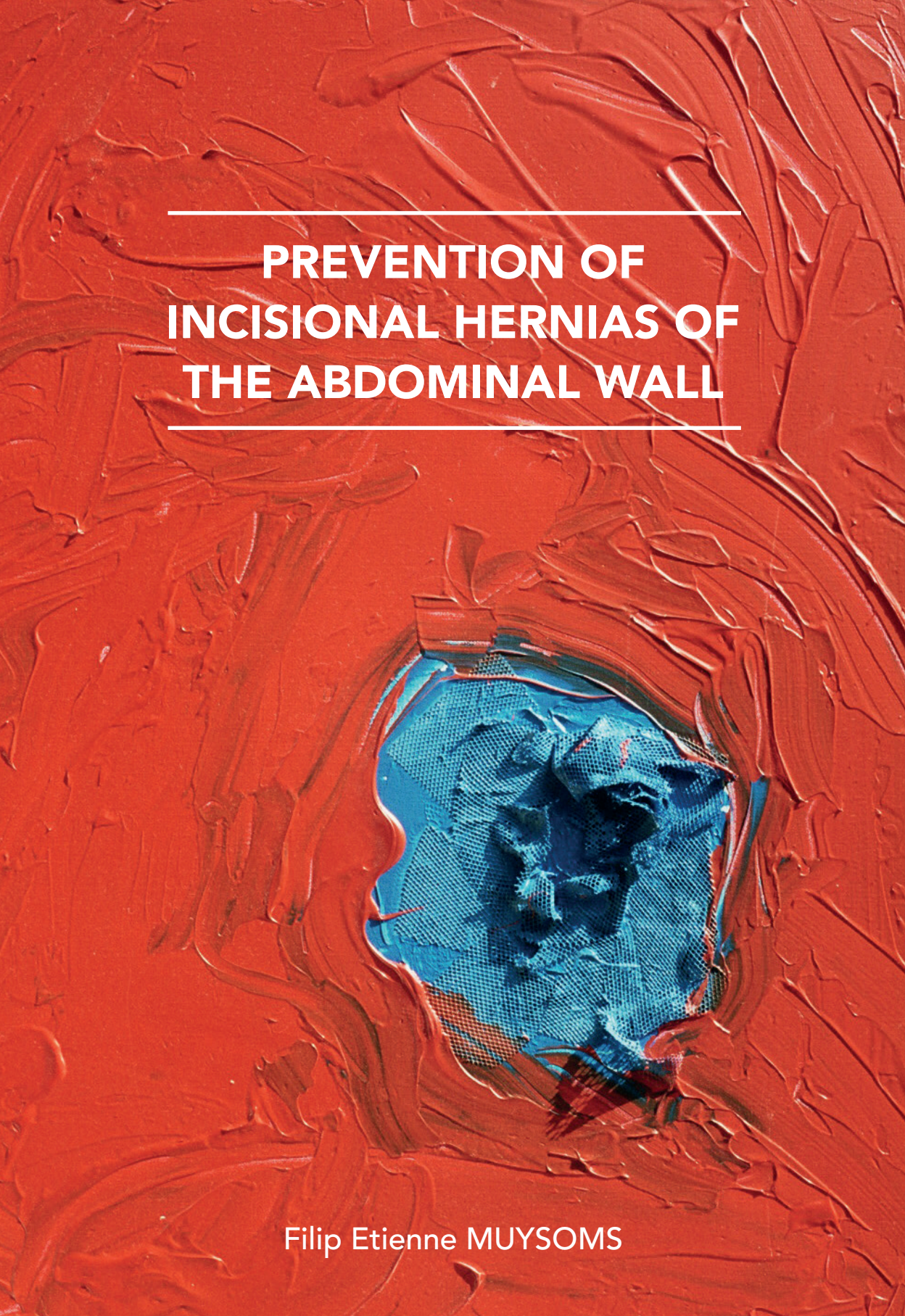
PREVENTION OF INCISIONAL HERNIAS OF THE ABDOMINAL WALL



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PREVENTION OF INCISIONAL HERNIAS OF THE ABDOMINAL WALL

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Doctoral Thesis, Doctoral School of Life Sciences and Medicine,
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Content

INTRODUCTION

In the past decades, surgery of the abdominal wall and, more specifically, the treatment of incisional hernias has become the topic of interesting innovations and increased clinical research. It has become a sub-specialty in many hospitals and surgical departments, with surgeons devoting much of their clinical time to abdominal wall repair operations. An increasing number of patients with large and complicated incisional hernias need treatment. Currently, the literature dealing with abdominal wall surgery is often flawed due to lack of adherence to accepted reporting standards and statistical methodology.

In *the first chapter* of this thesis, a classification of incisional hernias is published which was the result of consensus meeting of the European Hernia Society in Ghent (2008) [1]. With a working group of the EHS, the EuraHS (European Registry of Abdominal Wall Hernias), an online platform was created for registration and outcome measurement of abdominal wall repair. For this, a consensus was sought on clear definitions and terminology to be used, as well as on the outcome variables to be included [2]. The working group also found there was need for a list of recommendations for reporting outcome results in abdominal wall repair [3]. We think these publications, based on consensus and under the auspices of the European Hernia Society, form a good basis for improving the standardization and quality of research on abdominal wall repair.

In *the second chapter* of this thesis, the need and possibilities for optimizing the closure of abdominal wall incisions is addressed. Incisional hernias are a frequent complication of abdominal wall incisions, but a wide range of incisional hernia rates are reported [4-9]. The weighted mean incisional hernia rate at 23.8 months was 12.8 % in a systematic review and meta-regression study [10], but incidence rates up to 69 % have been reported in high-risk patients with prospective long-term follow-up [11]. The reported incidence is determined by several factors: the patient population studied, the type of abdominal wall incision, the length of follow-up and the method of incisional hernia diagnosis. Several patient risk factors have been identified and thus the incisional hernia incidence will depend on the number of patients in the studied population with these risk factors. Risk factors for incisional hernias include: postoperative surgical site infection, obesity, smoking and abdominal aortic aneurysm [12–14]. Preoperative counseling on weight control and smoking cessation would be a preventive measure to decrease postoperative complications after abdominal surgery, but is most often difficult to implement. The planning of the surgical approach to the abdomen also has a great potential to decrease the risk for incisional hernias. The incidence of incisional hernias is significantly decreased when non-midline incisions are chosen [15–17].

Nevertheless, many surgeons prefer a midline incision for major laparotomies. Moreover, it seems that the suture material and the surgical technique used to close an abdominal wall incision are the most important determinants of the risk of developing an incisional hernia [1,17-19]. In our department two retrospective studies were performed on the incidence of abdominal wall hernias following colorectal cancer surgery. Because of the retrospective character of these studies the risk of bias is high and the quality of retrospective data form a serious limitation of the studies and their conclusions. By re-evaluating the CT scans made during oncological follow-up in the years postoperatively, we have found the incidence of incisional hernia to be 35.0 % with a mean follow-up time of 30 months for colorectal cancer patients [7]. For patients undergoing low anterior resection of a rectal cancer, the incidence was 45.1% at the laparotomy site with a mean follow-up time of 1.9 years [20]. The presence of an incisional hernia is often accepted as "collateral damage" and considered of secondary importance in relation to the treatment of serious life-threatening diseases, like colorectal cancer or aortic aneurysms. This is an underestimation of their importance because the development of an incisional hernia has an important impact on the patients' quality of life and body image [21]. Considering the frequent multiple comorbidities of these patients, a surgical repair of the incisional hernia repair is often only proposed and done when major symptoms are related to the presence of the incisional hernia. Still, in the Danish nationwide study on patients after abdominal aortic surgery, 10.4% of patients underwent a subsequent incisional hernia repair with a follow-up time of 6 years [14]. Furthermore, the repair of incisional hernias still has a high failure rate with long term recurrence rates above 30 %, even when mesh repair is performed [22-24]. Therefore, optimizing the surgical technique to close abdominal wall incisions using evidence-based principles has the potential to prevent patients suffering from incisional hernias and the potential sequelae of incisional hernia repairs. The mean direct and indirect costs for the repair of an average incisional hernia in an average patient in France in 2011 was € 7089 [25]. Thus, reducing the incisional hernia rate by optimizing the closure of abdominal wall incisions might induce considerable costs savings in the use of health care facilities and an important reduction in postoperative disability. With colleagues from the Erasmus University, an institute renowned for their research on abdominal wall pathology, a review paper was written on the principles of abdominal wall closure techniques [26]. The presence of sound evidence of how to improve the closure of abdominal wall incisions and of how to decrease incisional hernia rates, in contrast to the low overall penetration of these "Principles" in the surgical community, has been the main motivator to produce guidelines on this topic. We publish in this thesis the European Hernia Society Guidelines on the closure of abdominal wall incisions [17].

In *the third chapter,* we add data from a Belgian randomized trial on mesh-augmented reinforcement of the abdominal wall during closure of abdominal wall incisions for repair of an aortic abdominal aneurysm as prevention for incisional hernias [27]. The evidence for prophylactic mesh augmentation is rapidly growing with the publication of a new prospective study or randomized trial almost every two months. Alain Pans from Belgium was the first to describe the concept of mesh-augmented reinforcement in 1998 with the publication of the results from a RCT in 288 patients undergoing gastric bypass surgery [28]. They placed an intra-peritoneal absorbable polyglactin mesh (Vicryl), but found no reduction in the incidence of incisional hernias. The prophylactic use of synthetic, non-absorbable mesh was pioneered in bariatric surgery by Janusz Strelczyk from Poland, published in 2002 [29], and for aortic aneurysm patients by Jonothan Earnshaw from the United Kingdom, published in 2003 [30,31]. Both first reported a prospective cohort study and subsequently published the results of a RCT several years afterwards [32,33]. During the development of the EHS Guidelines, a separate chapter was written on prophylaxis by mesh augmentation [17]. A new meta-analysis was performed of the six RCTs published at the time of the search for the guidelines, i.e. April 2014 [32-37]. Since this work, four additional publications on the results of RCTs about mesh-augmented prophylaxis in laparotomies are available [38-41]. Several other studies are ongoing. The evidence supporting mesh-augmented prophylaxis is growing rapidly and it is our opinion that the use of a mesh as prevention of incisional hernias will soon become common practice for several groups of patients at high risk for incisional hernia development.

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CHAPTER 1

Definition and classification of incisional hernias

1.1 CLASSIFICATION OF PRIMARY AND INCISIONAL ABDOMINAL WALL HERNIAS

Results of a consensus meeting in Ghent, Belgium, 2–4 October 2008

Hernia, 2009, 13:407-414

F.E. Muysoms, M. Miserez, F. Berrevoet, G. Campanelli, G.G. Champault, E. Chelala, U.A. Dietz, H.H. Eker, I. El Nakadi, P. Hauters, M. Hidalgo, A. Hoeferlin, U. Klinge, A. Montgomery, R.K.J. Simmermacher, M.P. Simons, M. Śmietański, C. Sommeling, T. Tollens, T. Vierendeels, A. Kingsnorth

"A classification of ventral and incisional hernias is important because at this moment we are comparing apples and oranges."

© Andrew Kingsnorth, ***May 7th 2007, EHS congress, Athens***

ABSTRACT

Purpose

A classification for primary and incisional abdominal wall hernias is needed to allow comparison of publications and future studies on these hernias. It is important to know whether the populations described in different studies are comparable.

Methods

Several members of the EHS board and some invitees gathered for 2 days to discuss the development of an EHS classification for primary and incisional abdominal wall hernias.

Results

To distinguish primary and incisional abdominal wall hernias, a separate classification based on localisation and size as the major risk factors was proposed. Further data are needed to define the optimal size variable for classification of incisional hernias in order to distinguish subgroups with differences in outcome.

Conclusions

A classification for primary abdominal wall hernias and a division into subgroups for incisional abdominal wall hernias, concerning the localisation of the hernia, was formulated.

INTRODUCTION

At the 29th Congress of the European Hernia Society in Athens in May 2007, Andrew Kingsnorth, the president of the EHS, stressed that a classification of ventral and incisional hernias is important because at this moment we are comparing "apples and oranges" in the different studies that are published and presented at meetings [1].

Already in 2000, Schumpelick stated that a classification of incisional hernias, like we have for groin hernias, is urgently needed. "Despite the magnitude of the problem, we do not have a classification that is simple, reproducible and internationally accepted" [2].

Since 2000, several authors have proposed classifications for incisional hernias, but none of them are widely used in the literature on incisional hernias [2–5].

MATERIALS AND METHODS

Methodology

Several members of the EHS board and some invitees gathered at the initiative of the Belgian Section for Abdominal Wall Surgery (BSAWS) and the Dutch Hernia Society (DHS) for 2 days to discuss the development of an EHS classification for primary and incisional abdominal wall hernias.[1]

During an initial discussion, the existing proposals were briefly presented by one of the participants.

Thereafter, a decision was taken concerning the purpose of a classification and the scope of this consensus meeting. Some of the participants saw it mainly as a search for a simple classification. Because it was supported by and originated from the EHS, this classification could have a greater application in hospitals and in the surgical literature than the previous proposals published originating from one centre. Others were more in favour of an open structured approach, in which "scientists" would gather a maximum number of data sets in a prospective registry. With this registry, it was hoped to discover the most valuable and important risks factors for recurrence in order to direct future guidelines and therapeutic choices. It was decided to focus first on a simple, reproducible classification, because getting results out of the registry may take many years. A classification was proposed as such, including localisation of the hernia and the size of the hernia defect as decisive for the outcome, not going into its use to direct therapeutic choices for the present time. During the last session of the meeting,

1 At the initiative of the first author, Filip Muysoms, current president of the Belgian Section for Abdominal Wall Surgery (BSAWS), and in collaboration with Rogier Simmermacher [member of the Dutch Hernia Society (DHS) and Secretary for Educational of the European Hernia Society (EHS)] and with Marc Miserez (member of BSAWS and Secretary Scientific Research of the EHS), a consensus meeting on the classification of primary and incisional abdominal wall hernias was organised. The BSAWS and the DHS are the National Chapters of the EHS, respectively from Belgium and The Netherlands. A first preparatory meeting took place with members of both Chapters during a whole day session in La Hulpe, Belgium, on 4 April 2008. This was followed by a second meeting in Brussels, Belgium, on 16 September 2008.As participants to the consensus meeting, held in Ghent, Belgium, on 2–4 October 2008, we invited the board members and past presidents of the EHS (A. Kingsnorth, G. Campanelli, G.G. Champault, A. Hoeferlin, S. Mandala, M. Miserez, R.K.J. Simmermacher, M. Śmietański, J.B. Flament and M. Hidalgo), the board members of the BSAWS (F.E. Muysoms, F. Berrevoet, E. Chelala, I. El Nakadi, P. Hauters, C. Sommeling, T. Tollens and T. Vierendeels) and the board members of the DHS (H.H. Eker and M.P. Simons). In addition we invited some other European experts (U.A. Dietz, U. Klinge and A. Montgomery) who by publications and organisation of national registries have shown major interest in hernia classification.

the development of a large, broad and open structured European registry was initiated.

Currently existing classifications

Chevrel and Rath [3] proposed a classification for incisional hernias in 2000. This classification is attractive, because it is simple, and the data required to reach the classification are readily obtained. Three parameters were utilised. Firstly, the localisation of the hernia of the abdominal wall: divided into median (M1–M4) and lateral (L1–L4) hernias. Secondly, the size of the hernia: it was postulated that the width of the hernia defect is the most important parameter (greater than hernia defect surface, length of the hernia or size of the hernia sac), which was divided into four groups (W1–W4). As a third parameter of this classification, subgroups were made for incisional hernias and recurrences: the number of previous hernia repairs was recorded as (R0, R1, R2, R3,…). Although apparently easy to use, this classification has not been commonly used in the literature.

In his book on hernia surgery, "Hernien", Schumpelick described a classification that divided incisional hernias into five classes [2]. The size of the defect, the clinical aspect of the hernia in lying and standing position, the localisation of the incision and the number of previous repairs were used for this classification.

Korenkov et al. [4] reported on the results of an expert meeting on classification and surgical treatment of incisional hernia, but no detailed classification proposal resulted from this meeting.

Ammaturo and Bassi [6] suggested an additional parameter to the Chevrel classification. The ratio between the anterior abdominal wall surface and the wall defect surface predicts a strong abdominal wall tension when closing the defect, with possible abdominal compartment syndrome development, and thus might influence the choice of surgical technique.

Recently, Dietz et al. [5] proposed another alternative classification of incisional hernias in which variables like body type, hernia morphology and risk factors for recurrence were included and recommendations made for surgical repair based on the different types. It is based on a self-explanatory taxonomy and is intended to tailor the repair to the body type and risk factors of the individual patient.

The Swedish Abdominal Wall Hernia Registry presented their data collection sheet for incisional and ventral hernias at the EAES congress in Stockholm in June 2008, which forms the basis for a classification and includes many prog-

nostic relevant variables. For this reason Agneta Montgomery was invited to the consensus meeting to present the method of classification used in Sweden.

Purpose of a classification

The primary purpose of any classification should be to improve the possibility of comparing different studies and their results. By describing hernias in a standardised way, different patient populations can be compared. The secondary purpose of a classification would be to collect results of different surgical techniques from the literature and develop evidence-based therapeutic guidelines using the classification. When a classification would become generally accepted, future studies might use the subgroups within the classification in their prospective registries and within the inclusion criteria for prospective studies.

Scope of the classification: primary ventral hernias versus incisional ventral hernias

The first decision to take was whether the classification would involve primary ventral hernias and incisional ventral hernias in one classification or if two separate classifications were preferable. A consensus was reached on the decision to separate the two entities, since in the authors' opinion primary ventral hernias have a different aetiopathology compared with incisional abdominal wall hernias resulting from failure of a previous incision. The group reached agreement on separating non-incisional hernias, "primary abdominal wall hernias" (also known as "ventral"). and the other "incisional abdominal wall hernias". A recurrent hernia after a primary abdominal wall hernia treatment will then fall into the incisional hernia group. To avoid confusion, the word "primary incisional hernia" should not be used.

There was a consensus to exclude "parastomal hernias" from this classification. Although they are by definition incisional hernias, they make up a distinct group, with specific properties and treatment options.

Format of the classification

In 2007 the EHS published a simple classification for groin hernias [7]. We agreed that a classification for primary abdominal wall hernias and incisional hernias should preferably be in a similar format to the EHS groin hernia classification. This would involve the development of a grid format for the classification, although this may place restrictions on the number of variables that can be used in this classification.

Variables for classification

When proposing a classification, it is important to determine the most suitable variables to include in the classification. However, it is important to keep a classification simple and practical to use. In Table 1 the potential variables are listed, as well as their use in previously proposed classifications. It is impossible to take all these variables into account for a practical classification, so a decision on inclusion or exclusion of various parameters was made.

VARIABLES FOR CLASSIFICATION OF PRIMARY OR INCISIONAL ABDOMINAL WALL HERNIAS	Chevrel & Rath [3]
Size of the hernia defect: surface area, length, width	Width
Size of the hernia sac	
Number of hernia defects	
BMI of the patient	
Ratio anterior abdominal wall surface/ wall defect surface	
Ratio between the abdominal volume / the volume of the hernia sac	
Primary versus incisional hernias	
Recurrent hernias (number of previous repairs)	X
Previous mesh implantation	
Indication for the operation causing the incisional hernia	
Type and localisation of the incision	
Symptoms of the hernia	
Reducibility of the hernia	
Localisation of the hernia	X
The anatomy of the patient in the subcostal area: sternocostal angle	
Other risk factors for hernia recurrence	

Table 1

Possible variables to use for classifying primary and incisional abdominal wall hernias and their use in previous classifications

Korenkov et al. [4]	Shumpelick [2]	Ammarturo & Bassi [6]	Swedish registry	Dietz et al. [5]
Width or length	Maximal size	Width	Width and length	Width and length
	X		X	
			X	X
		X		
X	X	X	X	X
			X	
			X	
			X	
X				
X	X		X	
X	X	X	X	X
				X
				X

CLASSIFICATION OF PRIMARY ABDOMINAL WALL HERNIAS

For the primary abdominal wall hernias, there was agreement on the use of localisation and size as the two variables to use.

Localisation of the hernia

Two midline (epigastric and umbilical) and two lateral hernias (Spighelian and lumbar) are identifiable entities with distinct localisations.

Size of the hernia

Primary abdominal wall hernias are usually more or less round or oval shaped. Therefore, the size can be described with one measurement. Width and length will be more or less comparable most of the time. We agreed to use the "diameter" of the primary abdominal wall hernia as the second variable. Cutoff values of 2 and 4 cm were chosen to describe three subgroups according to size: small, medium and large.

Taxomony

For the primary abdominal wall hernias, the choice was made for nominative description: epigastric, umbilical, small, medium and large.

Classification table

In Table 2 the grid format for classification of primary abdominal wall hernias is proposed.

EHS PRIMARY ABDOMINAL WALL HERNIA CLASSIFICATION		Diameter cm	Small <2cm	Medium ≥2-4cm	Large ≥4cm
Midline	Epigastric				
	Umbilical				
Lateral	Spigelian				
	Lumbar				

Table 2

European Hernia Society classification for primary abdominal wall hernias

Classification of incisional abdominal wall hernias

Definition of incisional hernia

It was decided to use the definition proposed by Korenkov et al. [4]: "Any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging".

Choice of variables used to classify

The task of developing a good classification for incisional hernias is much more difficult than for groin hernias or for primary abdominal wall hernias because of their great diversity. On the other hand, because of this diversity a classification is highly desirable in this group of hernias. The question remains as to whether a simple classification can cover the complexities of the great diversity of incisional hernias and their different variables.

There was a consensus that the localisation of the hernia on the abdominal wall and the size of the hernia defect are essential for classifying. There was less agreement on the inclusion of the number of previous hernia repairs as a variable for classifying. Including more variables (Table 1) in the classification will make it more complex and less practical. Other variables and risk factors will be part of the above-mentioned registry, but for the present, will not be part of a simple classification.

Localisation of the hernia

The abdomen was divided into a medial or midline zone and a lateral zone.

Medial or midline hernias

The borders of the midline area are defined as:

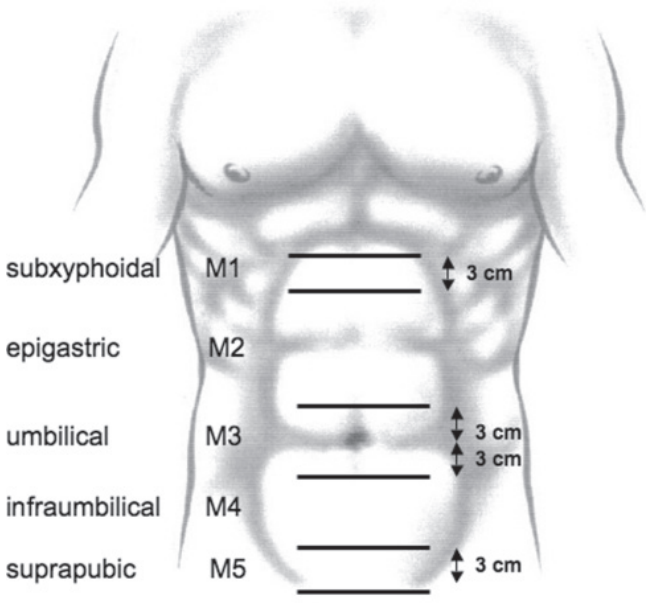
1. cranial: the xyphoid
2. caudal: the pubic bone
3. lateral: the lateral margin of the rectal sheath

Thus, all incisional hernias between the lateral margins of both rectus muscle sheaths are classified as midline hernias.

The Chevrel classification uses three midline zones [3]. Our group agreed that hernias close to bony structures have separate subgroups.
They pose specific therapeutic approaches and have an increased recurrence

risk. An easily memorable classification from M1 to M5 going from the xiphoid to pubic bone was proposed (Fig. 1). Therefore, we define 5 M zones:

1. M1: subxiphoidal (from the xiphoid till 3 cm caudally)
2. M2: epigastric (from 3 cm below the xiphoid till 3 cm above the umbilicus)
3. M3: umbilical (from 3 cm above till 3 cm below the umbilicus)
4. M4: infraumbilical (from 3 cm below the umbilicus till 3 cm above the pubis)
5. M5: suprapubic (from pubic bone till 3 cm cranially).



To classify midline incisional hernias between the two lateral margins of the rectus muscle sheaths, five zones were defined several questions arose from this classification:

1. How should hernias extending over more than one M zone be classified? No consensus was reached on this. One proposal was to allocate hernias to the M zone that is generally considered as the more difficult or more representative for the hernia. They are, in order of importance: first subxyphoidal (M1) and suprapubic (M5), then umbilical (M3) and finally epigastric (M2) and infraumbilical (M4). This would avoid making further subgroups (e.g. M1-2/M1-2-3/M2-3-4). So a hernia extending from M1 over M2 to M3 (thus from subxyphoidal to the umbilicus) would be classified as M1 (thus as a subxiphoidal hernia).

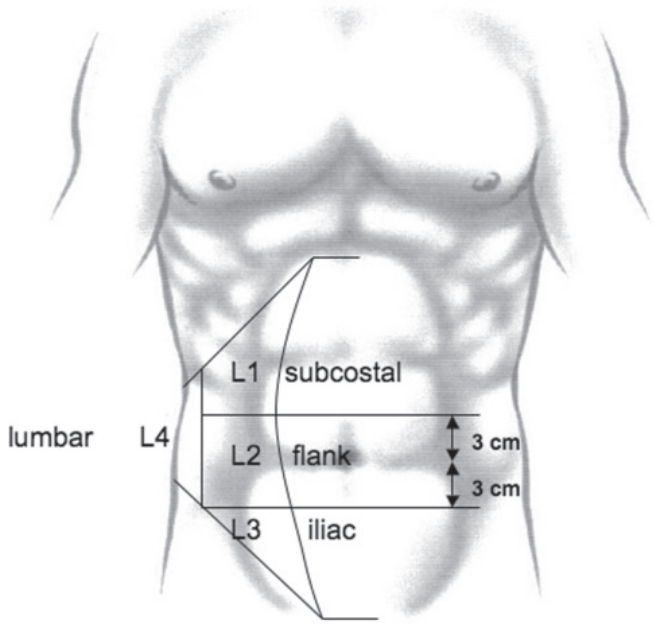
A hernia extending from M2 over M3 to M4 (thus from epigastric to infraumbilical) would be classified as M3 (thus as an umbilical hernia). No consensus was reached on this. It was decided to mark every zone in which the hernia was located when using the grid for incisional hernias.

2. How should incisional hernias with multiple defects be classified? Different hernia defects caused by one incision will be considered as one hernia. If the different defects were caused by two different incisions, they should be considered two different hernias.

Lateral hernias

The borders of the lateral area are defined as (Fig. 2).

1. cranial: the costal margin
2. caudal: the inguinal region
3. medially: the lateral margin of the rectal sheath
4. laterally: the lumbar region.



To classify lateral incisional hernias, four zones lateral of the rectus muscle sheaths were defined. Thus, four L zones on each side are defined as:

1. L1: subcostal (between the costal margin and a horizontal line 3 cm above the umbilicus)

2. L2: flank (lateral to the rectal sheath in the area 3 cm above and below the umbilicus)
3. L3: iliac (between a horizontal line 3 cm below the umbilicus and the inguinal region)
4. L4: lumbar (latero-dorsal of the anterior axillary line)

Taxomony

Once subgroups had been defined, it was important to give them a name. Some of the experts were in favour of using simple coded notations similar to the Chevrel classification: M1, M2, M3,… L1, L2…. W1, W2,…. Others preferred a descriptive name: umbilical, supraumbilical, subcostal,…. The advantage of a nominative description over a coded description is that it is more self-explanatory and comprehensible. No real consensus was reached over this topic, and a combination of coded and nominative descriptions is proposed.

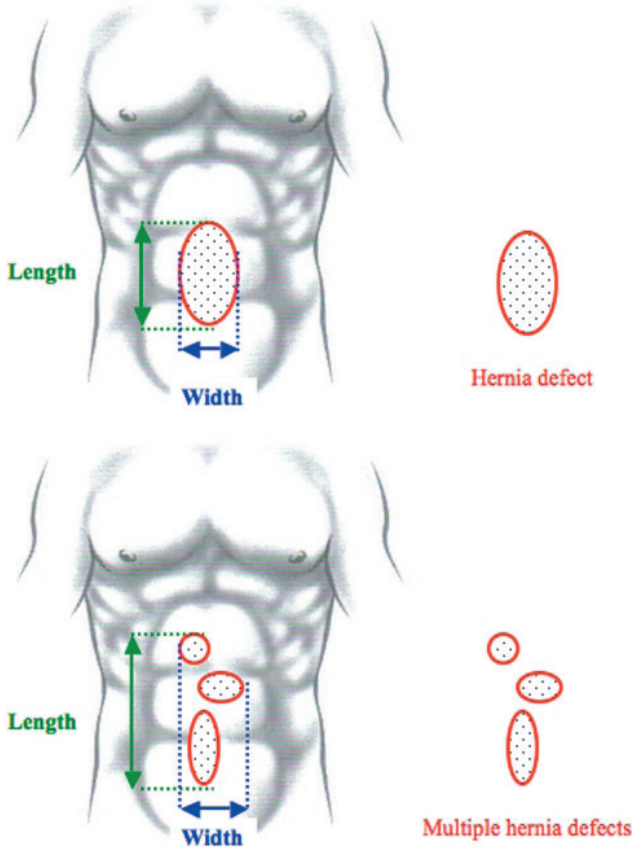
Much discussion took place concerning the best word to describe the area on the lateral side of the abdomen below the subcostal region and above the iliac region. It was agreed that the word "transverse" as used in the Chevrel classification was not satisfactory. Finally, it was agreed to call this area the "flank".

Size of the hernia

In contrast to primary abdominal wall hernias, incisional hernias come in many different sizes and shapes. So the size of an incisional hernia is not easily captured in only one variable or measurement. For classification in the two-dimensional grid format, it is essential to bring the variable "size of the hernia defect" in one quantitative or semi-quantitative measure. Chevrel solved this problem by choosing the width of the hernia defect as the one parameter to classify, stating that the width is the most important measurement of size to determine the difficulty of successfully repairing the hernia [3].

There was a consensus that the width of the hernia defect alone was insufficient to describe the hernia defect size adequately. We agreed that width and length should be used. This means that for a "grid format" both width and length have to be combined in one measurement.

The width of the hernia defect was defined as the greatest horizontal distance in cm between the lateral margins of the hernia defect on both sides. In case of multiple hernia defects, the width is measured between the most laterally located margins of the most lateral defect on that side (Fig. 3).



Definition of the width and the length of incisional hernias for single hernia defects and multiple hernia defects. The length of the hernia defect was defined as the greatest vertical distance in cm between the most cranial and the most caudal margin of the hernia defect. In case of multiple hernia defects from one incision, the length is between the cranial margin of the most cranial defect and the caudal margin of the most caudal defect (Fig. 3).

Hernia defect surface can be measured by combining width and length in a formula for an oval, thus trying to make an estimation of the real surface in cm^2.

This option was not withheld, because many incisional hernias are not oval shaped, and many hernias have multiple defects, making the correct estimation of hernia defect size difficult.

Because no consensus was reached on the variable "size of the hernia defect", it was not possible to make a "grid format" for an EHS classification for incisional abdominal wall hernias. Instead, the grid could be made for the localisation variable with space to note width and length correctly in cm. A semi-quantitative division, taking only the width as measurement for the size, was accepted to be included in the classification table. To avoid confusion with primary abdominal wall hernias (small, medium and large), a coded taxonomy was chosen (W1 < 4 cm; W2 ≥ 4–10 cm; W3 ≥ 10 cm) instead of a nominative one.

Previous hernia repairs

Several participants in the meeting considered that if an incisional hernia is a recurrence after previous repair of a hernia—either incisional or primary—then this variable should be included in the classification. The number of previous hernia repairs was not considered of enough importance to include in the table. A simple yes or no answer was chosen.

Classification table

E H S **INCISIONAL HERNIA CLASSIFICATION**			
MIDLINE	subxiphoidal	M1	
	epigastric	M2	
	umbilical	M3	
	infraumbilical	M4	
	suprapubic	M5	
LATERAL	subcostal	L1	
	flank	L2	
	iliac	L3	
	lumbar	L4	
RECURRENT INCISIONAL HERNIA?		Yes ❍ No ❍	
length:	cm	width:	cm
WIDTH CM	W1 < 4cm ❍	W2 ≥ ³4-10cm ❍	W3 ≥ ³10cm ❍

CONCLUSION

The goal of the consensus meeting, i.e. to make a definitive EHS classification of incisional hernias in a grid format, as has been done for inguinal hernias, was not realised. However, a classification for primary abdominal wall hernias and a division of subgroups of incisional abdominal wall hernias, concerning the localisation of the hernia, was formulated. Because no consensus was reached on a single size variable in incisional hernias, a simple classification grid was not possible.

Nevertheless, the participants in this meeting believe that, besides a more "scientific" registry (including risk factors, treatment and outcome data), a simple classification is urgently needed. This classification may provide enough information to establish incisional hernia registries and may be used to compare studies on treatment and outcome of incisional hernia repair. It has shortcomings, because of the large diversity and heterogeneity of incisional hernias, but it is a mandatory condition to improve the quality of reporting results in the field of incisional hernia surgery.

Therefore, we must use the momentum created by this first consensus meeting on classification of primary and incisional abdominal wall hernias. The current proposal should be tested and validated in our surgical practices. This will provide a basis for a new consensus meeting to try to define subgroups based on the size of the hernia defect.

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1.2 EURAHS: THE DEVELOPMENT OF AN INTERNATIONAL ONLINE PLATFORM FOR REGISTRATION AND OUTCOME MEASUREMENT OF VENTRAL ABDOMINAL WALL HERNIA REPAIR

Hernia, 2012, 16:239-250

F. Muysoms, G. Campanelli, G.G. Champault, A.C. DeBeaux, U.A. Dietz, J. Jeekel, U. Klinge, F. Köckerling, V. Mandala, A. Montgomery, S. Morales Conde, F. Puppe, R.K.J. Simmermacher, M. Śmietański, M. Miserez

"A complex hernia is a hernia in a specific patient that is considered by the evaluating surgeon to be at high risk for postoperative complications or recurrence."

ABSTRACT

Background

Although the repair of ventral abdominal wall hernias is one of the most commonly performed operations, many aspects of their treatment are still under debate or poorly studied. In addition, there is a lack of good definitions and classifications that make the evaluation of studies and meta-analyses in this field of surgery difficult.

Materials and methods

Under the auspices of the board of the European Hernia Society and following the previously published classifications on inguinal and on ventral hernias, a working group was formed to create an online platform for registration and outcome measurement of operations for ventral abdominal wall hernias. Development of such a registry involved reaching agreement about clear definitions and classifications on patient variables, surgical procedures and mesh materials used, as well as outcome parameters. The EuraHS working group (European registry for abdominal wall hernias) comprised of a multinational European expert panel with specific interest in abdominal wall hernias. Over five working group meetings, consensus was reached on definitions for the data to be recorded in the registry.

Results

A set of well-described definitions was made. The previously reported EHS classifications of hernias will be used. Risk factors for recurrences and co-morbidities of patients were listed. A new severity of comorbidity score was defined. Post-operative complications were classified according to existing classifications as described for other fields of surgery. A new 3-dimensional numerical quality-of-life score, EuraHS-QoL score, was defined. An online platform is created based on the definitions and classifications, which can be used by individual surgeons, surgical teams or for multicentre studies. A EuraHS website is constructed with easy access to all the definitions, classifications and results from the database.

Conclusion

An online platform for registration and outcome measurement of abdominal wall hernia repairs with clear definitions and classifications is offered to the surgical community. It is hoped that this registry could lead to better evidence-based guidelines for treatment of abdominal wall hernias based on hernia variables, patient variables, available hernia repair materials and techniques.

INTRODUCTION

Randomised clinical trials (RCT) remain the source of the best evidence. However, in a RCT, the randomised controlled variable is just one out of many. The long delay from surgery to the development of many complications such as recurrence and the impossibility to control all relevant parameters can hinder proof of the significant impact, in particular, when studying slight modifications of techniques or materials. For this reason, the alternative second choice is a registry. This allows the detection of poor and good results, if they appear more frequently than expected. National Scandinavian registries, like the Swedish Hernia Database and the Danish Hernia Database on hernia surgery, have demonstrated this [1–4]. Also multicentre databases like the Veterans Affairs Medical Centers database and the National Surgical Quality Improvement Program database have been able to detect poor outcome results in hernia surgery [5–7].

During the 4th International Hernia Congress in Berlin in 2009, a working group was formed under the auspices of the European Hernia Society board, with the task of developing a registry for operations on abdominal wall hernias. The project was named EuraHS (European Registry for Abdominal Wall HerniaS). The EuraHS working group was formed by the first author with a panel of surgeons from different European countries, who have a known interest in hernia surgery and research. Five working group meetings were organised to reach a consensus on a clear description of the scope of the registry and the data to be collected in the registry.[2]

The mission of the EuraHS working group is to provide an international online platform for registration and outcome measurement of hernia operations, which includes a set of definitions and classifications for use in clinical research on abdominal wall hernias.

2 At the initiative of the first author the EuraHS working group was formed during the board meeting of the European Hernia Society at the 4th International Hernia Congress in Berlin on September 10th 2009. The members of the EuraHS working group were either board members or others EHS members known for their interest in hernia classifications and registries. The board accepted the European internationally balanced composition of the working group. The working group members are the co-authors of this publication.

The EuraHS working group meetings were: Malmö, Sweden on November 28th 2009; Gdansk, Poland on February 6th 2010; Amsterdam, The Netherlands on September 4th 2010; Ghent, Belgium on May 13th 2011 and Gdansk, Poland on September 23rd 2011.

Materials and methods

A EuraHS logo is agreed upon and a website http:\\www.eurahs.eu is provided (Fig. 1). Access to the database will be through the website. The website will contain all the classifications and definitions as proposed by the EuraHS working group. Important papers and guidelines, as well as the reports from the database will be downloadable from the website. The IT platform for EuraHS is developed at the department of Artificial Intelligence and Applied Informatics, part of the Institute for Mathematics and Computer Science, at the University of Würzburg in Germany, under the supervision of Prof Dr Frank Puppe. From January 2012 till May 2012, a test phase on the performance of the EuraHS platform by the working group members is conducted. The EuraHS platform will be available for the surgical community as of 7 June 2012, when the platform will be launched during the EuraHS Launch Symposium.

Figure 1
Logo of EuraHS: European registry of abdominal wall hernias

A consensus model

The EuraHS working group decided on the variables to be included in the database. Existing classifications were used where possible, but many variables needed new descriptions, definitions and classifications. These were formed by consensus between the working group members from nine different European countries.

Scope of the database

The scope of the EuraHS registry will be primary ventral hernias, incisional ventral hernias and parastomal hernias in adult patients older than 18 years. Hernia operations and not patients will be registered. A patient who is operated a second will be recorded as a new case. An attempt will be made to convince existing

European hernia databases, to join the EuraHS and to collect their data on the same Internet platform.

The database will be used on a voluntary basis. A stratification of users will be offered. A *Level 1 user* will only have a small number of compulsory data fields to complete the registration of a case. These data will involve the variables needed for classification of the hernia, the surgical technique used and the materials used during the repair. Uploading a case should only take a few minutes. A *Level 2 user* will have the availability to complete a more comprehensive number of variables for surgeons with a specific interest in hernia surgery. This level is designed for surgeons or groups of surgeons who will collect the data set as complete as possible and who commit themselves to a follow-up of many years.

Ownership of the data

The surgeon uploading a case using his or her account will be the owner of the data. The user will be able to retrieve their data at any time in Excel files. Moreover, a standardised set of tables and figures with the users data will be available and downloadable.

Data can be shared in groups. A surgeon can decide to group their data with the data of other surgeons within the same hospital and therefore will be able to retrieve the overall data of the institution. Every user will be asked whether the institutional data can be shared amongst the members of the institution.

Multicentre groups can be formed. When uploading a case, a possibility will exist to upload this case into a multi-user group, with a specific name and password. The users can retrieve the specific data of the group. This will allow surgeons performing multicentre and even international trials to collect their data easily with a standardised set of data.

In every country where surgeons contribute cases to the EuraHS database, one or more national EuraHS representatives will be appointed. The national representatives will perform access control to the EuraHS. When making a new account, a user will need acknowledgement by a national representative to enter the database. The national representative will be able to extract the national overall data, anonymous for patients and surgeons.

The EuraHS working group will have access to all of the anonymous data held on the EuraHS database. This will allow an annual report to be published on the EuraHS website.

Acknowledgement of the EuraHS database as the source of the data has to be made every time it is used in public or in publications.

Quality of the data

The registry will not contain personal data like names or date of birth and will thus be completely anonymous. The link between the EuraHS registration number and the patients' identity will be the responsibility of the user. Tools with sets of data will be made available to track the patients' identity if the users lose the link between the EuraHS registration number and the patient identity.

The users of the database will be responsible for the quality of their data. All Level 1 data will be needed to complete a registration. The quality of the follow-up data will depend on the commitment of the users to perform the follow-up and upload the data. Tools will be made available to alert the users at specific follow-up time points if they choose to get these reminders.

Informatics and mathematics solutions for the database

The quality of EuraHS database and the dialogue[3] will have a huge impact on the success of our voluntary database. It is important that their quality equals the performance of other online applications we use in our daily life.

The technical requirements for the dialogue to input data in the database are complex, including a multilingual database, a compact layout and a fast reload time. To avoid too many simultaneous questions on the computer screen, the database will contain follow-up questions only showing when relevant (Fig. 2). The database will include image questions, where the answers are given by clicking on an area of the image. When needed "pop-up" boxes with key definitions of the variables will be available on demand. Some automatic computations like BMI from weight and height of the patient will be available. The materials used during surgery will be selected from alphabetic "drop-down" boxes.

3 A dialog box (or dialogue box) is a type of window used to enable reciprocal communication or "dialogue" between a computer and its user (Wikipedia).

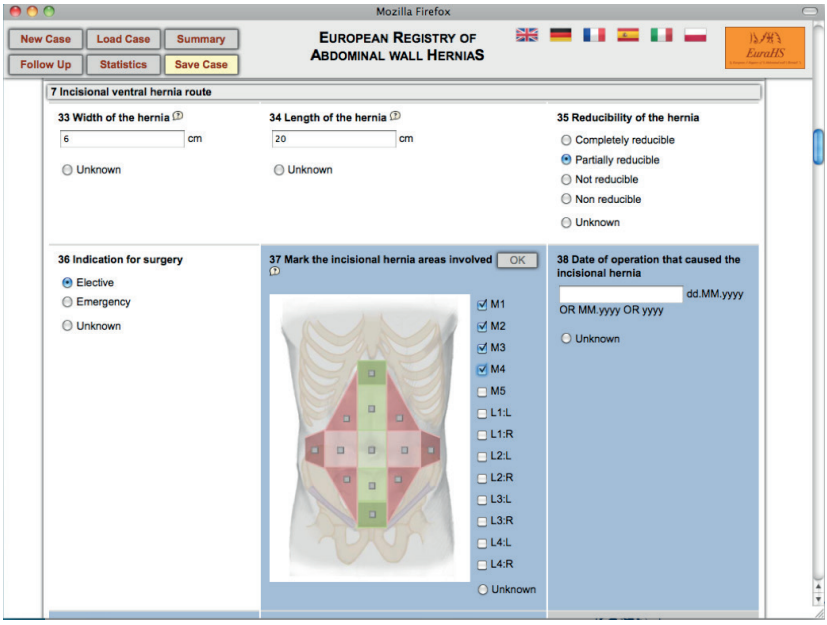

Figure 2

Screenshot of the dialogue for data input into the EuraHS database. A blue background of a question indicates that it has not been answered yet

The terminology of the database and the additional knowledge are entered with the semantic wiki KnowWe, from which the dialogue is generated with a dialogue prototyping tool allowing experimentation with different dialogue designs [8, 9].

The cases are stored in a database from which various statistical analyses can be started from the web interface (button "statistics"). The users will be able to extract their data in tables and in diagrams. The quality of this return data to the users will be the most important incentive for users to continue using the database.

Results

A comprehensive database on abdominal wall surgery can only be built if based on a clear set of definitions and classifications on the three *P-entities* involved in these operations: *Patient-Procedure-Prosthesis* (Fig. 3). The outcome of operations will depend on the interaction between these three entities and their different variables that all might have influence on the outcome. It is this large number of variables in each P-entity that can make evaluation of abdominal wall hernia repairs so difficult. Definitions and a clear nomenclature of the variables

are essential. Definitions and classifications on the outcome parameters were also needed to allow a coherent description of the results.

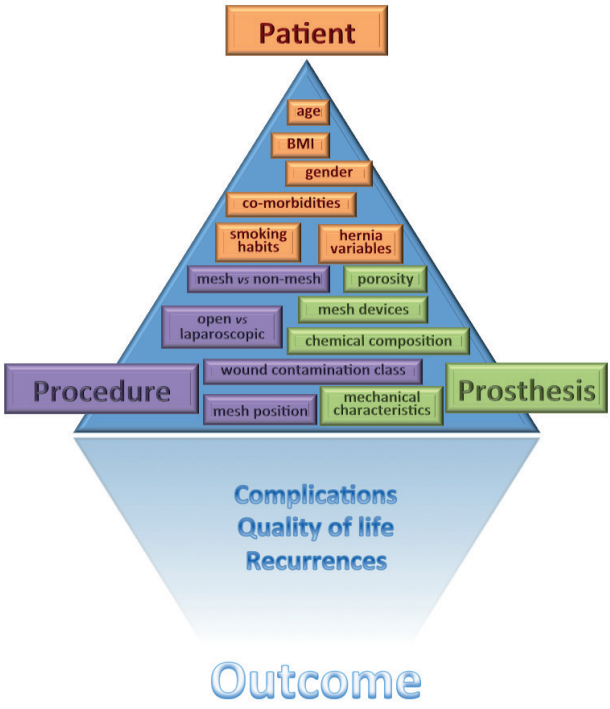

Figure 3
The triple-P triangle of abdominal wall hernia repair

Patient entity

One goal of the registry is to detect patient variables that are of importance for the outcome parameters: complications, recurrences and quality of life. Some patient variables are straightforward like age, gender, BMI. Other variables like the hernia characteristics and patient co-morbidities need specific definitions and classifications.

Definitions of abdominal wall hernias

Table 1 gives the EuraHS proposal of definitions for different ventral hernias. Inguinal hernias definitions have already been proposed in the EHS groin hernia classification and the EHS groin hernia guidelines [10, 11]. The proposed terminology being: medial inguinal, lateral inguinal and femoral hernias.

THE ABDOMINAL WALL	The *abdominal wall* is the musculo-fibrous covering of the abdomen containing the abdominal contents.
ABDOMINAL WALL HERNIA	An *abdominal wall hernia* is an abnormal protrusion of the contents of the abdominal cavity or of pre-peritoneal fat through a defect or weakness in the abdominal wall.
VENTRAL HERNIA	A *ventral hernia* is a hernia of the abdominal wall excluding the inguinal area, the pelvic area and the diaphragm.
PRIMARY VENTRAL HERNIA	A *primary ventral hernia* is a ventral hernia that was present at birth or that developed spontaneously without trauma to the abdominal wall as the cause of the hernia.
UMBILICAL HERNIA	A primary ventral hernia with its centre at the umbilicus.
EPIGASTRIC HERNIA	A primary ventral hernia close to the midline with its centre above the umbilicus.
SPIGHELIAN HERNIA	A primary ventral hernia in the area of the fascia Spigelian aponeurosis.
LUMBAR HERNIA	A primary ventral hernia in the lumbar area.
SECONDARY VENTRAL HERNIA	A secondary ventral hernia is a ventral hernia that developed after a traumatic breach of the integrity of the abdominal wall.
INCISIONAL VENTRAL HERNIA	A ventral hernia that developed after surgical trauma to the abdominal wall, including recurrences after repair of primary ventral hernias.
TRAUMATIC VENTRAL HERNIA	A ventral hernia that developed after non-surgical penetrating or blunt trauma to the abdominal wall.
ACUTE POSTOPERATIVE VENTRAL HERNIA	An incisional hernia resulting from an abdominal wall dehiscence, either complete (with skin dehiscence) or incomplete (covered with intact skin) within 30 days after the operation.
PARASTOMAL HERNIA	An incisional hernia through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma.

Table 1

EuraHS definitions of ventral abdominal wall hernias

Abdominal wall hernia classification

The previously described EHS classification of primary and incisional abdominal wall hernias will be used [12]. The user will indicate on a picture the abdominal wall areas that are involved (Fig. 4). The user of the registry will be asked to give the width and the length of the hernia according to the definition that will be shown in the dialogue with a "pop-up". An intra-operative measurement of width and length is preferred above preoperative measurement clinically or with medical imaging. The database will provide the hernia classification automatically.

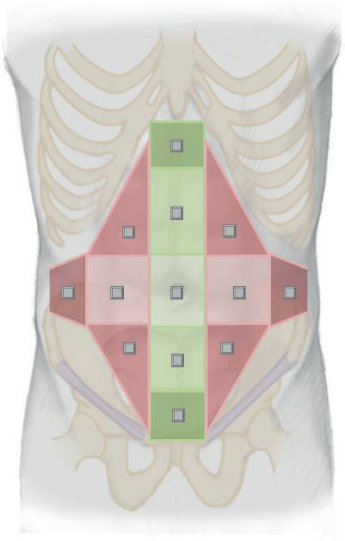

Figure 4

EuraHS ventral hernia model for registration and classification of abdominal wall hernias based on the localisation of the hernia

The SOC score: a severity classification of patient co-morbidities

Co-morbidity is generally considered to be an important risk factor for an unfavourable outcome. The American Society for Anaesthesiology Physical Status Classification System, better known as the ASA score, is widely used [13]. An increased ASA score correlates with an increased risk of operative morbidity and mortality. But ASA is not disease specific and will not allow the correlation of specific co-morbidities with an increased risk of unfavourable outcome in hernia operations. Therefore, the EuraHS database will include a novel severity classifi-

cation of co-morbidities. This classification was named *SOCscore or Severity Of Co-morbidity-score*, and the definitions are listed in Table 2. Validation of this SOC score will be one of the goals of the registry.

SEVERITY OF CO-MORBIDITY SCORE SOC-SCORE	
SOC-SCORE	**DEFINITION**
0	No co-morbidities
1	Asymptomatic, no medical consultation needed in last 12 months
2	Stable disease, intermittent therapy and medical consultation needed. ≤ 4x/year
3	Stable disease, continuous therapy with regular medical consultation. > 4x/year
4	Progressive disease, with changing or intensified therapy and frequent medical consultation. > 12x/year

Table 2

EuraHS SOC score: a severity of co-morbidity scoring

Smoking has been found in several studies to be an important risk factor for the development of incisional hernias or of recurrences after hernia repair [14, 15]. In addition, for this risk factor, a gradation is needed, taking into account the amount of tobacco used.

Procedure entity

Many different surgical options are available for the repair of abdominal wall hernias [16]. For most types of hernias, there is no widespread evidence-based consensus on the best treatment option. The type of surgical access, the use of mesh and the position of the mesh in relation to the abdominal wall will differ amongst these options.

Definitions of surgical techniques and mesh positions

The EuraHS database will capture the type of access to treat the hernia as open or laparoscopic surgery. In the laparoscopic group, there will be a subgroup for "conversions from laparoscopy to open surgery". The number of trocars used during laparoscopic surgery will be captured making it possible to identify the number of single-port operations. Operations will be registered as either mesh repair or non-mesh repairs.

There is very little coherence on terminology for mesh positions across the globe. "Sublay" is used for a retromuscular position but also for intraperitoneal or preperitoneal. "IPOM or intraperitoneal onlay mesh" is used frequently in Europe but not in the USA. "Inlay" is either a position of the mesh inside the defect or an intraperitoneal mesh. "Overlay" is used as terminology in the USA for a premuscular position, while in Europe we call this an "Onlay" repair. To end this confusion, the EuraHS working group proposes the terminology as defined in Table 3 and illustrated in Fig. 5 [17, 18]. The choices in the database will be limited to these 5 options. Sometimes more than one mesh is used during operations or sometimes a mesh is placed in different positions in a patient. For these cases, a separate box will be available as "combined positioning".

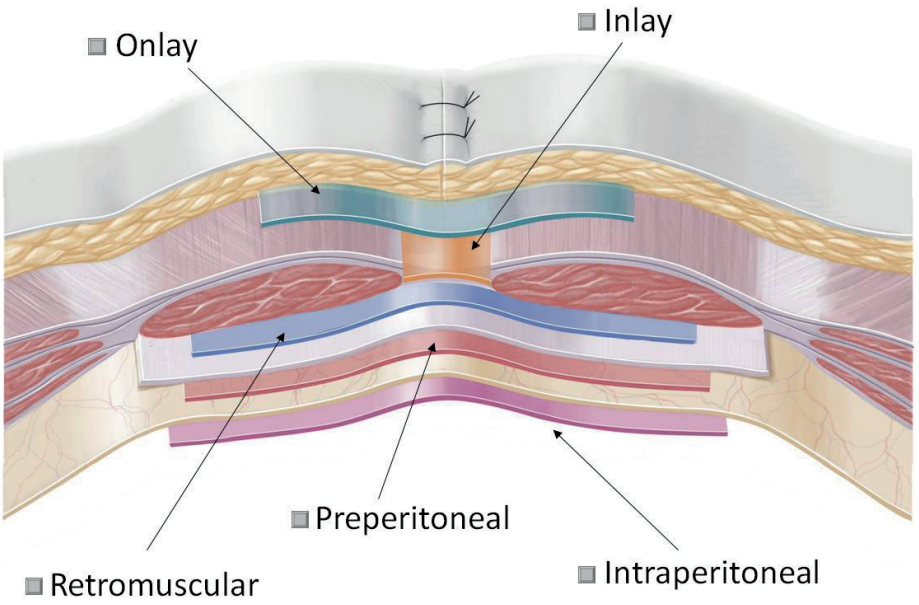

Figure 5

EuraHS terminology of mesh positions during ventral hernia repair

ONLAY	The onlay position if the mesh is positioned above the abdominal wall muscles and fascia, behind the subcutaneous fat.
INLAY	The inlay position if the mesh is positioned in the hernia defect, without overlap, and fixed to the margins of the defect
RETROMUSCULAR MEDIAL HERNIA	The retromuscular position for medial abdominal wall hernias if the mesh is positioned behind the rectus abdominis muscle and in front of the posterior rectus fascia or -caudal to the linea arcuata- in front of the peritoneum.
RETROMUSCULAR LATERAL HERNIA	The retromuscular position for lateral abdominal wall hernias if the mesh is placed in a plane between the lateral abdominal wall muscles.
PREPERITONEAL	The preperitoneal position if the mesh is placed in the plane behind all abdominal wall muscles in front of the peritoneum.
INTRAPERITONEAL	The intraperitoneal position if the mesh is placed behind all layers of the abdominal wall including the parietal peritoneum.

Table 3

EuraHS definitions of mesh position in ventral hernia repair

Surgical techniques can also be described considering the handling of the hernia defect during the operation. In a *mesh augmentation technique*, the anterior fascia of the hernia defect is closed. In a *mesh bridging technique*, the anterior fascia of the hernia defect is not completely closed.

Grading of intraoperative contamination

The degree of intraoperative contamination during the hernia repair is considered to be an important variable. The Centre for Disease Control (CDC) classification of wound contamination will be used [19]. This classification scheme has shown in numerous studies to predict wound infection rate. The CDC classification and some examples for abdominal wall hernia repair are given in Table 4.

CLASS OF OPERATION AND WOUND CONTAMINATION	CDC-DEFINITION	EXAMPLE FOR ABDOMINAL WALL HERNIA REPAIR
CLASS I: CLEAN	These are uninfected operative wounds in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered.	- Elective repair of a hernia.
CLASS II: CLEAN-CONTAMINATED	These are operative wounds in which the respiratory, alimentary, genital, or urinary tract is entered under controlled conditions and without unusual contamination.	- Bowel lesion during adhesiolysis, without gross spillage of bowel content. - Combined cholecystectomy and hernia repair. - Bowel resection for incarceration. - Presence of a colostomy.
CLASS III: CONTAMINATED	These include open, fresh, accidental wounds, operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered.	- Bowel lesion with gross spillage. - Enterocutaneous fistula.
CLASS IV: DIRTY	These include old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.	- Perforation of strangulated bowel. - Presence of infected mesh

Table 4

CDC (centre for disease control) classification of wound contamination and examples for surgery in abdominal wall hernia repair [19]

Prosthesis entity

Mesh repair is a Grade A recommendation for the treatment of inguinal hernias in adults given by the EHS guidelines [11]. There are no existing guidelines for incisional hernias, but the use of mesh is generally accepted for reinforcement of the abdominal wall during repair [20, 21]. The high number of hernia operations and thus the need for meshes has created a highly competitive market for

meshes. Innovations and research on new mesh materials and mesh designs have provided us with a variety of choices. Moreover, several innovative mesh fixation devices with different forms and components, sometimes absorbable, have been introduced on the market.

The EuraHS will use the new classification of meshes described by Klinge et al. to group the meshes for use in the analysis of the data from the registry [22]. The EuraHS database will register the meshes, fixation devices, sutures and glues used during the operation with the product name. We cannot expect the surgeons to describe the chemical features of the product (polypropylene, polyester, ePTFE, PVDF, composite meshes, etc.) or the physical features of the product (weight, porosity, etc.). The development of the EuraHS platform will thus necessitate the construction of a comprehensive list of all the available mesh products, fixation devices, glues and sutures on the European Market. This listing will be available for all at the EuraHS website and a continuous updating of the list will be needed.

Assessment of outcome: complications and recurrences

Complications can be defined according to the time of their occurrence in relation to the operation. Intra-operative complications, early post-operative complications, operative mortality, operative morbidity and late complications are defined in Table 5.

INTRA-OPERATIVE COMPLICATIONS	Are complications occurring during the time of the patients' arrival in the operating room and the patient leaving the operating room
"ACUTE" OR "EARLY" POSTOPERATIVE COMPLICATIONS	Are complications occurring during the hospitalisation or within 30 days postoperatively
LATE POSTOPERATIVE COMPLICATIONS	Are complications related to the hernia repair occurring after discharge and more than 30 days postoperatively
OPERATIVE MORBIDITY	The percentage of patients treated who had at least one complication occurring during the operation, during the hospitalisation or 30 days postoperatively
OPERATIVE MORTALITY	The percentage of patients treated who died during the operation, during the hospitalisation or within 30 days postoperatively

Table 5

EuraHS definitions of complications, morbidity and mortality

Classification of early post-operative complications

Early post-operative complications are defined as complications occurring within 30 days postoperatively or before discharge (if longer than 30 days). The EuraHS database will use the Clavien-Dindo classification for grading the severity of post-operative complications as shown in Table 6 [23]. We have made a slight modification of the Clavien-Dindo classification by qualifying a puncture of a seroma as grade I, rather than it being a grade IIIa complication. When registering complications in the EuraHS database, this classification will be completed by responding to queries that will automatically be linked to a grade of complication. In patients with multiple complications, the patient will be graded with the complication having the highest grade.

Grade 0
No complications

Grade I
Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions (are allowed: antiemetica, antipyretica, analgetics, diuretics, electrolytes and physiotherapy. This grade includes wound infections opened at the bedside *and a seroma requiring aspiration bedside*.)

Grade II
Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusion and TPN are included.

Grade III
Requiring surgical, endoscopic and radiological interventions
IIIa intervention not under general anesthesia
IIIb intervention under general anaesthesia

Grade IV
Life threatening complication requiring IC/ICU management
IVa single organ dysfunction
IVb multiorgan dysfunction

Grade V
Death of the patient

Table 6
Clavien-Dindo classification and grading of post-operative complications [23]

Late post-operative complications and recurrences

Late post-operative complications are defined as complications related to the hernia repair occurring after discharge of the patient and more than 30 days post-operatively. A recurrent abdominal wall hernia is a late negative event and is reported as a separate outcome measurement. We defined a hernia recurrence as follows: *A protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the abdominal wall at the site of a previous repair of an abdominal wall hernia.* In the EuraHS database, users will be asked to postulate the cause for the recurrence. More than one cause can be chosen.

Post-operative seroma is a frequent event after repair of abdominal wall hernias. Some surgeons even consider it to be present in nearly every case. It usually resorbs and is often considered to be part of the normal post-operative course. Morales et al. have proposed a classification for post-operative seroma after laparoscopic surgery [24]. We will use it in the EuraHS database for open and laparoscopic operations. This classification can be found in Table 7 and is based on clinical findings and the presence of seroma-related complications.

TYPE OF SEROMA	DEFINITION	CLINICAL SIGNIFICANCE
0	No clinical seroma	NO CLINICAL SEROMA
I	Clinical seroma lasting < 1 month	INCIDENT
II	Clinical seroma lasting > 1 month	
III	Symptomatic seroma that may need medical treatment: minor seroma-related complications	COMPLICATION
IV	Seroma that need to be treated: major seroma-related complications	

- ***Clinical seroma:*** those seromas detected during physical examination of patients which do not cause any problem, or just a minimum discomfort that allows normal activity.
- ***Minor complication:*** Important discomfort which does not allow normal activity to the patient, pain, superfitial infection with cellulitis, esthetic complaints of the patient due to seroma or seroma lasting more than 6 months.
- ***Major complication:*** Infection, recurrence, mesh rejection or need to be punctured.

Table 7

Classification of post-operative seroma after ventral hernia repair according to Salvador Morales et al. [24]

Another difficult issue is the *post-operative bulging* or so called pseudo-recurrence [25, 26]. If a surgical correction of the bulging is performed for cosmetic or symptomatic reasons, it will be considered a late complication.

Chronic post-operative pain is defined as pain present more than 3 months after surgery [27]. A verbal rating scale and classification of chronic pain has been published previously by Cunningham et al. and will be used in the EuraHS database [28]. Four grades are defined as follows: no pain, mild pain, moderate pain and severe pain (Table 8).

PAIN CLASS	DEFINITION
NO PAIN	no discomfort experienced
MILD PAIN	was defined to the patient as an occasional pain or discomfort that did not limit activity, with a return to prehernia lifestyle
MODERATE PAIN	was defined as pain preventing return to normal preoperative activities (i.e. inability to continue with prehernia activities such as golf, tennis and other sports, and inability to lift objects, without pain, that patient had been lifting before the hernia occurrence)
SEVERE PAIN	pain that incapacitated the patient at frequent intervals or interfered with activities of daily living (i.e. pain constantly present or intermittently present but so severe as to impair normal activities, such as walking.)

Table 8

Classification of chronic post-operative pain persisting 3 months after surgery according to Cunnigham et al. [28]

Assessment of outcome: quality-of-life assessment

Several quality-of-life scores (QOL) have been used after surgery. Short Form 36 (SF 36) is a validated QOL assessment tool for surgery in general, but for QOL evaluation after hernia repair and specifically after mesh implantation, it has not been so useful [6, 29]. A QOL score specifically targeting patients that had an abdominal wall hernia repair with a mesh has been developed by Heniford et al. at the Carolina Hernia Centre in Charlotte, NC, USA [30]. This Quality-of-Life scale is commonly referred to as the *Carolina Comfort Scale* (*CCS*). The CCS holds a

trademark, and thus, use of the CCS requires a licence agreement. Therefore, it cannot be integrated in our open access and free-for-all online platform.

The EuraHS working group proposed a "EuraHS-QoL" score for evaluation of QOL before and after ventral hernia repair and this is shown in Fig. 6. The score can be used for mesh and non-mesh repairs and is based on a Numerical Rating Scale for three dimensions: pain at the site of the hernia or the hernia repair, restriction of activities and cosmetic discomfort. The EuraHS-QoL adds some interesting features compared with other QOL scores, in particular, assessment made pre- and postoperatively and by including a cosmetic dimension which is an important but understudied element in ventral hernia repair. Validation of the EuraHS-QoL score will be part of the research by the EuraHS working group following the launch of the platform.

EuraHS-QoL Preoperative

Pain at the site of the hernia												
	0 = no pain										10 = worst pain imaginable	
In rest (lying down)	0	1	2	3	4	5	6	7	8	9	10	
During activities (walking, biking, sports)	0	1	2	3	4	5	6	7	8	9	10	
Worst pain felt during the last week	0	1	2	3	4	5	6	7	8	9	10	
Restrictions of activities because of pain or discomfort at the site of the hernia												
	0 = no restriction										10 = completely restricted	
Daily activities (inside the house)	0	1	2	3	4	5	6	7	8	9	10	X
Outside the house (walking, biking,driving)	0	1	2	3	4	5	6	7	8	9	10	X
During sports	0	1	2	3	4	5	6	7	8	9	10	X
During heavy labour	0	1	2	3	4	5	6	7	8	9	10	X
	X = If you do not perform this activity											
Cosmetic discomfort												
	0 = very beautiful										10 = extremely ugly	
The shape of your abdomen	0	1	2	3	4	5	6	7	8	9	10	
The site of the hernia	0	1	2	3	4	5	6	7	8	9	10	

EuraHS-QoL Postoperative

Pain at the site of the hernia repair												
	0 = no pain										10 = worst pain imaginable	
In rest (lying down)	0	1	2	3	4	5	6	7	8	9	10	
During activities (walking, biking, sports)	0	1	2	3	4	5	6	7	8	9	10	
Worst pain felt during the last week	0	1	2	3	4	5	6	7	8	9	10	
Restrictions of activities because of pain or discomfort at the site of the hernia repair												
	0 = no restriction										10 = completely restricted	
Daily activities (inside the house)	0	1	2	3	4	5	6	7	8	9	10	X
Outside the house (walking, biking,driving)	0	1	2	3	4	5	6	7	8	9	10	X
During sports	0	1	2	3	4	5	6	7	8	9	10	X
During heavy labour	0	1	2	3	4	5	6	7	8	9	10	X
	X = If you do not perform this activity											
Cosmetic discomfort												
	0 = very beautiful										10 = extremely ugly	
The shape of your abdomen	0	1	2	3	4	5	6	7	8	9	10	
The site of the hernia and the scars	0	1	2	3	4	5	6	7	8	9	10	

Figure 6

EuraHS quality-of-life score for pre- and post-operative assessment of patients with ventral abdominal wall hernias: EuraHS-QoL

DISCUSSION

The European Hernia Society was founded in 1979 as the Grepa (Groupe pour la recherche sur la paroi abdominal) and took its current name in 1998. The aim of the society is as follows: *The promotion of abdominal wall surgery, the study of anatomic, physiologic and therapeutic problems related to the pathology of the abdominal wall, the creation of associated groups which will promote research and teaching in this field, and the development of interdisciplinary relations* [31].

A classification and guidelines for groyne hernia were developed and published [10, 11]. For primary and incisional ventral hernias, a classification was proposed [12]. The level of evidence currently available makes it impossible to provide guidelines and EBM recommendations of level A on most of the topics concerning ventral hernia repair. The EuraHS working group was created to provide for the surgical community an online database to collect the data and the outcome of their patients.

The concept and the approach to the development of the EuraHS database is guided by "the four rules of the New Normal" as described by Peter Hinssen is his book on how to have success in a digitalised world [32]. The EuraHS database has to be up-to-date and in line with what is available in other IT services in our life. The database should be easy to use and quick. Although one of the main goals of the EuraHS is to allow individual surgeons to collect their data in a standardised manner, it will be the user who will decide how detailed their contribution to the database will be. The incentive for the surgeon to contribute to the EuraHS database will be the quality of the database and the direct access to their own data. One or several of the users at their own initiative can form research groups. They will be able to extract their data and use it for presentations and publications. It will be a dynamic process. It is hoped that this platform and database will lower the threshold for the individuals to perform prospective studies.

Post-operative complications are an important outcome parameter to be recorded, but it is difficult to compare the results from different studies in the literature because they usually lack a description of the severity of the complications. Dindo et al. have written extensively on the grading of post-operative complications [23]. This is usually referred to as the "Clavien-Dindo classification" and is used in many other fields of surgery to grade the severity of a complication rather than only stating a percentage of patients that had a complication. Kaafarani et al. validated this classification for ventral hernia repair [33]. In a follow-up paper by Dindo et al., they reported on the difficulty of registration of post-operative

complications [34]. The surgical residents, compared to the registration by a specially trained study nurse, did not record around 80 % of post-operative negative events. Indeed the Grade I—*any deviation from the normal post-operative course*—is depending of what the observer considers a normal post-operative course. Therefore, Grade I and Grade II will be underestimated, whereas Grade III–V will be more accurate. Considering this, data on post-operative complications gathered retrospectively will be very unreliable. For prospective studies, it is essential to describe what is considered *the normal post-operative course* for the operation studied if Grade I complications are to be registered accurately.

Chronic pain and quality of life are important outcome variables for ventral hernia repair. With the EuraHS-QoL score, we propose an evaluation for 3 dimensions. We evaluate pain, restriction of activities and the cosmetic outcome with a numerical rating scale. Loos et al. have found a verbal/numerical rating scale to be more efficient and have a lower failure rate than a visual analogue scale [35]. The EuraHS-QoL score can be used pre- and postoperatively, which will allow investigating the impact of our treatment on the patients' quality of life. The cosmetic result of ventral hernia repair is an outcome parameter that is missing at this moment in our research, although we think it is important when evaluating different surgical approaches.

In the rapidly growing market of medical devices for abdominal wall surgery, the surgeon has the difficult choice of what product to use in what patient. The innovations are providing us with a plethora of choices. There is no time to acquire high-quality data on all these new medical devices. Many products are on the market with little data on their safety and efficacy [36]. There is need for quality control on the implants we use during abdominal wall surgery. Medical devices need a CE mark to be used in the European Union member countries [37]. A CE mark does not guarantee that the medical device has shown to perform safely and efficiently in humans. *A CE certificate is not a quality mark of the devices' function, but of the quality of their manufacturing!* A system of post-market surveillance is mandatory in the interest of our patients. The European Union is currently also very much involved in these questions of post-market surveillance as was discussed during a "High Level Health Conference" in Brussels on 22 March 2011 [38]. The Council of the European Union adopted on 6 June 2011 in Luxembourg, conclusions on innovation in the medical device sector which are very much in line with our EuraHS project. Our platform will be a good instrument to acquire data concerning post-marketing surveillance.

In conclusion, we express our hope that the EuraHS database will increase the quality and the quantity of outcome reports in repair of ventral hernias. As of 7 June 2012, the platform will be online and will be presented to the surgical community during a EuraHS Launch Symposium in Brussels.

CONFLICT OF INTEREST

The authors report no conflict of interest with this publication. A non-profit-organisation under Belgian law, called "EuraHS VZW", was founded on 25 November 2011 in Brussels. They will be in charge of the platform and the fundraising to sustain the project on the longer term. The bylaws of "EuraHS VZW" are downloadable from the website www.eurahs.eu.

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1.3 RECOMMENDATIONS FOR REPORTING OUTCOME RESULTS IN ABDOMINAL WALL REPAIR

Results of a Consensus meeting in Palermo, Italy, 28-30 June 2012

Hernia, 2013, 17:423-433

F.E. Muysoms, E.B. Deerenberg, E. Peeters, F. Agresta, F. Berrevoet, G. Campanelli, W. Ceelen, G.G. Champault, F. Corcione, D. Cuccurullo, A.C. DeBeaux, U.A. Dietz, R. Fitzgibbons, J.F. Gillion, R-D. Hilgers, J. Jeekel, F. Köckerling, I. Kyle-Leinhase, V. Mandala, A. Montgomery, S. Morales-Conde, R. Simmermacher, V. Schumpelick, M. Śmietański, M. Walgenbach, M. Miserez

"Boredom must not be overlooked as a source of contemplation and reverie."

@ "Report from the interior" by Paul Auster, 2013

ABSTRACT

Background

The literature dealing with abdominal wall surgery is often flawed due to lack of adherence to accepted reporting standards and statistical methodology.

Materials and methods

The EuraHS Working Group (European Registry of Abdominal Wall Hernias) organised a consensus meeting of surgical experts and researchers with an interest in abdominal wall surgery, including a statistician, the editors of the journal Hernia and scientists experienced in meta-analysis. Detailed discussions took place to identify the basic ground rules necessary to improve the quality of research reports related to abdominal wall reconstruction.

Results

A list of recommendations was formulated including more general issues on the scientific methodology and statistical approach. Standards and statements are available, each depending on the type of study that is being reported: the CONSORT statement for the Randomised Controlled Trials, the TREND statement for non randomised interventional studies, the STROBE statement for observational studies, the STARLITE statement for literature searches, the MOOSE statement for metaanalyses of observational studies and the PRISMA statement for systematic reviews and meta-analyses. A number of recommendations were made, including the use of previously published standard definitions and classifications relating to hernia variables and treatment; the use of the validated Clavien-Dindo classification to report complications in hernia surgery; the use of "time-to-event analysis" to report data on "freedom-of-recurrence" rather than the use of recurrence rates, because it is more sensitive and accounts for the patients that are lost to follow-up compared with other reporting methods.

Conclusion

A set of recommendations for reporting outcome results of abdominal wall surgery was formulated as guidance for researchers. It is anticipated that the use of these recommendations will increase the quality and meaning of abdominal wall surgery research.

INTRODUCTION

The EuraHS (European Registry for Abdominal Wall HerniaS) working group was formed under the auspices of the European Hernia Society (EHS) board in 2009. An online platform for registration and outcome measurement of operations for ventral abdominal wall hernias has been developed. For this, a set of definitions and classifications were proposed [1]. The EuraHS working group organised a consensus meeting to prepare recommendations relating to the reporting of outcome results in abdominal wall hernia repair.[4]

Materials and methods

The scientific methodology of clinical studies including systematic reviews and meta-analyses were discussed with researchers and a statistician invited to the consensus meeting. Recommendations relating to study methodology, description of the patient population and statistical approach were proposed to research on abdominal wall surgery.[5] Specific recommendations on abdominal wall surgery for describing hernia variables, treatment variables and for reporting the outcome results in a uniform manner were formulated by consensus.

RESULTS

DESCRIPTION OF STUDY METHODOLOGY

A study describes a sample or cohort of patients. It is of utmost importance to know how the study population was decided upon, how the study was conducted, what was the primary aim or endpoint of the study and how was the endpoint analysed. This knowledge is essential to know whether the results of this study can be extrapolated and generalised to the larger group of patients with the disease treated, so that the study result might influence the treatment of future patients. Knowledge of the sample procedures used to determine the study population from the screened patients allows the readers to identify potential sources of bias and thus assess the external validity of the study results. In the

4 At the initiative of the first author, Filip Muysoms, current chairman of the EuraHS working group, and of Vincenzo Mandala, current president of the European Hernia Society, a consensus meeting was organised in Palermo, Italy, from June 28th till June 30th 2012. The participants to this consensus discussion and meeting were the EuraHS Working Group members and some other experts, editors and a statistician. The participants to the consensus discussions are the authors of this manuscript.

5 For taxonomy of the statistical items two basic textbooks on medical statistics were used as references: Everitt, Palmer [2] and Hulley et al. [3].

footnotes some exemplary hernia-related different types of studies are given for additional reading.

Study types

All reported studies should have a clear description of the study type, which should be mentioned in the title and/or the abstract of the manuscript. There is a fundamental distinction between observational studies or interventional studies (Fig. 1). An outcome variable(s) (aka dependent variable) will be studied in relation to one or more predictor variables (aka independent variables; aka risk factors) in an *observational study.* Analysis will focus on the association of the predictor(s) with the outcome(s) over a defined time period. A cohort study is a type of observational study in which a group (cohort) is defined, e.g. all patients undergoing a particular operation or having a certain type of hernia.[6] Most publications on ventral abdominal wall repair are classified as *non-comparative cohort studies* because there is no control group in the study. Rather the results are discussed in relation to other studies published on similar patient populations. In a *comparative cohort study or case–control study* at least two different populations are compared within the study.[7] *A registry* is a type of cohort study that has a specific purpose, defined in advance. The data entered are carefully crafted to answer important questions about the condition or symptom being studied. Results from registry studies are often very informative because such care is taken to assure consistent data definition, consistent data entry and the enrolment of a large number of patients in relationship to the total affected population.[8] A *cross-sectional study* is an observational study, which by definition is not longitudinal because subjects are studied at a single point in time. An example would be a study investigating the impact of the patients' BMI on the prevalence of incisional hernias in a population of patients with previous laparotomies.
In an *interventional study* the result of an intervention on a specific outcome variable is examined. The patient samples compared in the study should ideally only differ in the predictor variable that is influenced by the intervention. Other variables, called confounders, should be equally distributed between the study groups. Randomization for the predictor variable in a *randomized controlled trial* (RCT) is the best method to ensure "equality" of the study groups provided the study population is large enough.[9] For this reason RCTs are assigned a high

6 Example of a hernia related cohort study: Dietz et al. [4].

7 Example of a hernia related comparative cohort study: Kurian et al. [5].

8 Example of results from a hernia related registry: Helgstrand et al. [6].

9 Example of a hernia related randomized controlled trial: Bloemen et al. [7].

level of evidence because if the randomisation is performed adequately they have the smallest risk of bias between the study populations. In a *comparative non-randomized clinical trial,* it is less clear why a specific patient receives the intervention or not.[10]

In a *systematic review,* a comprehensive literature research is performed on a specific topic and a qualitative critical appraisal of the individual studies is performed. Only data from studies that are considered of sufficient methodological quality are summarised.[11] In a *meta-analysis* the quantitative data of the individual studies are pooled and statistically analysed.[12] A meta-analysis of RCTs is considered the highest level of evidence and thus allows for the highest grade of recommendation.

A *case report* or case series describes an observation or a treatment, which is considered by the authors as rare or novel and thus worthy of publishing in a manuscript.

As shown in Fig. 1, guidelines are available on the web for specific types of studies which provide step-by-step instructions including a check list for authors to assure correct conduct and reporting of their work [11–16]. The Cochrane Collaboration at http://www.cochrane.org summarises the websites. Many journals only accept manuscripts that conform to these guidelines and require their reviewers and editors to use them when assessing the quality of submissions. Critical appraisal sheets to assess the quality of a study report can be found on the website of the Centre for Evidence Based Medicine from Oxford [17].

10 Example of a prospective non-randomized clinical trial: Feliu et al. [8].

11 Example of a hernia related systematic review: Hansson et al. [9].

12 Example of a hernia related meta-analysis: Aslani et al. [10].

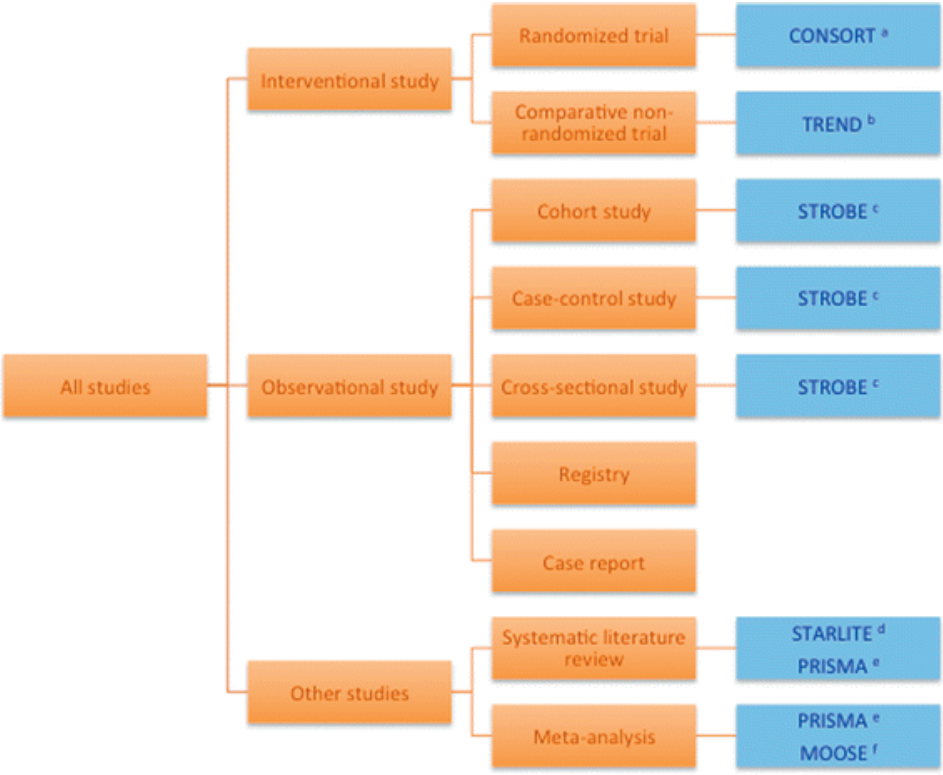

***Figure* 1**

Types of clinical studies: it is recommended to include the type of study clearly in the title and/or the abstract of a manuscript. Reporting guidelines (column 4) are available on the web to help authors in preparing manuscripts for publication.

a CONSORT statement: Consolidated standards of reporting trials. http://www.consort-statement.org [11],

b TREND statement: Transparent Reporting of Evaluations with Non-randomized Designs. http://www.cdc.gov/trendstatement/ [12],

c STROBE statement: Strengthening the reporting of observational studies in epidemiology. http://www.strobe-statement.org [13],

d STARLITE statement: Standards for reporting literature searches [14],

e PRISMA statement: Preferred reporting items for systematic reviews and meta-analyses. http://www.prisma-statement.org [15],

f MOOSE statement: Meta-analysis of Observational Studies in Epidemiology [16]

Prospective versus retrospective studies

In a *prospective study,* a cohort of patients is observed for a period of time to look at outcome, e.g. complications, and then relate this to the predictor variables, e.g. type of surgical technique. Interventional studies are prospective studies focused on the outcome of a specific intervention that is controlled but different in the study groups that are compared. A study qualifies as prospective if the outcome measurement of the primary endpoint is decided before the start of the study, and the endpoint measurements are performed in the future after the start of the study. Prospective studies are methodologically superior to retrospective studies because the measurements can be controlled and standardised. Moreover, the data gathered are usually more homogeneous and complete.
In a *retrospective study* the investigator looks backwards in time and examines exposure to possible risk or protective factors in relation to an outcome that is established before the start of the study. Thus the study looks at measurements made before the study was started and, therefore, the data will be less controlled and less homogeneous.

The research question and the primary endpoint

The manuscript of an interventional study should clearly state the research question and/or aim of the study. This research question is translated into a *scientific hypothesis* that will be the basis for the study design and the number of patients required to answer the research question. A clinically relevant primary endpoint will be chosen for which the hypothesis is formulated. The *primary endpoint or primary variable* of a study is the outcome parameter to be measured and compared, either to the control group in a comparative study or to results from the literature in non-comparative studies. For abdominal wall repair, the primary endpoint is most often hernia recurrence, but many other outcome parameters are possible to formulate the hypothesis: acute or chronic pain, Quality of Life, complications, reoperation rates, wound infections, mesh infections, etc. A *superiority study* investigates if the intervention is superior in comparison with the control group. The results of the study will be compared with the *null hypothesis* (*H*0), that there is no difference between the groups in the primary endpoint measurement. The analysis has to be performed on Intention-to-treat (ITT) basis. In ITT analysis, patient outcome is analysed according to the allocated treatment by randomization, regardless whether the patient actually received the treatment

or not [18].[13] In some specific clinical situations, an equivalence or non-inferiority design is preferred. An *equivalence study* investigates whether a new treatment is equivalent to the control with respect to a predefined indifference. The analysis will be performed on the Per Protocol Population (PP), i.e. the patients who adhered strictly to the protocol and actually received the intervention called for by the protocol. These different types of analysis aid investigators in determining if a new treatment or device is better or as good as, but cheaper than what is now available. Like most clinical studies, the use of a biomedical statistician at both the study design and study analysis stage is recommended.

The sample size

When designing a clinical trial it is important to estimate the number of patients needed to answer the research question. Performing a clinical trial is time consuming and expensive. It is also ethically mandatory to keep the number of patients that allow for valid study results as small as possible. Therefore, it is important to estimate the number of patients that should be included in the study at the onset to answer the clinical question and the scientific hypothesis the study is exploring. If the sample size is too small the study might not be able to reject the *H*0. In other words the study sample is too small to show a difference in the primary outcome, although in reality there is a difference (false negative; type II error). On the other hand if the sample size is too large, scares resources will be a spent unnecessarily. To calculate the sample size needed, there has to be agreement on several elements. First, the hypothesis type has to be clear: superiority, equivalence or non-inferiority. The expected mean value of the primary outcome parameter in the two groups and the difference in outcome considered clinically important have to be estimated, based on preliminary findings or results from similar studies in the literature. The significance level, i.e. the *a* or Type I error we accept (usually 5 %) and the statistical power (usually 80 % = 1 − *ß*, where *ß* denotes the Type II error level) have to be defined. These assumptions will provide the number of patients in each group needed to evaluate the primary endpoint. All studies have "dropouts" because the patients are lost to follow-up, die, or are not willing to continue participation. Therefore, the number of patients to enter in the study should be increased in line with the number of "dropout" patients anticipated, often 10–20 %.

13 According to the International Conference on Harmonisation (ICH) guidelines of Good Clinical Practice (GCP) a statistical test decision of a study should be conservative [18]. This is the rationale to use the ITT population for superiority studies and the PP population for equivalence studies. For non-inferiority trials the correspondence between ITT and PP should be used or a hybrid population.

Interim analysis

Prior to the onset of the study, the protocol of the study should state if an interim analysis will be conducted and the statistical rules should be given. An interim analysis is usually done for safety reasons. Therefore, an analysis of the patients "as treated" is the best approach. There are different interim analysis procedures and the procedure should be chosen carefully and described in the study protocol.
During an interim analysis the progress of the study inclusions, the occurrence of serious adverse events and the quality of the raw data can also be evaluated. A decision can be made to prolong the inclusion time to increase the sample size or to stop the trial prematurely. Ideally, an independent data monitoring committee (IDMC) takes such a decision.
An example is the study by Itani et al. [19] on ventral hernia repair comparing laparoscopic with conventional surgery. The infection rate was so much higher in the conventional group that the data safety monitoring board insisted the trial be stopped.

DESCRIPTION OF PATIENT POPULATION

The ultimate goal of a study is to generalise the findings in the study to the larger population of which the study population is a sample. To assess the external validity of a study, the exact method of determining the study sample or study cohort has to be clear.

Mono-centre versus multi-centre studies

There are advantages and disadvantages for both study strategies. *Mono-centre* interventional studies have a greater chance of having two comparable groups by excluding the variations in the confounding variables that arise from including patients treated in different centres. *Multi-centre* studies have a greater chance of correct inference and generalisation of the study results to the larger population in the community. But multi-centre studies are logistically more difficult to perform. Moreover, the homogeneity and the quality of the raw data are often inferior in the participating centres compared with the centre of the primary investigator. On the other hand, including patients from several centres will create a larger group of eligible patients and thus a higher likelihood of achieving the sample size in a shorter time period. For some less common conditions, a multi-centre approach is prerequisite to enrol a large enough cohort of patients. It is essential that the authors report variations in expertise related to the surgical technique under investigation.

Inclusion criteria, exclusion criteria and eligibility

To minimise selection bias all consecutive eligible patients during the study period should be considered for inclusion. The reasons for non-inclusion in the trial and the number of these should be monitored and reported. To know which patients are eligible a clear and detailed description of inclusion and exclusion criteria should be given.

Dropouts and lost to follow-up

Inevitably subjects will become lost to follow-up and will not be available for measurement of the primary endpoint. Some patients will not receive the allocated treatment according to the randomization because of errors, a preoperative surgical decision, an intraoperative change in therapy or because the patient withdraws consent to participate. Nevertheless, a description of the entire intention-to-treat (ITT) population has to be provided and every patient accounted for, preferably in a flow diagram. This will make it clear to the reader which patients are included in the study analysis. The baseline data of the study population with the distribution of the predictor variables and possible confounding variables should be provided for the ITT population in the first table of the manuscript. This table will allow evaluation of the concordance between different groups in comparative studies. The variables should be listed with their frequency or mean value, their range and their standard deviation. For analysis of the primary and secondary endpoints of the study the decision about the use of the ITT or PP population is based on the type of statistical hypothesis (superiority versus equivalence).

DESCRIPTION OF THE HERNIA VARIABLES, OPERATIVE PROCEDURE AND MESH VARIABLES

The literature dealing with the treatment of abdominal wall hernias would benefit from using a common standard for description of the hernias themselves, the operation performed and the mesh materials used. The European Hernia Society has previously published classifications for inguinal and ventral hernias [20, 21]. Moreover, during the development of the EuraHS platform for registration of ventral hernias many definitions and recommendations for describing variables of interest were proposed by consensus amongst the EuraHS working group members [1]. A general recommendation of the consensus meeting in Palermo is to use these existing classifications and terminologies to describe the hernia patients included in a study.

Hernia variables

It is recommended to use the EHS classifications for inguinal and ventral hernias. Primary ventral hernias and incisional ventral hernias should be distinguished and classified accordingly. The hernia size of ventral hernias is preferably an intra-operative measurement and the width and length will be described in centimetres (cm) as the mean and the standard deviation. If the hernia defect surface is reported, the method of calculation of the defect size in cm2 should be given. By multiplying width and length, the true hernia defect size is found to be smaller than the rectangle calculated and thus this value is an overestimation of the true abdominal wall defect size. Alternatively, the formula of an ellipse can be used to get a better estimation of the true hernia defect size. For calculating the real surface area of a hernia defect or several defects of an incisional hernia many measurements are needed and calculations depend on the form of the defect. Ammaturo and Bassi have published a method for calculating the wall defect surface and compare it with the surface of the anterior abdominal wall [22]. This method involves the use of transparent paper, a computer scanner and software to calculate the exact surface. For routine use in surgical practice this is not practical.

In order to classify the dimensions of an abdominal wall hernia the consensus is to use the terminology proposed in the previous classifications. For primary ventral hernias three groups are created using the hernia defect diameter: small (<2 cm), medium (≥2–4 cm) and large (≥4 cm). For incisional hernias, there is no common standard yet. The consensus panel recommends using the EHS classification and thus the width of the incisional hernia is the distinguishing parameter between groups: W1 (<4 cm), W2 (≥4–10 cm) and W3 (≥10 cm). If descriptive terminology like "large, giant, huge" are used, a clear description of the definition should be given. However, the use of such adjectives to define the hernia size is discouraged.

Operative techniques and mesh variables

Surgical technique and their outcome is an important issue in surgical studies. A detailed description of the surgical techniques used is important for the readers to understand the procedure(s) used in the patients studied. It should allow reproducing the technique in future patients. Authors should be encouraged to use clear terminology like those proposed by the EuraHS working group [1]. For prosthetic materials, fixation devices and other equipment, we recommend using not only the generic name of the material but also providing the prod-

uct and company name. When comparing different meshes the classification of meshes proposed by Klinge and Klosterhalfen is recommended [23]. A complete description of the size of implanted mesh, the overlap of the hernia defect and the detailed technique used for fixation will help the reader to understand the procedure used.

ASSESSMENT OF OUTCOME: RECURRENCES, COMPLICATIONS AND QUALITY OF LIFE

Recurrences

The outcome parameter recurrence is the primary endpoint in most studies of abdominal wall hernia surgery. A hernia recurrence is defined as "A protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the abdominal wall at the site of a previous repair of an abdominal wall hernia." [1]. Recurrence is a *categorical dichotomous variable*, which means the outcome cannot be quantified, but is a yes or no response. The definition used in the study of what constitutes a recurrence should be given as well as the method of follow-up that is used to look for possible recurrence. If the primary endpoint of the study is recurrence, the consensus is that only clinical follow-up will be considered adequate. In an interventional study, blinding of the evaluator to the treatment arm will minimize investigator bias and improve the quality of the data and is to be strongly encouraged.

Basically, there are two options to describe the primary endpoint recurrence in a cohort of patients. The "*recurrence rate*" can be measured at a specific time point (*T*x) during follow-up, as the number of patients of the ITT population that have developed a recurrence between the operation date (*T* 0) and Tx. This will leave us with the problem of what to do with the patients that were "*lost to follow-up*". This uncertainty about the status, i.e. recurrence or no recurrence, of the lost to follow-up patients will cause serious bias in the estimation of the calculated recurrence rate. A specific cohort of patients has no fixed recurrence rate because the recurrence rate will increase over time with longer follow-up. The result of a study with a recurrence rate at a specific point in time during follow-up should include 95 % confidence intervals. It is recommended that the statistical analysis of recurrence rates at a specified time in a comparative study be performed with the Fisher exact test and logistic regression to include prognostic factors.

A more sensitive method of reporting the outcome is by "*time-to-event analysis*" as introduced by Kaplan and Meier several decades ago for survival analysis [24]. The main reason to favour this approach is that patients lost to follow-up, the

dropouts, are accounted for. In abdominal wall surgery, the event studied is most often recurrence and thus "survival rate" can be best described as the "*freedom-of-recurrence*". For every patient in the study the time period of follow-up will be defined by the date of the hernia repair (*T* 0) to the date of recurrence or the date of the last follow-up recorded (*T* 1). At *T* 1 the status of the patient will be recorded: recurrence or no recurrence. The difference between *T* 1 and *T* 0 is the time the patient was at risk of development of a recurrence and was under "surveillance". During the study period the number of patients at risk will gradually decrease with every patient that has a recurrence or that is lost to follow-up, i.e. censored cases. The outcome of time-to-event data for hernia recurrence is given by a Kaplan–Meier plot of the freedom-of-recurrence and by calculating freedom-of-recurrence rates at predetermined time endpoints. Statistical analysis of time-to-event data is performed using the log rank test or Cox's regression model if prognostic factors are included. Time-to-event analysis is more powerful than comparing recurrence rates, thus requiring a smaller sample size to test a specific scientific hypothesis of an interventional study.

Complications

The consensus group recommends using the Clavien-Dindo classification as was proposed previously by the EuraHS working group [25–27]. A clear definition of the different complications evaluated and reported must be given, preferably using published classifications. Of specific interest for abdominal wall surgery is postoperative seroma. The seroma classification proposed by Morales-Conde is recommended [28].

The method of follow-up

The method for assessment of the primary and other endpoints of the study should be described clearly in the manuscript. Indeed, the recurrence rate measured will be influenced by the method of follow-up. Figure 2 illustrates an increase in quality of follow-up which can range from the number of reoperations for recurrences seen to systematic investigation with medical imaging. The Palermo consensus group considered that follow-up without clinical examination of the patient is likely to give an important underestimation of the true recurrence rate and thus should be avoided. For other endpoints such as quality of life assessment, a follow-up by phone or mail might be adequate.

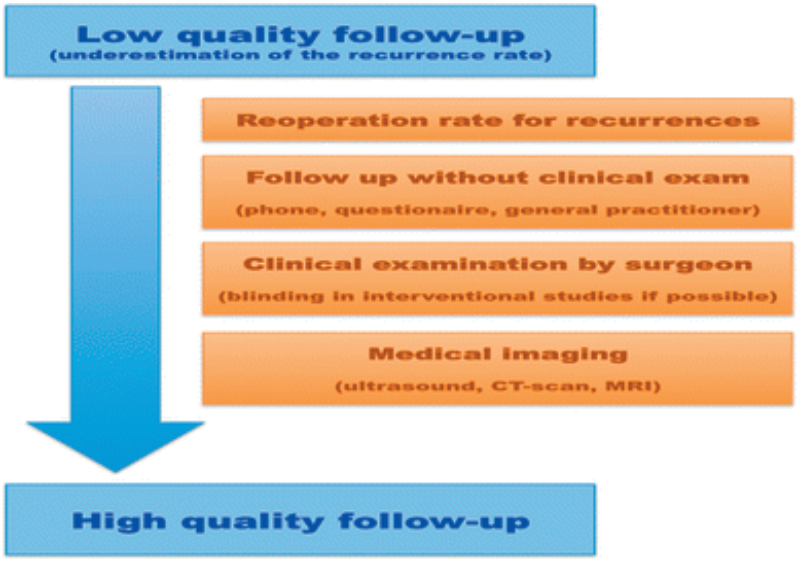

Figure 2

The validity of data for recurrence after hernia repair is dependent on the method of follow-up performed. It is recommended to consider only follow-up including clinical investigation as adequate

For large registries like the Danish Hernia Database, the Swedish Hernia Registry and the Herniamed database a clinical follow-up of all patients is not practical and achievable [29, 30]. In the population-based Danish Ventral Hernia Database the reoperation rate for recurrence is the primary outcome measurement as a "surrogate for recurrence". Helgstrand et al. [31] demonstrated using a questionnaire and subsequent selective request for clinical follow-up that the reoperation rate underestimated the overall risk for recurrence by four- to fivefold. In the Herniamed registry patients are followed up using a questionnaire send to the patient at 1, 5 and 10 years [29]. Patients reporting a problem are invited for an examination by a physician.

Blinding of the patient and the evaluator at the primary endpoint to the treatment group in an interventional study has some organisational and logistic difficulties, but should be considered when writing a study protocol because of the enhancement of the quality of the outcome data and the diminished risk of patient or investigator bias.

ETHICAL AND FINANCIAL CONSIDERATIONS

Studies should be performed according to the guidelines of the International Conference on Harmonisation (ICH) of Good Clinical Practice (GCP) [18]. This includes the approval by the ethical committee of the centre where the study is performed. Informed consent of the patients to be included in the study is mandatory.

Registration of the study protocol in an international database like http://www.clinicaltrials.gov is recommended and is mandatory for acceptance in some peer reviewed journals.

For studies of abdominal wall surgery it is very important that financial sponsors of the study are disclosed. The manuscript should state how the study was initiated: as an Investigator Initiated Study (IIS) or initiated by a commercial sponsor of the study. Conflicts of interest should be clearly stated at the end of the manuscript. If a research grant was received for the study, the name of the sponsoring organisation or company should be disclosed. Also the involvement of the sponsor in initiating or conducting the study and in reporting the results should be clearly delineated.

The consensus group also encourages investigators to report negative trial results. If the study methodology is appropriate, a negative outcome should not hinder the acceptance for publication.

DISCUSSION

The literature dealing with abdominal wall surgery often fails to meet good reporting standards and statistical methodology. Moreover the terminology used to describe the hernias and their therapies is very heterogeneous, often due to the lack of commonly accepted standards and definitions. This was the impetus for the formation of the EuraHS working group. By organising a consensus meeting including the editors of Hernia—the World Journal of Hernia and Abdominal Wall Surgery—and some specialists in statistics or systematic reviews, the aim was to suggest a set of recommendations to provide a standard for investigators writing a study protocol and to authors preparing a manuscript for submission. The recommendations are listed in Table 1.

TOPIC	RECOMMENDATION
Study type	The title and/or the abstract of the manuscript should have a *clear description of the study type*.
Reporting guidelines	Use standardised *reporting guidelines* (CONSORT, TREND, STROBE, STARLITE, PRISMA, MOOSE) to prepare a study protocol or manuscript.
Prospective vs retrospective	The abstract should report whether the study is *prospective or retrospective*, i.e. whether the data for the primary endpoint is assessed prospectively.
Primary endpoint or variable	Clearly define the *primary endpoint or variable* of the study, including the population analysed (ITT or PP) and a detailed description of how, when and by whom this primary endpoint was assessed.
Blinded assessment	State wether the evaluation of the primary endpoint was performed by a person *blinded* to the treatment group of the patient.
Sample size	Describe the method used for calculating the sample size and the software used for it.
Inclusion criteria, exclusion criteria and eligibility	Give a clear description of the study population by listing the inclusion criteria and exclusion criteria. Report the number of eligible patients not included in the study and the reasons for non-inclusion.
Dropouts	The percentage of patients not available for evaluation of the primary endpoint should be given, including the reasons for "lost to follow-up". The use of *a flow diagram* of the patients in the study is recommended.
Classifications	We recommend using the *EHS classification* for inguinal and ventral hernias.
Hernia size	The *width and the length* of the hernia from an intraoperative measurement are most appropriate. When the *hernia defect size* is reported the method of calculating this size should be given.
Surgical technique	The surgical techniques used in the study should be described in enough detail that the reader could perform the technique him or herself.

Meshes and devices	When referring to specific equipment items, we recommend the inclusion of the generic name (e.g. polypropylene), the product name and the manufacturer.
Mesh size and fixation	Report on the size of the implanted mesh, the overlap of the hernia defect and the fixation method in detail.
Time-to-event analysis	Time to event analysis using Kaplan-Meier estimates of "freedom of recurrence" is the preferred method for analysis of recurrences in hernia repair patients.
Recurrence rate	A recurrence rate should be given on the ITT population and reported with 95% confidence intervals. The duration of follow-up at which the recurrence rate was measured should be given.
Mean follow-up	If a *mean follow-up time* is given, the range should be given as well.
Method of follow-up	We recommend to consider *only clinically evaluated patients* as adequate follow-up to evaluate recurrence. In large patient registries clinical follow up in all patients is not achievable. Alternatively, follow-up with questionnaires and selective clinical follow-up is proposed.
Ethical considerations	Every study should mention the approval of the institutional ethical committee and informed consent of the patients.
Financial disclosures	Financial support of the study or the investigators should be mentioned by name of the organisation or company. Distinguish "Investigator Initiated Studies" from studies initiated by a commercial sponsor of the study.
Negative trial results	Negative findings or outcome of a study should not be a reason not to submit a manuscript. If methodologically correct, negative results can be informative.

Table 1

Summary of recommendations for reporting outcome results in abdominal wall surgery as formulated by the panel of a consensus meeting held by the EuraHS working group in Palermo, Italy, June 2012

The CONSORT statement is the common standard to use as guidance in performing and reporting RCTs (http://www.consort-statement.org). However, for ventral hernia repair, RCTs are not frequent and the majority of the literature is comparative retrospective studies or non-comparative cohort studies. For those studies the STROBE statement (STrengthening the Reporting of OBservational studies in Epidemiology) is the relevant guideline (http://www.strobe-statement.org) and the quality of the studies can be scored using the MINORS scale [32].

We consider that an author checklist specifically targeted at abdominal wall surgery based on accepted statements and scoring systems would increase the quality of submissions. Editors and reviewers can use a similar checklist for their evaluations.

The consensus panellists strongly believe that an effort is needed to increase the statistical and methodological basis of the abdominal wall research. Considering recurrence, which is the primary interest of most studies on hernia repair, it is recommended using time-to-event data of the freedom of recurrence to analyse and report study results. The number of dropouts from studies on hernia repair before the measurement of the primary endpoint is often high. Therefore, the use of time-to-event data is more suitable in hernia repair studies.

To reduce the heterogeneity of the description of the variables studied and the surgical techniques performed, we recommend using previously published terminology and definitions. Understanding the study population and the surgical technique is essential for the inference of the results to the larger population of which the study population is part. The external validity of a study is the main goal of scientific research and exact description of the study parameters is thus important.

Several clinicians and researchers feel that for most clinical questions we have, we will never get answers from RCT's and meta-analyses because the amount of variables is too large. Their frustration is that at this moment guidelines are focused mainly on this type of EBM research. Registers may be an important source of information for health care. In our particular field of research, a population-based register like the Danish Ventral Hernia Database or large surgical datasets of variables and outcomes like the Herniamed database and from the Würzburg University provides us with very interesting data [4, 29, 30]. However, the statements resulting from the analysis of register data, even by sound scientific multivariate statistical analysis, can be limited by various sources of bias. The selective inclusion of patients and their data may introduce selection bias. Some confounding variables may not be included in the dataset of the register and thus result in confounder bias. Nevertheless, we think that in practice registers may be good to generate scientific hypotheses and consider safety questions.

The EuraHS working group encourages researchers in abdominal wall surgery to use of the EuraHS platform to gather the data of their patients [1]. The platform can be used for clinical studies like RCTs and observational studies or for prospective registration of consecutive patients. The platform can be used individually, as an institutional registry, or in groups of participants (e.g. as national registry). Use of the platform will conform to the recommendation of using the consensus-based definitions and classifications of the EuraHS working group.
Knowledge of study design and statistical issues is of minimal interest to many surgeons. We think that a series of short statistical reviews related specifically to abdominal wall surgery would be a good start to improve awareness of the importance of a sound statistical approach to hernia repair research. Moreover, we would encourage the surgical societies to include courses on clinical research and statistical items in the program or in pre-congress courses during meetings of the societies.

CONFLICT OF INTEREST

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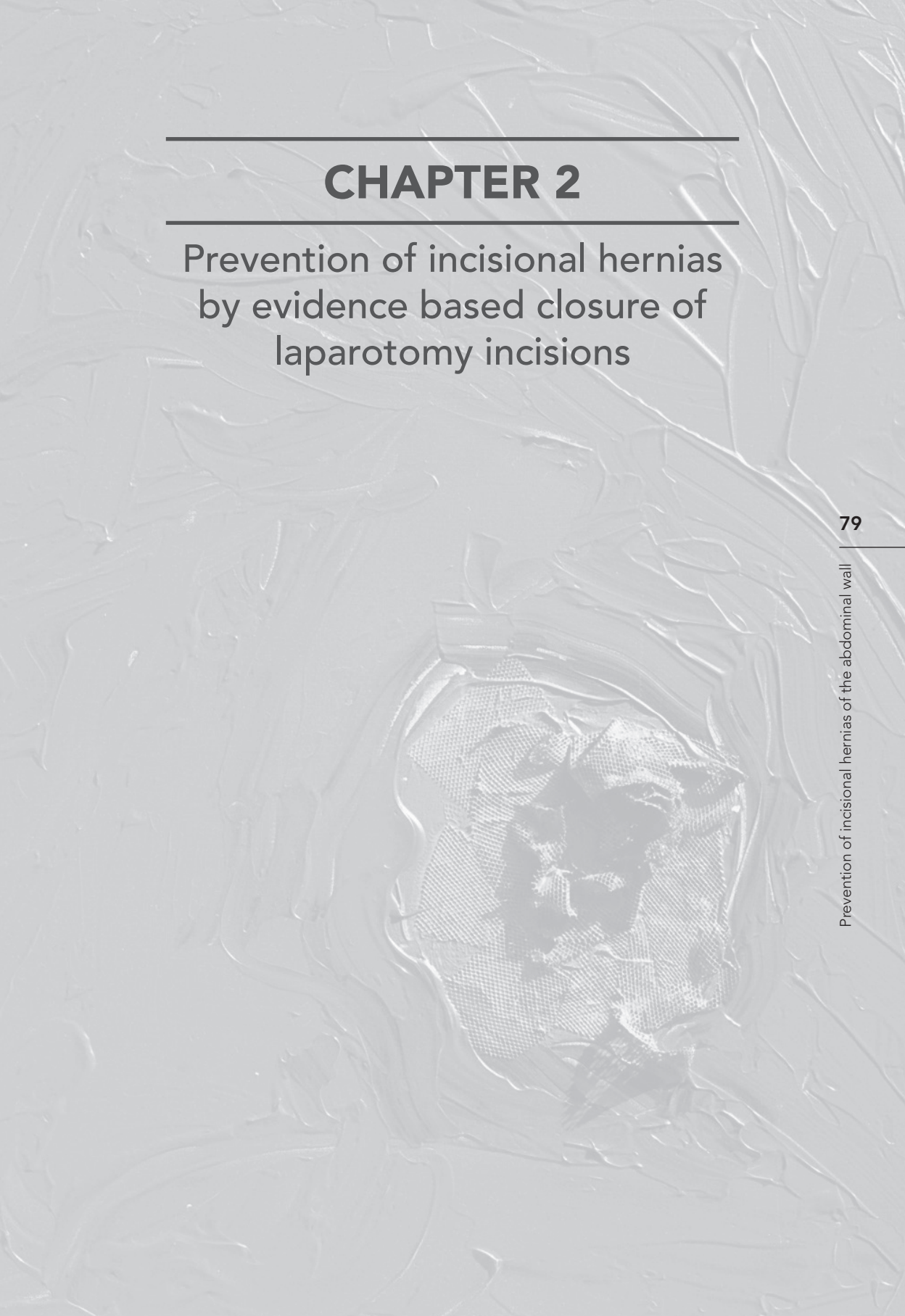
CHAPTER 2

Prevention of incisional hernias by evidence based closure of laparotomy incisions



2.1 THE INCIDENCE OF INCISIONAL HERNIAS AFTER COLORECTAL CARCINOMA RESECTION ON FOLLOW-UP CT SCAN

Hernia, 2014, 18:797-802

Claes KEY, Beckers R, Heindryckx E, Kyle-Leinhase I, Pletinckx P, Claeys D, Muysoms F

"Failure is simply an opportunity to begin again, this time more intelligently."

@ "My life and work" by Henry Ford, 1922

ABSTRACT

Background

Incisional hernia (IH) is the most frequent complication after colorectal carcinoma (CRC) resection. The incidence depends on the method of follow-up, where ultrasound yields a significant number of additional hernias compared to clinical examination alone. Not many studies have evaluated the value of computed tomography (CT) to diagnose IH.

Methods

The CorreCT study is a retrospective cohort study of IH after CRC surgery by clinical examination and by CT, as reported in the medical files. Additional independent reviewing of all CTs by two radiologists was performed.

Results

From the oncological database (2004–2008) of the hospital, 598 patients with CRC were identified. The data of 448 consecutive patients who underwent surgery were analyzed. Tumors were resected by laparotomy in 366 patients (81.7 %), by laparoscopy in 76 patients (17.0 %) and by laparotomy after conversion in 6 patients (1.3 %). A clinical follow-up by the surgeon in 282 patients (62.9 %) with a mean duration of 33 months, yielded 49 patients with IH (17.4 %). The mean time of IH diagnosis (T1) was 19 months. Only 16 patients (33 %) underwent a hernia repair. For 363 patients (81.0 %), CT follow-up was available for a mean period of 30 months. In 84 patients (23.1 %), an IH was diagnosed with a mean T1 of 21 months. The review of all CTs by two independent radiologists yielded additional IH in 19 and 21 patients, respectively, increasing the IH rate to 29.1 and 29.7 %, respectively, and with a decrease in mean T1 to 14 months. The inter-observer agreement between the radiologists had a Kappa-statistic of 0.73 (95 % CI 0.65–0.81). For those patients with disagreement between the radiologists, a final agreement was made during an additional reviewing session of both radiologists, increasing the IH rate to 35.0 %. Comparing clinical follow-up, routine CT follow-up, and reassessed CT follow-up we found a statistically significant difference between the three methods of IH detection ($p < 0.0001$).

Conclusion

CT follow-up can identify significantly more IH than clinical examination alone, in particular if the radiologist focuses on IH development. Furthermore, we showed that focused CT evaluation diagnosed IH 7 months earlier than routine CT and 5 months earlier than clinical follow-up alone.

INTRODUCTION

Background

Incisional hernia (IH) is a frequent long-term complication of abdominal surgery. The reported incidence varies depending on the study population, the method of follow-up, and the duration of follow-up [1, 2]. Obesity, postoperative wound infection, aortic aneurysm disease, and the surgical technique used to close the wound have been identified as risk factors for development of incisional hernias [2–4]. Studies implementing clinical examination alone will yield a lower incidence compared to studies incorporating medical imaging like ultrasound and/or computed tomography (CT) in the follow-up. Bloemen et al. [5] compared ultrasonography and clinical examination in the diagnosis of IH as part of a randomized clinical trial comparing two types of sutures to close a midline laparotomy. They found that including ultrasound during follow-up could detect a significant number of additional, mostly asymptomatic, hernias. In a cohort study of patients undergoing surgery of the abdominal aorta through a midline incision, den Hartog et al. [6] compared ultrasound with CT to diagnose incisional hernias. They found a prevalence of 42.5 % with ultrasound and 60.0 % with CT after a mean follow-up time of 3.4 years. In a retrospective study of patients after colorectal carcinoma (CRC) resection, very similar to our current study, Pereira et al. [7] found a prevalence of IH after a median follow-up of 19.7 months of 25.7 % by clinical examination alone. The prevalence increased to 39.9 % if review of follow-up CT was included in the diagnosis of incisional hernias. Next to the patient population and the method of follow-up, the duration of follow-up is an important determinant of incidence of incisional hernias found in studies. From the study by Hoër et al. [1] following 2,983 patients over a 10-year period, we know that 54 % of incisional hernias develop in the first 12 months, 75 % in the first 2 years and to detect 89 % follow-up of 5 years is needed. Also the methodology used to calculate the recurrence rate is of primordial importance when trying to compare different studies. Because follow-up time of the patients in a study population is often variable and some patients are lost to follow-up, time-to-event analysis using Kaplan–Meier estimates should be preferred [1, 8].

Objectives

To evaluate the incidence of incisional hernias in our patients operated for CRC more than 5 years ago, by a retrospective analysis of the clinical and radiological findings during the oncological follow-up. Moreover, we want to

evaluate if performing a reassessment of all the CT images can increase the accuracy of diagnosis.

METHODS

This manuscript was written in accordance with the STROBE statement: Strengthening the reporting of observational studies in epidemiology [9].

Study design

We performed a retrospective cohort study to investigate the incidence of incisional hernias in patients operated for CRC at the department of surgery of the AZ Maria Middelares Ghent, Belgium. We compared the incidence as diagnosed at clinical examination by the surgeon during the oncological control visits, with the diagnosis made by the radiologist on CTs performed during the oncological follow-up. Two independent radiologists reviewed all CTs with a specific focus on the abdominal wall to detect incisional hernias.

Setting and participants

The study cohort was formed by identification of all consecutive patients surgically treated in the hospital for CRC from the oncological database during a 5-year period, 2004–2008. All patients were operated by one of the three colorectal surgeons in the hospital. In collaboration with the oncologists, an intensive follow-up program is maintained post-operatively in our hospital. This includes clinical examination by the surgeon or the oncologist, and CT every 6 months in the first 2 years and yearly thereafter until the fifth postoperative year. All patients that had at least one clinical follow-up by a surgeon formed a first cohort. Incisional hernias were extracted by reviewing the surgical reports of the clinical examination. All patients for whom at least one postoperative CT was performed were included in the second cohort. Incisional hernias were extracted by reviewing the original study report from the radiologist. Subsequently all CTs were independently reviewed by two radiologists specifically focused on the abdominal wall (=reassessed CT). For most patients more than one CT was available and the CTs were reviewed consecutively, documenting the date of the CT on which the IH was visible for the first time. All data were collected in a MS Excel file including the patient data at baseline.

Variables

From the medical records following patient data at baseline (=time of surgery) were documented: age, gender, localization of the tumor, tumor stage (according to the TNM classification), tumor grading, administration of adjuvant chemotherapy or radiation therapy, type of surgical access (open, laparoscopy, conversion).
Primary outcome of the study was diagnosis of incisional hernias. Incisional hernia is defined as: "An abnormal protrusion of the contents of the abdominal cavity or of pre-peritoneal fat through a defect or weakness in the abdominal wall at the site of the surgical scar" [10].

Bias

The cohort was composed of a consecutive series of patients. Nevertheless, some patients, usually those with metastatic disease that received palliative chemotherapy, did not get a follow-up by the surgeon, because they were followed by the oncologist and thus no data on clinical follow-up by a surgeon was available. Some patients did not get a systematic follow-up CT either because they had limited disease or because of their advanced age.

Statistical methods

The inter-observer agreement between radiologists was evaluated according to the Kappa-statistic. The precision of this estimate was reflected in its 95 % CI. Estimation of recurrence-free survival curves was done according to the Kaplan–Meier method. Time-to-event curves were compared using the log-rank test. Statistical significance was assumed at $p < 0.05$. All statistical analyses were performed using SAS software (version 9.3) (The SAS system, Cary, North Carolina: SAS Institute Inc.).

RESULTS

Participants

From the oncological database of the hospital, 598 patients with CRC were identified during a 5-year period (2004–2008). Of these 448 were treated by surgery. In Fig. 1, a flow diagram of the patients is given including the type of surgery, type of follow-up, and the number of patients with an IH.

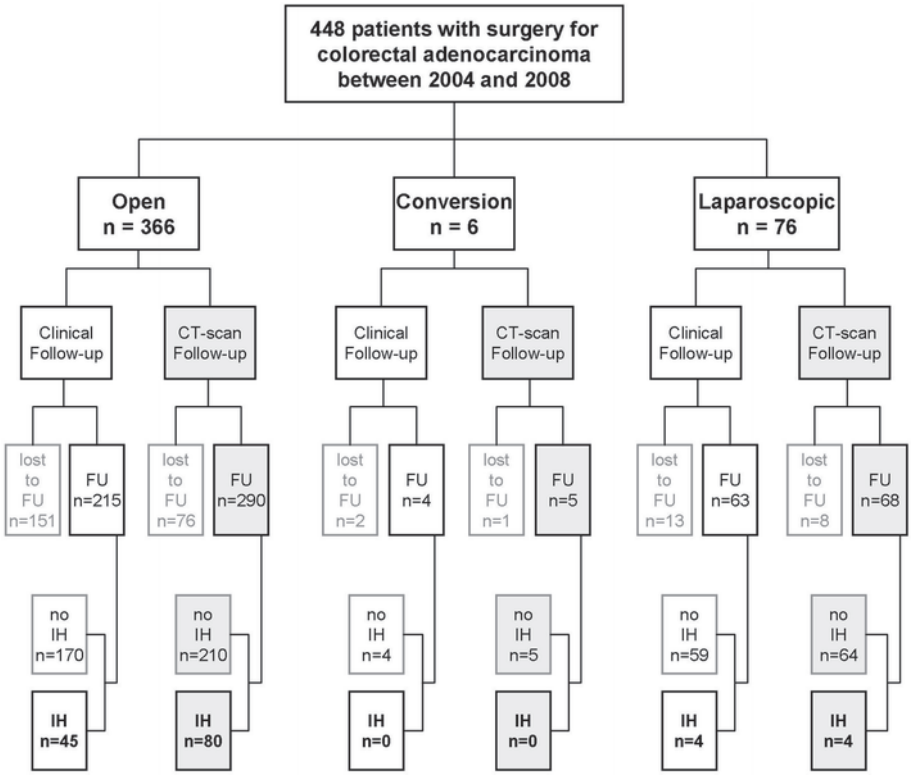


***Figure* 1**

Flow diagram of a retrospective study on the incidence of incisional hernias after surgery for colorectal carcinoma

Descriptive data

The data at baseline of the 448 surgically treated patients are given in Table 1. Because in 10 patients a synchronic second tumor was present, a total of 458 tumors are listed.

Patient data		% (n/N)* or Mean (SD) **
Age (at the time of surgery)		
Mean (SD)		69.8 years (11.8)
range		22 - 95 years
% **Women**		
		54.2 % (243/448)
Tumour localisation (n = 458)		
Appendix		1.7 % (8/458)
Cecum		7.4 % (34/458)
Ascending colon		13.5 % (62/458)
Hepatic flexure		3.3 % (15/458)
Transverse colon		6.8 % (31/458)
Splenic flexure		0.9 % (4/458)
Descending colon		3.7 % (17/458)
Sigmoid colon		30.1 % (138/458)
Recto-sigmoid		2.2 % (10/458)
Rectum		29.3 % (134/458)
Unknown		1.1 % (5/458)
Tumour staging TNM classification (n = 458)		
Stage 0	T0 N0	0.7% (3/458)
	Tis	2.0 % (9/458)
Stage I	T1 N0	4.8 % (22/458)
	T2 N0	12.0 % (55/458)
Stage II-A	T3 N0	21.2 % (97/458)
Stage II-B	T4 N0	3.5 % (16/458)

Stage III-A	T1-2 N1	2.0 % (9/458)
Stage III-B	T3-4 N1	13.1 % (60/458)
Stage III-C	any T, N2	15.5 % (71/458)
Stage IV	any T, any N, M1	17.7 % (81/458)
Tumour grading by differentiation (n = 458)		
Well differentiated		3.3 % (15/458)
Moderately differentiated		29.5 % (135/458)
Moderately/ Poorly differentiated		19.7 % (90/458)
Poorly differentiated		37.1 % (170/458)
Undifferentiated		0.7 % (3/458)
Unknown		9.8 % (45/458)
* % (n/N) / n = number of patients / N = total number of patients		
**Mean(SD) / mean value of variable (standard deviation)		

Table 1

Data at baseline of 458 colorectal carcinomas resected in 448 patients

Tumor resections were performed by midline laparotomy in 366 patients (81.7 %), by laparoscopy in 76 patients (17.0 %) or by laparotomy after conversion from laparoscopy in 6 patients (1.3 %). Of the operated patients, 213 received adjuvant chemotherapy (47.5 %).

Outcome data

Clinical examination during follow-up by the surgeon was performed in 282 patients (62.9 %) with a mean length of follow-up of 33 months (range 0.5–90 months). Incisional hernia was diagnosed in 49 patients (17.4 %) with a mean time to IH diagnosis (T1) of 19 months. During the observation period, 16 patients underwent an IH repair (16/49 patients; 32.7 %).

Follow-up by CT was available in 363 patients (81.0 %) with a mean length of follow-up of 30 months (range 0.1–94 months). Incisional hernia was diagnosed from the original radiological report in 84 patients (23.1 %) with a mean T1 of 21 months.

Two radiologists independently reassessed all CTs of the patients for which the images were available (357/363 patients; 98.3 %). This independent reas-

sessment yielded additional IH in 19 and 21 patients, respectively, increasing the IH rate to 29.1 and 29.7 %, respectively, and with a decrease in mean T1 to 14 months. For those CTs with disagreement between the radiologists, a final agreement was reached during an additional reviewing session of both radiologists. This yielded an IH diagnosis in 125 patients (125/357 patients; 35.0 %) with a mean T1 of 14 months. The large majority of the incisional hernias was in the midline and the umbilical region was most affected.

Main results

The highest number of incisional hernias was detected in the group of patients with a reassessed CT by a radiologist specifically focused on the abdominal wall. The inter-observer agreement between the radiologists was good, with a Kappa-statistic of 0.73 (95 % CI 0.65–0.81), but there was certainly an added value of the evaluation by two radiologists. Estimated freedom of IH survival curves with Kaplan–Meier is shown in Fig. 2. There was a statistically significant difference between the three methods of IH detection ($p < 0.0001$). Also mutual differences in comparison between two methods of detection were statistically significant (clinical vs CT $p = 0.03$; clinical vs reassessed CT $p < 0.0001$; CT vs reassessed CT $p = 0.0079$).

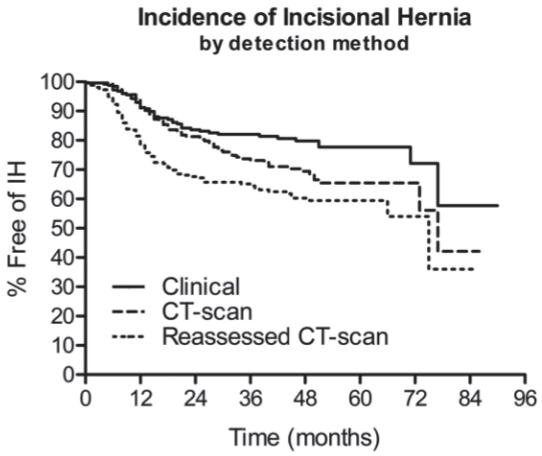


Figure 2

Estimated freedom of incisional hernia survival curves with Kaplan–Meier, comparing routine clinical examination (Clinical) and computed tomography evaluation (CT-scan) during oncological follow-up with CT evaluation specifically

focused on the abdominal wall (reassessed CT-scan). There was a statistically significant difference between the three methods of incisional hernia detection ($p < 0.0001$). Also mutual differences in comparison between two methods of detection were significant (clinical vs CT-scan: $p = 0.03$; clinical vs reassessed CT-scan: $p < 0.0001$; CT-scan vs reassessed CT-scan:$p = 0.0079$)

DISCUSSION

Key results

CT assessed by a radiologist focused on the occurrence of an IH showed a significant higher number of incisional hernias compared to routine CT assessment or routine clinical examination in an oncologic setting. The rate of incisional hernias after CRC resection was 35.0 % with a mean follow-up time of 30 months.

Limitations

Clinical examination was performed for oncological reasons without a specific focus of the surgeon on incisional hernias. Nevertheless, a thorough clinical examination of the scar is part of the routine and all incisional hernias are mentioned in the patient files. A small IH can be easily overlooked, certainly in obese patients. It is likely that a prospective clinical assessment focused on incisional hernias would enhance the detection rate and diminish the difference with CT-scan detection rate. Because the study is retrospective, many data at baseline are not recorded adequately. Therefore, we could not investigate risk factors like obesity and wound infection in relation to the development of incisional hernias.

Interpretation

The incidence of incisional hernias after CRC resection in our department is high, with 35.0 % after 30 months. This is in line with other studies with equal follow-up time and methodology. Pereira et al. [7] found an incidence of almost 40 % with CT follow-up. CT has a high reliability for diagnosing incisional hernias and maybe should be considered the "gold standard" to which other methods of follow-up should be compared. We found an inter-observer agreement for CT diagnosis with a Kappa-statistic of 0.73 (95 % CI 0.65–0.81), which is identical to the inter-observer agreement found by den Hartog et al. [6] (Kappa-statistic of 0.74 with 95 % CI 0.54–0.95) in their study. They also

found an increased reliability of CT-scan compared to ultrasound, increasing the incidence of incisional hernias in their patients from 42.5 to 60.0 %.
At the time the patients in this study were operated the abdomen was closed with a running loop suture of polydioxanone 1 without any consideration on the suture to wound length ratio (SL/WL) or on the size of the tissue bites during the closure. We have adopted nowadays the more evidence-based principles of abdominal closure, with a SL/WL of at least four and the use of small bites of fascia tissue as described in a recent review paper on this topic [4]. We think and hope that a similar study within 5 years would yield a lower incidence in our patients.

Generalisability

CT evaluation by a radiologist focused on the abdominal wall is probably the most sensitive method for diagnosing incisional hernias. It is important to know when evaluating studies reporting on the incidence of hernias that the method of follow-up will highly influence the results. Globally, the incidence of incisional hernias is higher than generally expected, not only in the high-risk group of aortic aneurysm patients or obese patients, but in all laparotomies. Prevention is thus of utmost importance with correct technique to close the abdominal wound. Prophylactic mesh augmentation of the wound is currently under investigation in several large trials and it might become a standard procedure for the high-risk groups in the not so distant future [11].

Conclusion

We found a significant increase in IH detection after surgery for colorectal carcinoma with CT assessed by a radiologist focused on the abdominal wall, compared to findings during routine clinical examination or routine CT reviewing during the oncological follow-up.

Acknowledgments

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Conflict of interest

The authors report no conflict of interest in relation to this study.

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2.2 RETROSPECTIVE OBSERVATIONAL STUDY ON THE INCIDENCE OF INCISIONAL HERNIAS AFTER REVERSAL OF A TEMPORARY DIVERTING ILEOSTOMY FOLLOWING RECTAL CARCINOMA RESECTION WITH FOLLOW-UP CT SCANS

Hernia, 2015, submitted on December 8th 2014

De Keersmacker G, Beckers R, Heindryckx E, Kyle-Leinhase I, Pletinckx P, Claeys D, Vanderstraeten E, Monsaert E, Muysoms F

" Never judge a surgeon until you have seen him closing the wound."

© Lord Moynihan, (1865-1936), Royal College of Surgeons of England

ABSTRACT

Background

Wounds resulting from the closure of temporary stomas have a high risk of developing an incisional hernia (IH) with incidences around 30% in studies designed to investigate this outcome. A temporary diverting ileostomy (TDI) is often used in patients after low anterior resection (LAR) for rectal cancer.

Methods

The OSTRICH trial is a retrospective cohort study of rectal cancer patients who had a LAR with a reversed TDI and at least one CT scan during follow-up. Two radiologists independently evaluated all abdominal CT scans to diagnose IH at the ileostomy wound and additionally, IH at the laparotomy site.

Results

From the oncological database of rectal cancer patients treated from 2003 till 2012 (n=317) a cohort of 153 patients that fulfilled the inclusion criteria was identified. Rectal cancer resection was performed by laparoscopy in 53 patients (34.6%) and by laparotomy in 100 patients (65.4%). A total of 17 IH (11.1%) was diagnosed at the former stoma site after a mean follow-up of 2.6 years. Of these, 8 IH were in patients who had a laparoscopic LAR (15.1%) and 9 IH in patients who had an open LAR (9.0%) (Fisher's exact test; p= 0.28). IH on the other abdominal wall incisions were reported in 69 patients (45.1%). Of these, 10 patients underwent laparoscopic rectal surgery (18.9%) and in 59 patients had open rectal surgery (59.0%) (Fisher's exact test; $p < 0.0001$).

Conclusion

We found a lower number of incisional hernias (11.1%) after reversal of ileostomies than reported in the literature. In contrast to the findings at the ileostomy site, a very high frequency of IH (59.0%) after LAR by laparotomy was found, which was significantly higher than after laparoscopic LAR.

INTRODUCTION

Background

A temporary diverting ileostomy (TDI) is frequently used after low anterior resection (LAR) for rectal cancer to protect a colo-anal anastomosis and to avoid intra-abdominal postoperative complications [1]. On the other hand, the use of a TDI has some short-term morbidity, like renal insufficiency [2] or peristomal skin complications [1]. Moreover, the site of the TDI is at risk for development of an incisional hernia (IH) after reversal of the stoma. A recent systematic review reported the median incidence of stoma site IH to be 8.3% (range 0%-33.9%) and to be 44.1% (range 8.7%-58.1%) for midline IH [3-4]. In 3 studies specifically designed to assess stoma site herniation and with a low risk of bias, the incidence of IH at the stoma site ranged from 30.1% to 32.4% [5-7]. Most studies included stoma sites after both ileostomies and colostomies.

Objectives

To evaluate the incidence of IH in patients treated for rectal cancer with a LAR and TDI between 2003 and 2012, by a retrospective analysis of the radiological findings on CT scans performed during the oncological follow-up. In addition we want to define risk factors for developing a hernia at the site of a TDI.

Methods

This manuscript was written in accordance with the STROBE statement: Strengthening the reporting of observational studies in epidemiology [8].

Study design

We performed a retrospective cohort study to investigate the incidence of incisional hernias at the stoma site of TDI in patients operated for rectal cancer at the department of surgery of the AZ Maria Middelares Ghent, Belgium. An extensive oncological follow-up program is maintained post-operatively in our hospital. This includes a CT scan every 6 months in the first two years and yearly thereafter until the fifth postoperative year. All patients who underwent TDI stoma reversal and for whom at least one postoperative CT scan was performed were included the study. Two radiologists independently reviewed all CT scans specifically focused on the abdominal wall (= reassessed CT scan). For most patients more than one CT scan was available and the CT scans were reviewed consecutively, documenting the date of the scan on which the incisional hernia, either at the TDI

stoma site or at the laparotomy incision, was visible for the first time. For those patients where the assessments of the two radiologists was discordant, a consensus decision was made during an additional reviewing by both radiologists. All data were collected in a MS Excel file including the patient data at baseline.

Setting and participants

The study cohort was formed by identification from the oncological database of all consecutive patients diagnosed in the hospital with a rectal carcinoma between 2003-2012. All included patients were operated by one of the three colorectal surgeons in the hospital.

Variables

From the medical records following patient data at baseline (= time of reversal of the TDI) were documented: age, gender, tumour stage (according to the TNM classification), administration of adjuvant chemotherapy or radiation therapy, type of surgical access (open, laparoscopy), comorbidities, previous laparotomy, previous abdominal wall hernia and the time-interval between the LAR with TDI and the stoma reversal.
Primary outcome of the study was diagnosis of incisional hernias at the ileostomy site. Incisional hernia is defined as: "An abnormal protrusion of the contents of the abdominal cavity or of pre-peritoneal fat through a defect or weakness in the abdominal wall at the site of the surgical scar" [9]. Secondary outcome was the diagnosis of incisional hernias at the site of the laparotomy incision.

Bias

The cohort was composed of a consecutive series of patients. Some patients did not receive a systematic follow-up CT scan, either because they had limited disease or because of advanced age (possible selection bias).
Assessment of the abdominal wall was performed retrospectively without clinical examination. Therefore, it can not be excluded that some concomitant abdominal wall hernias, not related to the rectal surgery or to the reversal of the TDI, were diagnosed as incisional hernia (possible assessment bias).

Statistical methods

The distribution of patient characteristics was described according to means (standard deviation) and proportions. The inter-observer agreement between ra-

diologists was evaluated according to the Kappa-statistic. The precision of this estimate was reflected in its 95% confidence interval. Estimation of IH-free survival curves was done according to the Kaplan-Meier method. Cumulative incidences of incisional hernia were compared according to Fisher's exact test. The hazard ratio (+ 95% confidence interval) relating laparotomy site with the occurrence of IH at the stoma site was obtained through a Cox regression model. Statistical significance was assumed at $p < 0.05$. All analyses were performed using SAS software (version 9.3) (The SAS system, Cary, North Carolina: SAS Institute Inc).

RESULTS

Participants

From the oncological database of the hospital, 317 patients with diagnosis of a rectal carcinoma were identified during a ten-year period (2003-2012). A flow diagram of the patients included in the study is shown in Figure 1. Of these 317 patients, subsequently 164 patients were excluded because they either had no surgery, no surgery involving the reversal of a TDI or had no follow up CT scan. Finally, 153 patients were included in the study.

Descriptive data

The data at baseline of the 153 patients are given in Table 1. Tumour resections were performed by midline laparotomy in 100 patients (65.4%) and by laparoscopy in 53 (34.6%). In the laparoscopic cases the resected rectum was extracted either by a vertical muscle-split incision through the rectus muscles in the left hypochondrium (n= 47), trans-anal (n=3), through a midline extraction incision (n=2) or through a Pfannenstiel incision (n=1). Postoperative chemotherapy was given in 88 patients and for 63 of these patients (71.5%) the chemotherapy was started between the rectal carcinoma resection and the reversal of the TDI. The median interval between the LAR and the reversal of the TDI was 66 days (range: 25 - 356 days).

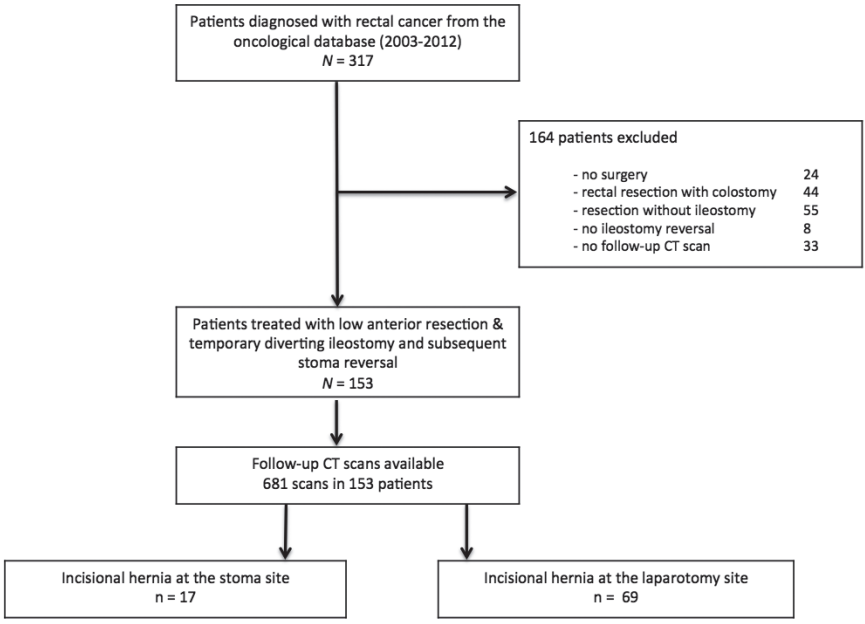

Figure 1

Patients flow diagram of a retrospective study on the incidence of incisional hernias following low anterior resection of rectal cancer with a temporary diverting ileostomy and subsequent stoma reversal.

PATIENT DATA	% (*N/N*)* OR MEAN (SD) †
Age (at the time of surgery)	67.1 years (11.6)
% Women	39.9% (61/153)
Comorbidities	
Diabetes mellitus	11.1% (17/153)
Chronic Obstructive Pulmonary Disease	5.9% (9/152)
Heart failure	4.6% (7/153)
Hemodialysis	0.7% (1/153)
Previous malignancy	12.4% (19/153)
Previous ventral abdominal wall hernia repair	9.8% (15/153)
Previous laparotomy	10.5% (16/153)
Previous inguinal hernia repair	11.1% (17/153)

Neoadjuvant treatment (preoperatively)	
Short course radiotherapy	69.7% (106/152)
Long course radiotherapy	17.1% (26/152)
Chemotherapy	19.1% (29/152)
Tumour staging TNM by pathology of resection	
Tumour	
T0	11.2% (17/152)
T1	26.3% (40/152)
T2	57.2% (87/152)
T3	5.3% (8/152)
Nodal involvement	
N0	51.3% (78/152)
N1	21.0% (32/152
N2	27.6% (42/152)
Metastatic disease	
M0	91.4% (139/152)
M1	8.6% (13/152)
Type of surgical access	
Laparoscopy	34.6% (53/153)
Open surgery	65.4% (100/153)
Adjuvant therapy (postoperatively)	
Radiotherapy following rectal surgery	2.6% (4/153)
Radiotherapy following stoma reversal	0.7% (1/153)
Chemotherapy following rectal surgery	41.7% (63/151)
Chemotherapy following stoma reversal	57.9% (88/152)
* % (*n/N*) / *n* = number of patients / *N* = total number of patients	
† Mean (SD) / mean value of variable (standard deviation)	

Table 1

Descriptive data at time of stoma reversal of 153 patients treated for a rectal carcinoma with a low anterior resection and a temporary diverting ileostomy.

Outcome data

An *incisional hernia at the stoma site* was diagnosed in 17 patients (11.1 %) with a mean follow-up of 2.56 years (SD 1.62 years), as shown in Table 2. Two radiologists reviewed all CT-scans (*n*= 681). The inter-observer agreement between the radiologists was good, with a Kappa-statistic of 0.88 (95% CI 0.81-0.94). The estimated freedom of IH at the stoma site curves according to the Kaplan-Meier method are shown in Figure 2.

Incidence of Incisional Hernias	
At the stoma site following reversal of a temporary diverting ileostomy	
Follow up time (years since stoma reversal)	
Mean (SD) in years	2.56 (1.62)
Median (P25-P75)	2.25 (1.30 to 3.85)
Number of Incisional Hernias	17
Cumulative incidence, %	**11.1%**
Incidence rate	4.3 per 100 person-years
At the laparotomy site following low anterior resection	
Follow up time (years since stoma reversal)	
Mean (SD) in years	1.95 (1.46)
Median (P25-P75)	1.63 (0.74 to 2.80)
Number of Incisional Hernias	69
Cumulative incidence, %	**45.1%**
Incidence rate	23.1 per 100 person-years

Table 2

The incidence of incisional hernias at the stoma site and at the laparotomy site in 153 patients treated for a rectal carcinoma with a low anterior resection and a temporary diverting ileostomy.

An *incisional hernia at the site of the laparotomy* was diagnosed in 69 patients (45.1%) with a mean follow-up of 1.95 years (SD 1.63 years), as shown in Table 2. The inter-observer agreement between the radiologists for IH at the laparotomy site had a Kappa-statistic of 0.76 (95% CI 0.71-0.81). The estimated freedom of IH at the laparotomy site curves according to the Kaplan-Meier method are shown in Figure 3.

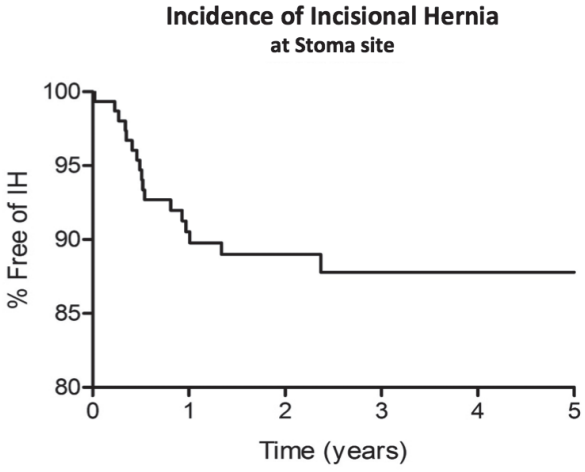

Figure 2

Estimated freedom of incisional hernia at the stoma site curves with the Kaplan-Meier method of 153 patients following low anterior resection of rectal cancer with a temporary diverting ileostomy and subsequent stoma reversal.

The cumulative incidence of IH at the stoma site was 9.5% (8/84) in patients with no IH at the laparotomy site, and it was 13.0% (9/69) in patients who had a concomitant IH at the laparotomy site (Fisher's exact test; $p = 0.61$). Thus no significant correlation between the occurrence of IH at the stoma site and at the laparotomy site was found (Hazard ratio: 1.28 and 95% CI: 0.50-3.33).

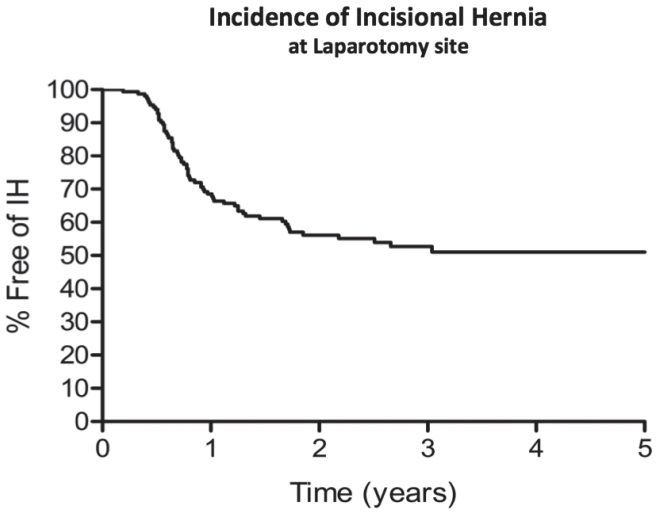

Figure 3

Estimated freedom of incisional hernia at the laparotomy site curves with the Kaplan-Meier method of 153 patients following low anterior resection of rectal cancer with a temporary diverting ileostomy and subsequent stoma reversal.

Risk factors

A number of possible risk factors were analysed according to the Fisher's exact test for their relevance to the development of an *IH at the stoma site*. The results are listed in Table 3. No statistically significant risk factor was found.

Additional analysis of risk factors for development of an *IH at the laparotomy site* showed a significant higher cumulative incidence according to the type of surgical access. For laparoscopic surgery the incidence was 18.9% (10/53) and for laparotomy it was 59.0% (59/100) (Fisher's exact test; $p < 0.0001$).

Cumulative incidence of incisional hernia at the stoma site *		Significance †
Age		**p = 0.29**
< 65 years	6.9% (4/58)	
≥ 65 years	13.7% (13/95)	
Gender		**p = 0.19**
Men	14.1% (13/92)	
Women	6.6% (4/61)	
Diabetes		**p = 0.99**
No	11.0% (15/136)	
Yes	11.8 (2/17)	
Chronic obstructive pulm nary disease		**p = 0.26**
No	10.5% (15/143)	
Yes	22.2% (2/9)	
Heart failure		**p = 0.7**
No	11.0% (16/146)	
Yes	14.3% (1/7)	
Previous malignancy		**p = 0.99**
No	10.5% (15/134)	
Yes	15.8% (2/19)	
Previous ventral abdominal hernia repair		**p = 0.07**
No	9.4% (13/138)	
Yes	26.7% (4/15)	
Previous laparotomy		**p = 0.99**
No	11.8% (16/136)	
Yes	6.3% (1/16)	
Previous inguinal hernia repair		**p = 0.41**
No	10.3% (14/136)	
Yes	17.6% (3/17)	
Type of surgical access		**p = 0.28**
Laparoscopy	15.1% (8/53)	
Laparotomy	9.0% (9/100)	
Postoperative chemotherapy		**p = 0.80**
No	12.5% (8/64)	
Yes	10.2% (9/88)	
* % (n/N) / n = number of patients / N = total number of patients		
† according to Fisher's exact test		

Table 3

Analysis of the cumulative incidence of incisional hernias at the stoma site in 153 patients treated for a rectal carcinoma with a low anterior resection and a temporary diverting ileostomy.

DISCUSSION

Key results

The rate of incisional hernias at the ileostomy site is 11.1% with a mean follow-up time of 2.6 years. The rate of incisional hernias at the site of the laparotomy is 45.1% with mean follow up time of 1.9 years. No specific risk factors were observed for developing an incisional hernia at the ileostomy site. Patients had significantly more incisional hernias at the laparotomy site if the operation was performed by laparotomy compared to resection by laparoscopy.

Limitations

Because the study is retrospective many data at baseline are not recorded adequately. Therefore we could not investigate risk factors like obesity or smoking habits in relation to the development of incisional hernias.

Interpretation

The incidence of incisional hernias at the ileostomy site in our department is only 11.1%. This is a lower incidence than previously reported in studies specifically designed to assess this outcome [5-7], but these studies most often involved both ileostomy and colostomy wounds. The patients included in this study are a homogenous group of reversed temporary ileostomies after LAR for rectal cancer. This difference in study population might influence the results. In our department ileostomy wounds are closed with two separate poly-dioxanone sutures, one for the retro-muscular fascia and a different one for the anterior fascia. The method and material used to close the abdominal wall could have an important impact on the incisional hernia rate [10].

The incidence of incisional hernias after LAR for rectal cancer in our department is high, with 45.1% after 1.9 years. This is in line with other studies with equal follow-up time and methodology [11-12]. Pereira et al. found an incidence of almost 40 % with CT follow-up [11] and we previously reported the incidence of incisional hernias after resection of colorectal carcinoma to be 35% with a methodology similar to the present study [12]. CT has a high reliability for diagnosing incisional hernias and maybe should be considered the "gold standard" to which other methods of follow-up should be compared. The technique used to close the abdominal wound in our department at the time the patients in this study were operated was far from what we now know to be the optimal closure technique. At that time the abdomen was closed with a running loop suture of poly-dioxanone

1 without any consideration on the suture to wound length ratio (SL/WL) or on the size of the tissue bites during the closure. We have adopted nowadays more evidence-based principles of abdominal closure, with a SL/WL of at least 4 and the use of small bites of fascia tissue as described in a recent review paper on this topic [10].
Because of the high incidence of incisional hernia at the site of a previous stoma, some have proposed to perform a mesh augmentation of the abdominal wall incision during the closure of the stoma [13-15]. Some randomized clinical trials (RCT) are on-going to research the benefits of such an approach. The ROCCS trial from the University of Birmingham (controlled-trials.com: ISRCTN46330337) will investigate the reinforcement of the stoma site with a biological mesh in a multicenter RCT in 560 patients with either an ileostomy or colostomy that is closed. The ILEOCLOSE study from the University of Vall d'Hebron (clinicaltrials.gov: NCT02226887) will investigate in a RCT the prophylactic mesh reinforcement of closure of TDI with an absorbable synthetic mesh in 120 patients.

Conclusion

We found a relatively low incidence of incisional hernias at the ileostomy site in patients treated with a TDI reversal after LAR for rectal carcinoma. No specific risk factors could be determined in this retrospective study. Special attention for the closure of the ileostomy site may be the reason for our low incidence. On the other hand, we found a high incidence of hernias at the laparotomy site. Optimizing the abdominal wall closure technique according to the current guidelines is warranted.

OTHER INFORMATION

Registration

The Ethical Committee at the AZ Maria Middelares Hospital Ghent Belgium reviewed the study (registration number SpV13.01.04) and a positive advice was given on September 30th 2013.

Funding

The BVBA Dokter Filip Muysoms paid the consultancy fee for the statistical analysis.

Disclosure statements

The authors report no conflict of interest in relation to this study.

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2.3 THE PRINCIPLES OF ABDOMINAL WOUND CLOSURE

Acta Chirurgica Belgica, 2013, 113:239-244

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"If you do something as a matter of principle, you do it because you believe it is the right thing to do."

@ The Cambridge International Dictionary of English, 1995

ABSTRACT

Background

Incisional hernia (IH) is a common complication of abdominal surgery. Its incidence has been reported as high as 39.9%. Many factors influence IH rates. Of these, surgical technique is the only factor directly controlled by the surgeon. There is much evidence in the literature on the optimal midline laparotomy closure technique. Despite the high level of evidence, this optimal closure technique has not met wide acceptance in the surgical community. In preparation of a clinical trial, the PRINCIPLES trial, a literature review was conducted to find the best evidence based technique for abdominal wall closure after midline laparotomy.

Methods

An Embase search was performed. Articles describing closure of the fascia after midline laparotomy by different suture techniques and/or suture materials were selected.

Results

Fifteen studies were identified, including five meta-analyses. Analysis of the literature showed significant lower IH rates with single layer closure, using a continuous technique with slowly absorbable suture material. No significant difference in IH incidence was found comparing slowly absorbable and non absorbable sutures. Furthermore, a suture length to wound length ratio of four or more and short stitch length significantly decreased IH rates.

Conclusions

Careful analysis of the literature indicates that an evidenced based optimal midline laparotomy closure technique can be identified. This technique involves single layer closure with a running suture, using a slowly absorbable suture with a suture length to wound length ratio of four or more and a short stitch length. We adopt this technique as the PRINCIPLES technique.

INTRODUCTION

Incisional hernia (IH) is a common long-term complication of abdominal surgery. The incidence has been reported as high as 39.9% varying depending on the study population and on the method and the duration of followup performed (1-4). Furthermore, studies implementing clinical examination alone will yield a lower incidence compared to studies incorporating medical imaging like ultrasound and/or CT-scan during follow-up (5). Several risk factors for the development of IH have been identified such as obesity, wound infection, diabetes mellitus, abdominal aortic aneurysm (AAA), and the surgical technique used to close the abdominal wound (6-9). The presence of IH has a large impact on the patients' quality of life (QoL) and body image, surgical repair frequently being indicated (4). Long-term studies have shown that mesh repair of IH results in a lower incidence of recurrence compared with suture repair, but patients treated with mesh repair still had a high 10-year cumulative recurrencerate of 32%(10). Mesh repair also proved to reduce re-operation rate after initial hernia repair. However, patients treated with mesh repair still had a high five-year cumulative re-operation rate of 11% (11). A recently published study of Helgstrand et al. compared the clinical recurrence rate and reoperation rate for recurrence after ventral hernia repair. After a mean follow-up of 41 months, the cumulative risk of reoperation for recurrence after IH repair was 8% and the clinical recurrence rate was 37% (12). This shows that reoperation rate does not reflect the overall clinical risk for recurrence.

Because of the impact on the patients' QoL and the high failure rate of surgical repair, the prevention of IH should be a major interest of all surgeons. Of the known risk factors involved in IH development, surgical technique is the only factor directly controlled by the surgeon. There is much evidence in the literature on the optimal midline laparotomy closure technique. Despite this evidence, the optimal closure technique has not met wide acceptance in the surgical community (13). The optimal closure technique, the ideal suture material and the best suture length to wound length ratio (SL/WL ratio) have been the subject of several studies and meta-analysis (14- 18).

This review of the literature is performed in preparation of the PRINCIPLES study: *"Prevention of Incisional Hernias by Primary closure of Midline Laparotomies with the Best Evidenced Suture Technique"*.

METHODS

An Embase search was performed, using the keywords 'fascia', 'abdominal wall hernia', 'suture', 'closure', 'method', 'technique', and 'material'.
The article selection was based on four subthemes: interrupted vs continuous suturing, mass closure vs layered closure, rapidly absorbable vs slow absorbable vs non-absorbable sutures, and suture length to wound length ratio and stitch size. For these themes we selected the most recent and relevant articles.

RESULTS

Interrupted vs continuous suturing

Five meta-analyses were found comparing the effect of interrupted with continuous suturing on IH incidence (13, 19-22).

The first meta-analysis was published by Weiland et al. in 1998, and included twenty-three randomized controlled trials (RCT) and two non randomized studies with a total of 12.247 patients (22). Eight of these studies compared continuous versus interrupted closure using both absorbable and non-absorbable sutures. Analysis of these studies demonstrated higher infection rates and hernia formation with continuous closure ($p = 0.001$, and $p = 0.05$ respectively).
The second meta-analysis was published by Hodgson et al. in 2000, and included thirteen randomized controlled trials that evaluated suture material or technique for abdominal fascial closure (vertical midline, oblique, and transverse incisions) (13). Six of these trials compared continuous versus interrupted technique. Continuous closure resulted in a significant reduction of IH compared with interrupted suture (OR 0.73, 95% CI 0.55-0.99).
The third meta-analysis was conducted by van 't Riet et al. in 2002 and compared different suture materials and techniques after midline incisions whereas Hodgson et al also included other types of incisions (21). A total of fifteen studies were included. Seven trials compared continuous with interrupted suture technique. Most of these studies showed no significant difference in IH incidence (OR 0.9, 95% CI 0.6-1.2). However in six of the seven studies the suture material in the interrupted group differed from the continuous group. This complicated the comparison between the two groups. All studies favoured continuous sutures, because this technique is faster and thus saved operating time.
The fourth meta-analysis was published by Gupta et al. in 2008 and included twenty-three RCTs comparing continuous and interrupted methods of laparotomy wound closure (20). Eighteen of these studies had IH as outcome. No significant difference in the IH rate was found between the two closure methods (OR

1.059, 95% CI 0.871-1.288).
The most recent meta-analysis was published by Diener et al. in 2010, and included five systematic reviews and fourteen trials with a total of 7711 patients (6752 midline incisions) (19). Of these fourteen trials, four reported results regarding interrupted closure compared with continuous closure. Patients undergoing elective primary midline laparotomy with a continuous technique had a significantly lower chance of developing IH (OR 0.59, 95% CI: 0.43-0.82).

Mass closure, layered closure or single layer closure

Two meta-analyses were found comparing the effect of mass closure and layered closure of the abdomen on IH incidence (22, 23). Furthermore an experimental study was found comparing the effect of mass closure and single layer closure on wound separation (24).
In the meta-analysis of Weiland et al. nine studies were included that compared mass closure with layered closure, with a total of 3,321 patients (22). The meta-analysis showed a significant increase in IH rates when layered closure was used ($p = 0.02$). This outcome was also confirmed by a meta-analysis by Rucinski et al. in 2001 (23). The authors concluded that a continuous mass closure is the optimal technique for fascial closure after laparotomy.
An experimental study by Cengiz et al. studied the separation of wound edges in midline laparotomy incisions closed with either a mass stitch or a stitch incorporating only aponeurosis. After three hours with raised intra-abdominal pressure the lateral edge of stitches became separated by a mean (SD) of 5.6 (1.3) mm with a mass stitch and by 0.5 (0.6) with a stitch only incorporating the aponeurosis ($p < 0.001$). Muscle tissue and peritoneum that were included in the mass stitch was compressed, darkly discoloured, and there were signs of haemorrhage.

Rapidly absorbable versus slowly absorbable versus non-absorbable sutures

Four meta-analyses investigated the effect of absorbability of sutures on IH incidence (13, 19, 21, 22). The meta-analysis conducted by Weiland et al. compared interruptedabsorbable and interrupted non-absorbable sutures. Interrupted non-absorbable sutures had a significantly higher rate of hernia formation compared to interrupted absorbable sutures ($p = 0.0002$). The authors also compared continuous absorbable and continuous non-absorbable sutures. IH rates were significantly higher when continuous absorbable sutures were used ($p = 0.0007$).
The meta-analysis by Hodgson et al. observed that patients closed with non-absorbable sutures had a significantly lower chance of developing IH (OR 0.68, 95%

CI 0.52-0.87) compared with absorbable sutures (13). In addition, interrupted non-absorbable sutures versus interrupted absorbable sutures were compared, however without significant results. The authors also compared continuous non-absorbable sutures versus continuous absorbable sutures. Incisional hernias were significantly less common in the continuous non-absorbable group (OR 0.61, 95% CI 0.46-0.80).

The meta-analysis by van 't Riet et al. studied slowly absorbable versus rapidly absorbable versus non-absorbable sutures (21). One study in this meta-analysis compared continuous rapidly absorbable with continuous non-absorbable sutures in 751 patients (25). Continuous closure with a rapidly absorbable suture was associated with significantly more IH than closure with a non absorbablesuture ($p < 0.001$). However patients that were closed with a non-absorbable suture material had significantly more suture sinuses ($p < 0.001$) and pro longed wound pain ($p = 0.003$). The same study compared continuous closure with a rapidly absorbable suturewith continuous closure with a slowly absorbable suture. Continuous closure with a rapidly absorbable suture was associated with a higher incisional hernia incidence ($p < 0.009$). Five studies compared slowly absorbing with non-absorbing continuous sutures in 2669 patients. No significant difference in incisional hernia incidence was found ($p = 0.75$). However increased incidences of suture sinus ($p = 0.02$) and prolonged wound pain ($p < 0.005$) were found after the use of non-absorbable sutures.

Similar results were found in the most recent metaanalysisby Diener et al on this subject (19). Patients closed in an elective setting with slowly absorbable sutures were observed to have a significant lower IH rate compared with rapidly absorbable sutures (OR 0.65, 95% CI 0.47-0.90).

A recent RCT by Bloemen et al. compared non-absorbable Prolene™ sutures with slowly absorbable PDS™ sutures. With a median follow-up of 31 months, including ultrasound investigation, the incidence in the Prolene™ group was 20.2% and 24.9% in the PDS™ group ($p = 0.297$) (2).

Suture length to wound length ratio and stitch length

Already in 1976 Jenkins et al. introduced the term suture length to wound length ratio (SL/WL ratio) (18). In this publication the authors showed that deep wound disruption (evisceration and ventral hernia) was associated with the use of a SL/WL ratio of two or less and that wound disruption could be prevented by the use of a SL/WL ratio of four or more.

A prospective study by Israelson et al. investigated the effect of SL/WL ratio on the healing of midline laparotomy wounds (15). Multivariate analysis identified

the SL/WL ratio, age and major wound infection as independent risk factors for IH development. IH occurred in 9% of the patients when the SL/WL ratio was four or greater and in 23.7% when it the ratio was less than four ($p = 0.001$). The same study group published several more articles on the effect of SL/WL ratio on IH rates and other wound complications (16, 17, 26, 27). All of these studies concluded that a SL/WL ratio of four or more reduced the incidence of IH.

Besides the SL/WL ratio, the stitch length (Fig. 1) has also been a subject of discussion in the literature. Two experimental studies and one RCT were found comparing a short stitch length with a long stitch length. The studies showed that using a short stitch length resulted in stronger wounds and faster wound healing than the routine long stitch technique (28, 29).

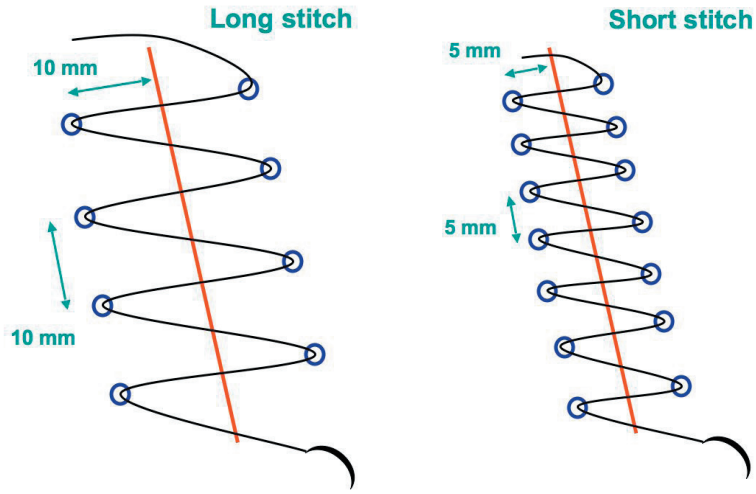

Figure 1
Short and long stitch length

There is high-level evidence that a suture to wound length ratio (SL/WL) of at least 4/1 reduces significantly the incidence of post-operative incisonal hernias. A SL/WL ratio of 4 can be obtained with a long stitch where stitches are placed at 1 cm from the fascial edge and 1 cm from each other. A short stitch technique where stitches are placed 5mm from the fascial edge and 5 mm between stitches also results in a SL/WL ratio of 4. Recent experimental and clinical studies indicate a better performance of the short stitch technique.

A RCT by Millbourn et al. investigated the effect of stitch length on wound dehiscence, surgical site infection and IH(30). A total of 381 patients were operated with a long stitch length and 356 with a short stitch length. At twelve month follow-up, patients operated with the long stitch had an 18% IH incidence compared with 5.6% of the patients operated with a short stitch ($p < 0.001$). In a multivariate analysis, a long stitch length was an independent risk factor for both surgical infection and IH.

DISCUSSION

Our literature search allowed us to define the best evidence-based technique to close a midline laparotomy. This technique is adopted as the PRINCIPLES technique and is summarized in Table I.

	Evidence based PRINCIPLES	Principles study technique
1	Closure with a continuous running suture	Single running suture.
2	Slowly absorbable monofilament suture	Monomax™ (Poly 4-hydroxybutyrate)
3	Size of the suture does not have to be bigger than 2/0	Suture size 2/0, 150 cm long
4	A small needle is preferred for the small bites technique	Needle: Taper point, 1/2 circle, 26 mm
5	Single layer closure	Suture only the fascia
6	Small stitches	Stitches should be placed 5 mm from the edge of the fascia
7	Suture to wound length ratio should be at least 4	Sutures should be placed at a distance of 5 mm from each other to obtain a SL/WL ≥ 4
8	The tension on the suture during the closure should be the minimum tension to approximate the fascia edges	Avoid tension on the suture by the assistant
9	Small, but strong knots might have less suture sinuses and wound problems	Start the sutures with a "self-locking knot" and end with a "stopping knot"
10	If more than one suture is used to close the abdomen:	Sutures will be knotted separately and not to each other

* SL = suture length; WL = wound length.

Table I

PRINCIPLES study technique

As far as technique concerned, there was much variety in the outcome of the different meta-analyses. One metaanalysis favoured continuous closure (13), two found no difference (21, 22), and one favoured interrupted closure (20). However the most recent meta-analysis by Diener et al. favoured continuous closure, and included all earlier published meta-analyses (19). Furthermore, continuous closure has the advantage of being easier and faster.

When focussing on the suture material, slowly absorbable and non-absorbable sutures were favoured over rapidly absorbable in all studies. No significant difference was found between the slowly and non-absorbable sutures when looking at IH rates (21). However increased wound pain and sinus formation were associated with non-absorbable sutures (25). We believe that the suture material needs to provide not only adequate tensile strength but also adequate elasticity to accommodate any increase in abdominal wall pressure postoperatively. Decreased compliance of the abdominal wall after closure leads to increased abdominal pressure and could cause a negative effect on pulmonary function. The development of extra long-term absorbable sutures with elastic properties is a new innovation in abdominal wall closure. Monomax™ is a monofilament poly-4 hydroxybutyrate suture that compared to polydioxanone suture (PDS™, Monoplus™) had a slower degradation rate and retained a tensile strength during a longer time period (31). The suture is elastic and this might absorb variations in postoperative abdominal wall tension. A recent historically controlled prospective study has shown the suture to be safe and efficient for abdominal wall closure (31).

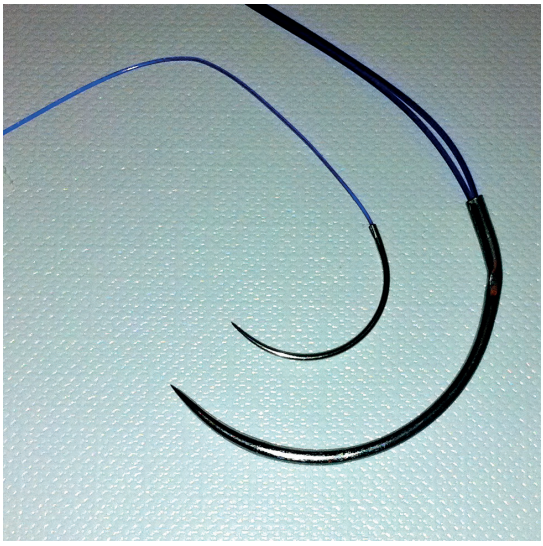

Figure 2
Needle sizes
Picture of the difference between a PDS™ (polydioxanone) 1 loop suture that is commonly used in abdominal wound closure and the Monomax™ (poly-4-hydroxybutyrate) 2/0 suture of the Principles study. The needle of the loop is a Taper Point, 1/2 circle, size 65 mm. The needle of the Monomax™ suture is a Taper Point, 1/2 circle, size 26 mm.

Not much literature is available on the dimensions of the suture and the size of the needle used during abdominal wound closure. The research group of Dr. Israelsson has used a size 2/0 suture mounted on a very small needle (30). Figure 2 shows the difference in needle and suture size between the commonly used PDS™ polydioxanone loop suture size 1 and the Monomax™ 2/0 as will be used in the Principles trial. The question that remains is how fascial sutures for median laparotomy closure should be inserted. When looking at mass closure versus layered closure both meta-analyses by Weiland et al. and Rucinski et al. favoured mass closure technique (22, 23). However an experimental study showed less separation of the wound edge when using a stitch only incorporating aponeurosis compared to a mass stitch (24). Regarding SL/WL ratio and stitch length, a ratio of four or more and a small stitch length reduces the IH rate. These results, however, came from the same research group (15-17, 26, 27, 29). Currently a RCT is being performed, comparing the short and long stitch, which may shed more light on the subject (32). Experimental studies showed an increased tensile strength using small stitch length (28, 29).

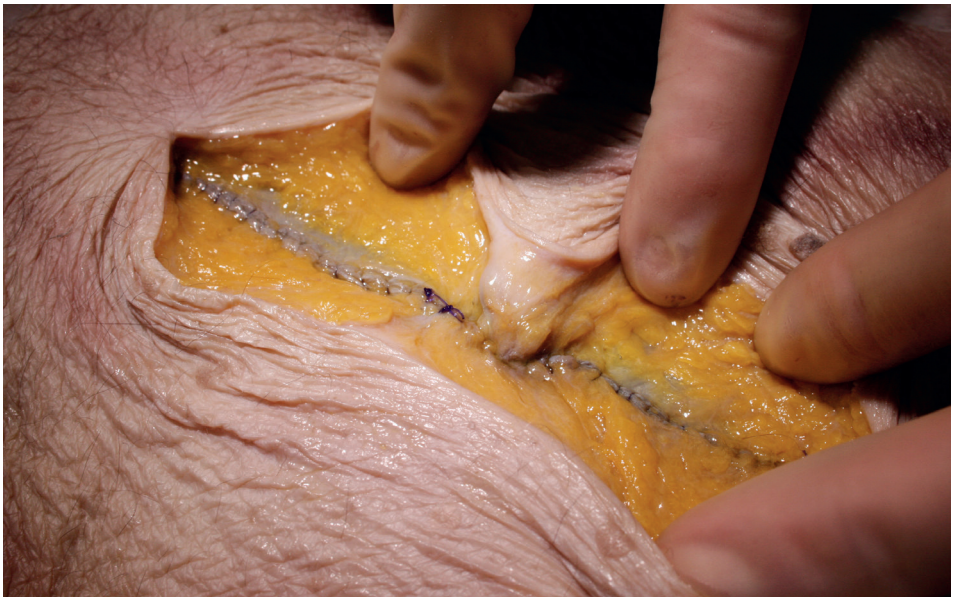

Figure 3

Intraoperative picture of a fascia closed with the Principles technique. It is recommended to avoid excessive tension on the suture during the closure of the laparotomy. As a rule the suture should still be visible on the fascia and not be buried into the tissue at the end of the closure. Separate sutures will be knotted separately and not to each other.

Two other aspects of abdominal wound closure that have not often been investigated and discussed in the literature are the pulling tension on the suture during abdominal wall closure and the impact of the knots on complications like suture sinuses and wound infections. Excessive tension on the suture during closure can induce tissue ischemia. This can lead to impaired wound healing, small fascial tears and the formation of fascial defects in the postoperative period. Increased postoperative pain might have an impact on complications like pneumonia. In 1999 a RCT comparing a new continuous double-loop closing technique with the conventional running suture was ended prematurely. The use of the continuous double-loop closure technique lessened the compliance of the abdominal wall resulting in signifi cantly higher pulmonary complications in this group (33). Therefore we recommend limiting the tension on the suture to that needed to approximate the fascial edges. To achieve this, the suture should be visible after closing and should not be buried into the tissues (Fig. 3). The knots fixating the suture have to be strong enough to resist in creases in the postoperative abdominal wall tension. Knot failure has been implicated as the cause of a burst abdomen in four percent of the patients (34). It is likely that the amount of suture material in a knot has impact on the rate of suture sinuses. Therefore using a smaller size suture and using a knot with little foreign material might be beneficial. Therefore we recommend, when using multiple sutures, to knot the sutures separately and not to each other.

In conclusion we have defined what can be considered as the best evidence-based technique to close a midline laparotomy wound. The optimal closing technique should be single layer closure, using a slowly absorbable suture material with a SL/WL ratio of four or more and a short stitch length. We adopt this as the Principles technique, which will be clinically evaluated in a multicentre study.

Figure 4

View of the Prima Principles workshop.
The first Prima Principles workshops were held at the anatomy lab of the "Vaardigheidscentrum Anatomie, Vesalius Instituut" University of Leuven in fall 2012. Surgeons were instructed on the Principles technique to close a midline laparotomy.*

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2.4 EUROPEAN HERNIA SOCIETY GUIDELINES ON THE CLOSURE OF ABDOMINAL WALL INCISIONS

Hernia, 2015, 19:1-24

F.E. Muysoms, S.A. Antoniou, K. Bury, G. Campanelli, J. Conze, D. Cuccurullo, A.C. de Beaux, E.B. Deerenberg, B. East, R.H. Fortelny, J-F. Gillion, N.A. Henriksen, L. Israelsson, A. Jairam, A. Jänes, J. Jeekel, M. Lopez-Cano, M. Miserez, S. Morales-Conde, D. Sanders, M.P. Simons, M. Śmietański, L. Venclauskas, F. Berrevoet

"Maybe we should first learn and teach how to prevent incisional hernias, rather than how to treat them?"

© Filip Muysoms, *September 28th 2013, EHS board meeting, Sperlonga, Italy*

ABSTRACT

Background

The material and the surgical technique used to close an abdominal wall incision are important determinants of the risk of developing an incisional hernia. Optimising closure of abdominal wall incisions holds a potential to prevent patients suffering from incisional hernias and for important costs savings in health care.

Methods

The European Hernia Society formed a Guidelines Development Group to provide guidelines for all surgical specialists who perform abdominal incisions in adult patients on the materials and methods used to close the abdominal wall. The guidelines were developed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach and methodological guidance was taken from Scottish Intercollegiate Guidelines Network (SIGN). The literature search included publications up to April 2014. The guidelines were written using the AGREE II instrument. An update of these guidelines is planned for 2017.

Results

For many of the Key Questions that were studied no high quality data was detected. Therefore, some strong recommendations could be made but, for many Key Questions only weak recommendations or no recommendation could be made due to lack of sufficient evidence.

Recommendations

To decrease the incidence of incisional hernias it is strongly recommended to utilise a non-midline approach to a laparotomy whenever possible. For elective midline incisions, it is strongly recommended to perform a continuous suturing technique and to avoid the use of rapidly absorbable sutures. It is suggested using a slowly absorbable monofilament suture in a single layer aponeurotic closure technique without separate closure of the peritoneum. A small bites technique with a suture to wound length (SL/WL) ratio at least 4/1 is the current recommended method of fascial closure. Currently, no recommendations can be given on the optimal technique to close emergency laparotomy incisions. Prophylactic mesh augmentation appears effective and safe and can be suggested in high-risk patients, like aortic aneurysm surgery and obese patients.

For laparoscopic surgery, it is suggested using the smallest trocar size adequate for the procedure and closure of the fascial defect if trocars larger or equal to 10 mm are used. For single incision laparoscopic surgery, we suggest meticulous closure of the fascial incision to avoid an increased risk of incisional hernias.

INTRODUCTION

Background

Incisional hernias are a frequent complication of abdominal wall incisions, but a wide range of incisional hernia rates are reported [1–6]. The weighted mean incisional hernia rate at 23.8 months was 12.8 % in a systematic review and meta-regression study [7], but incidence rates up to 69 % have been reported in high-risk patients with prospective long-term follow-up [8]. The reported incidence is determined by several factors: the patient population studied, the type of abdominal wall incision, the length of follow-up and the method of incisional hernia diagnosis. Risk factors for incisional hernias include postoperative surgical site infection, obesity and abdominal aortic aneurysm [9–11]. Nevertheless, it seems that the suture material and the surgical technique used to close an abdominal wall incision, are the most important determinants of the risk of developing an incisional hernia [1, 12]. The development of an incisional hernia has an important impact on the patients' quality of life and body image [13]. Furthermore, the repair of incisional hernias still has a high failure rate with long term recurrence rates above 30 %, even when mesh repair is performed [14–16]. Optimising the surgical technique to close abdominal wall incisions using evidence based principles, holds a potential to prevent patients suffering from incisional hernias and the potential sequelae of incisional hernia repairs [17]. The mean direct and indirect costs for the repair of an average incisional hernia in an average patient in France in 2011 was € 7,089 [18]. Thus, reducing the incisional hernia rate by optimising the closure of abdominal wall incisions holds a great potential for costs savings in the use of health care facilities and in reducing postoperative disability. The European Hernia Society (EHS) originated from the "Groupe de la recherche de la paroi abdominal" (GREPA), which was founded in 1979 with the aim: "The promotion of abdominal wall surgery, the study of anatomic, physiologic and therapeutic problems related to the pathology of the abdominal wall, the creation of associated groups which will promote research and teaching in this field, and the development of interdisciplinary relations". During the autumn board meeting of the EHS in September 2013 in Italy it was decided to extend our mission to actively promote the prevention of incisional hernias by the Sperlonga

statement: "Maybe we should first learn and teach how to prevent incisional hernias, rather than how to treat them?"

Objective

The objective is to provide guidelines for all surgical specialists who perform abdominal incisions in adult patients on the optimal materials and methods used to close the abdominal wall. The goal is to decrease the occurrence of both burst abdomen and incisional hernia. The guidelines refer to patients undergoing any kind of abdominal wall incision, including visceral surgery, gynaecological surgery, aortic vascular surgery, urological surgery or orthopaedic surgery. Both open and laparoscopic surgeries are included in these guidelines.

METHODS

As EHS secretary of Quality, Filip Muysoms, under the auspices of the European Hernia Society board, proposed the Guidelines Development Group. The project was presented to the EHS board and accepted during the board meeting in Sperlonga, Italy, on September 28th 2013. The members of the Guidelines Development Group were chosen to recruit key opinion leaders and researchers on the subject from Europe. A geographical distribution across European countries was attempted and some younger surgeons having performed research on the subject were included in the Guidelines Development Group. Many of the members have contributed previously in producing guidelines on a national and international level. The Guidelines Development Group included abdominal wall surgeons, upper gastro-intestinal surgeons, hepato-biliary surgeons, colorectal surgeons and a vascular surgeon.

During a Kick Off meeting of the Guidelines Development Group in the Bonham Hotel in Edinburgh on October 28th 2013, the members attended a seminar on the methodological aspect of developing guidelines by Robin T Harbour, the Lead Methodologist of the Scottish Intercollegiate Guidelines Network (SIGN) [19]. The AGREE II instrument was used from the start of the project to guide our methodology and structure of producing the guidelines [20]. AGREE II gives as definition for the Quality of a guideline: "The confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice." During this first meeting Key Questions were formulated and translated into 24 patients-intervention-comparison-outcome (PICO) formats. For each Key Question at least three Guidelines Development Group members were assigned

as investigators and specific search terms were formulated. The Key Questions with their PICO's and assigned authors are listed in addendum 1.
On November 11th 2013, a meeting in Glasgow at the SIGN headquarters was held with the steering committee of the Guidelines Development Group to discuss the search strategy. A clinical librarian working for SIGN performed the primary literature research for all Key Questions. This involved a search for systematic reviews and/or meta-analyses on the Key Questions in Medline, Embase, NIHR CRD, NICE and The Cochrane library. The PRISMA flow diagram is shown in Fig. 1 and the search terms used are in addendum 2. The Guidelines Development Group members evaluated the systematic reviews for their relevance to the Key Questions and a qualitative assessment was done using the SIGN checklist No 1 for systematic reviews and meta-analyses [19]. Only systematic reviews of High Quality were used as basis for the guidelines development. A second search (no filters) on the Key Questions was performed for relevant RCT's published after the end of the search performed for the systematic reviews involved. If no High Quality systematic review was identified for a Key Question, the working group members performed a separate systematic review using the PRISMA statement methodology [21]. To avoid lengthening of this guidelines manuscript, the results of these systematic reviews will be submitted as a separate manuscript on behalf of "The Bonham Group", which are the members of the Guidelines Development Group. The members working together on a Key Question provided a Summary of Findings table from the results of the literature search, which were presented and discussed during the second group meeting.

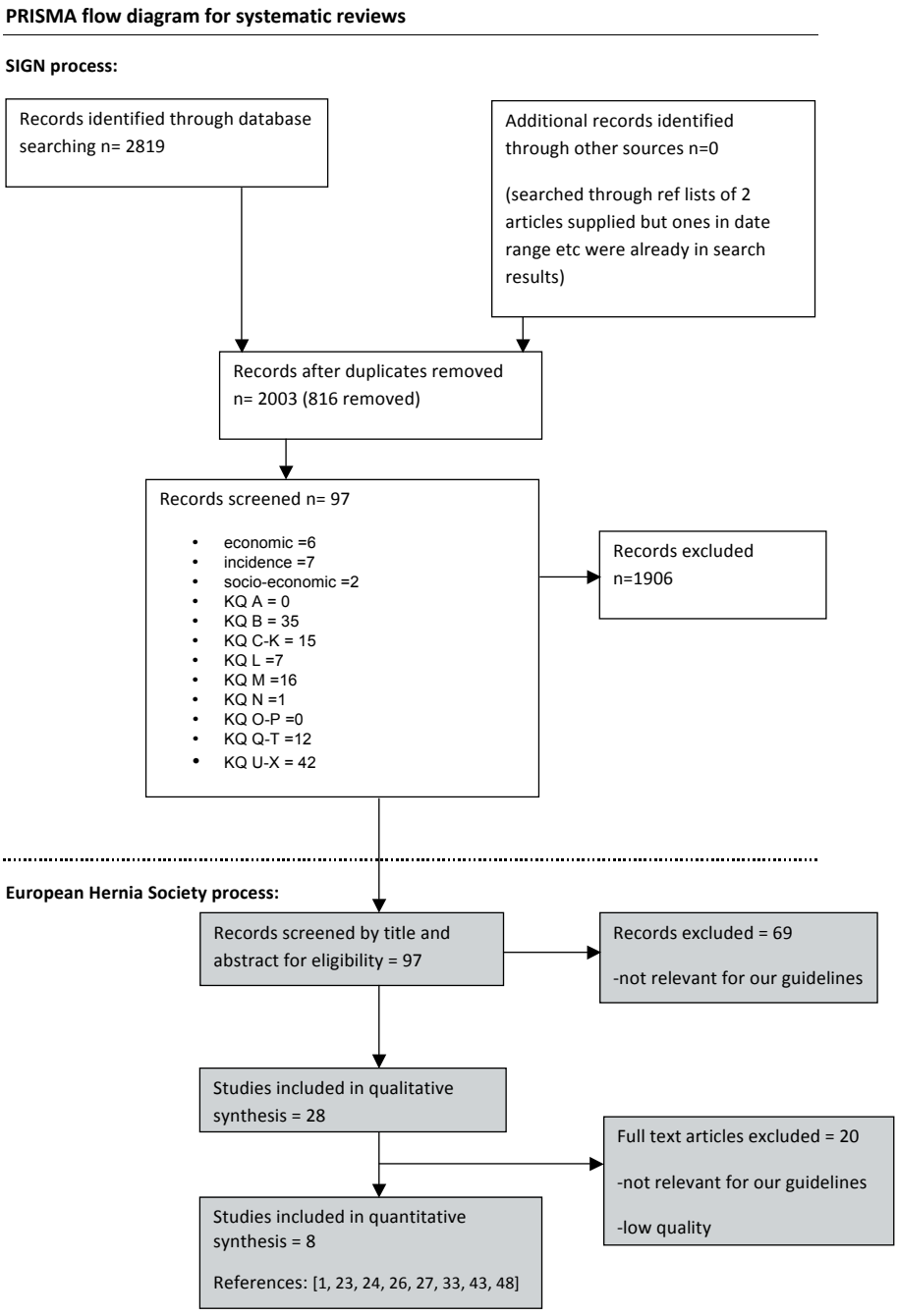

***Figure* 1**

PRISMA flow diagram for the search for systematic reviews and/or meta-analyses performed by Scottish Intercollegiate Guidelines Network (SIGN) for the

Guidelines Development Group of the European Hernia Society guidelines on the closure of abdominal wall incisions. The search was performed in November 2013 and included searches in Medline, Embase, NIHR CRD, NICE and The Cochrane library

The second Guidelines Development Group meeting was held in Edinburgh on April 25th 2014. For evaluation of evidence, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used [22]. For each Key Question, a level of evidence was proposed using the GRADE approach and four levels of quality of the body of evidence were used: high, moderate, low, very low (Table 1). Based on the research evidence, the clinical experience and patient values the Guidelines Development Group formulated a recommendation for each Key Question. In the GRADE approach only three levels of recommendation are used: strong recommendation, weak recommendation and no recommendation.

Grading the Quality of the body of evidence for each Key Questions using the GRADE approach			
Underlying methodology	**Quality rating**	**Symbols**	**Definitions**
Randomized trials; or double-upgraded observational studies.	High	⊠⊠⊠⊠	Further research is very unlikely to change our confidence in the estimate of effect
Downgraded randomized trials; or upgraded observational studies.	Moderate	⊠⊠⊠☐	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Double-downgraded randomized trials; or observational studies.	Low	⊠⊠☐☐	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Triple-downgraded randomized trials; or downgraded observational studies; or case series/case reports.	Very low	⊠☐☐☐	Any estimate of effect is very uncertain.

Grading of recommendations using the GRADE approach	
Strong recommendation	Based on the available evidence, if clinicians are very certain that benefits do, or do not, outweigh risks and burdens they will make a strong recommendation.
Weak recommendation	Based on the available evidence, if clinicians believe that benefits and risks and burdens are finely balanced, or appreciable uncertainty exists about the magnitude of benefits and risks, they must offer a weak recommendation.
No recommendation	If based on the literature research no evidence could be found, no recommendation can be made.

Table 1

Using the GRADE approach to guideline development [22] the Quality of the body of evidence is rated (high/moderate/low/very low) and the recommendations are graded as strong or weak

The results of the guidelines proposed by the Guidelines Development Group were presented during the 36th Annual International Congress of the European Hernia Society in Edinburgh on May 31st 2014. The manuscript was subsequently written by the first author in a uniform manner for all Key Questions and send for review and agreement by all co-authors. Prior to submission, the manuscript of the guidelines was externally reviewed by experts and evaluated using the AGREE II instrument.

Results

The results of the searches are shown in the PRISMA flow diagram in Fig. 1. From the 97 records detected by the SIGN process, 69 records were excluded based on the title and abstract as not being relevant to the guidelines. The remaining 28 systematic reviews [1, 23–49] were assessed by full text for their relevance to the Key Questions and if retained were assessed qualitatively using the SIGN checklist No 1 [19]. Additional searches on PubMed and by checking the references of all manuscripts were performed by the members of the Guidelines Development Group assigned to each Key Question. Relevant studies published up until April 2014 were included to provide the Summary of Evidence tables.

Which diagnostic modality is the most suitable to detect incisional hernias?

No systematic reviews on diagnostic modalities for incisional hernias were found. The PRISMA flow diagram is shown in addendum 3 (Key Question A). Fifteen records were included in the qualitative analysis [3–6, 50–60]. Only four studies were retained as High Quality and are listed in the Summary of Findings table (Table 2) [5, 50–52].

The quality of most studies investigating the diagnostic accuracy of imaging techniques was low to very low. Only some provided a sensitivity analysis. Because no studies compared different diagnostic modalities in a similar methodology and with similar study arms, no pooling of data was useful or possible. In general, most studies show that medical imaging will increase the rate of detection of incisional hernias compared to physical examination. In an everyday clinical setting this is usually not important, because most asymptomatic hernias do not require treatment and their diagnosis is thus not necessary.

CT scan is reliable and reproducible, whereas ultrasound is more operator-dependant. However, CT scan will induce a radiation load to the patients and ultrasound is more accessible in most health care settings. A good standardisation and dynamic evaluation by ultrasound of the abdominal wall is needed, as described by Beck et al. [51] as the dynamic abdominal sonography for hernia (DASH) technique.

The difference in accuracy between physical examination and imaging technique is most important in the context of comparative studies evaluating incisional hernia rate. Next to the method of incisional hernia diagnosis the length of follow-up is important. Fink et al. [2] reported in a follow-up study of two prospective trials an increase from 12.6 % at 12 months to 22.4 % at 36 months ($p < 0.001$) and concluded that follow-up for 3 years should be mandatory in any study evaluating the rate of postoperative incisional hernia after midline laparotomy.

Statement	It is recommended that prospective studies with incisional hernias as a primary outcome integrate medical imaging, either dynamic ultrasound or CT scan, in the follow-up.	☒☒☐☐	strong
Statement	It is recommended that studies with incisional hernias as a primary outcome include follow-up of at least 24 months (and preferably 36 months).	☒☒☐☐	strong

Bibliographic citation [reference]	Study type	SIGN assessment	Number of patients	Patient characteristics
Baucom et al. Journal of the American College of Surgeons 2013; 218(3):363-6. [50]	prospective cohort study	++	181	patients seen at a general surgery department who had a prior abdominal operation and an available CT scan within six months before the visit
General comments: Adequate designed study to compare physical examination to CT scan diagnosis of incisional hernias. CT scan was used a "gold standard" for the sensitivity analysis.				
Beck et al. Journal of the American College of Surgeons 2013;216(3):447-53. [51]	prospective cohort study	++	181	patients seen at a general surgery department who had a prior abdominal operation and an available CT scan within six months before the visit
General comments: Paper from the same group as Baucom et al. Concerns the same patient population. Adequate designed study to compare dynamic ultrasound to CT scan diagnosis of incisional hernias. CT scan was used a "gold standard" for the sensitivity analysis.				
den Hartog et al. Hernia 2009;13(1):45-8. [5]	prospective cohort study	++	40	patients that had aortic surgery by midline incision at least 12 months before
General comments: Adequate designed study to compare ultrasound to CT scan diagnosis of incisional hernias. No comparison to physical examination. Limited number of patients. CT scan was used as "gold standard" for the sensitivity analysis.				
Schreinemacher et al. Arch Surg. 2011;146:94-9. [52]	retrospective cohort study with prospective examination	++	111	patients that have a closure of a temporary stoma (42% ileostomies and 58% colostomies).
General comments: Both examinations were performed by the same person. Ultrasound was used a "gold standard" for the sensitivity analysis.				

Table 2

Summary of Findings table for Key Question A: which diagnostic modality is the most suitable to detect incisional hernias?

Intervention	Comparison	Length of follow-up	Outcome measure
Physical examination by a surgeon	CT scan reviewed by surgeon	not available	Physical examination had a low sensitivity (77%)and negative predictive value (77%). It fails to detect 23% of hernias and in 32% of the patients with a BMI ≥ 30 kg/m^2.
dynamic abdominal ultrasound by surgeon	CT scan reviewed by surgeon	not available	Dynamic Ultrasound has a high sensitivity (98%) and specificity (88%). It has a positive predictive value of 91 % and negative predictive value of 97%. It is a good alternative to CT scan diagnosis.
Ultrasound by radiologist	CT scan (by 2 independent radiologists.	mean 3.4 years	Incisional hernia prevalence was 60.0% with CT scan and 42.5% with ultrasound. The sensitivity of US was 70.8% and the specificity 100%. Us has a positive predictive value of 100% and a negative predictive value of 69.6%. CT scan diagnosis of the incisional hernias has a good intra- and inter -observer reliability.
Ultrasound of the abdominal wall by surgeon	Physical examination by surgeon	median 35 months	Incisional hernia prevalence was 32.4% with ultrasound evaluation. Physical examination had a sensitivity of 58.3% and a specificity of 97.3%. The positive predictive value was 91.3% and the negative predictive value was 83%.

Does the type of abdominal wall incision influence the incidence of incisional hernias or burst abdomen?

Laparotomy incisions can be classified as midline, transverse, oblique or paramedian incisions [61]. The PRISMA flow diagram is shown in addendum 3 (Key Question B). Six systematic reviews have compared midline laparotomies to alternative incisions [26, 27, 31, 36, 38, 61], but only two were considered High Quality [26, 27]. A recent systematic review by Bickenback et al. [26] compared midline, transverse (including oblique) and paramedian incisions. This review included all relevant studies from previous reviews and no additional RCT's were detected that were published after this review. The literature search of this systematic review [26] identified studies published until 2009 and 24 RCT's directly comparing different laparotomy incisions were included in the analysis. The incisional hernia rates after non-midline incisions were significantly lower compared to the incisional hernia rates after midline incisions, for both transverse incisions (RR = 1.77; 95 % CI:1.09–2.87) and paramedian incisions (RR = 3.41; 95 % CI: 1.02–11.45) [26]. However, data on burst abdomen (deep wound dehiscence or fascial dehiscence) were not significantly different between the different incisions types.
A Cochrane review by Brown et al. [27] published in 2005 and updated in 2011, compared transverse versus midline incisions, but excluded studies comparing paramedian incisions. A decreased incisional hernia rate after transverse incisions was reported compared to midline incisions (OR = 0.49; 95 % CI: 0.30–0.79).
Both reviews concluded that non-midline incisions significantly reduced the risk of incisional hernia compared to midline incisions, but did not influence the risk of burst abdomen. Interestingly, the Cochrane conclusions were more moderate, due to methodological and clinical heterogeneity of the studies and the risk of potential bias.

Statement	Non-midline incisions are recommended where possible.	☒☒☒☐	strong

What is the optimal technique to close a laparotomy incision?

Ten systematic reviews on the techniques and/or the materials to close abdominal wall incisions were identified [1, 32, 34, 37, 38, 42, 43, 48, 62, 63]. The PRISMA flow diagram is shown in addendum 3 (Key Question C–G). The data from the different systematic reviews are very incoherent and conclusions are often completely contradictory. The overall quality of most systematic reviews is low and therefore, several should be rejected as evidence to create guidelines. A major

problem to identify the evidence from the literature is the fact that most prospective studies compared several variables between the study arms. Moreover, the populations studied are often very different: midline only or including other incisions, emergency or elective surgery, and different operative indications.
The current guidelines on techniques and materials are based on the systematic reviews by Diener et al. [1] and van't Riet et al. [48] which were evaluated as High Quality. Both systematic reviews included only studies involving midline laparotomies and the review by Diener et al. was the only one to distinguish between elective or emergency surgery. The systematic review by Sajid et al. [43] was used for the question on suture materials and a recent Cochrane review by Gurusamy et al. [63] was used for the question on peritoneal closure.
Using separate PICO's the shortcoming of many study designs to deliver clear answers becomes obvious. Another shortcoming in most studies on closure of laparotomies is the failure to monitor the technical details of the suturing technique, like the SL/WL ratio and the stitch size. As demonstrated by Israelsson [64] this might be an important confounding factor in studies comparing different suture materials. An updated systematic review taking into account the mentioned shortcomings of individual studies might be performed, but for these guidelines the conclusions are based on the data from the currently available systematic reviews. The protocol for an ongoing Cochrane review [65] was published in 2006 but the final data have not yet been published.

Statement	It is recommended that prospective randomized studies on the suture material to close abdominal wall incisions use the same suturing technique in both study groups.		strong
Statement	It is recommended that prospective randomized studies assessing the technique to close abdominal wall incisions use the same suture material in both study groups.		strong

Continuous suturing versus interrupted sutures

Both meta-analyses concluded that continuous suturing for closure of midline laparotomies was beneficial compared to interrupted closure [1, 48]. Diener et al. [1] found a significant lower incisional hernia rate for continuous suturing (OR 0.59: $p = 0.001$) in elective surgery. Most of the included studies were at high risk of bias because the interrupted study arm used rapidly absorbable multifilament sutures and the continuous arm used either non-absorbable or slowly absorbable

monofilament sutures. van't Riet et al. [48] included studies involving emergency laparotomies and did not find any difference in incisional hernia rate between interrupted and continuous suturing. Continuous suturing was recommended because it was significantly faster.

Statement	Continuous suturing for closure of midline abdominal wall incisions in elective surgery is recommended.	⊠⊠□□	strong

Closure versus non-closure of the peritoneum

The Cochrane review by Gurusamy et al. [63] concluded that there was no short-term or long-term benefit in peritoneal closure. Five studies were included but were heterogeneous in type of incision (midline and non-midline) and included both elective and emergency laparotomies. In all studies, the peritoneum was closed as a separate layer in the study arm with peritoneal closure.

Statement	Closure of the peritoneum as a separate layer during closure of laparotomy incisions is NOT recommended.	⊠⊠□□	weak

Mass closure versus single layer closure

The search for the most appropriate layers to be sutured when closing a laparotomy is hampered by the lack of good definitions on what constitutes a mass closure, layered closure or single layer closure. No clinical studies directly comparing different closure methods were found.

For future research the Guidelines Development Group proposes the following definitions:
- *mass closure*: the incision is closed with a suture bite including all layers of the abdominal wall except the skin.
- *layered closure*: the incision is closed with more than one separate layer of fascial closure
- *single layer aponeurotic closure*: the incision is closed by suturing only the abdominal fascia in one layer.

Statement	For closure of midline abdominal wall incisions in elective surgery, a single layer aponeurotic closure is suggested.	⊠□□□	weak

Suture length to wound length ratio (SL/WL)

The beneficial effect of a high SL/WL ratio on reducing the incidence of incisional hernias has been recognised for a long time [66], but evidence from clinical prospective studies remains scarce and most of the work addressing the topic comes from the Clinic of Sundsvall in Sweden [64, 67, 68]. A RCT, performed in Sundsvall, demonstrated the importance of the SL/WL ratio in reducing incisional hernia rate. The critical value was determined to be at a ratio of 4/1 [64]. Although a SL/WL ratio ≥4 is often mentioned in the protocol of prospective studies, many fail to document that the SL/WL ratio was recorded for the individual study patients.

Statement	A suture to wound length ratio (SL/WL) of at least 4/1 for continuous closure of midline abdominal wall incisions in elective surgery is suggested.	☒☒☐☐	weak
Statement	It is recommended that all prospective studies on the closure of laparotomy incisions will document the suture to wound length ratio (SL/WL) in all patients, as well as the number of stitches.		strong

Small bites versus large bites

Millbourn et al. [69] demonstrated that closure of a midline laparotomy with a "small bites" technique resulted in significant less incisional hernias (5.6 vs 18.0 %; $p < 0.001$) and less surgical site infections (5.2 vs 10.2 %; $p = 0.02$). In the small bite technique the laparotomy wound is closed with a single layer aponeurotic suturing technique taking bites of fascia of 5–8 mm and placing stitches every 5 mm.

Statement	The "small bites technique" for continuous closure of midline incisions is suggested.	☒☒☒☐	weak

What is the optimal suture material to close a laparotomy incision?

The PRISMA flow diagram for our search on suture materials is shown in Addendum 3 (Key Question H–K). Despite significant heterogeneity and confounders in most systematic reviews identified, a study by Sajid et al. [43] focused solely on the suture material. Table 3 defines the suture materials used in the included studies.

	Producer	Material	Absorbable	Absorption time	Mono/ multifilament	Antibiotics impregnated
Prolene	Ethicon	Polypropylene	Non		Monofilament	No
Surgipro	Covidien	Polypropylene	Non		Monofilament	No
Ethilon	Ethicon	Nylon	Non		Monofilament	No
Monosof	Covidien	Nylon	Non		Monofilament	No
Ethibond	Ethicon	Polyethylene	Non		Multifilament	No
Mersilene	Ethicon	Polyester	Non		Multifilament	No
Surgilon	Covidien	Nylon	Non		Multifilament	No
Maxon	Covidien	Polyglyconate	Slowly	180 days	Monofilament	No
PDS	Ethicon	Polydioxanone	Slowly	183-238 days	Monofilament	No
PDS plus	Ethicon	Polydioxanone + Triclosan	Slowly	183-238 days	Monofilament	Yes
Monoplus	B Braun	Polydioxanone	Slowly	180-201 days	Monofilament	No
Monomax	B Braun	Poly-4-hydroxy-butyrate	Slowly	390-1080 days	Monofilament	No
Vicryl	Ethicon	Polyglactin	Rapidly	56-70 days	Multifilament	No
Vicryl plus	Ethicon	Polyglactin + Triclosan	Rapidly	56-70 days	Multifilament	Yes
Polysorb	Covidien	Polyglycolic acid	Rapidly	60-90 days	Multifilament	No
Dexon	Covidien	Polygglycolic acid	Rapidly	60-90 days	Multifilament	No

Table 3

List of the most commonly used suture materials to close abdominal wall incisions and their characteristics

Rapidly absorbable suture versus non-absorbable or slowly absorbable sutures

Diener et al. [1] reported a significantly lower incisional hernia rate with slowly absorbable sutures (OR 0.65: $p = 0.009$) in elective surgery. Subgroup analysis

performed by van't Riet et al. [48] comparing only continuous suturing studies, detected only one RCT by Wissing et al. [70] using continuous suturing in both study arms. This study, which included 21 % of emergency operations, showed significantly more incisional hernias with rapidly absorbable sutures compared to non-absorbable sutures ($p = 0.001$) and compared to slowly absorbable sutures ($p = 0.009$).

Statement	The use of rapidly absorbable suture material for closure of midline abdominal wall incisions in elective surgery is NOT recommended.	☒☒☒☐	strong

Non-absorbable versus slowly absorbable sutures

No difference in incisional hernia rate for continuous suturing of midline incisions with slowly absorbable versus non-absorbable sutures ($p = 0.75$) was identified [48]. However, an increased incidence of prolonged wound pain ($p < 0.005$) and suture sinus formation ($p = 0.02$) with non-absorbable sutures was reported [48]. Another meta-analysis (which included non-midline incisions) identified no difference in incisional hernia rate between slowly absorbable polydioxanone and non-absorbable sutures (OR 1.10: $p = 0.43$) [43]. Once again, non-absorbable sutures had a significant higher risk of suture sinus formation (OR 0.49: $p = 0.01$) [43].

Statement	Using slowly-absorbable suture material instead of non-absorbable sutures for continuous closure of midline abdominal wall incisions in elective surgery is suggested.	☒☒☐☐	weak

Monofilament versus multifilament sutures

Monofilament sutures are believed to be associated with a lower surgical site infection rate than multifilament sutures [12]. However, none of the systematic reviews commented on this issue specifically. If the previous recommendation to use slowly absorbable sutures for closure of elective midline laparotomies is followed, this question becomes superfluous because the slowly absorbable sutures are all monofilament sutures.

Statement	We suggest using monofilament suture material for continuous closure of midline abdominal wall incisions in elective surgery.	☒☐☐☐	weak

Concerning the size of the suture, no studies comparing directly the size of the sutures used to close abdominal wall incisions were identified during our searches. For the "small bites" technique, Isrealsson et al. [12] suggest to use a suture size USP 2/0 (USP = United States Pharmacopeia).

Statement	No recommendation on the size of the sutures for closure of abdominal wall incisions can be given due to lack of data.	☒☐☐☐	no

Sutures impregnated with antibiotics

Sutures coated with Triclosan as an antimicrobial agent have been introduced to decrease the rate of surgical site infection in surgery. A recent meta-analysis has demonstrated a significant beneficial effect in the prevention of surgical site infection after all kinds of surgery [71]. Surgical site infection is a risk factor for subsequent development of incisional hernias and therefore the use of antibiotics impregnated sutures to close laparotomies might be beneficial in the prevention of incisional hernias. Recently Diener et al. [72] published a large RCT on 1,224 patients undergoing an elective midline laparotomy comparing polydioxanone sutures with versus without triclosan impregnation. No reduction in the incidence of surgical site infection was reported (OR 0.91: CI 0.66–1.25; $p = 0.39$). Four other RCT's have compared sutures with or without triclosan in laparotomy closure, either with polyglactin sutures (Vicryl) [73, 74] or with polydioxanone (PDS) [75, 76]. A meta-analysis on all five studies performed by Diener et al. showed a significant decrease in surgical site infection (OR 0.67: CI 0.47–0.98). No data on incisional hernias are available from these studies.

Statement	Monofilament sutures impregnated with antibiotics for closure of elective midline incisions is NOT advised, because of insufficient data on their efficiency on prevention of surgical site infections and the lack of data on incisional hernias or burst abdomen.	☒☒☒☐	weak

Limitations of the statements in these guidelines on suture technique and suture materials

The statements are limited by the quality of the data on which they are based. In total, 61 RCT's have been identified that compared suture materials or techniques to close laparotomy incisions. Many studies have more than one variable between study arms and therefore, analysing them in meta-analyses is difficult. Moreover, many studies have flaws in the methodology increasing the risk of bias. We would like to encourage researchers that plan studies on abdominal wall closure to improve the methodology of their study protocol. Preferably, study arms are only different in the variable under investigation, either a suture technique or a suture material. Moreover, we recommend documenting the technical details such as SL/WL ratio, the number of stitches used in the patients and to provide a follow-up of at least 24 months.
Although some of the systematic reviews detected included non-midline incisions [43] or emergency operations [48], these guidelines are currently limited to elective midline laparotomies. For emergency operations and non-midline incisions there is currently not enough data available.

Statement	No recommendation on suture material or suturing technique for use in emergency surgery can be given due to lack of sufficient data.	☒☐☐☐	no

Statement	No recommendation on suture material or suturing technique for use in non-midline incisions can be given due to lack of sufficient data.	☒☐☐☐	no

Suture needles and retention sutures

Blunt tip versus sharp needles

Only one systematic review assessing the type of needle used to close the abdominal wall [23] and one RCT comparing blunt needles with sharp needles were identified. The PRISMA flow diagram is shown in Addendum 3 (Key Question L). The RCT reported no difference in SSI rate between blunt and sharp needles [77].

Statement	No recommendation on the type or the size of needle to close a laparotomy can be given due to lack of data.	☒☐☐☐	no

Is there a place for retention sutures when closing a laparotomy?

No systematic review on the use of retention sutures was found. The PRISMA flow diagram of our additional search is shown in Addendum 3 (Key Question M). Eight records were screened by full text [78–85]. Three RCTs on the prevention of burst abdomen using either retention sutures or a reinforced tension line suture in patients with increased risk for wound dehiscence and burst abdomen were identified [78–80]. Follow-up was too short to evaluate incisional hernia rate. The Summary of Findings is listed in Table 4. Two studies showed favourable results [78, 79], but one study reported a high number of adverse events when using retention sutures [80].

Statement	No recommendation on the use of retention sutures in patients with multiple risk factors for burst abdomen can be given due to insufficient data.	☒☒☐☐	no

Bibliographic citation [reference]	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measure
Khorgami et al. J Surg Res. 2013;180:238-43. [78]	RCT	300	Patients undergoing midline laparotomy with ≥ 2 risk factors of a list of defined risk factors for burst abdomen	extra retention sutures Nylon 1 (every 10 cm and with 5 cm bites of skin) kept for 3-4 weeks	continuous loop size 1 nylon suture (1 cm from the edge /1 cm intervals)	median 5 months	Wound dehiscence was 4.1% (6/147) in the intervention group and 13.5% (20/148) in the control group (p = 0.007). "We showed that prophylactic retention sutures could reduce wound dehiscence in midline laparotomy in high-risk patients with multiple risk factors without imposing remarkable postoperative complications."
Agrawal Trop Gastroenterol. 2009;30:237-40. [79]	RCT	190	Emergency midline laparotomy	reinforced tension line suture	continuous suture		Burst abdomen was 0.0% (0/90) in the intervention group and 13.0% (13/100) in the control group (p = 0.0026). "Closure of midline incision by RTL reduces the incidence of burst abdomen."
Rink et al Eur J Surg. 2000;166:932-7. [80]	RCT	95 (92 midline)	Patients needing major abdominal surgery with infective or malignant intra-abdominal diseases. + at least one risk factor	extra retention sutures with sutures retention bridge for 12 days	interrupted Vicryl 1 sutures	12 days	"Retention sutures used to close abdominal wounds cause inconvenience, pain, and specific morbidity."

Table 4

Summary of Findings table for Key Question M: is there a place for retention sutures when closing a laparotomy?

Postoperative care

Postoperative management and instructions for patients are not supported by high quality prospective data, but rely mostly on surgeons' habits, tradition and common beliefs [86–88]. Long-term follow-up studies are needed to research the impact on the occurrence of incisional hernias of prescribing abdominal binders or restricting postoperative activity. The additional searches as shown in PRISMA flow diagrams in Addendum 3 (Key Question N, O, P) did not reveal any relevant study on long-term outcome. Some studies on the short-term benefits of abdominal binders were found.

Subcutaneous drains in laparotomy incisions

Prophylactic routine placement of subcutaneous drains after laparotomy is occasionally used to decrease wound complications: infection, hematoma, seroma or wound dehiscence [86]. However, there are several disadvantages to the routine use of subcutaneous drains. Namely, they cause patient discomfort and pain at removal, they hinder early mobilisation and demand additional nursing care. Therefore, their use should be driven by a proven benefit.

One systematic review [89] and several RCTs [90–98] on the use of subcutaneous drains in abdominal surgery were found. They cover a wide range of operative indications: liver surgery, colorectal surgery, cholecystectomy, gynaecological surgery, caesarean section, and gastric bypass surgery. With few exceptions, most studies did not show a benefit for the use of subcutaneous drains. However, none of these studies had incisional hernias or burst abdomen as primary or secondary endpoint.

Statement	The routine placement of a subcutaneous drain during closure of abdominal wall incisions is NOT recommended.	☒☒☒☐	strong

Postoperative binders

One systematic review on the use of abdominal binders was found [87]. The review included four RCT's [99–102] and a national survey by questionnaire on the use of abdominal binders in French surgical practice [87]. One additional recent RCT was identified [103].

The French survey reported that postoperative support of the wound with an abdominal binder is common practice after major laparotomies in many surgical

departments (94 % use them in some patients). It is expected to reduce postoperative pain and to improve early mobilisation of the patients. Moreover, 83 % of users expect a benefit in the prevention of abdominal wall dehiscence [87].
No significant improvement for the short-term benefits was found by the small RCTs from the review [98–101]. The additional study by Clay et al. [102] found a significant lower Visual Analogue Scale (VAS) score for pain at the fifth postoperative day and no adverse effect on postoperative lung function. No studies were found that had burst abdomen or incisional hernias as primary or secondary endpoints.

Statement	No recommendation can be given on the use of postoperative abdominal binders due to lack of data on their effect on incisional hernias or burst abdomen rates.	☒☐☐☐	no

Postoperative restriction of activity

No prospective studies were found on the restriction of physical activity after abdominal incisions. Nevertheless, it is advocated by some surgeons to decrease the risk of incisional hernias, but there is no consensus on the level or the duration of the restriction [88]. Postoperative restriction might have an adverse impact on the return to normal activity and delay the return to work.

Statement	No recommendation can be given on routine restriction of activity after abdominal surgery due to lack of data on the effect on incisional hernias or burst abdomen rates.	☒☐☐☐	no

Prophylactic mesh augmentation

The PRISMA flow diagram for prophylactic mesh augmentation is shown in Addendum 3 (Key Question Q–T). Three systematic reviews on the topic were found [24, 39, 104].

1. Nachappian et al. [39] did not assess of the quality of the individual studies and included non published data. Therefore, this review did not qualify for inclusion in this guideline.
2. The systematic review by Bhangu et al. [24] is of High Quality and offers a good and extensive evaluation of the quality of the individual studies included. Howev-

er, the quality of the non RCTs was usually low and these studies were not used as evidence for these guidelines.

3. Timmermans et al. [104] published a good meta-analysis on five RCT's using polypropylene mesh, including a RCT published in 2013 by Abo-Ryia et al. [105].

One additional RCT published after the review by Timmermans et al. [106] was identified. In this RCT, one hundred and sixty patients were included. This is the first trial on non-selected elective midline laparotomies (with a majority of oncological patients). All the other trials have only included patients deemed at high risk for incisional hernias. In this RCT by Caro-Tarrago et al. the mesh augmentation was performed with a light weight polypropylene mesh in the onlay position. A significant reduction in incisional hernias at 12 months was observed clinically and with CT scan in favour of prophylactic mesh, 1.5 vs 35.9 % ($p < 0.0001$). A significantly higher number of postoperative seroma was detected in the mesh group, 11.3 vs 28.8 % ($p < 0.01$). No major complications related to the mesh augmentation were reported.

The details of the six published RCT's using polypropylene mesh including 506 patients are listed in Table 5 [105–110].

Using Review Manager 5.2 software a new meta-analysis was performed. The data for this meta-analysis were extracted from the Timmermans et al. meta-analysis and the additional RCT [104, 106]. A meta-analysis on the outcomes of incisional hernia, seroma and SSI was performed. The pooled analyses data are shown in a Forrest plot for each outcome in Fig. 2. Prophylactic mesh augmentation is effective in the prevention of incisional hernias (RR 0.17: CI 0.08–0.37). An increased incidence of postoperative seroma is identified, but the majority of these are from the single study by Caro-Tarrago et al. [106] where the mesh was placed in an onlay position, with a weight of 45.9 % on the cumulative Risk Ratio for seroma (RR = 1.71; 95 %CI: 1.06–2.76) (Fig. 2c).

								Incisional hernias			Effect size
RCT [reference]	publ. date	LoE	SIGN	n	population	mesh position	FU months	diagnosis incisional hernia	NO Mesh	Mesh	Risk Ratio (95% CI)
Gutiérrez [107]	2003	2b	+	88	High risk patients	onlay	36	clinical + selective CT scan	5/44	0/44	0.09 (0.01-1.60)
Strelczyk [108]	2006	1b	++	74	Obesity surgery	retro-muscular	28	clinical + ultrasound in all	8/38	0/36	0.06 (0.00-1.04)
El-Kadrawy [109]	2009	2b	+	40	High risk patients	pre-peritoneal	36	clinical	3/20	1/20	0.33 (0.04-2.94)
Bevis [110]	2010	1b	++	80	AAA	retro-muscular	25.4	clinical+ selective ultrasound	16/43	5/37	0.36 (0.15-0.90)
Abo-Ryia [105]	2013	2b	+	64	Obesity surgery	pre-peritoneal	48	clinical + selective ultrasound	9/32	1/32	0.11 (0.01-0.83)
Caro-Tarrago [106]	2014	1b	++	160	midline laparotomies	onlay	12	clinical + CT scan in all	30/80	2/80	0.07 (0.02-0.27)
Overall				506					71/257	9/249	0.17 (0.08 - 0.37)

Table 5

List of the randomized clinical trials and their characteristics on prophylactic mesh augmentation using a polypropylene mesh

Fig 2.A Incisional hernia

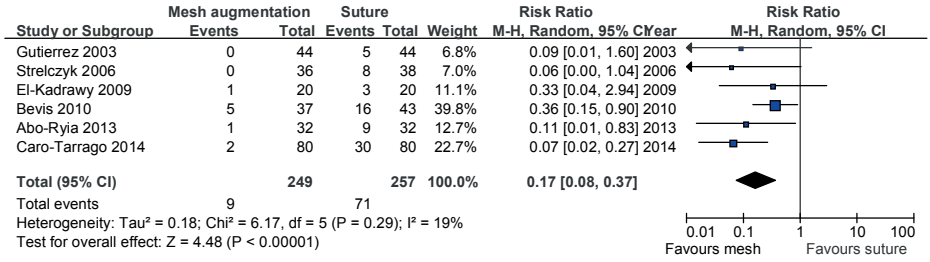

Fig 2.B Wound infection

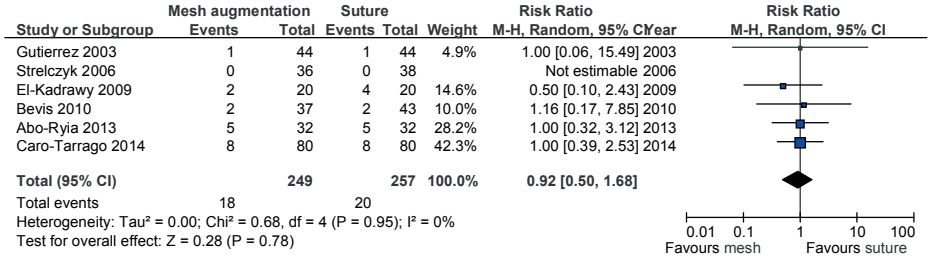

Fig 2.C Seroma

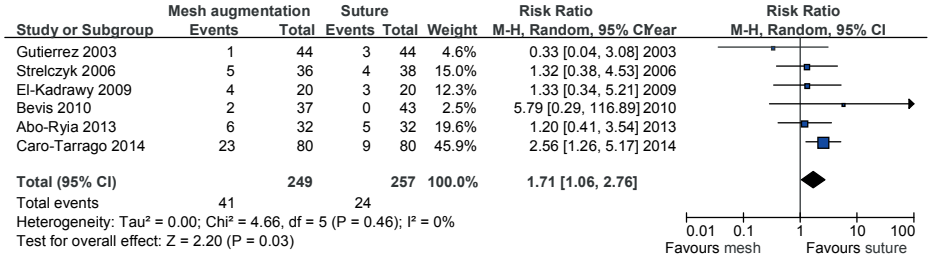

Figure 2

Forrest plots of a meta-analysis performed by the Guidelines Development Group on prophylactic mesh augmentation with polypropylene mesh after laparotomy. Analysis on the outcomes of incisional hernia, seroma and surgical site infection was performed

Although the data are favourable and consistent for prophylactic mesh augmentation, the Guidelines Development Group decided that larger trials are needed to make a strong recommendation to perform prophylactic mesh augmentation for all patients within certain risk groups.

Statement	Prophylactic mesh augmentation for an elective midline laparotomy in a high-risk patient in order to reduce the risk of incisional hernia is suggested.	⊠⊠⊠☐	weak

Which mesh type, which mesh position and which type of mesh fixation?

No comparative studies are published between different mesh type, mesh position or method of mesh fixation. Pans et al. [111] found no significant protective effect on incisional hernia rate by intra-peritoneal augmentation with a polyglactin mesh (Vicryl; Ethicon) on incisional hernia rate in a RCT on obesity surgery (n = 288). Llaguna et al. [112] placed a biological mesh (Alloderm; LifeCell) in a retro-muscular position in bariatric patients. In this non-randomised comparative study (n = 106 of which 44 with mesh) a significantly lower incisional hernia rate was observed in the mesh group, 2.3 vs 17.7 % (p = 0.014). All other studies published used a polypropylene mesh, most often a small pore/heavy weight mesh: Prolene; Ethicon [110], Premilene; B. Braun [107], no name mentioned [105, 108, 109]. Only Caro-Tarrago et al. [106] used a large pore/light weight mesh: Biomesh Light P8; Cousin Biotech.

There is a large variation between the studies on the mesh position for the prophylactic mesh augmentation. Onlay, retro-muscular and pre-peritoneal mesh positioning was performed in two studies each. No studies on the use of intra-peritoneal augmentation with a non absorbable synthetic mesh are reported. Only one study on the use of intra-peritoneal augmentation with an absorbable synthetic mesh is reported [111]. The mesh was in all studies fixed with sutures to the fascia except for the study of Pans et al. [111] which used no fixation. No studies on mesh augmentation with glue or a self-fixating mesh are reported.

Statement	No recommendation on the optimal mesh position for prophylactic mesh augmentation can be given due to lack of data.	⊠☐☐☐	no

Statement	No recommendation on the optimal method of mesh fixation for prophylactic mesh augmentation can be given due to lack of data.	⊠☐☐☐	no

Statement	No recommendation on the type of mesh for prophylactic mesh augmentation can be given due to lack of data.	⊠☐☐☐	no

Trocar wounds for laparoscopic surgery and single port surgery

The PRISMA flow diagram for the Key Questions on laparoscopic surgery and single incision surgery are shown in Addendum 3 (Key Question U–W and K, Q, X).

Trocar size and trocar type

The first search for systematic reviews resulted in five records [33, 40, 41, 46, 49] and 25 additional records were screened by full text [113–137]. Several studies comment on the incidence of trocar-site hernia for various trocar sizes. However, the quality of many studies is insufficient and challenges the validity of results. Shortcomings of the individual studies include retrospective study design, short or unclear length of follow-up and inappropriate or no information on diagnostic methods to detect incisional hernias. Most importantly, available data derive from studies in which the same patient serves as case and control; i.e. the incidence of trocar-site hernia is measured for different sizes of trocars inserted at different abdominal sites in the same patient. This may impose significant bias, related to the strength of the abdominal wall and the wound repair mechanisms at varying sites of the abdominal wall, in particular the linea alba to other parts of the abdominal wall.

Helgstrand et al. [33] performed a systematic review on the incidence of trocar-site hernia. Although they found a risk reduction after sutured closure and a lower hernia rate for 5-mm versus larger diameter trocars, no meta-analysis was undertaken. The poor quality and design of the majority of the included reports preclude further in-depth evaluation for supporting evidence. No RCT's have investigated the incidence of trocar-site hernia after insertion of blunt versus bladed trocars and no RCT's or case-control studies have investigated the incidence of trocar-site hernia with reference to trocar size or diameter. Available data derived from univariate and multivariate analyses of cohort studies, which have investigated the effect of potential risk factors for trocar-site hernia. Obesity, age above 60 years diabetes, long duration of surgery, and the need for fascia enlargement for specimen extraction were identified as risk factors for the development of trocar-site hernia [120, 137].

Statement	For laparoscopic procedures, using the smallest trocar size adequate for the procedure is suggested.	☒☒☐☐	weak

Statement	For laparoscopic procedures, suturing the fascial defect, if trocars larger than or equal to 10 mm have been used, in the presence of established risk factors for incisional hernia formation is suggested.	☒☐☐☐	weak

Closure of trocar incisions

There are no good quality comparative studies investigating different suture materials or techniques for closure of trocar fascia defects. Armananzas et al. [113] reported in a recently published RCT a benefit for prophylactic intraperitoneal placement of a ventral patch at the umbilical site in high-risk patients to reduce the incidence of trocar-site hernia from 18.5 to 4.4 % (OR 10.1: CI 2.15–47.6; $p < 0.001$). Larger sample-sized studies with a good risk–benefit assessment and longer follow-up are needed to confirm and support a stronger recommendation.

Statement	For laparoscopic procedures a mesh-augmented closure may be applied in patients at high risk for trocar-site hernia.	☒☒☒☐	weak

Single incision laparoscopic surgery and incisional hernia

The incidence of trocar-site hernia after single port surgery has been mostly investigated as a secondary outcome measure in the setting of RCTs and 3 High Quality meta-analyses were found [138–140]. Two meta-analyses of RCTs have found no difference in the incidence of trocar-site hernia between single port and multiple port surgery, although a trend in favour of multiple port surgery was demonstrated [138, 139]. The most recent meta-analysis included 19 RCTs involving 676 patients and found a higher incidence of trocar site hernia following single port surgery [140].

Statement	Emerging evidence suggests an increased incidence of trocar-site hernia for single-incision surgery as compared to conventional surgery; therefore meticulous closure of the incised fascia in single-port surgery is recommended.	☒☒☒☐	weak

DISCUSSION

Key results

A list of the statements from these guidelines is provided in Addendum 4 as a PDF file.

Limitations

Not many strong recommendations could be made due to lack of sufficient evidence on many of the PICO questions. It is somewhat confusing to notice that the first strong recommendation in these guidelines is to avoid midline laparotomies in favour of alternative incisions and that all other recommendations are only valid for elective midline incisions. Indeed most research is focused on midline laparotomies. A midline laparotomy is still the favoured approach for most surgeons. It allows quick entrance to the abdominal cavity and extension of the incision is easy if this is required for the operation. Nevertheless, the linea alba is probably the most vulnerable and least vascularized part of the abdominal wall. Some refer to incisional hernias as "a midline crisis". Optimising closure of abdominal wall incisions would appear to hold a large potential in reducing the incidence of incisional hernias and the subsequent need for incisional hernia repair. This has obvious benefits for the individual patient relating to an improved quality of life, avoidance of secondary operations and at a macro-economical level a significant reduction in costs for health care resources. It is not easy to see the impact of each recommendation separately. Therefore, implementation of the optimised abdominal wall closure is probably best done by teaching all involved specialists a standardised technique described as the "Principles" of abdominal wall closure [17]. This incorporates all recommendations, although the Guidelines Development Group is aware that the level of evidence for the different aspects is sometimes low to very low. David Sackett, a pioneer in evidence-based medicine wrote: "…any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied". [141].

Discussions

For most Key Questions on the technique and material to close abdominal wall incisions, the grading of the Quality of Evidence and the choice of recommendation was straightforward. For several recommendations, while the quality of evidence was low, there was good consensus between the members of the

Guidelines Development Group on the formulated statements. For prophylactic mesh augmentation there was disagreement on the strength of recommendation (weak or strong). For this reason, an additional meta-analysis was performed (Fig. 2). Although the effect size in favour of mesh augmentation is large and consistent over the studies, the Guidelines Development Group felt that larger trials are needed to support a strong recommendation for prophylactic mesh augmentation in high-risk patients. Indeed, the number of patients in the reported studies for each risk group separately (e.g. abdominal aortic aneurysm, obesity surgery, oncological surgery) seems too low to recommend prophylactic mesh augmentation in all these patient groups. Nevertheless, we are aware that several large RCT's are on-going and this grade of recommendation might be changed in the light of future publications.

No recommendations could be made on non-midline incisions due to insufficient evidence. Nevertheless, it seems reasonable to promote similar material (slowly absorbable suture) and techniques (continuous aponeurotic closure with small bites and SL/WL >4/1) for closure of non-midline incisions.

No recommendations could be made on the type or the size of the needle used to close abdominal incisions. No studies comparing the size of the sutures were identified in our searches.

No recommendation could be made for emergency surgery, which is often a contaminated procedure. The Guidelines Development Group consider that the use of retention sutures or of reinforced tension line sutures, should be prospectively studied in patients at high risk for development of burst abdomen. A risk model and score for burst abdomen has been developed by van Ramshorst et al. [142] and could be used as basis for including patients in these studies.

No recommendations could be made on the postoperative care after laparotomies. Long-term follow-up studies are needed to assess the impact on the occurrence of incisional hernias of prescribing abdominal binders or restricting or indeed encouraging early postoperative activity.

Applicability

To adopt the guidelines and "evidence based principles" for abdominal wall closure, surgeons must be convinced that these are valid recommendations with a large impact on the outcome for the patients. These guidelines are an attempt to create awareness amongst surgeons about these principles. Adaptation can be done by systematic quality control of the suturing technique as described by van Ramshorst et al. [143]. The EuraHS, European registry for abdominal wall hernias, has developed an online platform for registration and outcome measurement of

abdominal wall surgery [144]. An additional route in the database on the closure of abdominal wall incisions and for prophylactic mesh augmentation will be provided from 2015 onwards. It is hoped that such a registry database will facilitate the data collection for prospective studies.

Validity of the guidelines

Prior to submission of the manuscript the guidelines were evaluated and scored using the AGREE II instrument. The results of these assessments are presented in Table 6. Several large multi-centre studies on the closure of abdominal wall incisions are currently on-going. High Quality data on the use of the "small bites" technique in midline incisions, on the closure of laparotomies in emergency and on prophylactic mesh augmentation will be published in the coming years. The Guidelines Development Group has decided to update these guidelines in 2017 and present the results during the 39th Annual Congress of the European Hernia Society in Vienna in May 2017.

Conclusions

To decrease the incidence of incisional hernias it is recommended to utilise a non-midline approach to a laparotomy whenever possible. For elective midline incisions, it is strongly recommended to perform a continuous suturing technique and to avoid the use of rapidly absorbable sutures. It is suggested that the use of a slowly absorbable monofilament suture in a single layer aponeurotic closure technique without separate closure of the peritoneum and using a small bites technique with a SL/WL ratio at least 4/1 is the current recommended method of fascial closure. Currently, no recommendations can be given on the optimal technique to close emergency laparotomy incisions. Prophylactic mesh augmentation appears effective and safe and can be suggested in high-risk patients like, aortic aneurysm surgery and obese patients.

Table 6 *(next page)*

Results of the scoring of the guidelines by external experts using the AGREE II instrument [20]. Each item is scored between 1 (=strongly disagree) and 7 (=strongly agree). For each domain a scaled domain score is given as a percentage

Domain 1: Scope and purpose									Scaled domain score = 90.3%
	Item 1	Item 2	Item 3						Total
Appraiser 1	7	5	5						**17**
Appraiser 2	7	7	7						**21**
Appraiser 3	6	6	6						**18**
Appraiser 4	7	7	7						**21**
Total	**27**	**25**	**25**						**77**
Domain 2: Stakeholder involvement									**Scaled domain score = 76.4%**
	Item 4	Item 5	Item 6						Total
Appraiser 1	6	3	5						**14**
Appraiser 2	7	5	7						**19**
Appraiser 3	6	4	4						**14**
Appraiser 4	6	7	7						**20**
Total	**25**	**19**	**23**						**67**
Domain 3: Rigour of development									**Scaled domain score = 85.9%**
	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Total
Appraiser 1	7	7	6	6	5	6	7	4	**48**
Appraiser 2	7	7	7	7	6	6	7	6	**53**
Appraiser 3	6	6	6	5	4	4	5	4	**40**
Appraiser 4	7	7	7	7	7	7	7	7	**56**
Total	**27**	**27**	**26**	**25**	**22**	**23**	**26**	**21**	**197**
Domain 4: Clarity of presentation									**Scaled domain score = 87.5%**
	Item 15	Item 16	Item 17						Total
Appraiser 1	7	5	6						**18**
Appraiser 2	7	7	7						**21**
Appraiser 3	5	5	5						**15**
Appraiser 4	7	7	7						**21**
Total	**26**	**24**	**25**						**75**
Domain 5: Applicability									**Scaled domain score = 52.1%**
	Item 18	Item 19	Item 20	Item 21					Total
Appraiser 1	5	4	5	4					**18**
Appraiser 2	4	3	3	1					**11**
Appraiser 3	3	3	3	4					**13**
Appraiser 4	7	7	7	3					**24**
Total	**19**	**17**	**18**	**12**					**66**
Domain 6: Editorial independence									**Scaled domain score = 95.8%**
	Item 22	Item 23							Total
Appraiser 1	7	7							**14**
Appraiser 2	7	7							**14**
Appraiser 3	6	6							**12**
Appraiser 4	7	7							**14**
Total	**27**	**27**							**54**

Overall assessment		
	Rating of the overall Quality of the guideline.	**I would recommend this guideline for use.**
Appraiser 1	6	Yes
Appraiser 2	6	Yes
Appraiser 3	5	Yes
Appraiser 4	7	Yes

OTHER INFORMATION

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Conflict of interest

The authors report no conflict of interest in relation to this manuscript.

Electronic supplementary material

Below is the link to the electronic supplementary material.

Addendum 1: List of Key Questions and PICO's (Patients-Intervention-Comparison-Outcome) proposed by the Guidelines Development Group for the European Hernia Society guidelines on the closure of abdominal wall incisions (DOCX 114 kb)

Addendum 2: Search terms used for the search for systematic reviews and/or

meta-analyses performed by SIGN for the Guidelines Development Group of the European Hernia Society guidelines on the closure of abdominal wall incisions. The search was performed in November 2013 (DOCX 76 kb)

Addendum 3: PRISMA flow diagrams for the additional searches performed on the Key Questions by the members of the Guidelines Development Group of the European Hernia Society guidelines on the closure of abdominal wall incisions. Records found until April 2014 were included (DOCX 1148 kb)

Addendum 4: PDF file with a summary of European Hernia Society Guidelines on the closure of abdominal wall incisions (PDF 154 kb)

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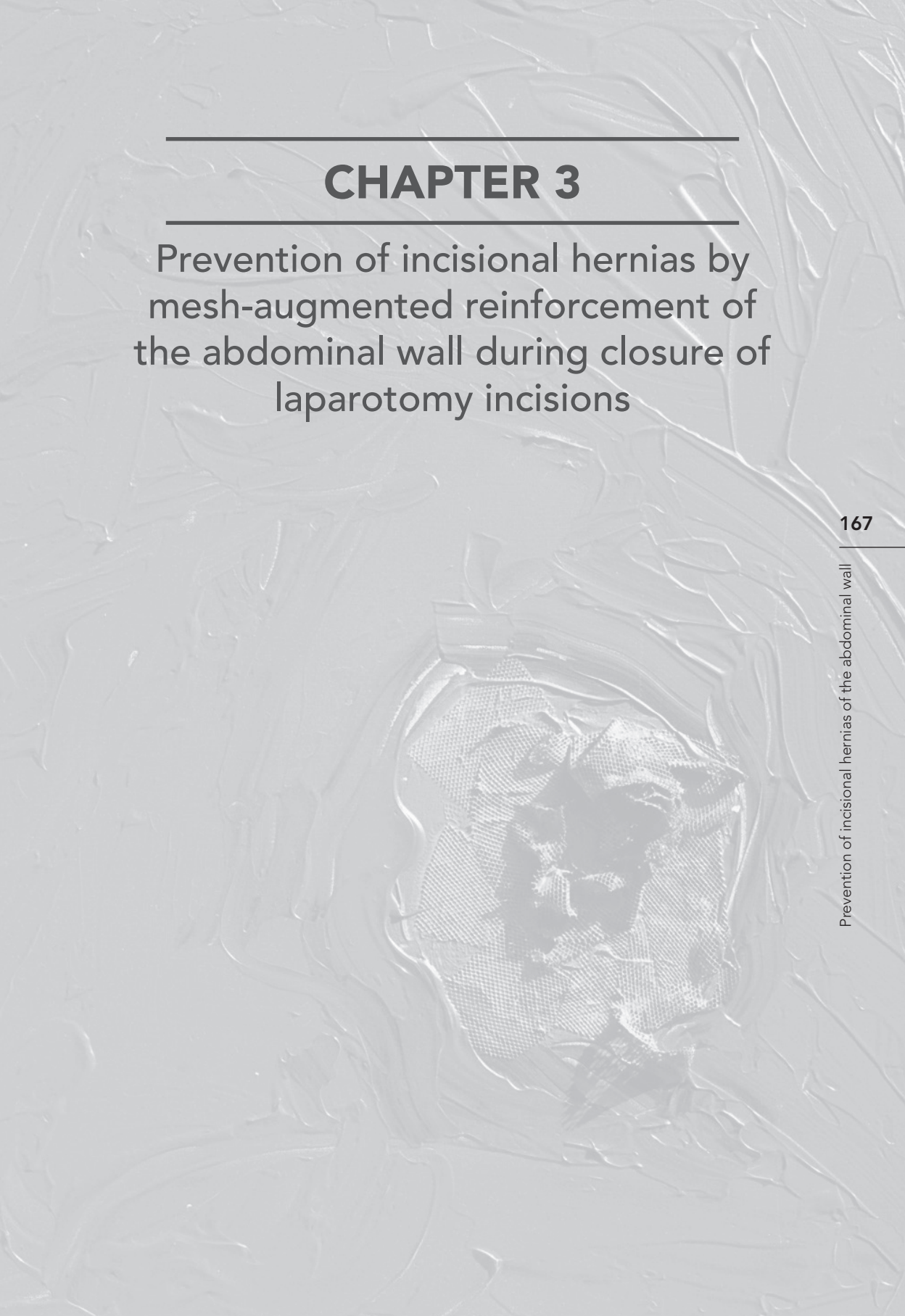
CHAPTER 3

Prevention of incisional hernias by mesh-augmented reinforcement of the abdominal wall during closure of laparotomy incisions



3.1 RANDOMIZED TRIAL ON THE PREVENTION OF INCISIONAL HERNIA BY MESH AUGMENTATION AFTER MIDLINE LAPAROTOMY FOR AORTIC ANEURYSM TREATMENT

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"Exceptional rare events are not seldom, but happen every day. "

@ "The improbability principle. Why coincidences, miracles and rare events happen every day." by David Hand, 2014

ABSTRACT

Background

The incidence of incisional hernias after abdominal aortic aneurysm (AAA) repair is high. Prophylactic mesh augmented reinforcement during laparotomy closure has been proposed in patients at high risk of incisional hernia.

Methods

A multicenter randomized trial was conducted on patients undergoing elective AAA repair through a midline laparotomy (Clinical.Trials.gov: NCT00757133). In the study group, retro-muscular mesh augmented reinforcement was performed with a large-pore polypropylene mesh (Ultrapro™, width 7.5 cm). The primary endpoint was the incidence of incisional hernias at 2-year follow-up.

Results

Between February 2009 and January 2013, 120 patients were recruited at 8 Belgian centers. Patients' characteristics at baseline were similar between groups. Operative and postoperative characteristics showed no difference in morbidity or mortality. The cumulative incidence of incisional hernias at 2-year follow-up after conventional closure was 28% (95% CI; 17% - 41%) versus 0% (95% CI; 0 % - 6%) after mesh augmented reinforcement ($P<0.0001$; Fisher's exact test). The estimated "freedom of incisional hernia" curves (Kaplan-Meier estimate) were significantly different across study arms ($X^2=19.50$, $P<0.0001$; Mantel-Cox test). No adverse effect related to mesh augmented reinforcement was observed, apart from an increased mean time to close the abdominal wall for mesh augmented reinforcement compared to the control group: 46.2 min (SD; 18.6) versus 29.6 min (SD; 18.5), respectively ($P<0.001$; Mann-Whitney U test).

Conclusions

Prophylactic retro-muscular mesh augmented reinforcement of a midline laparotomy in AAA patients is safe and effectively prevents the development of incisional hernia during 2 years, with an additional mean operative time of 16 minutes.

INTRODUCTION

Background

Patients treated for an abdominal aortic aneurysm (AAA) through a midline laparotomy have a high risk of developing an incisional hernia. Incidences higher than 60% have been reported during long term follow-up.[1,2] In Denmark the cumulative risk for subsequent incisional hernia repair following open elective aortic surgery was 10.4% after 6 years of follow-up.[3] Mesh augmented reinforcement (MAR) during laparotomy closure has been proposed in high-risk patients as a preventive procedure to reduce the risk of incisional hernia. A recent meta-analysis of six randomized studies shows a significant reduction of incisional hernia incidence by MAR, without increasing postoperative complications.[4] Only one of these trials concerned surgery of AAA patients.[5]

Objectives

Our research hypothesis was to reduce the incidence of incisional hernia from 25% to 5% by MAR at 2-year follow-up after midline laparotomy for elective treatment of AAA. Moreover we wanted to investigate if MAR can be performed without an increase in complications.

METHODS

Trial design

The study was designed as a prospective, parallel groups, multi-center, open label, randomized trial.

Setting and participants

The Belgian Section for Abdominal Wall Surgery, section of the Royal Belgian Society for Surgery, initiated the study. The study was performed in 8 Belgian hospitals with a close collaboration between the abdominal wall surgeons and the vascular surgeons to recruit eligible patients. Adult patients planned for elective AAA treatment by a midline laparotomy were eligible. Exclusion criteria were: emergency surgery, the presence of a mesh in the abdominal wall on the midline from previous hernia repair, ASA scores higher than 4, unavailability of the abdominal wall surgeon to attend the operation. All patients had to sign informed consent prior to randomization. All local ethical committees and the central ethical committee at the University Hospital Ghent approved the trial on November

6th 2008 with the Belgian Trial Registration Number: B67020084346. The study was registered at Clinical.Trials.gov (NCT00757133) on September 18th 2008. The study was named with the acronym PRIMAAT, Prevention of Incisional Hernias by Mesh Augmentation after midline laparotomy for Aortic Aneurysm Treatment.

Interventions

After completion of the vascular procedure, the abdominal wall surgeon was called and performed the abdominal wall closure according to the allocated treatment arm. In the conventional laparotomy closure group (NON-MESH group) the laparotomy was closed with a slowly absorbable running suture in a single layer and a suture to wound length ratio of 4/1. The wound length and the length of the suture used were documented. In the laparotomy closure with MAR (MESH group) a large pore, partially absorbable and lightweight polypropylene mesh of width 7.5 cm (Ultrapro™, Ethicon Inc, Johnson & Johnson) was placed in a retro-muscular position. The plane behind the rectus muscles, anterior to the posterior rectus fascia, was dissected for at least 3 cm on both sides of the midline. The posterior rectus fascia and the peritoneum were closed on the midline with a slowly absorbable running suture achieving a barrier between the mesh and the intestines. A mesh large enough to give an overlap of 3 cm in all directions was cut to appropriate dimensions and placed in the retro-muscular plane. The mesh was fixed with rapid absorbable sutures at its edges to the posterior rectus fascia. Above the mesh the anterior rectus fascia was closed with a slowly absorbable running suture. *(A video of the MAR technique is available in supplement)* Clinical follow-up by the surgeon was scheduled at 1 month, 12 months, 24 months and 60 months. No systematic imaging by ultrasound or CT scan was performed, but if available, was used for the diagnosis of incisional hernias.

Outcomes

The primary endpoint of the study was the incidence of incisional hernia at 2-year follow-up. Incisional hernia was defined as: "any abdominal wall gap with or without bulge in the area of the midline scar perceptible or palpable by clinical examination or imaging".
Secondary endpoints included: postoperative complications (classified according to the Clavien-Dindo classification[6]), surgical site infections (superficial, deep, mesh infection), duration of surgery (overall, abdominal wall closure time), the incidence of incisional hernia at 1-year follow-up.

Sample size

Our research hypothesis was to reduce the incidence of incisional hernia from 25% to 5% by MAR. The assumed incidence of 25 % in the control group was based on previous published data from systematic reviews.[7,8] The sample size calculation was based upon the difference of 20% that was considered clinically significant. In order to have 80% power of showing, two-sided, at the 5% level of significance, a difference of 20% between groups, there should be 50 evaluable patients in each treatment group. Accounting for approximately 20% lost to follow-up and non-evaluable patients a total of 120 patients had to be enrolled in the study.

Randomization

Randomization was done after enrollment of the patient and signature of the informed consent. Computer generated permutated blocks of 6 patients with an allocation ratio of 1:1 were used for randomization.

Blinding

Patients and vascular surgeons were preoperatively blinded for the allocated treatment arm. All data were collected on anonymous case record forms in a binder by the principal investigator, the abdominal wall surgeon. At discharge the forms related to the treatment allocation and the operative data were removed from the binder and send to the trial secretariat. During the follow up visit, performed by the abdominal wall surgeons, all previous data had been removed from the binder.

Data management

All data gathered were mailed to the study secretariat at AZ Maria Middelares Ghent. Feedback to the participating centers to organize the on-time follow-up was given by email. All data were entered in a MS Excel database. All data input was double checked with the case record forms by two persons different from the one who entered the data primarily. The database was closed at the end of January 2015 and submitted for analysis to an independent statistician.

Statistical methods

Common statistical measures of central tendency (mean) and spread (standard deviation, SD) were used to describe the distribution of study characteristics. To assess the adequacy of randomization, groups were compared by Fisher's exact test for categorical variables and the Mann-Whitney test for continuous variables. The exact Clopper-Pearson method, based directly on the binomial distribution, was used to calculate a 95% confidence interval for the cumulative incidence of incisional hernia in the NON-MESH group. Since no incisional hernias occurred in the MESH arm during follow-up, the rule-of-three method was used to obtain the corresponding 95% confidence interval in this group. Distribution of time until incisional hernia occurrence was estimated according to the Kaplan-Meier product-limit-estimator. The Mantel-Cox test was used to compare the estimated freedom of incisional hernia curves across study arms. Hazard ratios could not be estimated because no incisional hernias were observed in the MESH arm. Since randomization proved successful with respect to the balance of baseline characteristics between study arms, no indication of positive or negative confounding needed to be controlled in multivariate analysis. Statistical significance was established at an alpha value of 0.05. All reported P-values are two-tailed. Analyses were carried out using SAS software (The SAS system. Release 9.3; SAS Institute Inc., Cary, NC, USA).

RESULTS

Participant flow

The Consort flow diagram of the trial is shown in Figure 1. Of 120 randomized patients, 114 received the allocated treatment and formed the Intention-To-Treat population. For six patients (3 in each treatment arm) no clinical visit at 24 months was done and thus their 2-year follow-up was incomplete, but with a minimum of 1.29 years.

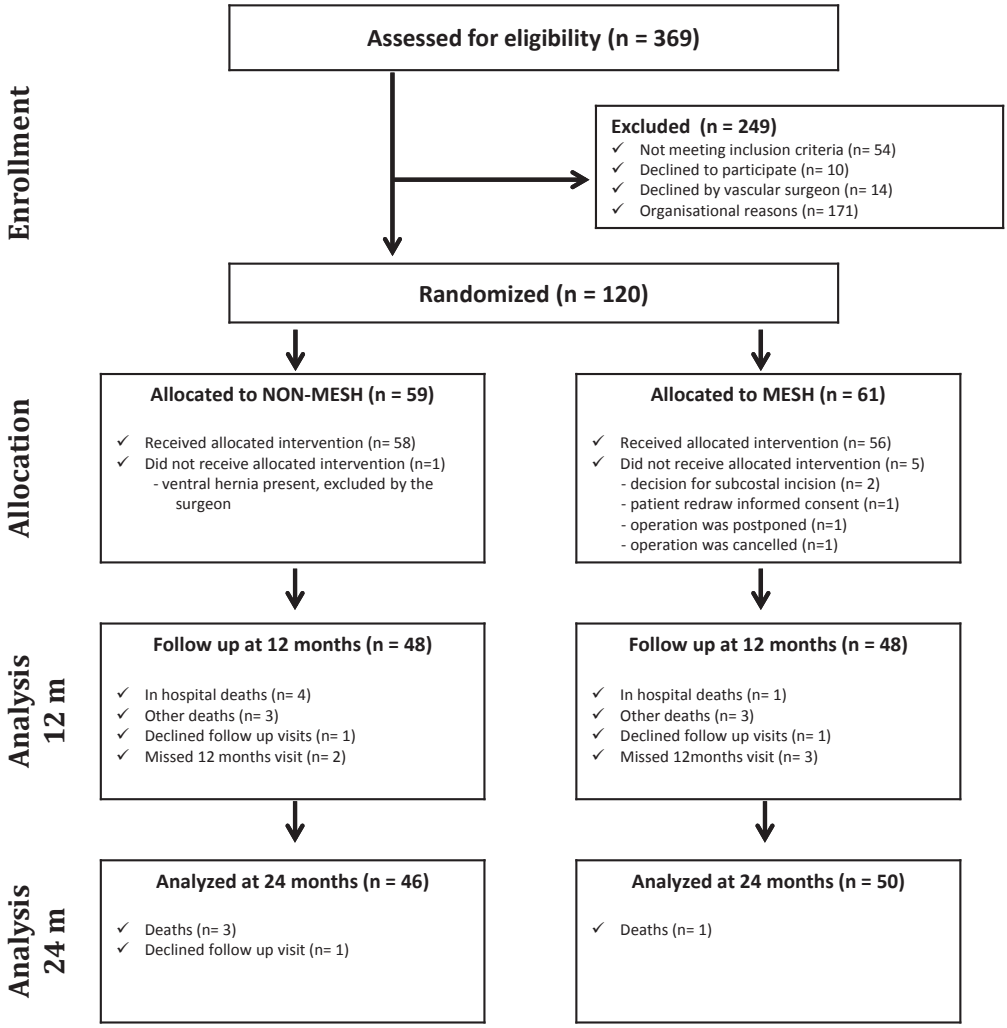

Figure 1

CONSORT flow diagram of the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by prophylactic mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

			NON-MESH (N= 58)	MESH (N= 56)
Age at time of surgery (years)			71.9 (8.5)	72.3 (7.4)
Women			12.1% (7/58)	3.6% (2/56)
Body Mass Index (kg/m^2)			26.5 (3.7)	25.5 (3.6)
	≥ 27 kg/m²		37.9% (22/58)	34.5% (19/55)
	≥ 30 kg/m²		8.6% (5/58)	10.9% (6/55)
ASA score:	Normal health		8.8% (5/57)	9.1% (5/55)
	Mild to moderate systemic disease		61.4% (35/57)	61.8% (34/55)
	Serious systemic disease		29.8% (17/57)	29.1% (16/55)
	Life threatening systemic disease		0.0% (0/57)	0.0% (0/55)
Risk factors				
	Chronic use of corticosteroids		5.3% (3/57)	1.9% (1/54)
	Use of immuno-suppressive medication		0.0% (0/57)	0.0% (0/54)
	Diabetes mellitus		17.9% (10/56)	17.0% (9/53)
	Current smoker		63.0% (34/54)	66.0% (35/53)
	Chronic obstructive pulmonary disease		35.2% (19/54)	27.3% (15/55)
	Coronary heart disease		47.4% (27/57)	52.7% (29/55)
	Hemodialysis		7.0% (4/57)	5.5% (3/55)
	Previous malignancy		8.8% (5/57)	9.3% (5/54)
	Previous midline incision		0.0% (0/52)	3.8% (2/52)
Previous hernia operation				
	Inguinal hernia operation		17.5% (10/57)	17.9% (10/56)
	Umbilical / Epigastric hernia operation		0.0% (0/57)	7.1% (4/56)
	Incisional hernia operation		0.0% (0/57)	0.0% (0/56)
Aortic aneurysm characteristics				
Maximum size (diameter) of the aneurysm			6.1 (1.5)	6.5 (1.4)
Type of aneurysm:		Infra-renal	77.2% (44/57)	91.1% (51/56)
		Juxta-renal	21.1% (12/57)	7.1% (4/56)
		Supra-renal	0.0% (0/57)	0.0% (0/56)
		Involving iliac arteries	3.5% (2/57)	5.4% (3/56)
Repair:	Straight tube		33.3% (19/57)	32.1% (18/56)
	Bifurcation, intra-abdominal anastomosis		38.6% (22/57)	42.9% (24/56)
	Bifurcation, distal anastomosis in the groin		28.1% (16/57)	25.0% (14/56)
Previous aneurysm treatment:		None	94.7% (54/57)	92.7% (51/55)
		Surgical	5.3% (3/57)	3.6% (2/55)
		Endovascular	0.0% (0/57)	3.6% (2/55)

Data are means (SD) or % (n/N); No significant difference between groups according to Fisher's exact test or Mann-Whitney U test

Table 1

Description of patients' characteristics at baseline according to randomization of the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by primary mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

Recruitment

The first patient was enrolled in February 2009 and the last patient in January 2013. The inclusions per center ranged between 33 and 4 patients.

Baseline data

Descriptions of patients' characteristics at baseline are given in Table 1. No significant differences between the groups were detected.

Outcome data

Descriptions of operative characteristics are given in Table 2. Only the overall operating time and the time to close the abdomen were significantly different for both groups. No difference in morbidity or mortality between the groups was observed.

		NON-MESH (N= 58)	MESH (N= 56)	
Length of fascia incision (cm)		28.3 (4.6)	26.9 (3.6)	
Length of suture used to close the fascia (cm)		111.8 (54.6)	93.9 (28.2)	
SL/WL ratio [a]		3.93 (1.61)	3.50 (0.98)	
SL/WL ratio ≥ 4		30.9% (17/55)	28.3% (13/46)	
Length of mesh used (cm)		--	32.3 (3.7)	
Estimated overlap of the mesh beyond the incision (cm)		--	3.3 (0.8)	
Number of fixation sutures used		--	12.4 (4.6)	
Drains used:	None	55.2 % (32/58)	57.1% (32/56)	
	Retromuscular (on the mesh)	--	8.9% (5/56)	
	Retro- or intraperitoneal	41.4% (24/58)	32.1% (18/56)	
	Subcutaneous	1.7% (1/58)	3.6% (2/56)	
Duration of surgery:				
	Overall operation time (min)	189.7 (83.1)	211.5 (61.9)	*
	Time to close the abdominal wall (min)	29.6 (18.5)	46.2 (18.6)	***
Intra-operative complications:				
	related to aneurysm surgery	5.2% (3/58)	5.4% (3/56)	
	related to abdominal wall closure	0.0% (0/58)	0.0% (0/56)	
Early postoperative complications [b]				
	None	51.7% (30/58)	55.4% (31/56)	
	Grade I	6.9% (4/58)	16.1% (9/56)	
	Grade II	19.0% (11/58)	12.5% (7/56)	
	Grade IIIa	1.7% (1/58)	0.0% (0/56)	
	Grade IIIb	1.7% (1/58)	8.9 (5/56)	
	Grade IV	12.1% (7/58)	5.4% (3/56)	
	Grade V (mortality)	6.9% (4/58)	1.8% (1/56)	
Hospital stay (days)		12.8 (10.6)	12.5 (7.4)	

Data are means (SD) or % (n/N); *P<0.05; **P<0.01; ***P<0.001
[a] SL/WL ratio = Suture Length to Wound Length ratio
[b] Classified according to the Clavien-Dindo classification of postoperative complications [6]

Table 2

Description of (post-)operative characteristics according to randomization of the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by prophylactic mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

The efficacy data on incidence of incisional hernia at 1-year and 2-year follow-up are given in Table 3. The cumulative incidence of incisional hernias at 12 months after conventional closure was 17% (95% CI; 9% - 30%) versus 0% (95% CI; 0 % - 6%) after MAR (P=0.0013; Fisher's exact test). The cumulative incidence of incisional hernias at 24 months after conventional closure was 28% (95% CI; 17% to 41%) versus 0% (95% CI; 0 to 6%) after MAR (p<0.0001, Fisher's exact test). The mean (SD) observation time across both study arms was 1.6 (0.7) years and 1.8 (0.4) years in the NON-MESH and MESH arm respectively (P=0.66, Mann-Whitney test).

		NON-MESH (n= 58)	MESH (n= 56)	
Cumulative incidence of incisional hernia at 12 months		**10 (17.2%)**	**0 (0.0%)**	**
Cumulative incidence of incisional hernia at 24 months		**16 (27.6%)**	**0 (0.0%)**	***
Lost to follow up by death < 24 months		**10 (17.2%)**	**5 (8.9%)**	
	hospital mortality	4	1	
	pulmonary cancer	2		
	gallbladder cancer	1		
	disseminated cancer of unknown origin	1		
	gastric cancer		1	
	colon cancer		1	
	urosepsis and multiple organ failure	1		
	cardiac failure	1		
	liver failure, small bowel ischemia		1	
	suicide		1	
Abdominal surgery during follow-up < 24 months		**7**	**6**	
	laparoscopic resection of renal carcinoma	1		
	colon cancer resection	1	2	
	incisional hernia repair	4		
	colon resection for diverticular disease	1	1	

	adhesiolysis for small bowel obstruction		1	
	groin hernia repair		1	
	laparotomy for peritonitis of unknown origin		1	
Assessment of chronic pain of the abdominal wall				
	Assessed at 12 months	**47**	**48**	
	No pain	42 (89.4%)	46 (95.8%)	
	Only mild pain and not frequent	2 (4.3%)	1 (2.1%)	
	Frequent but only mild pain	3 (6.4%)	0	
	Serious pain interfering with daily life	0	1 (2.1%)	
	Assessed at 24 months	**41**	**48**	
	No pain	40 (97.6%)	47 (97.9%)	
	Only mild pain and not frequent	1 (2.4%)	0	
	Frequent but only mild pain	0	1 (2.1%)	
	Serious pain interfering with daily life	0	0	
Data are means (SD) or % (n/N); *P<0.05; **P<0.01; ***P<0.001				

Table 3

Description of 2-year follow-up data according to randomization of the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by prophylactic mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

In Figure 2 the estimated fraction of patients remaining free of incisional hernia is depicted in function of time (Kaplan-Meier estimate). The Mantel-Cox test indicated that the estimated freedom of incisional hernia curves were significantly different across study arms (X^2=19.50, P<0.0001). Incisional hernia diagnosis was only clinically in 4 patients, confirmed by ultrasound in 4 patients and confirmed by CT scan in 8 patients.

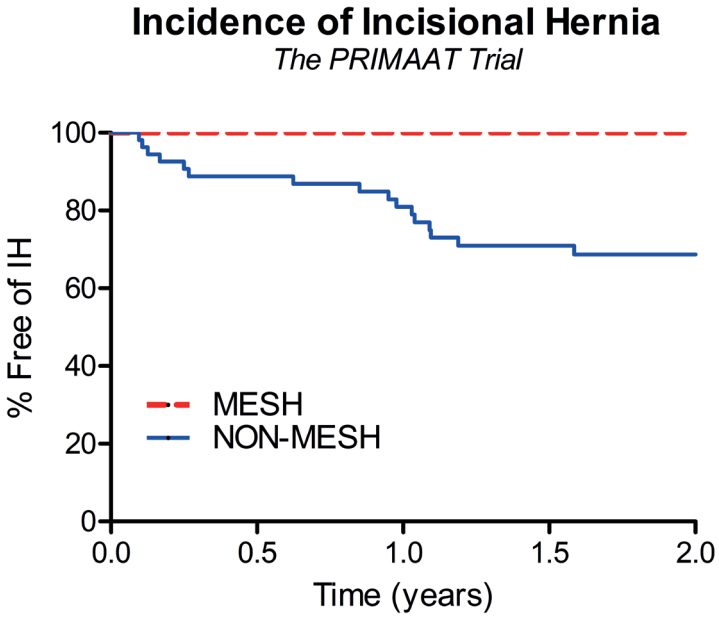

Figure 2

Estimated freedom of incisional hernia curves (Kaplan-Meier) in 114 patients treated for abdominal aortic aneurysm through a midline laparotomy randomly allocated to conventional laparotomy closure or closure of the wound with a prophylactic retro-muscular mesh augmented reinforcement. They were significantly different across study arms (X^2=19.50, P<0.0001; Mantel-Cox test).

Other analyses

Analysis of the risk for the development of incisional hernia in the NON-MESH arm did not show any significance for any of the evaluated risk factors. (Table 4)

		Incisional hernia % (N= 58)	Significance*
Age at the time of surgery	< 75 years	33.3% (10/30)	P=0.38
	≥ 75 years	21.4% (6/28)	
Gender	Women	0.0% (0/7)	P=0.17
	Men	31.4% (16/51)	
Body Mass Index	< 27 kg/m^2	27.8% (10/36)	P=0.99
	≥ 27 kg/m^2	27.3% (6/22)	
ASA score	Normal health	40.0% (2/5)	P=0.82
	Mild to moderate systemic disease	28.6% (10/35)	
	Serious systemic disease	23.5% (4/17)	
Diabetes mellitus	No	30.4% (14/46)	P=0.71
	Yes	20.0% (2/10)	
Current smoking	No	30.0% (6/20)	P=0.99
	Yes	29.4% (10/34)	
Chronic obstructive pulmonary disease	No	22.9% (8/35)	P=0.53
	Yes	31.6% (6/19)	
Coronary heart disease	No	23.3% (7/30)	P=0.56
	Yes	33.3% (9/27)	
Previous inguinal hernia operation	No	27.7% (13/47)	P=0.99
	Yes	30.0% (3/10)	
Maximum size (diameter) of aneurysm	< 6 cm	25.0% (7/28)	P=0.77
	≥ 6 cm	32.1% (9/28)	
Infrarenal aneurysm	No	30.8% (4/13)	P=0.99
	Yes	27.3% (12/44)	
Juxtarenal aneurysm	No	28.9% (13/45)	P=0.99
	Yes	25.0% (3/12)	

Straight tube prosthesis	No	26.3% (10/38)	P=0.76
	Yes	31.6% (6/19)	
Bifurcation, intra-abdominal anastomosis	No	25.7% (9/35)	P=0.76
	Yes	31.8% (7/22)	
Bifurcation, anastomosis in the groin	No	31.7% (13/41)	P=0.51
	Yes	18.8% (3/16)	
Length of fascia incision	< 28 cm	26.1% (6/23)	P=0.53
	≥ 28 cm	36.4% (8/22)	
Length of suture used to close the fascia	< 100 cm	20.0% (6/30)	P=0.36
	≥ 100 cm	32.0% (8/25)	
SL/WL ratio [a]	< 4	23.7% (9/38)	P=0.74
	≥ 4	29.4% (5/17)	
Early postoperative complications [b]	None	23.3% (7/30)	P=0.46
	Grade I	25.0% (1/4)	
	Grade II	36.4% (4/11)	
	Grade IIIa	0.0% (0/1)	
	Grade IIIb	100% (1/1)	
	Grade IV	42.9% (3/7)	
	Grade V	0.0% (0/4)	

* according to Fisher's exact test
[a] SL/WL ratio = Suture Length to Wound Length ratio
[b] Classified according to the Clavien-Dindo classification of postoperative complications [6]

Table 4

Analysis of the risk for the development of incisional hernia in the NON-MESH arm of the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by prophylactic mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

Harms

No difference in percentage or severity of postoperative complications (Table 2) between study arms was observed. A detailed description of the operative morbidity is given in Table S2, in supplement. There were no intra-operative complications related to the mesh augmentation. Overall renal and pulmonary complications were frequent with 19% (22/114) and 17% (20/114) respectively. Pulmonary complications were significantly more frequent in the NON-MESH group, 26% versus 9%; P=0.026 (Fisher's exact test). Overall hospital mortality was 4% (5/114). Wound complications occurred in 8% (9/114). No deep wound infections or mesh infections were observed. Seroma or hematoma was only seen in the MESH group, both in 2 patients. In two patients of each group an early re-laparotomy was indicated, and in one patient of the MESH group, the mesh was removed and not replaced. Events other than incisional hernia development detected during the 24 months follow-up are summarized in Table 3. Of all patients of our ITT population that survived the operation, 9% (10/109) had died before the 24 months follow up date and 10 patients were diagnosed with cancer, which could be treated curatively in 4 cases. Subsequent abdominal surgery was performed in 13 patients. No late complications of the mesh were observed and the presence of the mesh did not pose problems during the subsequent surgery. Patients were questioned for the presence of abdominal wall pain and in the MESH group no pain was reported by 96% and 98%, at 12 months and at 24 months respectively.

	NON-MESH (N= 58)	MESH (N= 56)
Intraoperative complications		
related to the aneurysm treatment	**3 (5.2%)**	**3 (5.4%)**
hypovolemic shock due to blood loss	1	1
atrial fibrillation	0	1
distal embolectomy	2	1
related to the abdominal wall closure	**0**	**0**
Operative morbidity (in-hospital or 30 days)		
vascular complications	**4 (6.9%)**	**7 (12.5%)**
bleeding AAA repair	1	1
peripheral vascular embolism	4	5
DVT		1
neurological complications	**3 (5.2%)**	**4 (7.1%)**
cerebral ischemia	1	0
disorientation	2	4

pulmonary complication	**15 (25.9%)**	**5 (8.9%)** *
pneumonia	11	3
ARDS	4	2
need of ventilation	4	2
cardiac complication	**3 (5.2%)**	**5 (8.9%)**
angina pectoris	0	1
aritmia	3	5
renal complications	**13 (22.4%)**	**9 (16.1%)**
renal failure	11	6
urinary track infection	2	4
hematuria	1	0
need for renal replacement therapy	3	0
gastro intestinal	**11 (19.0%)**	**8 (14.3%)**
prolonged ileus	6	3
colonic ischemia	3	2
stomach ulcer	1	1
pancreatitis	1	0
small bowel obstruction	0	2
wound complications	**3 (5.2%)**	**6 (10.7%)**
superficial wound infection	3	1
deep wound infection	0	0
mesh infection	0	0
partial dehiscence	0	1
seroma	0	2
hematoma	0	2
septic complications	**4 (6.9%)**	**2 (3.6%)**
fever of unknown origin	2	0
bacteremia	2	2
in hospital mortality	**4 (6.9%)**	**1 (1.8%)**
colonic ischemia	1	1
ARDS	2	0
cerebral anoxia after cardiac arrest	1	0
need for relaparotomy	**2 (3.4%)**	**2 (3.6%)**
colonic ischemia	2	1 **
AAA repair bleeding	0	1 ***

* P=0.026 (according to Fisher's exact test); **mesh replaced;
*** mesh removed

Table 5

Operative morbidity (≤ 30 days) of patients included in the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by prophylactic mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

DISCUSSION

Key results

A highly significant reduction of the incidence of incisional hernia was found at 2-year follow-up after retro-muscular MAR compared to primary closure of midline laparotomies for AAA repair: 0% (CI; 0 % - 6%) versus 28% (CI; 17% - 41%) with a P <0.0001. No adverse effect related to MAR was observed, apart from an increased mean time to close the abdominal wall for MAR compared to the control group: 46 min (SD; 18.6) versus 30 min (SD; 18.5), respectively (P<0.001; Mann-Whitney U test).

Limitations

Despite precautions taken, as described above, complete blinding of the assessor for the primary end point could not be guaranteed, because the evaluator usually had access to the patient file and operating report. The magnitude of the observed effect nevertheless makes it unlikely an assessment bias has influenced the final outcome of the study. Although we anticipated an inclusion period of 24 months at the start of the study, it took double the time to achieve the sample size. This was mainly due to the rapidly growing application of endovascular treatment of AAA during the study period and the difficulty to organize the availability of the abdominal wall surgeon during the vascular surgery program. This has led to a high number of non-included eligible patients as depicted in the flow diagram of the study in Fig 1. Our study size was not large enough to detect complications with a low frequency like mesh infection, chronic abdominal wall pain or difficulty to access the abdomen during subsequent abdominal operations.

Interpretation

No incisional hernias were observed in the MESH group. Many previous published RCT's have also resulted in an incisional hernia rate close to zero for MAR.[9-14] On the other hand, a RCT previously published in AAA patients had an incisional hernia rate in the mesh group of 14% (5/37) compared to 37% (16/43) in the control group (P=0.002).[5] In our study the randomized part of the operation was performed by surgeons with specific experience in abdominal wall surgery, which might have resulted in a more appropriate overlap of the mesh beyond the laparotomy incision. This is most critical in the cranial and caudal part of the incision. This is well known to be very important from successful retro-muscular incisional hernia repair.[15] The mesh is placed behind the intact linea

alba cranially and beyond the pubic bone caudally for at least 3 cm.
Although the study protocol required a SL/WL ratio of at least 4, this was only achieved in one third of the patients. It has been stated that a SL/WL ratio of < 4 is associated with a significant higher number of incisional hernia in AAA patients.[16] Therefore the correct application of the evidence based principles of abdominal wall closure is very important.[17,18] Our study shows that implementation of these principles is not easy, even with surgeons specialized in abdominal surgery. Nevertheless, analysis on the risk factors for incisional hernia as shown in Table 4 did not show an increased incidence of incisional hernia when the SL/WL ratio was < 4.
Some concerns have been raised on the prophylactic use of mesh augmentation in a study on 16 obese patients with a high number of mesh related complications.[19] Our study did not show any serious adverse event related to the mesh implantation in a retro-muscular position. The meta-analysis of MAR was reassuring on the complications of prophylactic mesh implants, with an increase of postoperative seroma, mainly attributable to MAR in an onlay position.[4,13] This was recently confirmed by the short term outcome published of a large RCT on MAR in patients with BMI > 27kg/m^2 or AAA.[20] In this three-armed RCT in 480 patients, primary suture was compared to MAR either in onlay or in retro-muscular position. On the basis of the short-term results, primary mesh augmentation was considered a safe procedure with only an increase in seroma formation after onlay mesh augmentation, but without an increased risk of surgical site infection.
A surprising finding during the analysis of our outcome data was a significant higher number of pulmonary complications in the NON-MESH group (Table 5). Baseline data of both arms showed no difference in number of smokers or patients with chronic obstructive pulmonary disease. Although one might expect an increase in pulmonary complications in the MESH group, because of an assumed decrease in abdominal wall compliance, the opposite was found. Because of the lack of rationale to explain this finding, it is probably a false positive observation that requires confirmation in other ongoing studies on MAR.
Of the 16 patients in the NON-MESH group diagnosed with an incisional hernia 4 patients had an incisional hernia repair and thus the incisional hernia repair rate at 24 months was 6.9% (4/58). This is in line with the data from the Danish database as reported by Henriksen et al.[3] The Danish national databases can only report on the number of patients that following a specific type of surgery (e.g. "elective aortic surgery") have a subsequent other intervention within Denmark (e.g. "incisional hernia repair"). This "incisional hernia repair rate" will obviously underestimate significantly the true number of incisional hernias in this patient population. From other publications of the Danish databases we know that the

"reoperation rate" after "incisional hernia repair" is underestimating the overall risk for recurrence by fivefold.[21] Thus only one out of five patients with a recurrence after incisional hernia repair had a repair operation. Probably comparable numbers would be found if a similar study was performed on the patients that had elective aortic surgery and the overall risk for incisional hernia. In our study 4 out of 16 patients (25%) with an incisional hernia had a repair operation in the first 24 months after surgery. A further increase, both in incisional hernia rate and incisional hernia operation rate, is expected with longer follow up.[2,3]

Generalizability

State of the art retro-muscular placement of a mesh requires some expertise and training. Vascular surgeons do not regularly perform abdominal wall reconstructions in their practice. Moreover the additional surgical time needed to perform a retro-muscular mesh implantation at the end of a long vascular procedure might be an important hindrance to the routine application of MAR in AAA patients. Nevertheless our results are overwhelmingly in favor of the MAR. Future research will focus on avoiding the retromuscular dissection during MAR, with onlay mesh positioning or with specific prophylactic mesh constructions.[20,22-25] This will make mesh augmentation easier and less time consuming.

OTHER INFORMATION

Publication statement

This manuscript was written in accordance with the CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. (www.consort-statement.org) [26]

Registration

Clinical.Trials.gov: NCT00757133 & Belgian Trial Registration Number: B67020084346

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Disclosure statements

The authors report no conflict of interest in relation to this study.

Video (in supplement)

The video shows the surgical technique of retro-muscular mesh augmented reinforcement of a midline laparotomy after repair of an abdominal aortic aneurysm, like performed in the treatment arm of the PRIMAAT trial: a randomized clinical trial on the prevention of incisional hernias by prophylactic mesh augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment.

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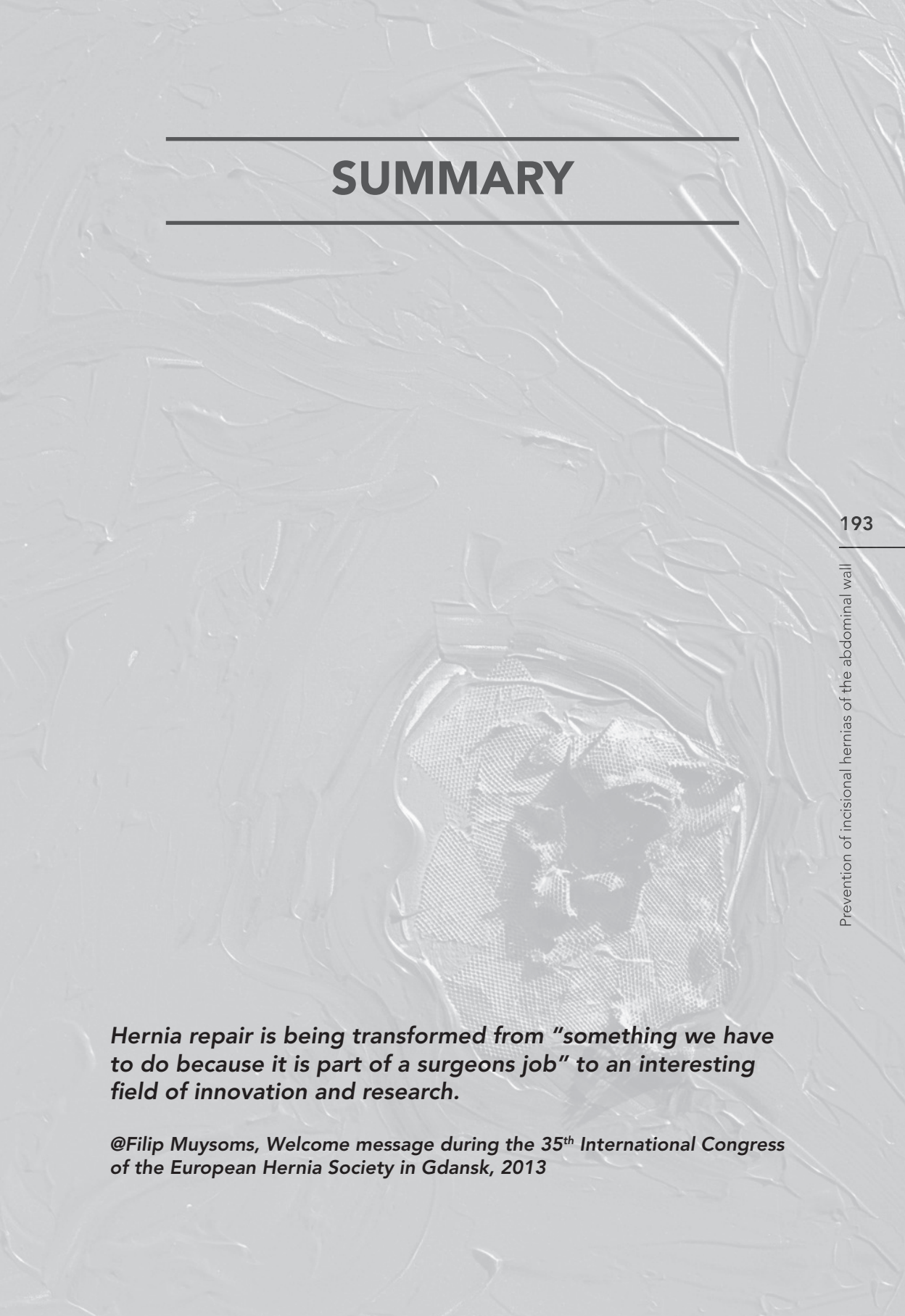
SUMMARY



Hernia repair is being transformed from "something we have to do because it is part of a surgeons job" to an interesting field of innovation and research.

@Filip Muysoms, Welcome message during the 35th International Congress of the European Hernia Society in Gdansk, 2013

Incisional hernias of the abdominal wall are a frequent complication of abdominal surgery. The repair of iatrogenic abdominal wall defects is often difficult, costly and with a variable success rate. Using techniques and materials, with proven lower incidences of incisional hernias, to close the abdominal wall incisions can prevent many incisional hernias. The evidence-based principles of abdominal wall closure are relatively simple to learn or teach. Some patients with increased risk of developing an incisional hernia will benefit from the use of a mesh augmentation during the closure of the abdominal wound.

Chapter 1 of this thesis consists of 3 articles based on a consensus model within the European Hernia Society (EHS).

Classification of primary and incisional abdominal wall hernias. Hernia, 2009, 13:407-414

Previously, individual researchers published several classifications of incisional hernias. None have found a widespread use in research or literature, although some were published more than a decade ago. The proposed classification is a modification of the Chevrel classification from 2000. By publishing the classification on behalf of the European Hernia Society and based on a consensus of a panel of experts, the classification has seen a rapid adoption by many authors of manuscripts and textbooks. Several currently active patient registries on incisional hernia repair (*Herniamed* in Germany, *Evereg* in Spain, *Club Coelio* in France) are using the "EHS classification" in their database.

EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair. Hernia, 2012, 16:239-250

Within the EHS, a working group was formed to develop an online platform for registration and outcome measurement. EuraHS was created (a non-profit association under Belgian law) for development and maintenance of this platform. The dataset used in the platform was discussed thoroughly at several meetings between the working group of experts. To do this, a clear set of definitions and classifications on the variables involved in the treatment of incisional hernias was created, as well as for the outcome parameters. The platform was launched during a symposium in Brussels in June 2012. It has not found widespread use yet, possibly because of the voluntary character of participation and because of the number of variables included in this comprehensive research platform.

Recommendations for reporting outcome results in abdominal wall repair. Results of a Consensus meeting in Palermo, Italy, 28-30 June 2012. Hernia, 2013, 17:423-433
The EHS board took the initiative to organize a meeting of experts to establish recommendations for the preferred methods and standards to report outcome results in abdominal wall surgery. The participants to this consensus meeting were the EuraHS board members and other experts, including some editors of surgical journals and two statisticians.

Chapter 2 of this thesis looks at the possibilities to decrease our incisional hernia rate by investigating the best evidence on the materials and methods for closing abdominal incisions. The first two publications are reports from studies performed in our department. To know your own incisional hernia rate is the first step towards implementing improvements in your own technique. The last two publications of this chapter seek to describe the best evidence abdominal closure methods and to provide the surgical community with a clear set of recommendations and guidelines.

Retrospective observational study on the incidence of incisional hernias after colorectal carcinoma resection with follow-up CT scan. Hernia, 2014, 18:797-802
This study is retrospective and therefor the data are qualitatively inferior to prospective registration of data and outcome. Nevertheless, the methodology of the study enabled an estimation of the incisional hernia rate after colorectal carcinoma resection. It shows the superiority of incisional hernia diagnosis by CT scan when assessed with specific attention to the abdominal wall. The incidence of incisional hernia was shown to be 35.0 % with a mean follow-up time of 30 months for colorectal cancer patients, which is higher than anticipated.

Retrospective observational study on the incidence of incisional hernias after reversal of a temporary diverting ileostomy following rectal carcinoma resection with follow-up CT scans. Hernia, 2015, submitted on December 5th 2014.
With a similar methodology to the previous study and thus with the same methodological weakness, this tudy investigated the incisional hernia rate after resection of rectal cancer. The study focused on patients that had a temporary diverting ileostomy and subsequent restoration of continuity by stoma closure. These wounds are known to have a rate of incisional hernias of up to 30%. This was not confirmed in our study, with an rate incisional hernia of 11% after 2.6 years mean follow-up. But, for patients undergoing low anterior resection of a rectal cancer, the incidence was 45.1% at the laparotomy site with a mean follow-up time of 1.9 years, which is higher than expected.

The principles of abdominal wound closure. Acta Chirurgica Belgica, 2013, 113:239-244
In collaboration with the Erasmus University of Rotterdam a review of the methods and material used to close a midline laparotomy was performed. This led to the description of a set of principles that, by adopting them in clinical practice, is expected to result in fewer incisional hernias. There is overlap with the following study, which reports on the EHS guidelines because both are based on the available literature and are thus evidence based. Nevertheless, this article does provide added value in that it is more pragmatic and gives a clear description of the "Principles technique" that incorporates all recommendations made in the guidelines.

EHS guidelines on the closure of laparotomy incisions. Hernia, 2015, 19:1-24
Under the auspices of the EHS board, a Guidelines Development Group was formed to develop recommendations on the closure of abdominal wall incisions. The GRADE methodology was used and guidance from the Scottish Intercollegiate Guidelines Network (SIGN) was sought. It was an extensive research project with several systematic reviews and critical appraisal of the literature. Most recommendations aligned with our expectations, but some were new. A strong recommendation to "use non-midline incisions when possible", was formulated based on high quality of evidence. This was never previously stated as clearly as, in these guidelines. One of the chapters of the guidelines manuscript is deals with prevention of incisional hernias by mesh-augmented reinforcement of the abdominal wall, which is the topic of Chapter 3 of this thesis.

Chapter 3 covers the result of a prospective randomized trial performed in 8 Belgian hospitals.

Randomized trial on the prevention of incisional hernia by mesh augmentation after midline laparotomy for aortic aneurysm treatment. Annals of Surgery, submitted March 2015
Because patients undergoing treatment of an abdominal aortic aneurysm (AAA) have a very high risk for developing incisional hernias, the prophylactic augmentation of the abdominal wall with a mesh has been proposed. A RCT on 120 patients showed that the retro-muscular placement of a synthetic mesh is very effective in preventing incisional hernias. The cumulative incidence of incisional hernias at 2-year follow-up after conventional closure was 28% (95% CI; 17% - 41%) versus 0% (95% CI; 0 % - 6%) after mesh-augmented reinforcement ($P<0.0001$; Fisher's exact test). The technique is safe and no adverse events relat-

ed to the mesh were observed. The placement of the mesh increased the operating time with 16 minutes. The study adds high quality data to the rapidly growing evidence on the use of prophylactic mesh augmentation in patients at high risk of development of incisional hernias. It is my opinion that the use of a mesh to prevent incisional hernias will soon become common practice for several groups of patients at high risk of incisional hernia development.

SAMENVATTING

De buikwandchirurgie transformeert van "iets wat we moeten doen als deel is van onze job als chirurg" tot een intressant gebied van innovatie en wetenschappelijk onderzoek.

@Filip Muysoms, Welkomst boodschap tijdens het 35th International Congress of the European Hernia Society in Gdansk, 2013

Littekenbreuken van de buikwand zijn een frequente complicatie van abdominale chirurgie. Het herstel van deze buikwanddefecten is vaak moeilijk, kostelijk en met een variabel slagingspercentage. Met behulp van technieken en materialen om de buikwand te sluiten met een bewezen lagere incidentie van littekenbreuken zouden we veel postoperatieve breuken kunnen voorkomen. De *evidence-based* principes van buikwandsluiting zijn niet moeilijk om te leren of te onderwijzen. Sommige patiënten met een verhoogd risico op het ontwikkelen van een littekenbreuk kunnen profiteren van het gebruik van een versteviging van de buikwand met een prothese bij het sluiten van de abdominale wond.

H**oofdstuk 1** van dit proefschrift omvat 3 artikelen ontstaan op basis van een consensus model binnen de Europese Hernia Society (EHS).

Classification of primary and incisional abdominal wall hernias. Hernia, 2009, 13:407-414

Voorheen werden reeds door individuele onderzoekers voorstellen tot classificatie van littekenbreuken gepubliceerd. Hoewel sommige reeds meer dan een decennium geleden werden gepubliceerd, heeft geen van deze classificaties een brede toepassing bij onderzoek of literatuur gevonden. De door ons voorgestelde classificatie is een aanpassing van de Chevrel classificatie gepubliceerd in 2000. Door de publicatie van de classificatie, gebaseerd op consensus in een panel van deskundigen, namens de Europese Hernia Society heeft deze een snelle toepassing gekend en wordt thans gebruikt door veel auteurs van manuscripten en leerboeken. Een aantal van de actieve patiënt registers voor littekenbreuken (Herniamed in Duitsland, Evereg in Spanje, Club Coelio in Frankrijk) gebruiken de "EHS classificatie" in hun database.

EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair. Hernia, 2012, 16:239-250

Binnen de EHS werd een werkgroep gevormd om een online platform voor de registratie en het resultaatsmeting te ontwikkelen. EuraHS werd opgericht (een VZW naar Belgisch recht) voor de ontwikkeling en het onderhoud van dit platform. De dataset voor dit platform werd uitvoerig besproken tijdens verschillende vergaderingen van de werkgroep van deskundigen. Er waren duidelijke definities en classificaties nodig voor de variabelen die betrokken zijn bij de behandeling van littekenbreuken en voor de beschrijving van de uitkomstparameters. Het platform werd gelanceerd tijdens een symposium in Brussel in juni 2012. Het heeft nog geen wijdverbreid gebruik gevonden, mogelijk als gevolg van de

vrijwillige karakter voor de deelname en vanwege het aantal variabelen in dit uitgebreide research platform.

Recommendations for reporting outcome results in abdominal wall repair. Results of a Consensus meeting in Palermo, Italy, 28-30 June 2012. Hernia, 2013, 17:423-433
De EHS bestuursraad, nam het initiatief om een bijeenkomst van deskundigen te organiseren om aanbevelingen op te stellen over de methoden en standaarden om de uitkomst en resultaten in buikwand chirurgie te rapporteren. De deelnemers aan deze consensus bijeenkomst waren de EuraHS bestuursleden en enkele andere deskundigen, waaronder een aantal redacteuren van chirurgische tijdschriften en twee statistici.

Hoofdstuk 2 van dit proefschrift beschrijft de mogelijkheden om de frequentie van littekenbreuken te verlagen door het onderzoeken van de *best-evidenced* materialen en methoden voor het sluiten van abdominale incisies. De eerste twee publicaties zijn rapporten van studies uitgevoerd in onze afdeling. Kennis van de eigen resultaten over littekenbreuken bij onze patiënten is een eerste stap naar de uitvoering van de veranderingen in de eigen techniek die nodig zijn om te verbeteren. De laatste twee publicaties van dit hoofdstuk gaan op zoek naar het beschrijven van de *best-evidenced* abdominale sluiting methoden en om de chirurgische gemeenschap te voorzien van een duidelijke reeks aanbevelingen en richtlijnen.

Retrospective observational study on the incidence of incisional hernias after colorectal carcinoma resection with follow-up CT scan. Hernia, 2014, 18:797-802
Deze studie is retrospectief en dus zijn de resultaten kwalitatief minderwaardig aan prospectieve gegevensverzameling. Desondanks liet de methodologie van de studie ons toe om een schatting van de frequentie van littekenbreuken na resectie van een colorectaal carcinoom te bekomen. Het toont de superioriteit voor de diagnositiek van littekenbreuken door CT-scan met specifieke aandacht voor de buikwand. We vonden een incidentie van littekenbreuken van 35,0% met een gemiddelde follow-up periode van 30 maanden voor colorectale kankerpatiënten. Dit is hoger dan verwacht.

Retrospective observational study on the incidence of incisional hernias after reversal of a temporary diverting ileostomy following rectal carcinoma resection with follow-up CT scans. Hernia, 2015, submitted on December 5th 2014.
Met een methodologie als vorige studie en aldus met dezelfde methodologische

zwakte, werd de frequentie van littekenbreuken na resectie van rectale kanker onderzocht. Er werd speciaal gekeken naar patiënten die een tijdelijke beschermende ileostoma hadden en die nadien een herstel van de continuïteit door afbraak van het stoma hebben ondergaan. Van deze wonde is bekend dat zij resulteert in een hoog percentage littekenbreuken, rondom 30%. Dit werd niet bevestigd in onze studie, met het voorkomen van een littekenbreuk op de stomaplaats in 11% van de patiënten na 2,6 jaar gemiddelde follow-up. Maar, voor patiënten die een lage anterieure resectie van een rectale kanker ondergingen, was de incidentie 45,1% in de laparotomiewonde na een gemiddelde follow-up periode van 1,9 jaar. Ook dit is hoger dan verwacht.

The principles of abdominal wound closure. Acta Chirurgica Belgica, 2013, 113:239-244

In samenwerking met de Erasmus Universiteit van Rotterdam werd een overzicht van de methoden en materialen beschreven om een middellijn laparotomie te sluiten. Dit liet ons toe om een set van principes op te stellen waarvan we denken dat, indien zij in de praktijk worden toegepast, zij aanleiding zullen geven tot minder littekenbreuken. Er is overlapping met het volgende artikel over de EHS richtlijnen voor het sluiten van de buik, omdat beide zijn gebaseerd op dezelfde beschikbare literatuur. Toch denk ik dat dit artikel een toegevoegde waarde heeft omdat het meer pragmatisch is en een duidelijke omschrijving van "Principles techniek" toelaat die alle aanbevelingen in de richtlijnen omvat.

EHS guidelines on the closure of laparotomy incisions. Hernia, 2015, 19:1-24

Onder auspiciën van de EHS bestuursraad werd een *Guidelines Development Group* gevormd om aanbevelingen over de sluiting van de buikwand te ontwikkelen. De GRADE methodiek werd gebruikt en bij mensen van het *Schotse Intercollegiate Guidelines Network* (SIGN) werd begeleiding gezocht. Het was een uitgebreid onderzoek met een aantal systematische reviews en kritische evaluatie van de literatuur. De meeste aanbevelingen waren in lijn met onze verwachtingen, maar sommige waren nieuw. We formuleerden een sterke aanbeveling op basis van hoog kwalitatief literatuurbewijs om niet-middenlijn incisies te gebruiken als dat mogelijk is en dus om een incisie op de middenlijn zoveel mogelijk te vermijden. Dit werd nooit eerder zo duidelijk geformuleerd. Eén van de hoofdstukken van de richtlijnen handelt over de preventie van littekenbreuken door de buikwand te verstevigen met een prothese, wat het onderwerp is van hoofdstuk 3 van dit proefschrift.

Hoofdstuk 3 beschrijft het resultaat van een prospectieve gerandomiseerde studie uitgevoerd in 8 Belgische ziekenhuizen.

Randomized trial on the prevention of incisional hernia by mesh augmentation after midline laparotomy for aortic aneurysm treatment. Annals of Surgery, submitted March 2015

Omdat patiënten die een behandeling ondergaan voor een abdominaal aorta aneurysma (AAA) via een middenlijnlaparotomie een zeer hoog risico hebben op de ontwikkeling van een littekenbreuk, heeft men het preventief plaatsen van een prothese in de buikwand voorgesteld. Een RCT met 120 patiënten toont aan dat het retro-musculair verstevigen van de buikwand met een synthetische prothese zeer effectief is in het voorkomen van littekenbreuken. De cumulatieve incidentie van littekenbreuken na 2-jaar follow-up was voor de conventionele sluiting 28% versus 0% voor de patiënten met een prothese (P <0,0001). De techniek is veilig en we zagen geen bijwerkingen gerelateerd aan de prothese. Voor de plaatsing van de prothese was gemiddeld 16 minuten extra operatietijd nodig. Onze studie zal een bijdrage leveren met hoogwaardige gegevens aan het snel groeiende bewijs dat het verstevigen van de buikwand met een prothese bij patiënten met een hoog risico op littekenbreuken aan te bevelen is. Het is onze mening dat het gebruik van een prothese als preventie van littekenbreuken gemeengoed zal worden voor verschillende groepen van patiënten met een hoog risico.

FUTURE PERSPECTIVES

"The essence of knowledge is, having it, to apply it; not having it, to confess your ignorance."

@ Confucius, 551-479 BC

This thesis is not an endpoint, but it is the basis and the start for more research. Several projects on the topic of incisional hernia prevention are in progress and could not be included in this thesis.
Together with *Dr Willem Willaert*, vascular surgeon, a prospective study has been set up: "Aneurysm Hernia Study", (clinical trials number: NCT02012270). For this study we motivated two young vascular surgeons, *Dr Igor Koncar*, from the University of Belgrade, and *Dr Kamil Bury*, from the Medical University of Gdansk, to collect data on the methods and material they used for the closure of midline laparotomies in AAA patients. Thereafter, we organized a workshop in Belgrade to teach the closure of a laparotomy according to the "Principles" we have described (Fig 1 & 2).

Fig 1
"Principles workshop" in Belgrade, with open repair of an aortic abdominal aneurysm, November 2013.

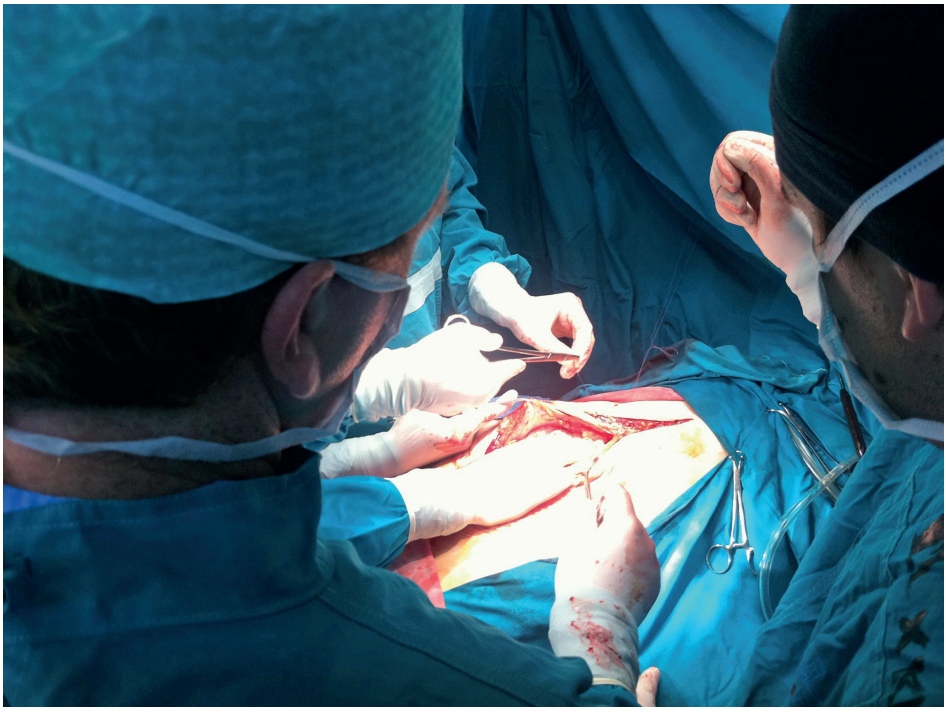


Fig 2
Closure of the midline laparotomy with the "Principles technique" using a continuous suturing technique with small tissue bites and a suture to wound length of at least 4/1, during a "Principles workshop" in Belgrade in November 2013. The suture used is a slowly absorbable suture (Monomax, 2/0).

The patients subsequently closed, "after training", according to the introduced principles will also be monitored and followed. Primary endpoint will be the incisional hernia rate at 12 months. At this moment, a total of 408 patients are included, 204 before training and 204 patients after the training. Follow-up is ongoing. This study will be a good evaluation of our possibility to implement the guidelines and teach other surgeons to achieve the desired decrease in incisional hernias.

The PRIMAAT study is not yet finalized, because the long-term follow-up at 5-year is a secondary endpoint of the study. This follow up is continuing in the different centres. Results are steadily coming in, allowing us to diagnose five more patients in the control group and thus have a cumulative incidence of incisional hernia at 60 months of at least 36.2% (21/58 patients). Until now, no incisional hernia in the

MESH group was reported. Publication of these results will only be possible after completion of the 5-year follow-up in February 2018.

Another research project will be set up in collaboration with *Prof Johan Lange* from the Erasmus University. As we have demonstrated in the manuscript of the guidelines, in the chapter on mesh-augmented reinforcement, this is an efficient manner for preventing incisional hernias, with a RR of 0.17 (CI 0.08-0.37). The statistical heterogeneity of the studies included in the meta-analysis is low (I^2 = 19%), but here is a relevant clinical heterogeneity between the studies. In this meta-analysis only one RCT on 80 patients with AAA was included. Therefore, we considered it to be impossible to make a strong recommendation to perform a mesh augmentation in all AAA patients based on the currently published evindence. Several studies with AAA patients, including our PRIMAAT trial and the PRIMA trial from Rotterdam, will be published in the coming months. With collaboration of the authors and researchers of all published studies on prophylactic mesh augmentation in AAA patients, we intend to perform the PRIMULA study (Acronym for: Primary Mesh Augmentation of Midline Lapartomies for AAA treatment). PRIMULA will be an IPD-meta-analysis: Individual Participants Data meta-analysis. This is a Cochrane methodology where instead of collecting data from published manuscripts of RCTs, a new database is built with the data from the individually included patients in the studies. By the end of 2015 a total of 500 AAA patients will have been randomized and published in at least 5 studies. This should allow a meta-analysis with less clinical heterogeneity and might be the data we need to allow for a strong recommendation in the update of the guidelines on the closure of abdominal wall incisions that is planned for 2017.