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ORIGINAL ARTICLE



A vascular multi-arm multi-stage trial to prevent groin wound surgical site infection: A feasibility survey

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Abstract

Surgical site infection (SSI) is common following arterial surgery involving a groin incision. There is a lack of evidence regarding interventions to prevent groin wound SSI, therefore, a survey of vascular clinicians was undertaken to assess current opinion and practice, equipoise and feasibility of a randomised controlled trial (RCT). Participants at the Vascular Society of Great Britain and Ireland 2021 Annual Scientific Meeting were surveyed regarding three separate interventions designed to prevent SSI in the groin; impregnated incise drapes, diakylcarbomoyl chloride dressings and antibiotic impregnated collagen sponges. Results were collated via an online survey using the Research Electronic Data Capture platform. Seventy-five participants completed the questionnaire, most were consultant vascular surgeons (50/75, 66.7%). The majority agree that groin wound SSI is a major problem (73/75, 97.3%), and would be content using either of the three interventions (51/61, 83.6%) and had clinical equipoise to randomise patients to any of the three interventions versus standard of care (70/75, 93.3%). There was some reluctance to not use impregnated incise drapes as may be considered "standard of care". Groin wound SSI is perceived as major problem in vascular surgery, and a multicentre RCT of three preventative interventions appears acceptable to vascular surgeons.

K E Y W O R D S

surgical site infection, vascular surgery

Key Messages

- Groin wound surgical site infection (SSI) is an important problem in vascular surgery
- This survey of 75 participants at the 2021 Vascular Society of Great Britain and Ireland Annual Scientific Meeting demonstrates that the UK vascular surgical community are prepared to randomise patients in a multi-arm multi-stage randomised trial to investigate the efficacy of simple adjuncts designed to reduce SSI in the groin

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1 | INTRODUCTION

Groin wound surgical site infection (SSI) following arterial surgery has an incidence of 2%-30%.¹⁻³ This disparity is due to heterogenous reporting and follow-up.⁴ The recent Groin wound Infection after Vascular Exposure (GIVE) multicentre, prospective, cohort study reported an SSI incidence of 8.6%,⁴ using The Centres for Disease Control and prevention (CDC) criteria.⁵ The GIVE study included 1337 incisions in 1039 patients from 37, mostly UK, vascular units. Many simple, cheap adjuncts to prevent SSI are used in vascular practice, but lack supportive evidence provided by pragmatic, rigorous scientific scrutiny. A recent systematic review and meta-analysis of 3747 patients undergoing 4130 groin incisions found that only closed incision negative pressure wound therapy and subcuticular sutures had some efficacy in reducing groin wound SSI.⁶

Iodine-impregnated incise drapes are commonly used to prevent SSI supported by microbiocidal efficacy in vitro⁷ and randomised evidence in cardiac surgery, that suggests a reduction in SSI rate from 6.5% to 1.9% (P = .0001) when using iodinated versus noniodinated incise drapes.⁸ The baseline SSI rates following arterial groin surgery are often reported to be much higher, for example, 17.7% in the recent metaanalysis,⁶ therefore, the effectiveness of iodine impregnated incise drapes in arterial groin surgery perhaps merits specific investigation.

Dialkylcarbomoyl chloride (DACC) coated dressings irreversibly bind bacteria potentially reducing SSI. A single centre, single blinded pilot study randomised 162 women undergoing caesarean section to either standard or DACC dressing and demonstrated a reduction in SSI rate from 9.8% to 2.8% with the DACC dressing (P = .08).⁹ However, a systematic review identified no randomised controlled trials (RCTs) comparing DACC to control in patients with vascular incisions.¹⁰ A pilot RCT has since been performed that has shown promising results in patients undergoing vascular surgery.¹¹ Following the results of this a formal RCT has been funded and is due to complete in 2025.¹²

Gentamicin impregnated sponges (GIS) have been developed and are licenced to prevent SSI. A systematic review and meta-analysis of three RCTs (3994 participants) demonstrated a significant reduction in deep SSI with GIS in high-risk cardiac surgery patients undergoing median sternotomy (odds ratio 0.6, 95% confidence interval: 0.39–0.98).¹³ A small prospective cohort study in 60 patients undergoing femoro-popliteal bypass with synthetic conduit demonstrated a significant reduction in SSI with GIS (P = .024), but high-quality evidence in vascular surgery is lacking.¹⁴

Given the relative uncertainty and poor-quality evidence for these frequently used adjuncts we aimed to assess the feasibility of a prospective RCT that would address the current evidence gap by surveying vascular clinicians at a large, UK, annual scientific meeting.

2 | METHODS

The Checklist for Reporting Of Survey Studies was used to compile this manuscript.¹⁵ A questionnaire was designed by a group of two consultant vascular surgeons, two clinical lecturers in vascular surgery and one professor of colorectal surgery (Vascular Groin Wound Infection Working Group). Questions were assessed by the group for suitability as well as readability. The questionnaire was validated by sending a pilot version to three consultant vascular surgeons who were representative of the target population. This resulted in some rewording to improve readability as well as the addition of free text sections to provide qualitative information prior to its distribution. The finalised version of the questionnaire can be found in the supplementary materials accompanying this manuscript.

A prospective, cross-sectional survey of attendees at the Vascular Societies of Great Britain and Ireland (VSGBI) Annual Scientific Meeting 2021 (Manchester, UK) was performed.¹⁶ The target population were consultant vascular surgeons, vascular trainees of all grades and all allied health care practitioners involved with the care of vascular surgical wounds. The meeting was attended by over 1000 people. There are approximately 400 consultant surgeon members of the society. The VSGBI administration office kindly provided attendance figures for the meeting. Members of industry were excluded. Simple random sampling was performed via an online questionnaire that was captured and managed using Research Electronic Data Capture (REDCap) tools hosted by The University of Birmingham, UK.^{17,18} The guestionnaire was accessed by scanning a custom generated QR code advertised at a research booth at the meeting. Responses were collated over the duration of the meeting from 1st to the 3rd of December 2021. Questionnaire participants were anonymous but provided their occupation, grade and current institution to inform the survey results. Participants also provided an email address so that contact could be made regarding any future study. This information was also used to screen for multiple participation.

The questionnaire included 12 questions related to SSI, participant current practice, participant equipoise and willingness participate in a potential RCT investigating the effectiveness of three defined interventions (iodine impregnated incise drapes, DACC dressings and GIS). Participants unwilling to use the interventions or participate in a RCT were requested to provide



FIGURE 1 Grade of survey respondents.

explanations. Responses were either dichotomous or multiple choice via tick box or dropdown menus.

Ethical approval was not sought as the survey involved health care practitioners and did not meet the requirements stipulated by the Health Research Authority.¹⁹ The principles of Good Clinical Practice were followed.²⁰

Survey results and data could only be accessed by authorised personnel through the password protected REDCap© system which was hosted by the sponsor (University of Birmingham, UK). Data were exported from REDCap© into Microsoft Excel© for cleaning and analysis which was password protected and only accessed by the first author (MP). Incomplete questionnaires were included in the analysis. Dichotomous data were expressed as a percentage and multiple-choice elements were expressed as parts of the whole (%). Graphical illustrations were prepared using GraphPad Prism version 9.

3 | RESULTS

3.1 | Survey respondents

The VSGBI had 1084 attendees at the Annual Scientific meeting in 2021. Of these, 184 (17.0%) were consultant vascular surgeons. Seventy-five individuals completed the questionnaire. Most respondents were consultant vascular surgeons (50/75, 66.7%) which represented 27.2% (50/184) of the attending consultant body (Figure 1). Respondents represented 31 separate UK vascular centres, covering a variety of regions in the UK geographically (Table 1, Figure 2). This represented 45.5% (31/68) of all UK vascular centres currently providing arterial surgery.²¹ Virtually all respondents (73/75, 97.3%) felt that groin wound SSI is a major problem for vascular surgeons.

3.2 | Current practice

There was varying current practice in the use of the three pre-specified interventions, with impregnated incise

drapes being the most frequently used intervention in routine vascular practice (48/74, 64.8%, Figure 3). The routine use of GIS (24/74, 32.1%) and DACC dressings (2/74, 2.7%) was less common. One person did not respond to this question.

3.3 | Equipoise

Most respondents (51/61, 83.6%) would be content to use either of the three proposed interventions either in isolation or in combination. A small number of respondents would not be happy to use each of the interventions (Figure 4). Sixty-one people (61/75) from the surveyed population responded to this question.

Participants gave the following reasons for not wanting to consider a prophylactic intervention; costs, not wanting to "leave anything behind in a groin wound," lack of data to support efficacy and a lack of experience in their use.

3.4 | RCT participation

Most respondents (70/75, 93.3%) stated they would be happy to participate in a RCT involving any or all three interventions versus control (standard of care). All participants who were not happy to participate were asked to expand on the reasons why in a freetext section. From the five, three participants (3/75, 4%) responded. Reasons listed were that iodine impregnated drapes were already considered as standard of care in their unit, and they would be hesitant about not using them in the groin (2 participants). One participant commented that their trust would not support the extra cost of an impregnated incise drape.

4 | DISCUSSION

Questionnaire respondents came from a geographical variety of UK vascular centres (31 centres) in similar frequency to the GIVE audit (30/37 centres where UK based).⁴ Most responses were from consultant vascular surgeons who are directly responsible for patient care in theatre and the most likely to interact and use the interventions described. Scotland, Wales and Ireland were poorly represented, perhaps due to the more extensive centralisation in these parts of the UK, also, the conference was held in Manchester, England.

Almost 65% of questionnaire respondents already use impregnated incise drapes and a few had concerns regarding stopping their use in the context of a RCT.

Region/unit	No. of respondents
East Midlands	
Leicester Vascular Institute ^a	3
Nottingham Queens Medical Centre	3
East of England	
Basildon and Thurrock University Hospitals	1
Bedfordshire Hospitals NHS Foundation Trust	4
Norfolk & Norwich Hospitals ^a	3
Kent Surrey and Sussex	
Royal Sussex County Hospital Brighton	1
London	
Northwick Park	2
Royal Free London ^a	1
St Georges Vascular Institute ^a	1
St Mary's ^a	1
North East	
Freeman Hospital ^a	1
North West and Mersey	
Countess of Chester	1
Liverpool University Hospital Trust ^a	1
Manchester University NHS Foundation Trust ^a	1
Royal Preston	1
Severn	
Bristol Southmead ^a	1
North Bristol Trust	1
Somerset	1
West Midlands	
Black Country Vascular Unit	4
University Hospitals Birmingham ^a	9
University Hospital Coventry and Warwick ^a	1
University Hospitals North Midlands	1
Yorkshire	
Doncaster Royal Infirmary	1
Hull University Teaching Hospitals ^a	4
Leeds Vascular Institute ^a	4
The York Hospital	1
Scotland	
Queen Elizabeth Hospital Glasgow	1
Royal Infirmary of Edinburgh	3
Wales	
Aneurin Bevan ^a	2
Cardiff Regional Vascular Unit ^a	2
Missing	14/75 (18.7%)

TABLE 1Responses fromindividual institutions in the UK in avascular multi-arm multi-stage trial toprevent groin wound surgical siteinfection: A feasibility survey.

^aDenotes academic institution.

FIGURE 2 Geographical distribution of vascular units represented in the vascular multi-arm multi-stage groin wound surgical site infection trial: A feasibility survey. Figure created using MapChart.net (https://www.mapchart.net/).



There is no evidence to support the clinical and cost effectiveness of impregnated incise drapes in arterial groin surgery. The multi-arm multi-stage (MAMS) Reduction of Surgical Site Infection using Novel Interventions 2 (ROSSINI-2) trial in patients undergoing laparotomy recently dropped all the arms containing impregnated incise drapes due to a robust lack of effect seen.²² ROSSINI-2 is still recruiting, and the results are eagerly awaited, however, it is currently unknown whether the findings will be transferable to vascular groin incisions.

Interestingly, 4% of respondents claimed that they would not be happy to stop using impregnated incise drapes as they considered their use as "standard of care" despite no significant evidence base in vascular patients.

The use of GIS was more contentious, with 32% of respondents routinely using them and 21% unwilling to use them. No concerns were raised regarding antibiotic stewardship in the collated free-text response section with specific reference to GIS. Literature specific to the efficacy of GIS in vascular surgery is sparse. A multicentre, Dutch RCT randomised patients undergoing arterial surgery



FIGURE 3 Interventions currently used in daily vascular practice. Respondents could select multiple options.



FIGURE 4 If you do not use any of these interventions in the groin are there any that you would not be happy to use in your routine surgical practice? Respondents could select multiple options.

involving a groin incision to GIS versus control (no implant) and found no significant difference in SSI between the two groups (7% vs 12%, P = .17).²³ However, the study barely reached 50% of its recruitment target (305/608), and therefore was underpowered. Clearly further high-quality evidence is required.

The use of DACC dressings in current use was very low in the surveyed population. This could suggest a lack of awareness in their existence or unwillingness to use due to additional perceived costs. Although the use of DACC dressings was low, only 14.8% (11/75) of the surveyed population would not be willing to use them in the context of an RCT (Figure 4). Participants were given an opportunity to explain why they would not be happy to use DACC, 2 out of 11 commented giving the following reasons; "unnecessary expense," "I have never used them and don't know their efficacy." There are no large RCTs assessing the effectiveness of DACC dressings in patients undergoing vascular groin surgery. A pilot feasibility trial randomised 144 patients undergoing vascular surgery (not specifically groin surgery) to DACC or non-DACC dressings and found a 36.9% relative risk reduction of SSI as measured by CDC criteria at 30 days in the DACC arm (16.22% vs 25.71%, odds ratio 0.559, P = .161).¹¹ The trial showed

promise for the dressing, but clearly a larger trial is needed to demonstrate clinical and cost-effectiveness.

Importantly, most of the respondents had equipoise regarding the three interventions and would be happy to participate in a multi-centre RCT. This together with the large number of vascular groin incisions performed in the UK each year (around 8000 per annum⁴) suggests a large RCT is deliverable.

4.1 | Limitations

The questionnaire was prone to bias given that respondents were random and more likely to complete if they have an interest in research specific to wound care or research in general. The questionnaire respondents, although from a wide geographical net may still not represent all the views and opinions of the wider UK vascular network. The surveyed population were all present at a large, UK scientific meeting which may introduce some bias into our results. In that, attendees are those more likely to share an active interested in research and research methodology (33/75 respondents [44.0%] represented academic institutions). There did also appear to be clusters of respondents in the West Midlands, Yorkshire, and the East of England which may represent some geographical bias. However, there was deemed to be enough interest and support in the surveyed population to support the development of a RCT.

With regards to multiple participation screening, from those who responded, 52 out of 75 (69.3%) provided a unique email address. Twenty-three did not. Fourteen participants who did not provide an email did provide information regarding the institution that they represented, and all these responses emanated from different vascular units except for two people who represented the same one. In these two responses and the nine who did not provide either email or institution, it is difficult to completely exclude multiple responses.

There may also be other interventions not covered by the questionnaire that are equally important to assess or may have demonstrated efficacy in other trials. We chose these three interventions as they are used at different stages of the operation in isolation or in combination, relatively inexpensive, widely available and are supported by promising preliminary data. However, more rigorous scientific testing is required to demonstrate clinical and cost-effectiveness. Negative pressure therapy was not included as there is already reasonable evidence of its efficacy.²⁴ We did not include other dressings, such as silver-based or polyhexamethylene biguanide dressings as there is good evidence already that they do not reduce SSI in primary surgical wounds.²⁵

5 | CONCLUSIONS

Groin wound SSI is major problem for vascular surgeons and patients, associated with increased morbidity, mortality and length of stay. It is also a potentially avoidable drain on National Health Service finances. With an increasing prevalence of diabetes and chronic limb threatening ischaemia and evidence that open surgery may be more effective than minimally invasive endovascular revascularisation²⁶ the incidence of groin incisions and associated SSI is likely to increase. Additionally, the growing problem of antibiotic resistance, means interventions to minimise groin SSIs are invaluable but must be supported by robust high-level evidence. The overwhelming majority of respondents surveyed have equipoise and would be willing to randomise patients to three separate interventions designed to reduce SSI. Many currently used adjuncts are widely available but lack the essential underpinning evidence to support their use. The findings of this survey support the development of a modern MAMS RCT to assess the clinical and cost effectiveness of these interventions on SSI following vascular groin surgery.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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