16)	0.99[a]
Body Mass Index, mean (SD)	26,5	(4.6)	25,9	(4.2)	0.46[a]
Length of incision, mean centimeters (SD)	22	(7)	25	(3.9)	0.08[a]
Duration of surgery, mean minutes (SD)	139	(72)	217	(86)	<0.01[a]
Abdominal closure by residents, n (%)	1	(6)	6	(33)	0.09[b]
Type of surgery, n (%)					0.09[c]
Upper gastro-intestinal surgery	4	(22)	10	(55)	
Lower gastro-intestinal surgery	12	(67)	5	(28)	
Other surgery	2	(11)	3	(17)	

[a] Mann-Whitney *U*-test. [b] Fisher exact test. [c] Chi-square.

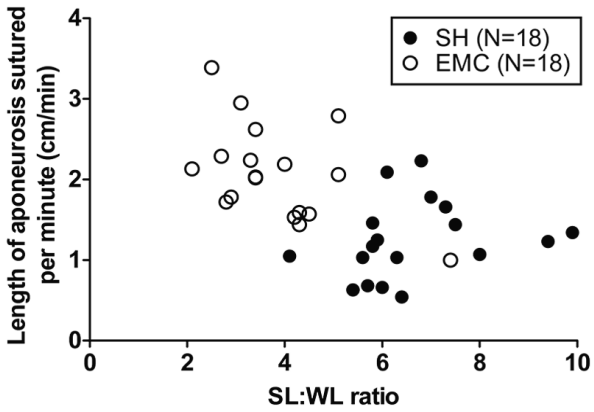

Figure 2. Scatterplot with suture length to wound length ratio (SL:WL) versus the length of aponeurosis sutured per minute at Sundsvall Hospital (SH) and Erasmus University Medical Centre (EMC). A high SL:WL ratio correlated with a shorter length of aponeurosis being sutured per minute (correlation coefficient 0.53, p=0.001).

Discussion

The suture technique used at SH took 5 minutes longer than the large bite, mass closure technique, which corresponds with previous reports.[9,14,15] The longer closure time is probably related to the use of shorter stitch intervals, increased number of stitches, and longer suture. The longer closure time has been found to be cost effective for the prevention of incisional hernia.[8]

Surgeons at SH, who have been instructed to suture with an SL:WL ratio of more than 4 using small stitches, achieved a ratio of more than 4 in all cases. This protocol has not been implemented at EMC, and most surgeons do not aim for a specific ratio. At EMC, this has resulted in an SL:WL ratio of less than 4 in more than half of all studied patients. These patients are exposed to an increased risk for the development of incisional hernia and abdominal wound dehiscence.[7,8,11–14,16]

The task of calculating and documenting the SL:WL ratio is assigned to the surgical nurses at SH. The majority of surgical nurses did not report any problems in performing the necessary measurements and calculating the SL:WL ratio complementary to their other assisting tasks. Sterile rulers in laparotomy boxes and calculators were routinely available in all operating theaters, which supported overall adherence to the protocol. A uniform practice by surgeons, urologists, and gynecologists avoided the possibility of confusion among surgical nurses, thereby enhancing quality and efficiency.

Despite the reported advantages of the described technique, it is understood by the authors that a change of a surgeon's attitude is essential to establish a change of technique. Surgeons may be reluctant to change their suture technique, which often has been used for many years.[17] As an example, surgeons from SH had only been willing to uniformly change their suture technique after being presented with their own results.[8] The following recommendations are given for a successful introduction to close abdominal midline incisions with an SL:WL ratio of more than 4:

1. All staff members, preferably in all departments, should uniformly support the change of suture technique.
2. The importance of incisional hernia prevention should be thoroughly explained to surgical nurses. They should be given instructions on how to calculate the SL:WL ratio.
3. Instrument boxes for laparotomies should be routinely equipped with sterile rulers. Calculators should be available in all operating theaters.
4. The SL:WL ratio should be documented in the patient's medical records for feedback to the surgeon and for future evaluation of treatment results.

Conclusion

Closing midline incisions with small tissue bites and short stitch intervals requires a median of 5 minutes extra, which in our opinion outweighs the morbidity of incisional hernia and wound infection. Without a structured implementation to suture with an SL:WL ratio of more than 4, a lower ratio is often achieved. The SL:WL ratio can be easily measured, calculated, and documented by surgical nurses.

Author Disclosure Statement

None of the authors has competing interests.

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Chapter 12

Effect of Stitch Length on Wound Complications

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We enjoyed the article by Millbourn et al[1] published in the November 2009 issue of the *Archives*.[1] This study is the first to investigate the role of stitch length—or bite size—in conjunction with suture length to wound length (SL:WL) ratio in a randomized controlled setting. A long stitch length and an SL:WL ratio below 4 were found to be independent risk factors of incisional hernia formation after a follow-up of 12 months. In an experimental study, tissue breaking strength was significantly higher if small bites were used compared with large bites, which could explain the higher incidence of incisional hernia in the long stitch group.[2] The mean achieved SL:WL ratio in both groups (6.4 in the long stitch group vs 5.7 in the short stitch group) was considerably higher than the generally aimed at SL:WL ratio of 4. In our experience, the SL:WL ratio depends on the number of stitches, the amount of tissue incorporated in the suture, and the strength with which the suture is pulled through. We therefore wonder if subcutaneous fat tissue and/or rectus muscle were incorporated in the suture in the long stitch group and how the suture was pulled through. Was the suture pulled farther after approximation of the wound edges had been achieved in the long stitch group? Was the SL:WL ratio of 4 a risk factor of comparable size for both groups or was the relative weight of this risk factor higher in the long stitch group? In addition, we would like to know if the results of the short stitches vs the long stitches differed between operations conducted in the lower vs upper abdomen, because the aponeurosis is less developed in the lower abdomen.

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In reply

The aim of our clinical trial was to investigate if closure of midline incisions with an SL:WL ratio of at least 4 should be done with small or large tissue bites.[1] The rate of both wound infection and incisional hernia was then lower with small tissue bites.[1] Experimental findings of a higher tissue breaking strength with small tissue bites compared with large bites certainly offer an explanation for the lower rate of incisional hernia.[2,3]

In the long stitch group, tissue other than aponeurosis was included in the stitch. With stitches placed more than 10mmfrom the wound edge, it is inevitable that some amount of subcuticular fat and muscle is included. Compression of such tissue forms the experimental explanation for a high rate of wound infection with large bites.[4] For all wounds, surgeons were instructed not to place too much tension on the suture and the aim was only to approximate wound edges. We found it difficult to achieve a higher degree of standardization or to measure the tension on the suture in this large clinical trial. Closing wounds with an SL:WL ratio lower than 4 increased the herniation rate 2.5 times with both small and large tissue bites. However, as the rate of incisional hernia was very low with small bites, the herniation rate was 18% with a ratio of less than 4. Thus, it was actually similar to the herniation rate achieved with large tissue bites and a ratio of more than 4.

Right now we cannot answer Harlaar and colleagues' question concerning the interesting issue of the distribution of incisional hernia between the upper and lower midline, but we intend to study this matter in a future article and our material offers the possibility of doing that.

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Chapter 13

A multicenter randomized controlled trial evaluating the effect of small stitches on the incidence of incisional hernia in midline incisions

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Abstract

Background: The median laparotomy is frequently used by abdominal surgeons to gain rapid and wide access to the abdominal cavity with minimal damage to nerves, vascular structures and muscles of the abdominal wall. However, incisional hernia remains the most common complication after median laparotomy, with reported incidences varying between 2-20%. Recent clinical and experimental data showed a continuous suture technique with many small tissue bites in the aponeurosis only, is possibly more effective in the prevention of incisional hernia when compared to the common used large bite technique or mass closure.

Methods/Design: The STITCH trial is a double-blinded multicenter randomized controlled trial designed to compare a standardized large bite technique with a standardized small bites technique. The main objective is to compare both suture techniques for incidence of incisional hernia after one year. Secondary outcomes will include postoperative complications, direct costs, indirect costs and quality of life.
A total of 576 patients will be randomized between a standardized small bites or large bites technique. At least 10 departments of general surgery and two departments of oncological gynaecology will participate in this trial. Both techniques have a standardized amount of stitches per cm wound length and suture length wound length ratio's are calculated in each patient. Follow up will be at 1 month for wound infection and 1 year for incisional hernia. Ultrasound examinations will be performed at both time points to measure the distance between the rectus muscles (at 3 points) and to objectify presence or absence of incisional hernia. Patients, investigators and radiologists will be blinded during follow up, although the surgeon can not be blinded during the surgical procedure.

Conclusion: The STITCH trial will provide level 1b evidence to support the preference for either a continuous suture technique with many small tissue bites in the aponeurosis only or for the commonly used large bites technique.

Background

The median laparotomy is frequently used by abdominal surgeons to gain rapid and wide access to the abdominal cavity with minimal damage to nerves, vascular structures and muscles of the abdominal wall. However, incisional hernia remains the most common complication after median laparotomy, with reported incidences varying between 2-20%.[1-5] Even higher incidences up to 30-35% have been reported in obese and aortic aneurysm patients.[6-10] Incisional hernia can cause discomfort, impair quality of life or result in serious life-threatening conditions, such as incarceration or strangulation of the bowel.[5] Median laparotomies and incisional hernias have been subject of investigation for a long period of time already. Although a lot is known about patient related risk factors and suture materials, technical risk factors such as suture techniques have not been investigated thoroughly.[5,11,12]

For prevention of incisional hernia, many clinical trials and meta-analyses have demonstrated that a mass closure technique with a simple running suture is the best option to close a midline incision. A mass closure technique with a running suture is also easier and quicker to perform than layered techniques with interrupted sutures.[5,12-14] Furthermore, the use of slowly resorbable suture material compared with non-resorbable suture material decreases the incidence of incisional hernia, and it also lowers the incidence and intensity of postoperative pain and wound infection.[12,15,16]

Suture length to wound length ratio and small bites

Several authors have stated that a suture length to wound length ratio (SL:WL) of four or more must be achieved, since a lower ratio is associated with an increased rate of incisional hernia.[7,17-20] It has often been recommended to place continuous stitches more than 10 mm from the wound edge in combination with a long stitch length.[19,21-28] A long stitch is the result of a large bite with the largest portion of fascia possible, aiming to increase tensile strength and to decrease the risk of fascial dehiscence. However, long stitches have been associated with high rates of both wound infection and incisional hernia.[17,29,30] A long stitch length may be associated with higher risks of wound infection due to an increase in the amount of necrotic tissue within the wound. In experimental studies, the long stitch length has been found to compress or cut through soft tissue included in the stitch.[31,32] The risk of incisional hernia may be higher because the stitch tends to slacken, which allows wound edges to separate.

Small stitches, placed 4-6 mm from the wound edge, only cut through the aponeurosis and not through the rectus abdominis muscle. Recent experimental data show that the small bites technique results in stronger wounds and faster healing than the routine

large bite technique.[33] Our experiments in a porcine model showed a 47% increase in breaking strength when small bites were used compared to the routine technique.[32] A recent randomized of randomised clinical study by Millbourn et al. reported a decrease of incidence of incisional hernia of 70% 18% to 5.6%, p<0.001) and a decrease of 50%, (10.2% to 5.2%, p=0.020) of wound infection.[34] These results are very promising with regard to the prevention of incisional hernia and wound infection. The benefits of this technique need to be confirmed in a multicenter double-blinded randomized controlled trial.

In daily practice, most surgeons in the Netherlands use the large bite technique with large suture distances. With large bites, SL:WL ratio depends on the thickness of the abdominal wall including the muscles, the bite size, the number of stitches and the traction on the sutures during suturing. With large bites, an unanswered question remains with regard to how the SL:WL ratio of 4 should be reached. With a low traction force, fewer stitches are needed, but the slacking effect during the postoperative period may influence results.

With small stitches, SL:WL ratio is mostly dependent on the number of stitches. There is no sufficient evidence to prefer one suture closure technique over the other in order to prevent incisional hernia and fascia dehiscence.

Objective

The objective of the STITCH trial (Suture Techniques to reduce the Incidence of The inCisional Hernia) is to compare the small bites technique decribed by Millbourn et al. with a standardized large bites technique.

The overall objective of the study is reduction of the incidence of the most frequent complication of abdominal surgery, i.e., incisional hernia. We hypothesize that the small bites technique will result in a significant reduction of the incidence of incisional hernia, which may lead to a reduced morbidity and a better quality of life for patients and a significant reduction of costs.

Primary endpoint will be incisional hernia occurrence within one year after surgery, either clinically and/or ultrasonographically detected. Secondary endpoints include postoperative complications, in particular surgical site infection, burst abdomen and wound pain in the first postoperative month.

Methods/Design

Trial Design

The STITCH trial has been designed as a prospective, multicenter, double-blind, randomized controlled trial, in which the large bites technique will be compared with the small bites technique.

Participants

Patients scheduled for an elective abdominal operation through a midline incision will be asked for informed consent at the outpatient clinic or in hospital on the day preceding the day of surgery. Also, emergency laparotomies can be included in this trial if the patient is able to sign the informed consent. We intend to investigate the efficacy of the small bites technique in all risk groups. This also includes oncological gynaecological patients in centers with at least 50 median laparotomies a year.

Inclusion criteria

- Signed informed consent
- Laparotomy through a midline incision
- Age 18 years or older

Exclusion criteria

- Previous incisional hernia or fascial dehiscence with secondary healing after a midline incision
- Abdominal surgery through a midline incision within the last three months
- Pregnancy

Since the STITCH trial is an intervention study, it is not considered desirable to combine this trial with other intervention studies. In case of non-intervention (registration) studies, it will be judged on individual basis whether it is suitable and ethically correct to include a patient in both the STITCH trial and in another study. Patients will be included in the STITCH trial in combination with one other trial (registration trials only), provided that it is possible to organize the informed consent and the follow up in a proper way for the individual patient for both trials.

Registration procedure

Included patient are registrated before surgery in an online database (designed and managed by HOVON data center, Rotterdam, the Netherlands,) after signed informed consent via the Internet via TOP (Trial Online Process; see http://www.stitchtrial.nl). The patient namecode, date of birth, name of caller, name of responsible physician, sex and eligible criteria will be registered. Every participating institution has its own login code.

Randomisation procedure

The randomization process is started only 15 minutes before closure to prevent consequences due to the trial during the operation with the online TOP randomisation.

Patients will be randomized between closure with the large tissue bites technique or with the small tissue bites technique. Randomisation is stratified by center, and between surgeon or resident with a minimization procedure, ensuring balance within each stratum and overall balance. The randomization result will be given immediately by TOP. A confirmation email without randomization result will be send to the investigator.

Patients will be kept unaware of the type of closure until the endpoint of the trial. Surgeons or residents blinded for the procedure will perform out patient clinic controls. Postoperative ultrasonography will be performed by radiologists blinded for type of closure. The randomisation procedure, blinding and objectification of incisional hernia by ultrasound will provide the best possible data to support preference for the large bites technique or the small bites technique over the other for closure of the abdominal wall.

Interventions

In this trial the large bites technique will be compared with the small tissue bites technique as developed in Sundsvall Hospital, Sweden.[18] In the first group, the conventional large bites technique will be applied with bite widths of 1 cm and intersuture spacing of 1 cm with the use of one PDS plus II loop with a 48 mm needle. In the second group, the small bites technique will be applied with bite widths of 0,5 cm and intersuture spacing of 0,5 cm with the use of PDS plus II 2-0 with a 31 mm needle. In the small bites technique, twice as many stitches will be placed per sutured cm, with a smaller needle and thinner suture material. In the Swedish hospital where the small bites techniques has been in use for many years, this combination proved the easiest and safest method to perform the small bites technique.[18,34]

In both groups wound length is measured before closing of the fascia. After measument of the wound length, the number of stitches is calculated. In the large bites technique at least one suture per cm wound length must be placed. In the small bites technique at least two sutures per cm wound length must be placed. The number of stitches is counted by the assistant during closure.

In both arms, suturing is initiated at both ends of the incision towards the middle where an overlap will be created of at least 2 cm. The remaining sutures will be measured and the suture length used for closure of the fascia and the SL:WL ratio will be calculated by the scrub nurse. In both arms, suture length to wound length ratios (SL:WL) of 4:1 are aimed at.

Implementation

In every hospital the OR nurses the surgeons or gynecologists and residents are instructed before the start of the trial in the individual institution during presentations and demonstration movies. During at least the first five inclusions the study coordinator will be present in the OR before randomization to assist randomization and control the correct applying of the standardized techniques. For every included patient a form with the detailed closing protocol is added to the clinical chart. Only when the surgeon is familiar with both the techniques, the nurses with the counting and measuring of the stitches and suture material and the study, centers are allowed to run the trial. Also, for every included patient a form with the detailed closing protocol is added to the clinical chart. During the study unplanned audits are performed to control quality.

Outcome parameters

Primary outcome

• Primary outcome will be incisional hernia occurrence within one year after surgery, either clinically and/or ultrasonographically detected.

Secondary outcome

• Postoperative complications
• Pain
• Quality of life
• Cost effectiveness

We use the definition of the incisional hernia by the European Hernia Society: 'any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging'. The classification made by the European Hernia Society is used.[35] The classification of incisional hernias: Incisional hernias will be classified according to their localization, size, reducibility and symptoms.

Discharge dates and complications will be registered. Patients who fail to keep their annual clinic appointment will be given the option of a further appointment at a more suitable date or a visit to their home if they cannot make it to the outpatient clinic. The following data will be gathered at different points in time:

Preoperative data

- Date of birth
- Length and weight
- Current smoker (Yes or No)
- Medical history (including chronic obstructive pulmonary disease (COPD), diabetes mellitus, cardiac disease, prior laparotomies)
- Preoperative radiotherapy or chemotherapy
- Preoperative or perioperative corticosteroids
- Previous abdominal operations
- Other abdominal wall hernias
- American Society of Anaesthesiologists (ASA) classification
- Width of linea alba (if preoperative Computed Tomography Imaging is available)

Operation data

- Type of operation
- Suture length: wound length ratio
- Number of stitches
- Length of incision
- Closure time
- Blood loss
- Operation time
- Antibiotic prophylaxis
- Drains and location
- Thrombosis prophylaxis
- Pain medication
- Peroperative complications (intestinal lesions, bleeding, other)
- Epidural catheter

Postoperative data

- Blood transfusion
- Postoperative ventilation and duration
- Postoperative corticosteroids
- Postoperative radiation therapy
- Postoperative pain medication
- Postoperative ileus and duration

• Postoperative complications:
  - Centers for Disease Control criteria for Surgical Site Infection, according to the guidelines proposed by Mangram in 1999[36] (Appendix 1).
  - Wound haematoma: accumulation of blood in the wound area, which warrants surgical exploration and intervention.
  - Pulmonary infections
  - Ventilation problems
  - Re-admission and indication
  - VAS pain score until day 6 post operative

At 1 and 12 months, ultrasound imaging will be performed to examine the midline for any asymptomatic clinically not detectable incisional hernias. Size and location of any incisional hernias will be registered.

Outpatient clinic follow up

• Outpatient clinic visit at 1 and 12 months
  - Incisional hernia
  - Wound infection
  - Seroma formation
  - Other wound problems
  - Other abdominal wall hernia
• Ultrasound at 1 and 12 months
• VAS pain scores and Quality of Life forms preoperatively (day of operation or the day before) and at 1,3, 6 and 12 months

Ultrasound examinations

During the 1 month and 1 year follow up an ultra sound examination will be performed to measure the distance between the rectus muscles at 3 point in the incision and check for incisional hernia. A specific score is used for the ultrasound examination. At ten points, which include 4 measurements of the distance between the rectus muscle, the quality of the scar in the abdominal wall is objectified. With this method the conclusion if there is an incisional hernia can also be made on the score list. In this list is controlled for:
An intact linea alba?
Bulging without Valsalva manouvre?
Bulging with Valsalva manouvre?
Distance between rectus muscles in scar on 1/3 cranial part in cm?
Distance between rectus muscles in scar on 1/3 caudal part in cm?
Maximum distance between rectus muscles in scar in cm?

Maximum distance between rectus muscles at place of bulging or defect in cm?
Is there a defect? If yes, the size of the defect and location
Is there fatty tissue in the defect?
Is there a bowel loop in the defect?
The radiologist is asked to make prints of every measurement and finding.
Quality of life will be assessed based on standardized Quality of Life forms including the EuroQol-5D and Short Form-36 before and at 1 month, 3 months, 6 months, and 12 months after surgery.

Economic evaluation

We will perform an ex-post economic evaluation in which a new suture technique using small bites is compared with the traditionally applied large bites technique, from a societal perspective. The economic evaluation will be performed in accordance with Dutch guidelines.[37]

To measure the economic impact of the new suture technique using small bites the cost-effectiveness will be assessed by calculating the incremental cost-effectiveness ratio, defined here as the difference in average costs between both suture techniques divided by the difference in average effects. The primary outcome measure will be the costs per reduced incisional hernia within 1 year. Secondary, a cost-utility analysis will be performed using costs per quality adjusted life year (QALY) as outcome measure, using the EQ-5D.

Costs for all separate actions and time used by all individual health care professionals, and all other materials will be measured from a societal perspective for both bites techniques, which means that both direct medical costs (e.g. intervention costs, intramural and extramural medical costs) and indirect costs (absence from work, patient costs) will be included in the analysis.

For the most important cost items, unit prices will be determined by following the micro-costing method[38], which is based on a detailed inventory and measurement of all resources used. Resource costs arise within the hospital and consist of outpatient visits, inpatient days, use of the operation room, radiology examinations, blood tests, etc. Real medical costs will be calculated by multiplying the volumes of health care use with the corresponding unit prices. For instance, the calculation of the costs of both suture techniques will consist of detailed measurement of investments in manpower, equipment, materials, housing and overhead. The salary schemes of hospitals and other health care suppliers will be used to estimate costs per hour for each health care professional. Taxes, social securities and vacations will be included.

Data on effects (reduction of incisional hernia), costs (time costs of new suture technique and material and development costs) and savings (reduced health care use of patients without

incisional hernia) will all be collected in this study. Data on treatment (hospitalisation) and follow-up consultations will be collected retrospectively from (electronic) patient charts and hospital administration. This data will be collected by health care professionals using a data-collection form. Information will collected on:

- length of hospital stay
- length of stay in ICU
- reinterventions

Data on extramural care, work absence and other patient costs will be gathered via questionnaires at each follow-up (1 and 12 months).

For a description of the calculation of the effect measures see paragraph 'outcome parameters'. Discounting of future costs and effects is not relevant because of the limited time horizon of 1 year. When costs of a treatment are similar across subgroups, the absolute benefit determines the cost-effectiveness of a treatment for a specific subgroup. Randomized controlled trials are designed to evaluate the effects of treatment at the group level, and cost-effectiveness is usually calculated for this group as a whole. There could however be substantial and relevant between subgroup variability. It is therefore common to consider subgroup specific effects of interventions. The subgroup specific cost-effectiveness will be estimated by first deriving a prognostic index, based on the predefined predictors of incisional hernia: abdominal aneurysm aorta (AAA), obesity, diabetes, COPD, corticosteroid usage, radiotherapy, cardiovascular disease, smoking, age, cancer, other abdominal wall hernias and collagen disorders.

Sample size calculation

Millbourn et al. found a decrease in the incidence of incisional hernia from 18% to 5,6% in a randomized controlled trial.[34] In this trial, follow-up consisted of clinical instead of radiological examination for incisional hernia occurrence. In this trial, ultrasound examination will be used in order to be able to diagnose incisional hernia with higher sensitivity. It is expected that a relative decrease of the incidence incisional hernia after one year of 50% is reasonable. The mean reported one year incidence of incisional hernia in literature is 15%.[1-5] In order to reduce the mean incidence of incisional hernia from 15 to 7.5%, power calculations showed that two groups of 259 evaluable patients each are needed (power = 0.80, alfa = 0.05). Loss to follow-up is estimated at 10% of included patients. A total of 576 patients (2 × 288) will be included in the study to correct for loss to follow-up. Overall effects will be calculated adjusted for predictive baseline characteristics, which will lead to a higher statistical power.

Statistical analysis

Descriptive statistics will include median and interquartile range for continuous variables, and absolute numbers (with %) for categorical variables. Randomized groups will be compared for imbalance without formal statistical testing. Analysis will be by intention-to-treat. Differences between randomized groups will be tested with appropriate statistical methods, including t-tests or Mann-Whitney tests for continuous variables (considering whether the normality assumption is rejected by the Kolmogorov-Smirnov test with Lilliefors correction test), and chi-square tests for categorical variables. The primary outcome (incisional hernia) will be analyzed with Kaplan-Meier analysis and a Cox regression analysis, to adjust for any loss to follow up between 30 days and 1 year after surgery. The primary analysis is a covariate adjusted Cox model, which includes the following predefined, well-establihed predictors of incisional hernia: abdominal aneurysm aorta (AAA), obesity, diabetes, corticosteroid usage, radiotherapy, COPD, smoking, age, cancer, inguinal hernia, cardiovascular disease and collagen disorders.

Subgroup effects will be assessed by tests of interaction to prevent overinterpretation of apparent differences in effectiveness. Quality of life data will be analyzed by paired T-tests, comparing baseline with follow-up measurements, and repeated measures analysis. A two-sided $p < 0.05$ will be taken to indicate statistical significance.

Monitoring

The Erasmus University Medical center is the sponsor of this trial. Adverse events are defined as any undesirable experience occurring to a subject during a clinical trial, whether or not considered related to the investigational intervention. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded. A serious adverse event (SAE) is any untoward medical occurrence or effect that at any dose results in death; is life threatening (at the time of the event); requires hospitalization or prolongation of existing inpatients' hospitalization; results in persistent or significant disability or incapacity; is a new event of the trial likely to affect the safety of the subjects, such as an unexpected outcome of an adverse reaction, major safety finding from a newly completed animal study, etc. All SAEs will be reported to the accredited Medical Ethical Committee (MEC) that approved the protocol, according to the requirements of that MEC. Serious Adverse events are death and burst abdomen. Adverse Events are readmission and reoperations.

An independent data and safety monitoring committee will evaluate the progress of the trial and will examine safety parameters every 3 months. The committee can unblind the data whenever deemed necessary based on reported adverse events. All involved physicians will repetitively be asked to report any potential adverse events caused by the

study protocol. These adverse events will be listed and discussed with the monitoring committee. The monitoring committee can ask for a full report in order to discuss a specific adverse event. A copy of this report will be sent to the central ethics board and to the involved physicians. All deceased patients will be evaluated by the safety committee for cause of death and possible trial related serious adverse effects. Every death will be reported to the central ethics board and the local ethics board. The Data Safety Monitoring Board will consist of an epidemiologist/statistician and two independent surgeons.

Ethics

This study will be conducted in accordance with the principles of the Declaration of Helsinki and 'good clinical practice' guidelines. The Medical Ethical Committee of the Erasmus University Medical Center Rotterdam has approved the protocol. The Ethical Committees of the participating centers are applied for local feasibility. Prior to randomization, written informed consent will be obtained from all patients.

Discussion

A major issue in all suture studies is standardisation of technique. In a multicenter trial it is difficult to achieve standardisation because many surgeons and residents will contribute in this trial. The benefit of a large group of participants is that the results will be representable for daily practice.

In this trial two major parameters have been standardized: the difference between small and large bites and the amount of stitches per running cm of wound resulting in an appropriate SL:WL ratio.

In daily practice, most surgeons use the large bite technique with large suture distances. With large bites, SL:WL ratio depends on the thickness of the abdominal wall including the muscles, the bite size, the number of stitches and the traction on the sutures during suturing. With large bites there is an unanswered question under which conditions an optimal SL:WL ratio of 4 should be reachable. With low traction on the suture fewer stitches are needed, but the slacking effect during the postoperative period will influence the results. For this reason in a RCT on suture techniques it is necessary to standardize the amount of stitches per centimetre of wound length.

Conclusion

The STITCH trial is a multicenter randomized trial (trialregister:http://clinicaltrials.gov/ct2/show/NCT01132209) comparing the costs and effectiveness of a standardized small tissue bites suture technique with a standardized large tissue bites technique in midline incisions. This trial will provide the surgical society the evidence needed to optimize a surgical technique used to prevent common surgical complications.

Competing interests

The Erasmus MC "Doelmatigheids Onderzoek grant 2008" and Johnson and Johnson Medical BV, the Netherlands, Investigator Initiated Clinical Research Funding Grant (09-107) have financially supported this trial.

Authors' contributions

JJH drafted the manuscript. EBD, GHR, EWS and JFL co-authored the writing of the manuscript. All other authors participated in the design of the study during several meetings and are local investigators at the participating centres. All authors edited the manuscript and read and approved the final manuscript.

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Appendix 1

Criteria for defining a Surgical Site Infection (SSI)

Superficial Incisional SSI

Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do not report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

Deep Incisional SSI

Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissue (e.g., fascial and muscle tissue) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (> 38°C), localized pain, or tenderness, unless site is culture negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during re-operation, or by histopathological or radiological examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Notes

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Organ/Space SSI

Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:

1. Purulent drainage from drain that is placed through a stab wound into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep organ/space SSI by a surgeon or attending physician.

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Chapter 14

General discussion and future perspectives

Risk factors

Surgery will never be free from risk of complications. It is up to surgeons to inform patients on the expected benefit and possible complications associated with surgical procedures, enabling informed treatment decisions. The surgical community has become increasingly aware of the need for individualized treatment strategy, based on patient specific risk profiles such as in breast cancer.

The risk model for burst abdomen was based on a large group of patients with burst abdomen and a large control group, and showed high predictive value for burst abdomen in the validation population. We found that the probability of developing burst abdomen increased exponentially with higher scores and more risk factors. Independent risk factors for burst abdomen that were included in the risk model were emergency surgery, old age, chronic pulmonary disease, jaundice, anemia, male gender, ascites, type of surgery, postoperative coughing, and postoperative wound infection. Risk factors without independent effects included hypertension, uremia, and corticosteroid use, although these factors have been described as risk factors by others.[1-4] Corticosteroids were used more frequently in chronic pulmonary disease patients, in our study both in patients with and without burst abomen. In contrast with other authors, no significant effects on the occurrence of abdominal wound dehiscence were found for diabetes mellitus, previous laparotomy, malignancy, sepsis, and postoperative vomiting.[1-3, 5-7]

It was hypothesized, though, that presence of scar tissue, microvascular changes due to hypertension and diabetes, poor tissue perfusion, and poor overall condition of the patient, associated with sepsis and malignancy, were risk factors. Jaundice, on the other hand, was found to be an independent risk factor. This was not confirmed by other studies.[2, 3, 5-8] Most importantly, Armstrong investigated jaundice in relation to hematocrit and albumin levels and malignancy.[5] Jaundice was found a significant variable in univariate analysis, but not in multivariate analysis. Armstrong argued that wound healing was affected in jaundiced patients due to the association with low hematocrit and albumin levels and malignancy and not to high bilirubin levels. Low protein and albumin levels and deficiencies of several vitamins and minerals (such as vitamins A, B1, B2, B6, C, zinc and copper) have been associated with poor wound repair.[9] Unfortunately, smoking and nutritional status could not be included in the analysis due to lack of data.

The consequences of the risk score are limited by the inclusion of risk factors that occur in the postoperative phase, such as coughing and wound infection. Since the model has been demonstrated to be highly predictive for burst abdomen, it could be used to identify high risk patients. High risk patients would be most suitable for inclusion in future prevention studies. Also, if significant differences are found in incidence of burst abdomen between two groups, it would be preferable to make adjustments in these analyses for this risk

score. From our results can also be concluded that perioperative care for prevention of pneumonia and wound infection may be important for prevention of burst abdomen.
Gomez Diaz et al validated our risk score for abdominal wound dehiscence in a retrospective cohort of 176 patients who underwent midline laparotomies, including 15 patients with abdominal wound dehiscence (AWD, 8.5%).[10] Risk scores were significantly higher in patients with AWD ($p<0.001$) compared to patients without AWD (mean: 4.97; IC 95%: 4.15-5.79 versus mean: 3.41; IC 95%: 3.20-3.62). Calculated risk scores for preoperative risk factors were signficantly higher for patients with AWD ($p<0.05$) compared to patients without AWD (mean: 3.27; IC 95%: 2.69-3.84 versus mean: 2.77; IC 95%: 2.64-2.89). In ROC analyses, the risk score showed better accuracy than the preoperative risk score (area under the ROC curve: 0.79 versus 0.64). The authors concluded that our risk model was useful for prediction of AWD. They also concluded that patients with scores of 4 or higher were eligible for preventive measures. Additional modifications of the score were suggested improve the usefulness of the preoperative risk score.[10]

We were able to investigate a large number of variables as potential risk factors for burst abdomen in pediatric surgery by performing a multicenter retrospective case-control study. As demonstrated previously, wound infection and emergency surgery were important independent risk factors for burst abdomen. Children under the age of one year suffered significantly more often from burst abdomen than older children, which may be due to the high prevalence of necrotizing enterocolitis and the immaturity of the immune response in these children. As found in other (pediatric) surgical studies, median incisions were correlated with higher incidence of burst abdomen than other types of incisions.[8, 11-13] Our study, which was the second largest performed on this topic in pediatric surgery, thus supports avoidance of median incisions in children. The influence of suture technique has been less emphasized in literature than in adults, probably due to the low incidence of incisional hernia in this age group. More research on the influence of type of suture material and suture technique (SL:WL ratio, small versus large bites) could be initiated to better serve those patients at risk for developing burst abdomen and/or incisional hernia.

Our prospective study on clinical patient-related and wound-related variables (chapter 4) showed that 27.6% of 914 patients included in these analyses developed events (superficial SSI, deep SSI, organ/space SSI and/or AWD). In this study, no significant effects were found in univariate analyses for any of the tested patient- and surgery-related variables with exception of operation time, which was also identified as a risk factor for wound dehiscence by others.[14,15] In this study, smoking could not be identified as a risk factor for AWD, nor was the amount of cigarettes consumed per day of influence. Similar

results were found by Kenig et al.[16] Our study results showed that presence of mechanical ventilation, postoperative cough, emesis and nasogastric tube use postoperatively were signifantly more prevalent in patients who developed abdominal wound dehiscence. This implies that in both elective and acute patients, optimal pulmonary status should be aimed for by offering perioperative nebulizing therapy and physiotherapy to patients at risk for developing abdominal wound dehiscence. Principles from fast-track surgery, such as adequate pain management, applying minimally invasive surgery or avoiding midline incisions if possible, and early postoperative mobilisation can possibly shorten paralytic ileus and enhance overall recovery. Assessment of the abdominal wound should be structured, for instance by using a checklist, and focus on the degree of wound edge separation, (amount of) wound exudate, presence of wound slough/necrosis, presence of wound malodour, and degree of granulation/epithelialisation, as all these variables were significantly affected in patients with abdominal wound dehiscence. Mechanical factors proved important in the pathophysiology of abdominal wound dehiscence, which stresses the need for optimal abdominal wall closure. Any aberration from normal, uncomplicated wound healing with regard to the aforementioned variables necessitates evaluation of the abdominal wound.

Surgical site infection

We compared different methods of surgical site infection registration in abdominal surgery patients. Abdominal wounds were inspected and photographed daily by two research fellows from postoperative day 2 onward (including weekends and holidays) to observe for the presence of SSIs. Thirty-day follow-up was completed for 85.4% of the 967 patients whose data were available for analysis. In addition, patient charts, discharge letters, wound photographs, and culture results were reviewed after a minimum period of 3 months following discharge to verify the incidence of SSI. We found surgical site infections in 26.8% of all patients, the majority of which (61%) were not reported in any of the tracking systems used by surgeons. Reporting systems used by surgeons, thus, proved unreliable for monitoring the incidence of SSI, and consequently, this method of self-reporting constituted a poor indicator of quality of care. The routine plenary and electronic tracking system relied on presence of involved doctors and individual responsibility. Frequent shift changes and compensatory leave are inevitable properties of the curriculum of surgical residents as a consequence of the 48-hour work week in the Netherlands and could endanger both diagnosis and tracking of SSI. Since nurses generally inspect wounds more often than doctors, it might be that involvement of (trained) nurses or physician assistants in registration of in hospital SSI under supervision of surgeons will be far more successful than trying to increase compliance in ward

residents. Tracking of SSI and other complications in patients has proven difficult at our hospital and other hospitals if patients were either not operated upon and/or admitted to non-surgical wards. Registration of complications might be improved if electronic patient records with electronic alerts are used, both for the in and out patient periods. Another option can be involvement of infection prevention personnel by using electronic (automatic) selection of high-risk patients for documentation of nosocomial infections. This could increase sensitivity of SSI registration, and might also lead to earlier discovery of deficiencies in SSI prevention and process-specific interventions, such as focussing on timely administered antibiotic prophylaxis. According to a report by the European Centre for Disease Prevention and Control, the Netherlands were amongst the countries with the highest percentage of infections diagnosed after discharge at 58%.[17] Post-discharge data, preferably performed at the out patient clinic, ought to be included in audit meetings and databases. Surgeons should feel obliged to be involved in collection of these data especially if implanted materials of non-human origin were used in surgery. Comparison of quality of care between different hospitals should not be based on the SSI rate, but on comparing process indicators which have been proven effective against SSI. Uniform definitions for SSI must be used in future research. Assessment of acute surgical wounds by residents and nursus should be regularly supervised by experienced surgeons.

Long-term outcome

We investigated long-term outcomes of patients with burst abdomen in our prospectively followed patient cohort. Unfortunately, only 23 of 37 patients were alive after a mean follow-up of 40 months which is in consistency with other reports.[18, 19] The majority of patients (83%) developed incisional hernias. After adjustments for age, gender, comorbidity and length of follow-up, patients with burst abdomen reported significantly lower scores for SF-36 physical and mental component summaries, general health, mental health, social functioning, and change. Also, patients with burst abdomen reported significantly lower cosmetic scores and total body image scores, which could be explained by the high incidence of incisional hernia. It is not easily explained why patients with burst abdomen reported significantly lower mental health scores, as adjustments were made voor patient comorbidity, and no significant differences were found for vitality and role emotional. In contrast with impaired physical scores, mental health scores were not affected in patients with incisional hernia included in the separate long-term follow-up study as presented in chapter 8. As social functioning and change scores were also significantly lower in patients with burst abdomen, it appeared that patients with burst abdomen had become more socially incapacitated and isolated than control patients. As this relatively small study is one of the very few on this topic, future contributions will be valuable. However, in order

to be able to present prospectively collected data on a larger patient population, inclusion of burst abdomen as variable in a (inter-)national hernia database could be a viable alternative. Examples of hernia databases already exist and are in use in Sweden and in Denmark.[20] Furthermore, the European Hernia Society and its members have been active in designing a platform for registration and outcome measurement of hernia operations by founding the EuraHS (European Registry of Abdominal wall HerniaS).[21] Regular follow-up should be inititated with use of standardized health- and physical function-related questionnaires and predefined outcomes, such as incisional hernia. Physical examination with objective evaluation of abdominal trunk function is preferred to be included in follow-up. With registration of reburst rates, reoperations and patients' function, these data would eventually aid patients and surgeons to make informed treatment decisions and would allow more exact estimation of costs associated with burst abdomen.

From unpublished data appeared a small subset of patients who develop burst abdomen repeatedly. In these patients, one of the components in wound healing may be malfunctioning. Maturation of the wound involves collagen crosslinking, remodelling and wound contraction which leads to increase in tissue tensile strength. Six weeks postoperatively, tissue tensile strength is increased up to 80% of the preoperative level.[9, 22] Since most patients with burst abdomen present within the first two weeks after surgery, the epithelialisation and early maturation phases, and especially fibroblast function, appear to be most interesting as focus for future basal science research.[23-28] Meena et al found increased levels of TGF-beta in patients' fascia biopsies on the day of clinical presentation of abdominal wound dehiscence compared to the day of primary surgery, but the study lacked control patients with postoperative biopsies.[15] In a small study, Renvall et al found that the amount of collagen decreased in both the fascial and subcutaneous layers in patients with burst abdomen compared to control patients. No data were provided with regard to the ratio between collagen I and collagen III.[29]

Treatment

Our review of management options for burst abdomen revealed the level of evidence regarding treatment does not exceed level 2b. Any advice on the management of burst abdomen should therefore be interpreted cautiously and well-documented personal experiences could be valuable contributions to this field. Based on existing evidence, conservative management may be reserved for patients whose general health status does not allow for acute surgery. In clean and clean-contaminated wounds, primary suture closure could be attempted, although this repair has been associated with considerable recurrence (reburst) rates of up to 35%, and incisional hernia incidence of over 40% in several studies.[4, 18, 19, 30-32] If tension-free closure is not possible, relaxing incisions in the

rectus sheath, and fascias of the transversus abdominis and internal and external oblique muscles can be considered, especially if the use of mesh is (relatively) contra-indicated.[28, 34, 35] Other options include component separation technique as described by Ramirez.[36] If intra-abdominal pressure is elevated, primary suture repair will presumably be associated with an even worse surgical outcome, which would support a preference for mesh repair. An alternative might be use of NPWT combined with mesh-mediated fascial traction as described in a Swedish study, which resulted in less and smaller incisional hernias at long-term follow-up.[37, 38] In clean wounds, polypropylene or composite meshes could be used. Intraperitoneal placement of polypropylene mesh, however, has been associated with high complication rates after subsequent surgical interventions.[33] A biological mesh repair could be considered in clean-contaminated wounds as an alternative for a two-staged repair with temporary closure of the abdomen (with or without NPWT) or open abdomen treatment. In contaminated-dirty wounds, treatment should be aimed at source control, eg, by excluding intra-abdominal abscess or anastomotic leakage. Primary suture repair should be discouraged in patients with obvious necrosis of deeper layers or abdominal wall loss.[22] In these patients, open abdomen treatment (with or without NPWT) as part of a two-staged repair or closure of the abdomen with absorbable polyglactin or biological mesh should be preferred. An attempt to investigate the use of crosslinked biological mesh as treatment for burst abdomen, "Repair of Challenging Abdominal Wall Defects: Strattice™ in Abdominal Wall Repair trial (StAR)" was terminated due to inclusion problems (Clinical trial identification no NCT01083472).[39] The termination of this trial illustrated that inclusion of ill patients with complications such as burst abdomen in the acute setting in small numbers pro institution remains challenging. Besides the collection of treatment data in hernia databases as earlier referred to, studies like these are warranted to provide the surgical community with more evidence regarding the treatment of burst abdomen. Future (randomized) studies should focus on determining short and long term benefits of operative treatment (primary suture techniques, biological and synthetic mesh) compared to conservative approach. Without evidence for improvement in surgical outcome due to biological mesh use, it will be restrained by higher material costs.

Prevention of burst abdomen

The previously mentioned risk score for burst abdomen can be used to select patients with estimated high preoperative risk for developing burst abdomen or stratify according to estimated risk. Risk profiles of patients in intervention and control groups can be compared to ensure that no significant differences existed at time of randomisation that could have influenced study outcomes.

Several strategies might reduce the incidence of burst abdomen. First, attention must be brought to decreasing tension at incision level. The perfect suture material is infection resistant, slowly resorbable, and biologically and mechanically compatible with the human abdominal wall. It should be a combined effort of the medical industry and surgical scientific community to develop, test, and improve new suture materials, for instance with elastic properties. Most studies in literature have focussed on suture closure techniques of midline incisions, and more data is needed on the optimal closure of other types of incisions, for example, transverse and oblique incisions. Little is known about the possible different healing reactions of lower midline incisions, where the posterior rectus fascia is less developed or absent, compared to upper midline incisions.

Improvement of suture technique has been a constant focus of hernia surgery. Niggebrugge et al have shown that creation of an abdominal wall with low compliance by using continuous double loop closure was associated with increased mortality due to pulmonary complications.[40] Conflicting data of poor quality have been published with regard to the possible protective effect of retention sutures against burst abdomen.[8, 13, 41-43] Retention sutures have been known to cause pressure-related skin necrosis and pain and have been abandoned by most surgeons.[8, 13, 43] One of the aspects of suturing technique that has formed part of this thesis is the application of small bites with small inter suture distances compared to large bites with large inter suture distances. Our study in porcine abdominal walls has shown that more stitches resulted into a better division of tension over the abdominal wall in the small bites group. Tension was divided over a longer suture thread due to the high SL:WL ratio achieved in this group. In the large-stitch group, high SL:WL ratios were needed to create acceptable tissue tensile strength. This implies that during closure of the abdominal wall, the suture should by no means be pulled by surgeon or assistant to avoid lowering of the SL:WL ratio. An SL:WL ratio of four was often not achieved, so measurement and documentation of reached SL:WL ratio appear necessary for quality control. It has been feared by many that placement of many stitches in the aponeurosis of the abdominal wall would cause local necrosis by devitalizing tissue trapped within the suture. However, the opposite seemed to occur in the many studies performed by Cengiz and Israelsson: better wound healing, no separation of wound edges, and less trauma to abdominal musculature.[44-46]

In order to provide more evidence to support preference for small or large bites, a multicenter randomized controlled trial was designed. In preparation for this trial, personnel were interviewed at Sundsvall Hospital with regard to their experiences with use of and compliance with the technique. Comparative measurements of laparotomy

closure times and SL:WL ratio measurements at Sundsvall Hospital and Erasmus University Medical Center showed that the small bites with short stitch lengths technique took (median) five minutes longer to perform, but resulted in an SL:WL ratio above four in all cases, compared to 8/18 cases at Erasmus University Medical Center.
In the designed multicenter trial described in chapter 13, the effect of small stitches on the incidence of incisional hernia in midline incisions (STITCH trial) are evaluated in 576 included patients who are randomized between small bites and large bites. Main outcomes of this trial will include incidence of incisional hernia, postoperative complications including burst abdomen, direct and indirect costs and quality of life.

Several studies have been conducted in which prosthetic materials were used in primary closure of laparotomies for prevention of wound complications, and of incisional hernia in particular. A recent meta-analysis by Timmermans et al, including 282 patients from 4 randomized controlled trials, showed that primary augmentation with non-absorbable mesh was associated with a significantly lower incidence of incisional hernia compared to suture repair.[47-51] No significant differences were found for occurrence of wound infection or seroma, but a trend was observed for chronic pain (p=0.09). In the study by El-Khadrawy et al (n=40), burst abdomen occurred in 1 patient with subfascial polypropylene mesh inforcement and in 3 patients with primary suture repair.[48] No eviscerations occurred in the studies by Gutiérrez de la Peña et al or Strzelczyket al, whereas dehiscence rate was not reported by Bevis et al.[49-51]

In contrast, reinforcement of abdominal incisions with mesh has not been investigated extensively for prevention of burst abdomen. The use of intraperitoneal polyglactine 910 mesh was investigated in two retrospective studies and one prospective randomized study, all performed in France in the 1980's.[4, 30, 52] Reference surgical procedures included polyamide mesh glued to the skin, and extraperitoneal retention sutures; which have both been abandoned. As the design of these studies contained several important flaws, little can be concluded on the value of the studied procedures. The method of closure described by Ton, also referred to as Ton's apparatus, was in use in the Netherlands in the 1970's and, eventually, abandoned.[53] Polyglactin 910 mesh is absorbed within a few weeks; it looses tensile strength very quickly. It has been observed that tearing of the mesh can lead to recurrent evisceration before granulation occurs if used for treatment for burst abdomen. Infection-resistent biological or synthetic meshes with high and early tissue incorporation would be very appealing for placement in onlay or sublay position, but these are yet to be developed.

The effects of perioperative care on abdominal wound failure have not been the main focus of our studies. Effects of pre- and post-operative feeding, prevention of postoperative ileus, and early ambulation, as part of fast track surgery, would be worthy of future studies with regard to abdominal wound failure. Based on the relatively low incidence of burst abdomen, combining various types of abdominal wound failure as study outcome (surgical site infection, burst abdomen, enterocutaneous fistula formation) will probably be necessary.

Although no conclusive evidence is available that abdominal binders in the perioperative period have any preventive effect on burst abdomen, recurrences (rebursts) or development of incisional hernia, these are still in use in various hospitals. The use of these binders illustrates that it sometimes is harder for doctors to omit therapy than to continue to apply therapy without proven benefit. One should keep in mind that treatment without proven benefit does not imply that 'no harm' can be done – patients often complain about discomfort caused by abdominal binders and associated pulmonary complications are not unimaginable.

Furthermore, the options of minimally invasive surgery or alternative types of incisions may be considered in all patients to prevent short- and long-term abdominal wound failure. The continuing process of centralisation of specialized minimally invasive surgical procedures could result in decrease of the number of laparotomies, and thus, decrease the number of patients at risk for developing wound infections, burst abdomen, and incisional hernia. It is hoped for that the results of our studies will contribute to better, evidence-based prevention and treatment of abdominal wound failure.

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Summary

Summary

Wound failure is a common complication of abdominal surgery, and includes surgical site infections (SSI), abdominal wound dehiscence (or 'burst abdomen') and incisional hernia.

Chapter 1 introduced the topic of this thesis: wound failure in laparotomy. The anatomy of the abdominal wall as well as definitions of incisional hernia and burst abdomen were discussed. Risk factors described in literature related to patient profiles, operation-related and postoperative risk factors were summarized. The type of incision was discussed as putative risk factor for burst abdomen and incisional hernia. Also, data from literature on type of suture material and suture method for prevention of burst abdomen were presented. The various clinical presentations of laparotomy wound failure were described, as well as different treatment options for acute fascial defects. Finally, the aim and outline of this thesis were presented.

In chapter 2, a retrospective case-control study on risk factors for abdominal wound dehiscence in adults was presented. The study included 363 cases of abdominal wound dehiscence and 1089 control patients from a period of twenty years. Major independent risk factors were age, gender, chronic pulmonary disease, ascites, jaundice, anaemia, emergency surgery, type of surgery, postoperative coughing and wound infection. The study included the design of a risk model. This model was validated in a separate cohort of patients and proved to have a high predictive value for abdominal wound dehiscence.

Chapter 3 consisted of a retrospective study on risk factors for burst abdomen in children, performed at three pediatric surgical centers. In this study, 63 patients with burst abdomen and 252 control patients under the age of 18 years were included. Multivariate stepwise logistic regression analyses showed that age under 1 year, wound infection, median incision, and emergency surgery were major independent risk factors for burst abdomen. Burst abdomen was associated with high morbidity in affected patients.

Chapter 4 was a prospective observational study on clinical patient and wound related variables in a cohort of 914 patients who underwent open abdominal surgery. Wounds were inspected daily for abdominal wound dehiscence and surgical site infections (SSI). In analyses, five groups were discerned: no event, superficial SSI, deep SSI, organ/space SSI, and abdominal wound dehiscence. Patients with abdominal wound dehiscence showed the highest rates of postoperative mechanical ventilation, productive and non-productive cough, emesis, and nasogastric tube use before clinical manifestation of abdominal

wound dehiscence. Wound edge separation, amounts of exudate and wound slough, and wound malodour rates were significantly increased, whereas significantly less wound granulation was found in patients before development of abdominal wound dehiscence compared to all other patient categories. Length of stay, readmission and mortality rates were significantly increased in patients with abdominal wound dehiscence.

Chapter 5 discussed a long-term evaluation of patients with abdominal wound dehiscence who were included in the aforementioned prospective observational study. All patients were requested to complete Short Form 36 quality of life questionnaires as well as body image questionnaires, and participated in semi-structured telephone interviews at a mean follow-up of 40 months. In analyses, data from 23 patients with abdominal wound dehiscence were compared to 92 control patients. A high incidence of incisional hernia (83%) was identified in patients with abdominal wound dehiscence. Patients with abdominal wound dehiscence reported significantly lower scores for physical and mental component summaries, general health, mental health, social functioning, and change. No differences were found for physical functioning, role physical, bodily pain, vitality, or role emotional. Further, patients with abdominal wound dehiscence reported significantly lower cosmetic scores and total body image scores.

Chapter 6 was a literature review on therapeutic alternatives for patients with burst abdomen. A total number of 27 retrospective studies were identified that reported on at least one surgical outcome (recurrence, mortality, or incisional hernia rate) of at least 10 patients with burst abdomen. A minority of studies reported outcomes of considerable numbers of patients. Treatment options inclused use of saline-soaked gauze dressings, negative pressure wound therapy, temporary closure options, primary closure with various suture techniques, application of relaxing incisions, use of synthetic and biological meshes, and use of tissue flaps. No treatment option was associated with satisfactory surgical outcomes.

Chapter 7 represented a study on the validity of diagnosis of superficial infection of laparotomy wounds by different surgeons using digital photography. Four surgeons independently assessed photographs of 50 wounds opened for infection within hours after photography and of 50 normally healed wounds. Wound pain scores, morning temperature, and postoperative day were presented. Surgeons' opinions on presence of infection and treatment were noted for each wound. Paired kappa values were calculated and intra-observer agreement was measured after 4-6 weeks. Mean specificity with regard to infection was 97% (94-100%), and mean sensitivity was 42% (32-48%). Paired

kappa-values with regard to infection varied between 0.54-0.68. Agreement on treatment was present in 76/100 wounds. Intra-observer kappa-values varied between 0.43-0.76. This study showed that inter- and intra-observer agreement on diagnosis of superficial infection using digital photography was moderate, but specificity was high.

Chapter 8 was focussed on the reliability of two department tracking systems for diagnosis of surgical site infections. Outcomes from the department's systems, an electronic and a plenary tracking system, were compared with outcomes from our prospective observational study, which included daily surveillance and follow-up after discharge. SSI were diagnosed in 26.9% of 967 included patients; 18.0% superficial, 5.5% deep, and 3.4% organ/space. Over 60% of SSI were not reported in either of the department's tracking systems. For these systems, independent major risk factors for missing registrations were no occurrence of SSI, transplantation surgery, and admission to non-surgical departments. The department's tracking systems proved poor alternatives to our daily surveillance method for measuring incidence of SSI. It was concluded that protocolled wound assessment and on-site documentation are mandatory tools for measuring realistic incidence of SSI.

Chapter 9 presented a follow-up study from the aforementioned prospective observational study. A total number of 374 patients participated in the study and were physically examined after a median follow-up of 16 months. All patients were requested to complete Short Form 36 quality of life questionnaires and body image questionnaires. Seventy-five patients had developed incisional hernia (20%); 63 (84%) were symptomatic. Adjusted for age, gender, and Charlson Comorbidity Index score, patients with IH reported significantly lower mean scores for Short Form 36 components physical functioning, role physical, and physical component summary. A trend towards significance was found for general health (p=0.061). Patients with incisional hernia reported significantly lower mean cosmetic scores, body image, and total body image scores. In summary, patients with incisional hernia reported lower mean scores on physical components of health-related quality of life and body image.

Chapter 10 was an experimental study on suture techniques in porcine abdominal walls. In this study, thirty-eight porcine abdominal walls were removed shortly after death following approved experiments performed in another department. The specimens were divided into two groups (A and B, n=19 each). Midline incisions of 14-cm were created and closed using double-loop polydioxanone. In group A, large stitches (1 cm) with a large suture distance (1 cm) were used, in group B small stitches (0.5 cm) with a small suture

distance (0.5 cm) were used. Each specimen was tested for tensile strength in a tensile tester. The geometric mean tensile force in group B was significantly higher than in group A (787 N vs 534 N, p=0.006). These results support the use of small stitches to prevent development of burst abdomen or incisional hernia after midline incisions.

Chapter 11 was a letter in reaction to an article published by Millbourn et al in Archives of Surgery, which described a randomized controlled trial comparing small and large stitches for closure of the abdominal wall.

Chapter 12 presents a study in which practical aspects of using small stitches and short stitch intervals were investigated at Sundsvall Hospital in Sweden. Personnel were interviewed with respect to their experiences with the introduction and compliance to the new technique. Laparotomy closure times were significantly longer in Sundsvall Hospital compared to Erasmus University Medical Center (n=18 in both groups, median 18 vs. 13 min, p=0.023). Suture length to wound length ratios were above four in all patients operated in Sundsvall Hospital and in 8/18 patients operated in Erasmus University Medical Center. Our results showed that the new technique was well adapted in Sundsvall Hospital. Also, lack of structured implementation to suture with a suture length to wound length ratio of more than 4 often results in a lower ratio.

Chapter 13 formed a study protocol for a double-blinded multicenter randomized controlled trial evaluating the effect of small stitches on the incidence of incisional hernia in midline incisions (STITCH trial, clinicaltrials.gov NCT01132209). In this trial, a total of 576 patients were scheduled to be randomized between a standardized small bites or large bites technique, with calculation of suture length to wound length ratio in each patient. Main objective of the trial was to compare the incidence of incisional hernia after one year, by clinical and ultrasound examination. Secondary outcomes were postoperative complications including SSI, direct costs, indirect costs, and quality of life. Blinding of patients, investigators, and radiologists was to be performed during follow-up. With the completion of this trial, level 1b evidence will become available to support preference for a continuous suture technique with many tissue bites or for the commonly used large bites technique.

Chapter 14 formed the general discussion and future perspectives. Risk factors for burst abdomen and the developed risk score for burst abdomen are discussed as well as the latter's clinical implications. Secondly, our study on risk factors in the pediatric surgical population was evaluated, and a plea was made for future research on suture technique

in this patient group. The results from our prospective study showed that patients at risk for developing AWD can be identified in the early postoperative period, by assessment of presence of mechanical ventilation, postoperative cough,emesis and nasogastric tube use. Data also supported that wound inspection should focus on the degree of wound edge separation, amount of wound exudate, presence of wound slough/necrosis and wound malodour, and degree of granulation/epithelialisation. Tracking of surgical site infections proved to be difficult to perform in daily surgical practice. Involvement of protocollized wound assessment and/or trained personnel appeared necessary to achieve reliable SSI incidence rates. Long term outcomes of our prospectively followed cohort of burst abdomen patients were unsatisfactory in terms of health-related mental and physical components of quality of life, body image, and high incidence of incisional hernia. Unfortunately, our group size was small. In order to collect more data on patients with burst abdomen, it was suggested to register these patients in (inter-)national hernia databases. Evaluation of treatment methods for burst abdomen, including use of (biological) mesh, will also profit from standardized data input from multiple centers. Prevention of burst abdomen and incisional hernia may be influenced by adjusting suture techniques, eg, by using small tissue bites and short stitch intervals. The influence of suture length to wound length ratio should not be underestimated. Experimental data showed that especially in the commonly used large bites, long stitch intervals, a suture length to wound length ratio above four is mandatory to achieve adequate tensile strength. In the future, more attention is needed for postoperative care, development of new suture materials and prophylactic mesh placement in high risk patients who are unfit for minimally invasive surgery.

Samenvatting

Samenvatting

Wondfalen is een veelvoorkomende complicatie na abdominale chirurgie, en omvat postoperatieve wondinfecties (POWI), fasciedehiscentie (of 'Platzbauch'), en littekenbreuken.

In hoofdstuk 1 werd het onderwerp van dit proefschrift, 'Wondfalen van de laparotomie', geintroduceerd. De anatomie van de buikwand en definities van littekenbreuk en fasciedehiscentie werden gepresenteerd. In de literatuur beschreven risicofactoren met betrekking tot patiëntkarakteristieken, operatiekenmerken en postoperatieve factoren werden besproken. Ook werd aandacht besteed aan het type incisie als mogelijke risicofactor voor het ontwikkelen van fasciedehiscentie en littekenbreuken. Daarnaast werden data uit de literatuur besproken met betrekking tot het type hechtmateriaal en hechtmethode voor de preventie van fasciedehiscentie. De verschillende klinische presentatievormen van wondfalen werden beschreven, evenals de verschillende behandelmethoden voor acute fasciedefecten. Het hoofdstuk werd besloten met een beschrijving van het doel van dit proefschrift en een uiteenzetting van de inhoud.

Hoofdstuk 2 bestond uit een retrospectieve case-control studie over risicofactoren voor fasciedehiscentie bij volwassenen. De studie betrof 363 patiënten met fasciedehiscentie en 1089 controle-patiënten uit een periode van twintig jaar. Belangrijke onafhankelijke risicofactoren waren leeftijd, geslacht, chronische longziekte, ascites, geelzucht, anemie, spoedoperaties, type operatie, postoperatief hoesten en wondinfectie. In deze studie werd ook een risicomodel ontworpen, welke gevalideerd werd in een apart patiëntencohort en een hoge voorspellende waarde bleek te hebben voor fasciedehiscentie.

Hoofdstuk drie omvatte een retrospectieve studie over risicofactoren voor fasciedehiscentie bij kinderen afkomstig uit drie kinderchirurgische centra. In deze studie werden 63 patiënten met fasciedehiscentie en 251 controle-patiënten geincludeerd. Multivariate logistieke regressie analyse toonde aan dat leeftijd onder 1 jaar, wondinfectie, mediane incisie en spoedoperaties belangrijke onafhankelijke risicofactoren waren voor fasciedehiscentie. In deze studie bleek dat fasciedehiscentie geassocieerd was met hoge morbiditeit.

Hoofdstuk 4 betrof een prospectieve observationele studie naar de dynamiek van de wondgenezing in een cohort van 914 van 1000 geincludeerde patiënten die open abdominale chirurgie ondergingen. Wonden werden dagelijks geïnspecteerd en

gecontroleerd op aanwezigheid van fasciedehiscentie en POWI. In de analyses werden vijf groepen onderscheiden: geen complicaties, oppervlakkige POWI, diepe POWI, POWI van anatomische ruimten/organen, en fasciedehiscentie. Patiënten met fasciedehiscentie vormden de groep met de hoogste percentages postoperatieve beademing, productieve en niet-productieve hoest, braken, en gebruik van maagsondes vóórdat de klinische diagnose fasciedehiscentie gesteld was. De wonden van deze patiënten toonden een grotere mate van wijken van de wondranden, grotere hoeveelheid wondvocht en wondbeslag, gaven vaker een riekende wondgeur af en toonden minder granulatie dan alle andere patiëntengroepen. Patiënten met fasciedehiscentie hadden een significant langere opnameduur en hogere heropname- en sterftepercentages dan patiënten zonder fasciedehiscentie.

In hoofdstuk 5 werden de lange termijn resultaten van patiënten met fasciedehiscentie besproken die geïncludeerd waren in de reeds genoemde prospectieve observationele studie. Alle patiënten participeerden in een semi-gestructureerd telefonisch interview en alle patiënten werd gevraagd een Short Form 36 kwaliteit van leven vragenlijst en Body Image vragenlijst in te vullen na een gemiddelde follow-up van 40 maanden. In de analyse werden de gegevens van 23 patiënten met fasciedehiscentie vergeleken met de gegevens van 92 controlepatiënten. Er werd een hoge incidentie van littekenbreuken vastgesteld (83%) bij patiënten met fasciedehiscentie. Patiënten met een fasciedehiscentie rapporteerden significant lagere scores voor samenvattingen van fysieke en mentale componenten, algehele gezondheid, mentale gezondheid, sociaal functioneren, en verandering. Er werden geen verschillen gevonden in scores voor fysiek functioneren, fysieke rol, lichaamspijn, vitaliteit, of emotionele rol. Patiënten met fasciedehiscentie rapporteerden significant lagere cosmetiek scores en totale body image scores.

Hoofdstuk 6 bestond uit een review van de literatuur over behandelingsopties voor patiënten met fasciedehiscentie. In totaal werden 27 studies gevonden die minimaal 1 chirurgische uitkomst rapporteerden (recidief, mortaliteit, of percentage littekenbreuken) van minimaal 10 patiënten met fasciedehiscentie. Een klein aantal studies rapporteerde uitkomsten van aanzienlijke patiëntaantallen. Behandelopties waren gebruik van natte gazen, negatieve druk wondtherapie, tijdelijke sluitingsmanieren, primair sluiten met verschillende hechttechnieken, aanbrengen van relaxerende incisies, gebruik van synthetische en biologische matten, en gebruik van weke delenflappen. Geen enkele behandeloptie gaf bevredigende resultaten.

Hoofdstuk 7 omvatte een studie naar de validiteit van de diagnose van oppervlakkige wondinfectie door verschillende chirurgen bij gebruik van digitale fotografie. Vier chirurgen bestudeerden onafhankelijk van elkaar foto's van 50 wonden die binnen enkele uren na fotografie geopend waren voor infectie en foto's van 50 wonden die normaal genezen waren. Wondpijn scores, ochtendtemperatuur en postoperatieve dag werden bekend gemaakt. De meningen van chirurgen over de aanwezigheid van infectie en behandeling werden voor elke wond vastgesteld. Gepaarde kappawaarden werden berekend en de intra-observeerder overeenstemming werd gemeten na 4-6 weken. De gemiddelde specificiteit met betrekking tot infectie was 97% (94-100%), en de gemiddelde sensitiviteit was 42% (32-48%). Gepaarde kappawaarden met betrekking tot infectie varieerden tussen 0.54-0.68. Overeenstemming over behandeling was aanwezig in 76/100 wonden. De kappawaarden voor intra-observeerder overeenstemming varieerden tussen 0.43-0.76. Deze studie toonde aan dat de inter-observeerder en intra-observeerder overeenstemming met betrekking tot de diagnose van oppervlakkige wondinfectie bij gebruik van digitale fotografie matig was, maar dat de specificiteit hoog was.

Hoofdstuk 8 was gericht op het bepalen van de betrouwbaarheid van de registratiesystemen van de afdeling Heelkunde voor de diagnose van POWI's. Uitkomsten van de afdelingssystemen, een elektronisch en een plenair registratiesysteem, werden vergeleken met de uitkomsten van onze prospectieve observationele studie, waarin dagelijkse wondinspectie werd verricht en follow-up na ontslag. POWI's werden vastgesteld bij 26.9% van 967 van de in deze studie geïncludeerde patiënten: 18.0% oppervlakkig, 5.5% diep, en 3.4% anatomische ruimten/organen. Meer dan 60% van de POWI's bleek in geen van beide registratiesystemen van de afdeling gerapporteerd te zijn. Belangrijke onafhankelijke risicofactoren voor ontbrekende registraties van patiënten in deze systemen waren afwezigheid van POWI's, transplantatiechirurgie, en opname op niet-chirurgische afdelingen. De registratiesystemen van de afdeling vormden een slecht alternatief voor onze methode van dagelijkse wondinspectie voor het meten van de incidentie van POWI's. Hieruit werd geconcludeerd dat geprotocolleerde wondbeoordeling en het ter plekke documenteren van POWI's noodzakelijk zijn voor het meten van realistische incidentiecijfers van POWI's.

Hoofdstuk 9 betrof een follow-up studie van de eerder genoemde prospectieve observationele studie. In totaal participeerden 374 patiënten in de studie, welke lichamelijk onderzoek ondergingen na een mediane follow-up periode van 16 maanden. Alle patiënten werd gevraagd een Short Form 36 kwaliteit van leven vragenlijst en een Body Image vragenlijst in te vullen. Vijfenzeventig patiënten hadden een littekenbreuk

ontwikkeld (20%); 63 (84%) waren symptomatisch. Aangepast voor leeftijd, geslacht, en Charlson comorbiditeit index score, rapporteerden patiënten met littekenbreuken significant lagere gemiddelde scores voor Short Form 36 componenten fysiek functioneren, fysieke rol, en fysieke component samenvatting. Een statische trend werd gevonden voor algemene gezondheid (p=0.061). Patiënten met littekenbreuken rapporteerden significant lagere gemiddelde cosmetiek scores, body image, en totale body image scores. Samenvattend rapporteerden patiënten met littekenbreuken lagere gemiddelde scores voor fysieke componenten van gezondheid-gerelateerde kwaliteit van leven en body image.

Hoofdstuk 10 was een experimentele studie naar hechttechnieken uitgevoerd in varkensbuikwanden. In deze studie werden 38 varkensbuikwanden kort na overlijden verwijderd na afronding van goedgekeurde experimenten door een andere afdeling. De preparaten werden verdeeld in twee groepen (A en B, 19 voor elke groep). Mediane incisies van 14 cm werden verricht en gesloten met een dubbele polydioxanondraad. In groep A werden grote steken (1 cm) gebruikt met grote hechtingintervallen (1 cm), en in groep B werden kleine steken (0.5 cm) met kleine hechtingintevallen (0.5 cm). De treksterkte van elk preparaat werd getest in een treksterktemeter. De geometrische gemiddelde treksterkte in groep B was significant hoger dan in groep A (787 N vs. 534 N, p=0.006). Deze resultaten ondersteunen het gebruik van kleine steken om de ontwikkeling van fasciedehiscentie en littekenbreuken te voorkomen na mediane incisies.

Hoofdstuk 11 betrof een ingestuurde brief als reactie op het artikel gepubliceerd door Millbourn et al in Archives of Surgery, welke een gerandomiseerde studie beschreef waarin kleine en grote steken met elkaar werden vergeleken voor het sluiten van de buikwand.

Hoofdstuk 12 omvatte een studie waarin de praktische aspecten van het gebruik van kleine steken met een klein hechtinginterval werd onderzocht in Sundsvall Ziekenhuis in Zweden. Personeel werd geinterviewd met betrekking tot hun ervaringen met de introductie en compliantie van de nieuwe techniek. Het sluiten van de buikwand duurde significant langer in het Sundsvall Ziekenhuis vergeleken met het Erasmus MC (n=18 in beide groepen, mediaan 18 vs. 13 min, p=0.023). De draadlengte-wondlengte ratio was boven 4:1 in alle patiënten die werden geopereerd in het Sundsvall Ziekenhuis en in 8/18 patiënten die werden geopereerd in het Erasmus MC. Onze resultaten toonden aan dat de nieuwe techniek goed gebruikt werd in het Sundsvall Ziekenhuis. Tevens werd duidelijk dat gebrek aan een gestructureerde implementatie van het hechten met een draadlengte-wondlengte ratio van meer dan 4 vaak leidde tot het behalen van een lagere ratio.

Hoofdstuk 13 vormde een studieprotocol voor een dubbelblinde multicenter gerandomiseerde studie waarin de effecten van kleine steken op de incidentie van littekenbreuken in mediane laparotomieën wordt onderzocht (STITCH trial, clinicaltrials. gov NCT01132209). In dit onderzoek zal worden beoogd in totaal 576 patiënten te includeren, die gerandomiseerd zullen worden tussen een gestandaardiseerde kleine steken of grote steken techniek, met berekening van de draadlengte-wondlengte ratio in elke patiënt. De primaire uitkomstmaat van het onderzoek wordt de incidentie van littekenbreuken na 1 jaar, vastgesteld door klinisch en echografisch onderzoek. Secundaire uitkomstmaten zijn postoperatieve complicaties waaronder POWI's, directe kosten, indirecte kosten, en kwaliteit van leven. Gedurende follow-up worden patiënten, onderzoekers, en radiologen geblindeerd. De studie zal de voorkeur voor het gebruik van een continue hechttechniek met kleine of gebruikelijke grote steken met een hoog niveau van bewijskracht (1b) ondersteunen.

Hoofdstuk 14 bestond uit de algemene discussie en toekomstperspectieven. Risicofactoren voor fasciedehiscentie en de ontwikkelde risicoscore voor fasciedehiscentie worden besproken, evenals de klinische implicaties van de risicoscore. Vervolgens werd onze studie naar risicofactoren in de kinderchirurgische populatie geëvalueerd, waarbij een pleidooi werd gehouden voor toekomstig onderzoek naar hechttechnieken in deze patiëntengroep. De resultaten van onze prospectieve studie toonden aan dat patiënten met een risico voor het ontwikkelen van fasciedehiscentie in de vroege postoperatieve periode geïdentificeerd kunnen worden door de aanwezigheid van beademing, postoperatief hoesten, braken en maagsonde te evalueren. Op basis van deze resultaten werd gesteld dat wondinspectie gefocust zou moeten zijn op de mate van wijken van de wondranden, hoeveelheid wondexsudaat, aanwezigheid van beslag/necrose en riekende wondgeur, en de mate van granulatie/epithelialisatie. Het registreren van POWI's bleek een lastige taak te zijn in de dagelijkse chirurgische praktijk. Geprotocolleerde wondinspectie en/of getraind personeel leken noodzakelijk om betrouwbare incidentiecijfers van POWI's te kunnen bepalen. Lange termijn uitkomsten van onze prospectief gevolgd cohort van patiënten met fasciedehiscentie waren ongunstig voor gezondheid-gerelateerde mentale en fysieke componenten van kwaliteit van leven, body image, en er was een hoge incidentie van littekenbreuken. Helaas was onze groepsgrootte klein.

Om meer data te kunnen verzamelen, analyseren en rapporteren over patiënten met fasciedehiscentie werd gesuggereerd om deze patiënten te registreren in (inter-)nationale hernia databases. Evaluatie van behandelmethoden voor fasciedehiscentie, inclusief het gebruik van (biologische) matten, zal ook vergemakkelijkt worden door de aanbod van

gestandaardiseerde data uit verschillende centra. Voorkómen van fasciedehiscentie en littekenbreuken kan mogelijk beinvloed worden door de hechttechniek aan te passen, bijv. door het gebruik van kleine steken met kleine hechtingintervallen. De invloed van de draadlengte-wondlengte ratio moet niet onderschat worden. Experimentele data toonden dat bij het gebruik van de grote steken in het bijzonder, een draadlengte-wondlengte ratio boven de 4 noodzakelijk is om adequate weefseltrekkracht te bereiken. In de toekomst is meer aandacht nodig voor postoperatieve zorg, ontwikkeling van nieuwe hechtmaterialen en preventieve matplaatsing bij hoog-risico patiënten die niet geschikt zijn voor het ondergaan van minimaal invasieve procedures.

List of publications

List of publications

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PhD portfolio

PhD portfolio

Name: Drs. G.H. van Ramshorst **PhD period: 2006-2013**
Erasmus MC **Promotor: Prof.dr. J.F. Lange**
Department: Surgery **Co-promotor: Prof.dr. J. Jeekel**

1. PhD training	Year	Workload Hours	ECTS
General courses			
Basiscursus Regelgeving en Organisatie van Klinische trials	2007		1
Specific courses			
Laboratory Animal Science Course	2006		3
Postgraduate course Component Separation Technique	2012	8	
Seminars and workshops			
Workshop hernia surgery Masterclass laparoscopic incisional hernia surgery	2011	8	
National conferences			
Nederlandse Vereniging voor Heelkunde (5 oral presentations, 1 poster presentation)	2007-2010		5
Symposium Experimenteel Onderzoek Heelkundig Specialismen (poster presentation)	2007		1
Nederlandse Vereniging voor Medische Microbiologie (oral presentation)	2008		1
Congres wondgenezing en wondbehandeling (oral presentation)	2008		1
Meat &Treat Wondinfectie – V&VN Decubitus en Wondconsulenten (oral presentation)	2009		1
Wound Consultant Society congres (oral presentation)	2009		1
International conferences			
European Hernia Society (8 oral presentations)	2007-2013		8
European Society for Surgical Research (oral presentation)	2007		1
Congrès Français de Chirurgie (oral presentation)	2007		1
European Society for Surgical Research (oral presentation)	2007		1
European Paediatric Surgeons' Association (oral presentation)	2008		1
Surgical Infection Society of North America (oral presentation, Best oral presentation Europe award)	2009		1
Joint meeting of the American and European Hernia Society (oral presentation, poster presentation)	2009; 2012		2

2. Teaching		Workload	
	Year	Hours	ECTS
Supervising 16 Master theses	2006-2009		16
Supervising 1 'keuze-onderwijs' thesis	2009	14	
Supervision of 4 wound consultant nurses' theses	2007-2009		4
Teaching wound consultant nurses	2007-2012	26	
Teaching of nurses	2008-2009	10	
3. Other			
Organisation Rotterdam Interactive Congress on Hernia	2007-2009		2
Total		**66**	**51**

Curriculum vitae

Grada Hendrika (Gabrielle) van Ramshorst was born on February 8, 1980 in Groningen, the Netherlands. After graduating from Christelijk Lyceum Delft in 1997, she studied medicine at Leiden University. In 2000, she attended Uppsala University in Sweden for a 6-month clinical clerkship in Swedish. She then performed fieldwork and laboratory work in a rural area of Ghana for a period of 3 months in 2001 to investigate infection rates of the endemic *Oesophagostomum bifurcum* and other parasites in preparation for a mass treatment of the local population. In 2003, she spent 3 months in Surinam for the clinical clerkship Gynaecology and Obstetrics. After graduating from Leiden University in January 2004, she worked as a resident at the Department of Surgery at Vlietland Ziekenhuis in Vlaardingen. In August 2005, she was employed as a resident at the Department of Pediatric Surgery of Erasmus University Medical Center – Sophia Children's Hospital in Rotterdam. She was subsequently employed as a research fellow by Prof.dr. J.F. Lange and Prof.dr. J. Jeekel at the Department of Surgery of Erasmus University Medical Center, which resulted in this thesis. In July 2009, she commenced training in General Surgery at Red Cross Hospital Beverwijk (Head: Dr. H.A. Cense) and VU Medical Center (Head: Prof.dr. H.J. Bonjer) in Amsterdam. This surgical training will focus on gastrointestinal surgery, surgical oncology, and of course, abdominal hernia surgery. Gabrielle currently lives in Delft with Jurriaan and their son Hugo.