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Feasibility work to inform the design of a randomized controlled trial of wound dressings in elective and unplanned abdominal surgery

SPARCS* and WMRC[±] on behalf of the Bluebelle study group

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Authors' contributions: This study was conceptualised by members of the core study group (JMB, NB, LE, TP, BR, CR, SS and AT), and Bluebelle co-applicants (see below) contributed to its design. Trainee collaborators (see below) collected the data, which was co-ordinated by NB, LE and AT. Data were analysed by GC and CR. NB wrote the first draft of

the paper which was edited by JMB and all members of the core study group approved the final version. JMB is the chief investigator of the Bluebelle study and the guarantor for this paper.

Paper category: Original article

Trainee collaborators: The trainees listed below collected data from hospitals across the West Midlands (West Midlands Research Collaborative) and South West of England (Severn and Peninsula Audit and Research Collaborative for Surgeons).

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Abstract

Background: Designing randomized controlled trials (RCTs) in surgery requires consideration of existing evidence, stakeholders' views and emerging interventions, to ensure that research questions are relevant to patients, surgeons and the health service. When there is uncertainty about RCT design, feasibility work is recommended. This study aimed to assess how feasibility work could inform the design of a future pilot study and RCT (Bluebelle, HTA-12/200/04).

Methods: A prospective survey of dressings used to cover abdominal wounds was undertaken. Surgical trainees from 25 hospitals were invited to participate. Information about patient risk factors, operation type and type of wound dressings used were recorded for elective and unplanned abdominal procedures over a two week period. The type of dressings used were summarized and associations with operation type and patient risk factors explored.

Results: Twenty hospitals participated, providing data from 727 patients (1794 wounds). Wounds were predominantly covered with basic dressings (n=1203/1769, 68%) and in 27% (485/1769), tissue adhesive was used; dressing type was missing for 25 wounds. Just 4% (63/1769) wounds did not have a dressing applied at the end of the procedure. There was no evidence of an association between type of dressing used and patient risk factors, type of operation, or between elective and unscheduled surgery.

Conclusions: Based on the findings from this large study of current practice, the pilot study design has evolved. The inclusion criteria have expanded to encompass patients undergoing unscheduled surgery, and tissue adhesive as-a-dressing will be evaluated as an additional intervention group. Collaborative methods are recommended to inform the design of RCTs in surgery, helping to ensure they are relevant to current practice.

Introduction

Dressings are widely used to cover wounds at the end of surgical procedures; however, in some specialized areas (e.g. paediatric surgery) they are not applied routinely. This may reflect the different ways that approaches to treatment are adopted in clinical practice, or the lack of evidence to suggest dressings confer any benefit^{1, 2}. A Cochrane systematic review summarizing evidence for the use of dressings to prevent surgical site infection (SSI) was published in 2011 and updated in 2014^{3, 4}. Twenty randomized controlled trials (RCTs) were included, which examined different types of dressing and 'no dressing' on a closed wound. All trials were assessed as having an unclear or high risk of bias and were underpowered to detect SSI events. No evidence was identified to suggest that any dressing significantly reduced the risk of developing an SSI compared with leaving wounds exposed; neither was there any benefit associated with particular dressing types. The review concluded that decision-making around dressings may need to be informed by cost and practical issues surrounding symptom management. It also recommended that the design of future RCTs should focus on surgical procedures at highest risk of an SSI, such as abdominal surgery, and evaluate the dressings that health professionals use most widely. The uncertainties raised in this review led the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) to identify wound dressings as a research area likely to make a substantial difference to people's health. Research was commissioned to examine whether an RCT in this area would be possible and the Bluebelle pilot study (HTA 12/200/04) was funded to address this question⁵. If deemed possible, the main trial will investigate which type(s) of dressing reduce the risk of SSI amongst patients undergoing abdominal surgery.

One current area of uncertainty facing surgical RCTs is selecting which interventions to evaluate. This requires consideration of existing evidence, current practice and emerging novel interventions to ensure that the RCT findings would be relevant to patients, surgeons and the health service. There are many different wound dressings available, ranging from basic to advanced with varying absorbent, adherent and interactional properties⁶. The NIHR HTA commissioned call highlighted the need to justify which interventions should be evaluated. This study therefore aimed to understand and characterize the use of peri-operative abdominal wound dressings in current practice, to inform the design of the future pilot study.

Methods

A prospective multicentre study was undertaken by members of the Severn and Peninsula Audit and Research Collaborative for Surgeons (SPARCS)⁷ and the West Midlands Research Collaborative (WMRC)⁸. All hospitals within the two trainee-led research collaborative networks were invited to participate, via emails and personal communication. A surgical trainee-level principal investigator, responsible for local co-ordination of data collection and entry, was identified within each participating hospital. The study was registered with the clinical audit department in each hospital and approval was obtained for the Bluebelle study from the National Research Ethics Service (14/LO/0640, Camden and Islington, 10th April 2014).

Abdominal wounds created during elective or unplanned abdominal surgery, and closed primarily, were surveyed during a two-week period in January 2015. A wound was considered to be closed primarily if the edges of incised skin were opposed (using suture material, tissue

adhesive or clips) at the end of the procedure. Vascular, gynaecological, urological and paediatric procedures were excluded. Cases were only included if trainees were present (and therefore able to collect the data prospectively). Trainees completed anonymised data collection forms at the end of each surgical procedure, recording information about skin closure and dressings (Appendix 1). Dressings were categorised as 'advanced' (i.e. with advanced practical and/or therapeutic properties, including amorphous material, silicone, hydrocolloid, foam, anti-microbials or negative pressure) or 'basic' (i.e. dressings without advanced or therapeutic properties which are adherent around the perimeter or entire surface, with or without a pad to absorb exudate). 'No dressing' was documented when an already closed wound was left without a covering at the end of the operation. Use of tissue adhesive to cover an already closed wound (whereby it was used as a dressing rather than wound closure technique) was categorised separately.

Operative and patient-related risk factors that might influence dressing selection were recorded. Operative risk factors included the type of procedure performed and access (i.e. open, laparoscopic or laparoscopic-assisted), whether a stoma was formed, and the degree of wound contamination (clean, clean-contaminated, contaminated and dirty)⁹. Procedures were classified as planned (elective) or unplanned (emergency). The following patient-related risk factors were recorded: age, gender, body mass index, diabetic status and American Society of Anaesthesiologist (ASA) grade.

The rationale for dressing selection (by the surgeon responsible for closing the wound) was recorded in the following three categories: personal preference, selected due to specific wound characteristics, or that the dressing was simply handed to the surgeon at the end of the procedure, without discussion. Dressings could be selected for multiple reasons and space

for free text answers was provided. To supplement this, procurement officers from each hospital were contacted to obtain information about local policies for purchasing dressings.

Data management and analysis

Data were entered into a password-protected online database held on a server (developed and maintained by the Bristol Clinical Trials and Evaluation Unit) in one of the participating hospitals. Analyses were performed in Stata version 13 (Stata Corporation, Texas) and summarised the frequency of different dressing types using descriptive statistics. Descriptive statistics were also used to examine whether patient characteristics or the type and urgency of surgery were associated with particular dressing strategies.

Results

In total, 25 hospitals within the SPARCS and WMRC networks were approached and 20 (80%) participated. Data from 727 patients (1794 wounds) were included of whom 193 (27%) underwent upper gastrointestinal surgery (Table 1). The number of wounds per patient varied from 1-7: one (n=299, 41%) two (n=51, 7%), three (n=155, 21%), four (n=190, 26%), five (n=25, 4%) and just seven patients (1%) had more than five wounds. Complete datasets were submitted for 675 (93%) patients. There was one missing data item for 36 (5%) patients and 16 (2%) had more than one missing item.

Sutures were most commonly used to achieve skin closure (n=1531, 87%), with clips (n=9%) and steri-strips (n=48, 3%) less commonly used. Of the 1794 wounds, dressing type was recorded for 1769, with 1706/1769 (96%) covered and 63/1769 (4%) not covered by a

dressings. The majority of dressings were classified as basic (n=1203/1769, 68%) with just 1% (18/1769) advanced. Tissue adhesive was applied over closed skin to 27% (485/1769) of wounds.

Use of dressings according to operative and patient risk factors

Variation in the types of dressing according to the category, urgency and modality of surgery is described in Tables 2 and 3. Dressing types were similar across different types of procedure, and between elective and unscheduled surgery. There was no apparent association between the type of dressing used and patient risk factors such as diabetes, stoma formation, body mass index and ASA grade.

Reasons for selection of dressings

Most (n=925, 75%) surgeons used the dressings that were handed to them by the nursing staff at the end of the operation (Table 4). Information from procurement staff (n=29) revealed that cost was the overwhelming factor when selecting which dressings to purchase, enabling bulk ordering and keeping the range of available dressings to a minimum.

Discussion

This multicentre study has comprehensively described the use of peri-operative wound dressings in elective and unplanned abdominal surgery across two regions of the United Kingdom. A total of 727 patients (1794 wounds) were studied over a two week period and data completeness were very high (93%). Of the covered wounds, basic wound dressings were mainly used (n=1203/1769, 68%) and advanced dressings rarely applied (n=18/1769, 1%).

Unexpectedly, tissue adhesive (which had not been included in either basic or advanced categories) was used as a dressing in 485/1769 (27%) wounds. Dressing types were similar across different types of procedure, and between elective and unplanned surgery, and were not influenced by patient or operative risk factors. Surgeons typically used the dressings handed to them by nursing staff (according to local hospital policy) rather than favouring one particular type, even if patients were high risk (e.g. severe obesity or diabetes). These findings have important implications for the design of a main RCT. They highlight the need to evaluate ~~evaluate~~ tissue adhesive as a separate trial group, and to increase the inclusion criteria to encompass patients undergoing unscheduled as well as elective surgery.

Pre-trial work is increasingly seen as crucial to the success of RCTs, and may be particularly relevant to complex interventions such as surgery¹⁰. Recommendations for good practice in the design of pre-trial work highlight several opportunities to reduce uncertainty¹¹. These include estimating the size of the eligible population and recruitment rates, developing and selecting outcome measures, estimation of parameters required for sample size calculations and determining the acceptability of interventions. The design of some studies may expose further uncertainties such as specifying the most appropriate interventions or eligibility criteria. One way of resolving these uncertainties is to study current practice in a representative sample, which may be challenging in complex environments such as the operating theatre. Trainee surgeons have formed 'research collaboratives' as a novel solution to undertaking multicentre surgical studies. These regional networks recently delivered the National Appendicectomy Audit, which included 3326 consecutive patients across 95 centres¹²⁻¹⁴. Although impressive, the quality of collected data has not previously been examined, inviting sceptics to question the rigour of trainee-led work. In the current study, complete datasets were submitted for 93% of patients, demonstrating the enormous

potential for trainees to efficiently generate large amounts of high quality data which are directly relevant to an RCT.

Specific strengths of this study are the contemporaneous collection of prospective data across multiple operating theatres in different hospital trusts with very few missing fields, and the inclusion of elective and unplanned abdominal surgery. Despite this, some weaknesses remain. It is possible that some eligible patients were not captured during the study, meaning that variations in practice may have been missed, although the large sample size from 20 different centres means that this is less likely. A further limitation is that data were collected from two distinct geographical regions and it is possible that findings are not representative of the entire UK.

This study, undertaken by surgeons and methodologists, demonstrates the importance of collaboration and teamwork to ensure how information can be obtained efficiently to inform trial design. The finding that tissue adhesive was widely used as a dressing was unexpected. Currently, there are only four RCTs that have evaluated tissue adhesive as a dressing¹⁵⁻¹⁸, none of which included patients undergoing gastrointestinal surgery. Additionally, they are small, single centre studies and each has aspects of their design that were subject to a high risk of bias. There is, therefore, a need for this product to be fully evaluated in a pragmatic trial to generate high quality evidence to inform practice. Based on the findings from the current study, the pilot study design has evolved. Firstly, the inclusion criteria will be expanded to encompass patients undergoing unscheduled as well as elective surgery. Secondly, three groups (tissue adhesive as-a-dressing *versus* a basic dressing *versus* 'no dressing') rather than two groups (basic dressing *versus* 'no dressing') will be evaluated. Inclusion of the 'no dressing' group is important because of a lack of evidence to support the use of dressings^{3,4}

and because not applying dressings to closed wounds is common in paediatric practice. Whether it is possible to randomize patients into an RCT with a 'no dressing' group, and whether patients and staff can comply with treatment allocations, is unknown. These uncertainties justify the need for a pilot study prior to a definitive multicentre RCT, which is scheduled to open imminently. As well as collecting data about SSI (the proposed primary outcome), the pilot study will collect information about secondary measures such as practical wound management issues, cosmesis and cost effectiveness.

In summary, the successful design and conduct of RCTs in surgery can be optimized by appropriate, high quality pre-trial work. Whilst such work has traditionally focused on recruitment, outcome assessment and completeness of follow-up data it is also critical to identify the appropriate interventions to evaluate, especially in the context of surgical RCTs. This may also be beneficial in helping to structure and populate future modelling studies and meta-analyses. Contemporaneous surveys, undertaken across multiple centres as a collaborative effort between methodologists, surgeons and trainee research collaboratives, are a useful and efficient way of obtaining generalizable information about current practice. We recommend that trials teams routinely consider undertaking pre-trial feasibility work, especially when the design process highlights important uncertainties.

Table 1. Descriptive data about patients and procedures

			n= 727 (%)
Patients	Sex^a	Male	348 (48)
		Female	375 (52)
	Age^b	< 30	119 (16)
		30-40	90 (12)
		41-50	104 (14)
51-60		109 (15)	
61-70		144 (20)	
> 71		157 (22)	
ASA grade^c	1	224 (31)	
	2	342 (47)	
	3	140 (19)	
	4	15 (2)	
Diabetic status^d	Non-diabetic	659 (91)	
	NIDDM	51 (7)	
	IDDM	12 (2)	
BMI^e	<20	50 (7)	
	20-25	276 (39)	
	26-30	237 (34)	
	>30	142 (20)	
Procedures	Upper gastrointestinal surgery	Oesophagogastric resection	8 (1)
		Pancreaticobiliary resection	11 (2)
		Anti-reflux surgery	10 (1)
		Bariatric surgery	11 (2)
		Cholecystectomy	153 (21)
	Lower gastrointestinal surgery	Colectomy	82 (11)
		Hartmanns procedure	10 (1)
		Rectal resection	40 (6)
		Stoma formation	24 (3)
		Stoma closure	24 (3)
	General surgery	Groin hernia repair	90 (12)
		Abdominal wall hernia repair	38 (5)
		Appendectomy	109 (15)
		Laparoscopy/laparotomy	81 (11)
		Small bowel resection	9 (1)
Adhesiolysis		8 (1)	
Other		19 (3)	

Key:

Information missing for: ^a 4 patients, ^b 4 patients, ^c 6 patients, ^d 5 patients, ^e 22 patients

ASA = American Society of Anaesthesiologists, BMI = Body Mass Index, NIDDM = non-insulin dependent diabetes mellitus, IDDM = insulin dependent diabetes mellitus

Table 2. Dressing types according to operative factors*

	Basic		Advanced		Tissue adhesive		No dressing	
	Patients n =512 (%)	Wounds n =1203 (%)	Patients n = 17 (%)	Wounds n = 18 (%)	Patients n=186 (%)	Wounds n = 485 (%)	Patients n = 31 (%)	Wounds n = 63 (%)
Operation category								
<i>Clean</i>	199 (39)	449 (37)	2 (12)	2 (11)	58 (31)	128 (26)	11 (35)	24 (38)
<i>Clean contaminated</i>	242 (47)	606 (50) ^a	12 (71)	13 (72)	106 (57)	305 (63)	14 (45)	33 (52)
<i>Contaminated</i>	50 (10)	115 (10)	2 (12)	2 (11)	12 (6)	32 (7)	5 (16)	5 (8)
<i>Dirty</i>	21 (4)	33 (3)	1 (6)	1 (6)	10 (5)	20 (4)	1 (3)	1 (2)
Urgency of surgery^b								
<i>Elective</i>	320 (63)	809 (67)	10 (59)	11 (61)	132 (71)	371 (76)	22 (71)	51 (81)
<i>Emergency</i>	191 (37)	393 (33)	7 (41)	7 (39)	54 (29)	114 (24)	9 (29)	12 (19)
Modality of surgery								
<i>Open</i>	245 (48)	296 (25)	9 (53)	10 (56)	75 (40)	96 (20)	12 (39)	15 (24)
<i>Laparoscopic</i>	264 (52)	907 (75)	8 (47)	8 (44)	111 (60)	389 (80)	19 (61)	48 (76)
Type of operation								
<i>Upper gastrointestinal</i>	132 (26)	465 (39)	1 (6)	1 (6)	55 (30)	211 (44)	7 (23)	22 (35)
<i>Lower gastrointestinal</i>	119 (23)	256 (21)	11 (65)	12 (67)	54 (29)	122 (25)	7 (23)	17 (27)
<i>General</i>	261 (51)	482 (40)	5 (29)	5 (28)	77 (41)	152 (31)	17 (55)	24 (38)

* The total number of patients across all dressing groups is 746 (not 727) as some patients had different types of dressing applied and therefore fell into more than one category.

This table does not include the 25 wounds for which dressing type was not recorded.

^a Interpret as: There were 606 clean contaminated wounds in 242/512 patients in the basic dressing group.

^b Missing information for 1 wound [1 patient] (basic dressing category)

Table 3. Dressing types according to risk factors*

	Basic		Advanced		Tissue adhesive		No dressing	
	Patients n =51 (%)	Wounds n =1203 (%)	Patients n = 17 (%)	Wounds n = 18 (%)	Patients n =186 (%)	Wounds n = 485 (%)	Patients n = 31 (%)	Wounds n = 63 (%)
Stoma formation	56 (11)	96 (8)	5 (29)	5 (28)	32 (17)	70 (14)	6 (19)	9 (14)
Diabetes^a	43 (8)	85 (7)	2 (12)	2 (14)	17 (9)	51 (11)	3 (10)	6 (10)
ASA grade^b								
1	163 (32)	403 (34)	5 (29)	6 (33)	55 (30)	148 (31)	8 (27)	20 (32)
2	238 (47)	584 (49)	7 (41)	7 (39)	92 (50)	231 (48)	16 (53)	31 (50)
3	98 (19)	198 (17)	5 (29)	5 (28)	36 (19)	96 (20)	6 (20)	11 (18)
4	10 (2)	11 (1)	0 (0)	0 (0)	2 (1)	6 (1)	0 (0)	0 (0)
BMI^c								
< 20	36 (7)	81 (7)	1 (6)	1 (6)	12 (6)	19 (4)	3 (11)	9 (15)
20-24	196 (40)	426 (37)	5 (31)	5 (29)	74 (40)	175 (36)	13 (46)	23 (39)
25-29	163 (33)	401 (35)	6 (38)	7 (41)	63 (34)	165 (34)	8 (29)	19 (32)
>30	101 (20)	246 (21)	4 (25)	4 (24)	36 (19)	122 (25)	4 (14)	8 (14)

* The total number of patients across all dressing groups is 746 (not 727) as some patients had different types of dressing applied and therefore fell into more than one category.

This table does not include the 25 wounds in which dressing type was not recorded. BMI = body mass index

^a Missing information for 8 wounds [3 patients] (4 [2] basic, 4 [1] advanced)

^b Missing information for 12 wounds [4 patients] (7 [3] basic, 4 [1] tissue adhesive, 1 [1] no dressing)

^c Missing information for 58 wounds [20 patients] (49 [16] basic, 1 [1] advanced, 4 [1] tissue adhesive, 4 [3] no dressing)

Table 4. Reasons for dressing selection, according to type of dressing*[‡]

	Basic		Advanced	
	Patients n =512 (%)	Wounds n = 1203 (%)	Patients n= 17 (%)	Wounds n = 18 (%)
Handed by nursing staff^a	380 (75)	909 (76)	15 (88)	16 (89)
Personal preference^b	170 (34)	371 (31)	1 (6)	1 (6)
Wound characteristics^c	53 (10)	120 (10)	5 (29)	5 (28)
Other^{d,e}	4 (1)	10 (1)	0 (0)	0 (0)

* The total number of patients across all dressing groups is 746 (not 727) as some patients had different types of dressing applied and therefore fell into more than one category.

[‡] Dressings could be selected for multiple reasons and therefore totals can add up to more than 100%.

^a Missing information for 12 wounds [6 patients] (all basic dressings)

^b Missing information for 12 wounds [6 patients] (all basic dressings)

^c Missing information for 10 wounds [5 patients] (all basic dressings)

^d Missing information for 13 wounds [7 patients] (12 [6] basic, 1 [1] advanced)

^e Common reasons included: standard practice and to keep the wound waterproof to allow showering.

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WOUND DETAILS (excluding drains)

17. Wound type	18. Which of the following were used to close the skin?	19. Which of the following were used after skin closure?	20. Was a dressing initially applied after surgery?	21. If yes, give trade name of dressing	22. If yes, why was this type of dressing used?
Wound 1 Port site wound Yes <input type="checkbox"/> No <input type="checkbox"/>	Glue Yes <input type="checkbox"/> No <input type="checkbox"/> Clips Yes <input type="checkbox"/> No <input type="checkbox"/> Steri-strips Yes <input type="checkbox"/> No <input type="checkbox"/> Sutures Yes <input type="checkbox"/> No <input type="checkbox"/>	Glue Yes <input type="checkbox"/> No <input type="checkbox"/> Steri-strips Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Trade name _____ Total size (cm) Width <input type="text"/> Length <input type="text"/> Dressing ID number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Personal preference Yes <input type="checkbox"/> No <input type="checkbox"/> Handed by nursing staff Yes <input type="checkbox"/> No <input type="checkbox"/> Characteristics of wound Yes <input type="checkbox"/> No <input type="checkbox"/> Other Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please give reason _____
Wound 2 Port site wound Yes <input type="checkbox"/> No <input type="checkbox"/>	Glue Yes <input type="checkbox"/> No <input type="checkbox"/> Clips Yes <input type="checkbox"/> No <input type="checkbox"/> Steri-strips Yes <input type="checkbox"/> No <input type="checkbox"/> Sutures Yes <input type="checkbox"/> No <input type="checkbox"/>	Glue Yes <input type="checkbox"/> No <input type="checkbox"/> Steri-strips Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Trade name _____ Total size (cm) Width <input type="text"/> Length <input type="text"/> Dressing ID number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Personal preference Yes <input type="checkbox"/> No <input type="checkbox"/> Handed by nursing staff Yes <input type="checkbox"/> No <input type="checkbox"/> Characteristics of wound Yes <input type="checkbox"/> No <input type="checkbox"/> Other Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please give reason _____
Wound 3 Port site wound Yes <input type="checkbox"/> No <input type="checkbox"/>	Glue Yes <input type="checkbox"/> No <input type="checkbox"/> Clips Yes <input type="checkbox"/> No <input type="checkbox"/> Steri-strips Yes <input type="checkbox"/> No <input type="checkbox"/> Sutures Yes <input type="checkbox"/> No <input type="checkbox"/>	Glue Yes <input type="checkbox"/> No <input type="checkbox"/> Steri-strips Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Trade name _____ Total size (cm) Width <input type="text"/> Length <input type="text"/> Dressing ID number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Personal preference Yes <input type="checkbox"/> No <input type="checkbox"/> Handed by nursing staff Yes <input type="checkbox"/> No <input type="checkbox"/> Characteristics of wound Yes <input type="checkbox"/> No <input type="checkbox"/> Other Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please give reason _____

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