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Groin wound infection after vascular exposure (GIVE) multicentre cohort study

Groin wound Infection after Vascular Exposure (GIVE) Study Group

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Abstract

Surgical site infections (SSIs) of groin wounds are a common and potentially preventable cause of morbidity, mortality, and healthcare costs in vascular surgery. Our aim was to define the contemporaneous rate of groin SSIs, determine clinical sequelae, and identify risk factors for SSI.

An international multicentre prospective observational cohort study of consecutive patients undergoing groin incision for femoral vessel access in vascular surgery was undertaken over 3 months, follow-up was 90 days. The primary outcome was the incidence of groin wound SSI.

1337 groin incisions (1039 patients) from 37 centres were included. 115 groin incisions (8.6%) developed SSI, of which 62 (4.6%) were superficial. Patients who developed an SSI had a significantly longer length of hospital stay (6 versus 5 days, $P = .005$), a significantly higher rate of post-operative acute kidney injury (19.6% versus 11.7%, $P = .018$), with no significant difference in 90-day mortality. Female sex, Body mass index≥30 kg/m^2, ischaemic heart disease, aqueous betadine skin preparation, bypass/patch use (vein, xenograft, or prosthetic), and increased operative time were independent predictors of SSI.

Groin infections, which are clinically apparent to the treating vascular unit, are frequent and their development carries significant clinical sequelae. Risk factors include modifiable and non-modifiable variables.

KEYWORDS
vascular

1 | INTRODUCTION

Surgical site infections (SSIs) are the most common type of healthcare-associated infections worldwide, complicating up to one-third of surgical procedures,[1] and varying between countries and specialties.[1,2] SSIs increase healthcare costs and represents a significant cause of preventable morbidity and death.[3,4] SSIs after vascular intervention are potentially catastrophic, with prosthetic graft infection generally mandating the explanation of infected material. This carries a risk of limb loss and death, therefore, research into their occurrence and prevention has been the focus of recently published guidelines.[5]

Groin incisions allow access to the femoral vessels and are the most frequently performed surgical exposures in vascular surgery. Proximity to the anal canal, external genitalia, and the presence of skin folds result in difficulties in local decontamination. Furthermore, patients

frequently suffer comorbidities such as diabetes mellitus, renal impairment, and malnutrition, which are independent risk factors for SSI development.[6-8] Published groin SSI rates varies considerably, ranging from 6.4% to 38.5%[9-12]; however, these studies are generally small, retrospective, or use heterogeneous definitions of SSI.[7,11]

The National Institute for Health and Care Excellence (NICE) guidelines regarding the prevention and treatment of SSI recommend preoperative, intraoperative, and postoperative strategies.[13] In addition, relatively novel interventions and adjuncts have been developed for clinical use aiming to reduce SSIs, including antimicrobial wound products,[14] bacteria-binding dressings,[15] or closed incision negative pressure wound therapy.[16,17] It is unknown whether vascular units follow NICE guidelines, or how frequently wound adjuncts are used.

The Groin wound Infection after Vascular Exposure (GIVE) study's primary aim was to determine the contemporaneous incidence of groin wound SSI in vascular patients. Secondary aims were to identify the clinical sequelae for those who developed an SSI and identify risk factors for SSI in this patient population.

Key Messages

- the GIVE Multicentre Cohort Study is one of the largest non-registry prospective cohort study to examine groin SSIs among vascular patients
- while it is well documented that SSIs are the cause of significant morbidity for patients undergoing arterial exposure of the groin, a contemporaneous incidence, and the resultant sequelae, have not been established
- we identified an incidence of clinically relevant groin wound SSIs of 8.6%
- female sex, BMI≥30 kg/m^2, ischaemic heart disease, aqueous betadine skin preparation, bypass/patch use (vein, xenograft, or prosthetic), and increased operative time predicted for increased SSI risk.

2 | METHODS

A detailed study protocol has been published in full.[18] An abridged protocol was circulated to all centres prior to starting (Supplementary Material 1).

2.1 | Study design and setting

GIVE was an international multicentre prospective observational cohort study of patients undergoing groin incision for access to the femoral arteries during vascular surgery. GIVE was designed and run by the Vascular and Endovascular Research Network (VERN; https://vascular-research.net/), a multidisciplinary trainee-led vascular research collaborative,[19] with a track record for delivering on multicentre research projects.[20-24] The study was conducted in hospitals providing emergency and/or elective vascular surgery. Invitations to participate were disseminated by VERN using social media, email, and personal contacts.

The study opened to site set up on January 21, 2019, and closed to site recruitment on 01/05/2019. Each centre's designated study lead determined an appropriate start date. Centre's undertook a three-month period of data collection, followed by 3 months of patient follow up.

The study was considered complete at centres when the last recruited patient completed follow up. Follow-up was complete for all centres by 01/11/2019.

2.2 | Population, recruitment, and inclusion/exclusion criteria

Potential participants were identified by the local study team in each centre by a screening of local theatre management systems. Patients were deemed eligible for inclusion if they were aged >18, undergoing emergency/urgent/elective groin incision(s) for arterial intervention, including endarterectomy, embolectomy, thrombectomy, bypass, repair of (non-infected) traumatic injury (e.g. iatrogenic arterial pseudoaneurysm), or exposure for an endovascular procedure. Groin incisions that extended down the leg or above the groin were included; however, SSI outcomes were based on the portion of the wound overlying the femoral triangle. In bilateral cases, both sides were included in data capture. Participants were excluded if undergoing groin incision for an active infected process (e.g. infected pseudoaneurysm), venous access only, arterial exposure for cardiac procedures, and percutaneous only procedures.

2.3 | Data collection, management, and validation

A data collection pro forma was designed and refined by the VERN committee (Supplementary Material 2). Explanatory variables were selected based on published work on SSIs, clinical relevance, and mechanistic plausibility.

Definitions of co-morbidities and specific outcomes are given in Supplementary Material 3. Data were collected prospectively and held electronically on a single secure hospital computer, in accordance with local guidelines. Study participants were pseudonymised at the local centre. Pseudonymised data were uploaded via a web-based interface or sent via a secure National Health Service (NHS) email. Data were collected, stored, and analysed in the Aneurin Bevan University Health Board, Newport, UK, following local Caldicott guardian approval.

Data points recorded as "unknown" counted as complete data. However, any patient with missing data (i.e. data entry absent) of >5% was returned to the team for further data extraction, or (if unable) the record was removed from the analysis. To examine data accuracy, a smaller subset of centres underwent a review of >5% of their data points by an independent data extractor. The accuracy of data extraction was examined by comparing the original and re-extracted data. *A priori* it was decided that an accuracy of <95% would prompt a review of the entire centre's data collection.

2.4 | Team organisation

Each centre organised a team of healthcare professionals who would gain local audit approval (or ethical approval), identify suitable patients, and capture data. Teams would typically include a single senior team member (consultant or equivalent), who would act as a local Principal Investigator (PI). A detailed authorship policy, developed in accordance with the International Committee of Medical Journal Editors (ICMJE) authorship guidelines, was provided in the GIVE protocol (Supplementary material 1).

2.5 | Outcomes

The primary outcome was the development of a groin wound SSI, defined according to the 2019 Centre for Disease Control (CDC) criteria.[25] Superficial infections presenting within 30 days of surgery, and deep/organ/space infections presenting within 90 days of surgery, within the femoral triangle of the index groin, were considered SSIs. SSIs apparent to the secondary care vascular team were identified from local hospital electronic records and notes; patients were not contacted directly to obtain outcome data. In the case of uncertainty, the view of the local PI was sought.

Secondary outcomes were:

1. Incidence of deep tissue/organ SSI;
2. Incidence of surgical and radiological re-interventions used to manage SSI;
3. Incidence of SSI resulting in sepsis;
4. Incidence of SSI resulting in unplanned admission to a critical care setting;
5. Incidence of post-operative acute kidney injury (AKI);
6. Length of stay (LOS) in hospital;
7. Mortality;
8. Incidence of additional dressings used to manage SSI;
9. Incidence of vacuum dressings used to manage SSI;
10. Incidence of antibiotics used to manage SSI; and
11. Organisms grown from microbiology samples.

2.6 | Statistical analysis

Results are reported as per the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for observational studies.[26] Continuous variables were analysed using parametric or non-parametric tests as appropriate. Percentages were calculated using the total number of patients (for patient-specific variables) or the total number of groins (for operative and post-operative variables and outcomes) as a denominator as appropriate. SSI rates from individual centres were presented as funnel plots using a Microsoft Excel macro.[27]

Multiple imputation was undertaken using the Markov chain Monte Carlo method (25 imputed data sets; 25 iterations) prior to univariate and multivariate binary logistic analysis of predictors of all SSIs. A sensitivity analysis without multiple imputation (casewise deletion) was performed, using univariate and multivariate multilevel binary logistic regression analysis. Further analyses examining predictors of deep/organ/space SSIs, regression for UK and Ireland patients only, and regression excluding centres with an SSI rate above three standard deviations were also undertaken. For all analyses, univariate regression was undertaken using a threshold of $P < .10$. Significant variables were subsequently included in a backward stepwise multivariate regression, with statistical significance defined as $P < .05$. Data were analysed in SPSS (IBM, New York, version 24).

2.7 | Local audit and ethical approval

For UK centres, the study did not require approval from an NHS Research Ethics Committee as per guidance by the Healthcare Research Authority (HRA) and NHS Good Clinical Practice (GCP) principles. The study was registered locally at each participating centre prior to data collection (audit and service provision registration at all NHS sites involved). Those centres outwith the United

TABLE 1 Baseline demographic variables and univariate analysis

Variable	SSI #/median (%/IQR)	No SSI #/median (%/IQR)	Odds ratio	95% CI	*P* value
All cases	115 (8.6)	1222 (91.4)			
Outside of United Kingdom	7 (6.1)	154 (12.6)	0.449	0.205-0.983	.045*
Age	72 (65-79)	71 (64-77)	1.015	0.996-1.034	.116
Sex-Female	39 (33.9)	297 (24.3)	1.598	1.063-2.402	.024*
Emergency	41 (35.7)	494 (40.6)	0.811	0.544-1.207	.302
Rutherford-(0-3)	51 (45.9)	575 (48.8)	Reference		
Rutherford-(4-6)	60 (54.1)	603 (51.2)	1.117	0.760-1.643	.573
Body mass index-normal weight (18.5-24.9 kg/m^2)	18 (25.0)	326 (41.1)	Reference		
Body mass index-underweight (<18.5 kg/m^2)	5 (6.9)	26 (3.3)	2.104	1.020-4.341	.044*
Body mass index-Overweight (25-29.9 kg/m^2)	15 (20.8)	262 (33.0)	1.164	0.603-2.246	.650
Body mass index - Obese (≥30 kg/m^2)	34 (47.2)	180 (22.7)	2.527	1.365-4.678	.003*
Diabetes (any)	44 (38.6)	322 (26.5)	1.74	1.169-2.591	.006*
Alcohol excess	12 (11.3)	104 (9.6)	1.271	0.677-2.387	.455
eGFR <30 mL/min/1.73 m2	8 (8.6)	45 (4.2)	2.142	0.986-4.652	.054*
Hypertension	88 (77.2)	896 (73.3)	1.194	0.758-1.879	.445
Congestive cardiac failure	13 (34.2)	127 (10.5)	1.128	0.615-2.071	.697
Chronic obstructive pulmonary disease	39 (34.2)	266 (22.0)	1.835	1.218-2.765	.004*
Ischaemic heart disease	58 (51.8)	376 (31.5)	2.250	1.526-3.319	<.001*
Hyperlipidaemia	54 (51.9)	545 (50.5)	1.116	0.749-1.662	.590
Neurological disease	17 (14.9)	182 (15.0)	0.984	0.574-1.688	.954
Immunomodulators	5 (4.3)	58 (4.8)	0.901	0.354-2.294	.826
Previous SSI	6 (5.3)	38 (3.2)	1.75	0.736-4.162	.205
Bilateral groin incisions	36 (31.3)	560 (45.8)	0.539	0.358-0.812	.003*
American Society of Anaesthesiologists classification - 1-2	21 (19.4)	229 (19.6)	Reference		
American Society of Anaesthesiologists classification - 3-5	87 (80.6)	937 (80.4)	1.067	0.649-1.754	.797
Open wound on lower limb(s)	31 (27.0)	282 (23.3)	1.202	0.780-1.853	.405
Re-do groin incision	23 (20.2)	199 (16.5)	1.277	0.788-2.068	.320
Antibiotic prophylaxis (any)	110 (99.1)	1166 (98.9)	1.200	0.218-6.609	.833
Pre-operative hair removal with clippers	96 (92.3)	1042 (92.3)	0.896	0.442-1.817	.761
Skin prep - Alcoholic chlorhexidine	52 (52.5)	608 (55.1)	Reference		
Skin prep - Aqueous chlorhexidine	5 (5.1)	79 (7.2)	0.763	0.294-1.977	.577
Skin prep - Alcoholic betadine	19 (19.2)	301 (27.3)	0.788	0.458-1.354	.388
Skin prep - Aqueous betadine	23 (23.2)	110 (10.0)	2.303	1.342-3.953	.002*
Skin prep - Two solutions	0	5 (0.5)	1.376	0.440-4.302	.581
Adhesive skin prep - None	12 (12.1)	117 (10.8)	Reference		
Adhesive skin prep - Iodinated	71 (71.7)	830 (76.3)	0.803	0.433-1.490	.487
Adhesive skin prep - Non-iodinated	16 (16.2)	141 (13.0)	1.089	0.501-2.366	.830
Longitudinal groin incision	97 (85.1)	935 (78.0)	Reference		
Oblique groin incision	17 (14.9)	263 (22.0)	0.607	0.356-1.035	.066*
Abdominal/leg incisions - None	72 (64.3)	803 (67.0)	Reference		

(Continues)

TABLE 1 (Continued)

Variable	SSI #/median (%/IQR)	No SSI #/median (%/IQR)	Odds ratio	95% CI	*P* value
Abdominal/leg incisions - Separate abdominal incision	12 (10.7)	125 (10.4)	1.032	0.545-1.954	.923
Abdominal/leg incisions - Groin incision extended to leg	5 (4.5)	65 (5.4)	0.855	0.339-2.159	.741
Abdominal/leg incisions - Separate leg incision	23 (20.5)	206 (17.2)	1.223	0.747-2.002	.423
Open procedure only	74 (64.3)	724 (59.3)	Reference		
Aneurysmal endovascular procedure +/− open procedure	10 (8.7)	273 (22.4)	0.356	0.181-0.698	.003*
Occlusive endovascular procedure +/− open procedure	31 (27.0)	225 (18.5)	1.339	0.858-2.090	.198
Bypass/patch material-None	12 (10.6)	369 (31.2)	Reference		
Bypass/patch material-Vein	28 (24.8)	281 (23.7)	3.109	1.556-6.212	.001*
Bypass/patch material - Xenograft	37 (32.7)	202 (17.1)	5.513	2.817-10.788	<.001*
Bypass/patch material-Prosthetic	36 (31.9)	332 (28.0)	3.274	1.679-6.382	<.001*
Muscle flap used	1 (0.9)	9 (0.7)	1.280	0.185-8.875	.802
Drain(s) used	55 (48.2)	418 (34.7)	1.784	1.213-2.623	.003*
Local antibiotic use	12 (10.8)	172 (14.4)	0.754	0.410-1.387	.363
Closure-subcuticular suture	88 (77.2)	902 (75.3)	Reference		
Closure-skin clips	16 (14.0)	223 (18.6)	0.744	0.428-1.294	.295
Closure-external suture	10 (8.8)	73 (6.1)	1.349	0.670-2.714	.402
Dressing-absorbent adhesive	95 (84.1)	1020 (85.8)	Reference		
Dressing-skin glue only	8 (7.1)	125 (10.5)	0.685	0.325-1.445	.321
Dressing-closed incision negative pressure therapy	9 (8.0)	41 (3.4)	2.372	1.123-5.011	.024*
Dressing-open wound negative pressure therapy	1 (0.9)	3 (0.3)	1.061	0.161-6.992	.951
Operative time (hours)	3.3 (2.5-4.5)	3.0 (2.0-4.0)	1.181	1.064-1.310	.002*
Estimated blood loss (L)	0.255 (0.200-0.500)	0.250 (0.100-0.500)	1.144	0.838-1.561	.397
Intraoperative glycaemic control	19 (19.2)	160 (14.2)	1.476	0.896-2.430	.126
Intraoperative transfusion	15 (15.6)	101 (9.4)	1.708	0.985-2.961	.057*
Laminar flow theatre	54 (48.2)	556 (47.2)	1.049	0.713-1.543	.807

*Statistically significant.

Kingdom were compliant with local regulations prior to commencing the study, most of which required formal ethical approval.

3 | RESULTS

3.1 | Demographics

A total of 37 centres participated in GIVE, 30 of which were within the United Kingdom, 1 from Greece, 1 from Ireland, 2 from Australia, and 3 from Libya. 25 patients were excluded from analysis due to unacceptable levels of missing data (>5%) or insufficient follow up data. Data originating from Libya were excluded from analyses, as data capture was delayed due to a civil war. 1039 patients (938 from the United Kingdom) were included in the final analysis. 298 patients (28.7%) had bilateral groin incisions resulting in 1337 groin incisions in total (1176 UK groin incisions). Centres reported data on a median of 30 patients (range 5–92; 40 groin incisions, range: 6–111). The centres participating in data validation had >95% accuracy.

Baseline demographic details are given in Table 1. 272 patients (26.2%) were female and the median age was

71 years (Interquartile range (IQR) 64–77). The median body mass index (BMI) was 26 kg/m^2 (IQR 23 - 30 kg/m^2). 311 patients (30.1%) had diabetes (any type). 814 (82.2%) were American Society of Anaesthesiologists (ASA) physical status 3–5, and 447 (43.2%) underwent an urgent or emergency procedure.

3.2 | Operative Interventions and post-operative outcomes

A total of 1032 (78.7%) incisions were longitudinal (versus oblique) and 222 (16.8%) were "re-do" incisions. Operations were classified into one of three groups: "open" procedure only, which included any arterial surgery requiring groin exposure without endovascular intervention, comprised 798 (59.7%) of operations; "aneurysmal endovascular" procedures, involving groin access (+/− groin intervention) for an endovascular aorto-iliac aneurysmal repair, comprised 283 (21.2%) operations; and "occlusive endovascular" procedures, involving groin access (+/− groin intervention) for endovascular aorto-iliac/infra-inguinal occlusive disease, comprised 256 (19.1%) operations. SSIs occurred in 74 (9.3%) "open procedure only" cases (reference), 10 (3.5%) "aneurysmal endovascular procedure +/- groin intervention" cases (OR 0.492, $P = .018$), and 31 (12.1%) "occlusive endovascular procedure +/- groin intervention" cases (OR 1.306, $P = .237$). In the group of patients that developed an SSI, patients who underwent an endovascular procedure (either for aneurysmal or occlusive disease) were significantly more likely to develop post-operative AKI compared to those who did not (10 (15.6%) versus 13 (46.4%), $P = .019$). This difference was not observed in the group who did not develop SSI.

Antibiotic prophylaxis was given in 1276 (98.9%) incisions. 1138 (92.3%) had pre-operative hair removal with clippers. The most commonly used skin preparation solution was alcoholic chlorhexidine (660 groins; 54.9%); an iodinated adhesive skin drape was used in 901 groins (75.9%). Local antibiotics (e.g. Collatamp®) were used in 184 groins (14.1%). The most common method of skin closure was a continuous subcuticular suture (990 groins; 75.5%). The most common dressing type used was absorbent adhesive (1115 groins; 85.6%). Closed incision negative pressure therapy was used in 50 groins (3.8%). Median (IQR) operative time and estimated blood loss (EBL) were 3 hours (2–4) and 0.250 L (0.125–0.500), respectively.

A total of 54 (5.2%) patients died within 90 days of surgery. The median LOS was 5 days (IQR 3–10). 128 patients (12.4%) developed a post-operative AKI.

3.3 | Surgical site infection rates

A total of 107 patients (10.3%) developed 115 SSIs (Figure 1), which equates to a rate of 8.6% per groin incision (Figure 2). 62 (4.6%) groin SSIs were superficial, 51 (3.8%) were deep/organ/space infections (Figure 3). A pus swab or tissue sample was sent for microbiological analysis in 83 (76.1%) of SSIs. The most commonly found organisms were coliforms (72.3%). Details of the microorganisms grown are given in Table 2.

SSIs resulted in sepsis in 17 patients (1.6%). 50 (3.7%) groins required further surgical or radiological intervention, 37 of which (2.77%) required management of infected fluid/tissue, and 13 (0.97%) required explantation of foreign material. Limb loss occurred as a result of SSIs in four cases (0.30%). Other outcomes are shown in Table 2.

Patients who developed an SSI had a significantly longer median LOS (6 versus 5 days; $P = .005$), and a significantly higher rate of post-operative AKI (19.6% versus 11.7%; $P = .018$). There was no significant difference in 90-day mortality rate (8.4% versus 4.9%; $P = .114$). Sensitivity analysis of LOS excluding patients who underwent an amputation as a result of SSI (N = 4) produced consistent results; patients who developed an SSI had a significantly longer median LOS (6 versus 5 days; $P = .005$).

3.4 | Regression analysis

Multiple imputation was undertaken as described above. Details of unknown/missing data per variable are given in Supplementary Material 4. A comparison of patient and operative factors between those who did and did not develop an SSI is shown in Table 1. Significant predictors of SSI on univariate analysis are given in Table 1. Details of which antibiotic agents were used as prophylaxis were captured and each agent subjected to univariate analysis, none were identified as significant predictors for SSI. The variables remaining significant in multivariate analysis include female sex, BMI ≥30 kg/m^2, ischaemic heart disease (IHD), aqueous betadine skin preparation, use of bypass/patch material (vein, prosthetic, or xenograft), and increased operative time (Table 3). Sensitivity analysis with case-wise deletion resulted in a broadly similar model (Supplementary Material 5). A further regression analysis of significant variables predicting deep/organ/space SSIs is given in Supplementary Material 6. A sensitivity analysis only including patients from the UK and Ireland is shown in Supplementary Material 7. Sensitivity analysis excluding centres with an SSI rate above three standard deviations is shown in Supplementary Material 8.

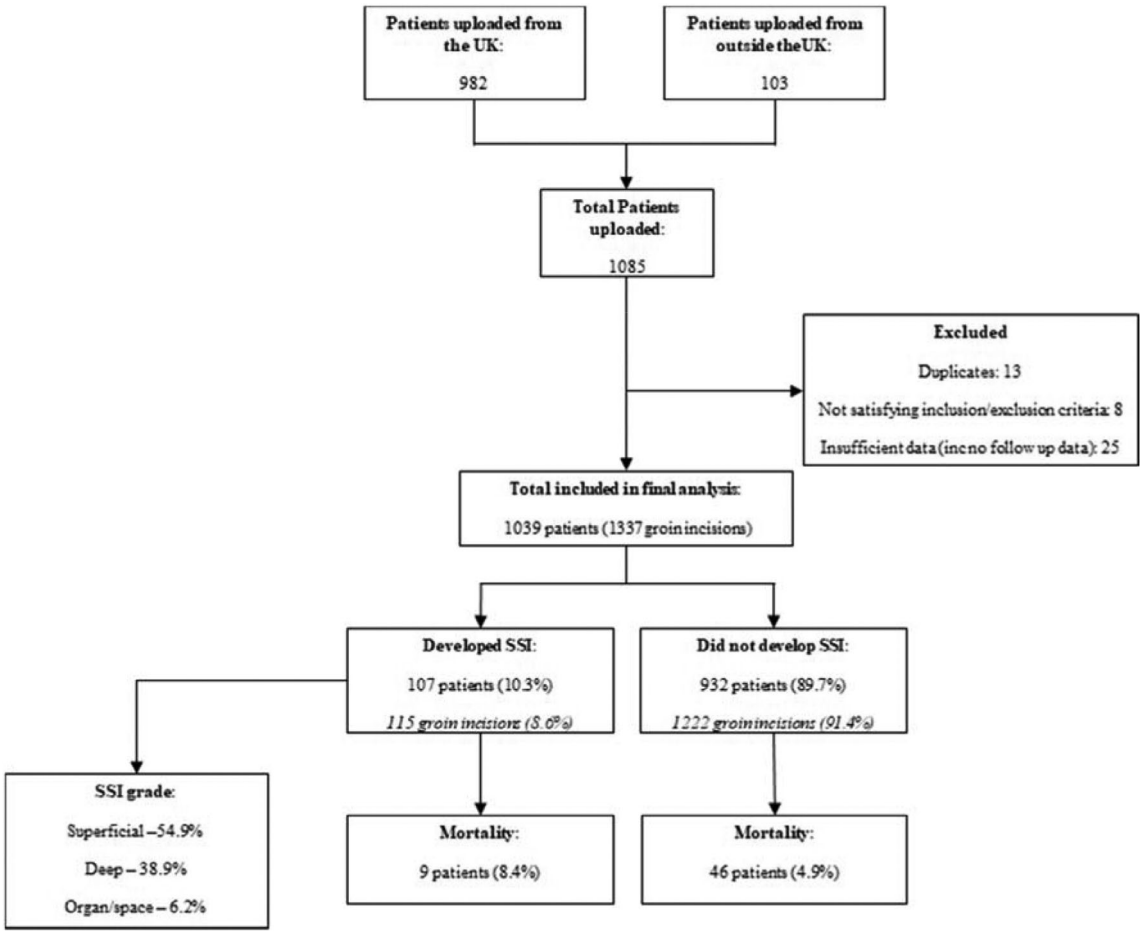

FIGURE 1 Flow diagram of patient recruitment and outcomes

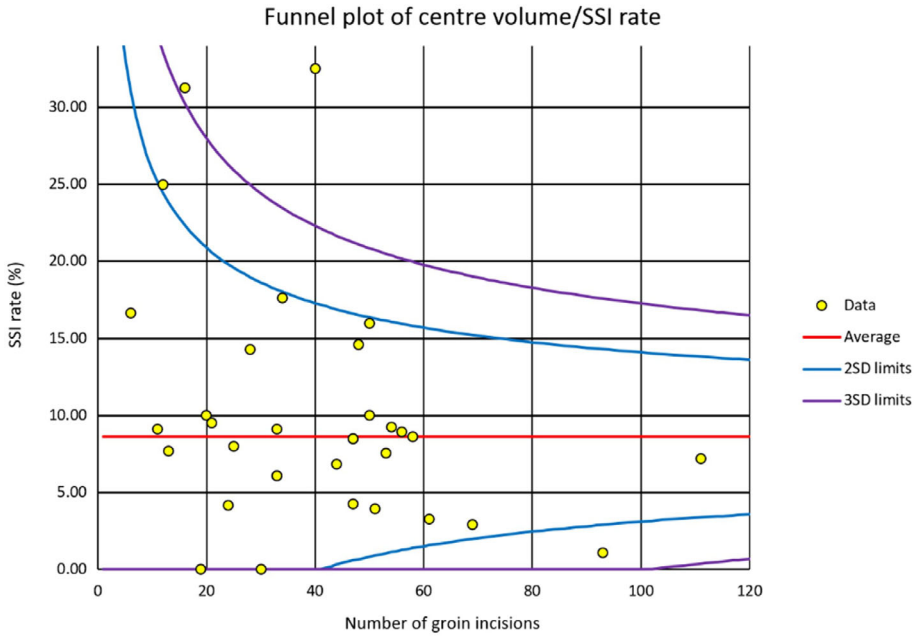

FIGURE 2 Funnel plot of SSI rates of each centre, with +/−2 and +/−3 SD lines

4 | DISCUSSION

This contemporary, international, multicentre, cohort study has found that the incidence of all SSIs in 1337 groin incisions was 8.6% with deep/organ/space SSIs being 3.8%. Patients who developed an SSI had a significantly increased LOS and incidence of AKI and had a non-significant greater 90-day mortality. Further

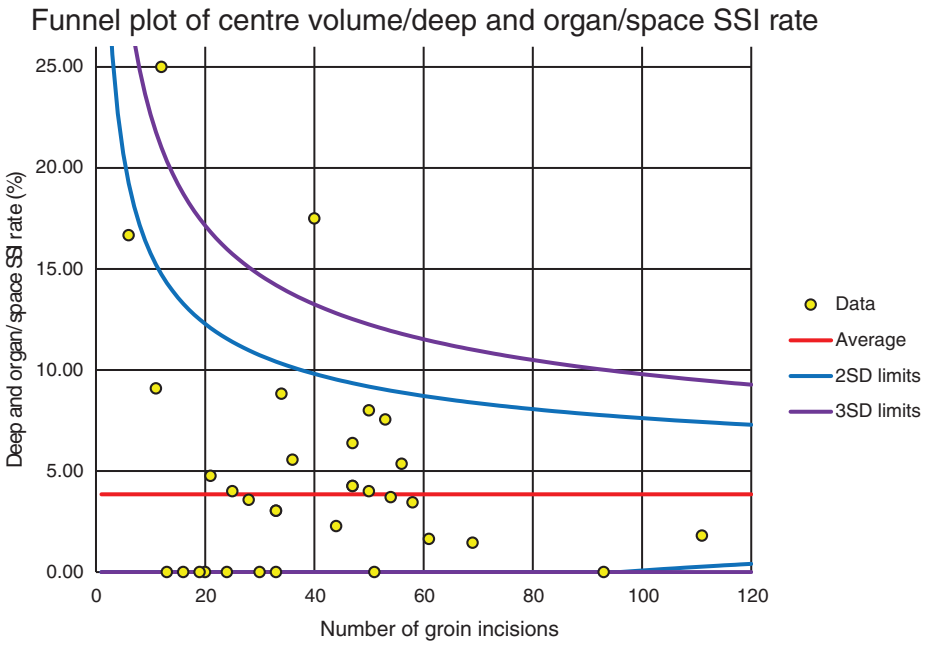

FIGURE 3 Funnel plot of deep and organ/space SSI rates of each centre, with +/−2 and +/− 3 SD lines

interventions were required in 43.6% of patients who developed an SSI. A BMI of ≥30 kg/m^2, aqueous betadine skin preparation and the use of xenograft significantly increased the risk of developing an SSI threefold. The use of prosthetic material (either for patch or bypass), IHD, and longer operative time also increased the risk of SSI. Sensitivity regression analyses including UK and Ireland patients only, and excluding centres with an SSI rate above three standard deviations produced similar results indicating a stable model.

The majority of published literature regarding groin SSIs have been small,[28] from single centres,[10,11] historical, reliant on national registry data,[7,28] use varying definitions of SSI[29] and are retrospective.[28] This has made it difficult to benchmark practice and provide estimates to inform the design of future randomised trials. This study provides valuable and robust data on groin SSI rates and outcomes. The increase in LOS and AKI is consistent with the previous studies.[7] However, confounding could account for these findings, further analysis of the SSI group revealed that a significantly higher proportion of patients who underwent an endovascular procedure developed post-operative AKI, compared to those who did not. Sensitivity analysis excluding patients who underwent an amputation as a result of SSI was consistent with the main analysis, however, it is unknown whether these amputations were performed during the same hospital admission. Some additional post-operative events that may increase LOS were not captured in the study introducing further potential confounding.

Multivariate analysis identified numerous independent predictors for SSI development. Aqueous betadine is the fourth choice of surgical skin preparation recommended by NICE guidance,[13] with alcoholic chlorhexidine preferred over other preparations.[13] Aqueous betadine was used in 133 (11.1%) of all groins, its replacement with aqueous chlorhexidine may represent the most easily attainable change in practice for clinical benefit.

Obesity and morbid obesity have been well described as risk factors for the development of SSI.[30,31] Patients with a BMI of >30 kg/m^2 were more than three times more likely to develop an SSI postoperatively. Alternative access may be considered, such as exposure of the superficial femoral artery with an incision below the groin, or exposure of the external iliac artery through an oblique lower abdominal incision, although these do not provide access to the Profunda, and are in practice infrequently used.

Xenograft material use was associated with increased SSI risk. The use of bovine pericardium has been extensively investigated in the context of carotid endarterectomy (CEA) and was found to have no association with SSI development.[32] These findings seemingly cannot be extrapolated to groin incisions. There are intrinsic biases, which may account for this finding; prosthetic material is less likely to be used in high-risk groins, greater wound dissection is required for harvesting a vein, and prosthetic grafts may present with late infection. While autologous tissues are generally preferred, the harvest of autologous vein for arteriotomy patch-plasty will affect future conduit availability.

Female sex was an independent predictor of both all SSIs, and deep/organ/space SSI, consistent with findings from previous observational studies of vascular

TABLE 2 Outcomes of SSI development

SSI specific outcomes		
Variable	**#**	**Valid %**
Grade of SSI (per groin incision)		
Superficial SSI	62	4.6
Deep SSI	44	3.3
Organ or space SSI	7	0.5
Interventions for SSI (per groin incision)		
Additional dressings used to manage SSI	83	6.2
Vacuum dressings used to manage SSI	27	2.0
Antibiotics used to manage SSI	107	8.0
SSI required radiological or surgical intervention	37	2.8
SSI required explantation of foreign material	13	1.0
Microbiology (per groin incision)		
Swab/pus/fluid/tissue/foreign material sent for microbiological analysis	83	6.2
Culture result-No organism grown	12	0.9
Culture result-Skin commensals	11	0.8
Culture result-*Staphylococcus aureus*	13	1.0
Culture result-Streptococci	4	0.3
Culture result–Coliforms	60	4.5
Culture result-Methicillin Resistant Staphylococcus Aureus (MRSA)	1	0.1
Culture result-Vancomycin resistant enterococcus (VRE)	4	0.3
Clinical outcomes of SSI (per patient)		
SSI resulting in sepsis	17	1.6
SSI resulting in additional or unexpected HDU/ITU stay	8	0.8

cohorts.[33,34] A potential reason for this finding is the difference in fat distribution between genders, and differences in groin skin flora.

Coliforms were the most frequently isolated organisms from groins, which developed an SSI, 6% of which were multidrug-resistant. In contrast, a previous US observational study reported that the most commonly isolated organism was staphylococcus followed by coliforms.[28] This may represent a difference in microbiome between UK and US populations, or antibiotic prophylaxis regimes, which predominantly cover skin organisms. Alternatively, this may be indicative of the fact that more superficial SSIs, of which the majority would be Staphylococcal, may have been treated in the community and not identified in this study. None of the antibiotic agents used in the study were significant predictors on univariate analysis.

This study has several strengths. It utilised the well-established trainee-led collaborative model to collect prospective data on a large number of patients from the many UK and international centres without funding, expediting the process and producing up-to-date results. It addresses a pertinent clinically relevant issue; the importance of SSIs have been highlighted in a recently completed UK Vascular Surgery Delphi exercise.[35] To the best of our knowledge, this represents the largest prospective study of SSI rates after groin incision. Missing data are minimal and internal validation was reported at 95% accuracy. Sensitivity analyses were consistent, with minimal changes to variable effects, implying that the process of multiple imputation was robust.

As with any observational study, there are a number of limitations. In order to avoid the need for UK ethical approval, the GIVE study team made the pragmatic decision to only record SSIs that became evident to the index vascular centre. Milder community treated SSIs, or SSIs treated at a different centre, will have been missed, introducing bias to our results. The true incidence of SSIs will likely be higher than reported here, however, the rate of deep/organ/space SSIs reported is likely to be true and is similar to the published literature.[36] The data is self-reported by the treating teams and has not been externally validated, potentially limiting reliability. Centres

TABLE 3 Independent predictors of vascular groin incision SSI on multivariate analysis

Variable	Odds ratio	95% CI	*P* value
Female	1.708	1.095-2.663	.018*
BMI - Normal weight (18.5-24.9 kg/m^2)	Reference		
BMI - Underweight (<18.5 kg/m^2)	1.868	0.822-4.243	.135
BMI - Overweight (25-29.9 kg/m^2)	1.302	0.648-2.618	.457
BMI - Obese (≥30 kg/m^2)	2.916	1.511-5.626	.002*
IHD	2.213	1.471-3.330	<.001*
Skin prep - Alcoholic chlorhexidine	Reference		
Skin prep - Aqueous chlorhexidine	0.674	0.251-1.810	.434
Skin prep - Alcoholic betadine	0.944	0.540-1.650	.840
Skin prep - Aqueous betadine	2.784	1.515-5.117	.001*
Skin prep - Two solutions	1.022	0.329-3.172	.970
Bypass/patch material - None	Reference		
Bypass/patch material – Vein	2.420	1.178-4.970	.016*
Bypass/patch material - Xenograft	4.864	2.427-9.748	<.001**
Bypass/patch material - Prosthetic	2.556	1.268-5.149	.009*
Operative time (hours)	1.152	1.022-1.299	.021*

*, **Statistically significant.

were provided with criteria for SSI diagnosis; however, there was no independent wound assessment. Some variables, for example, anaemia,[28] and smoking,[8] were not collected. We were, therefore, unable to account for potential confounding from these variables, limiting the accuracy of our multivariate analysis results. Variables such as BMI had many missing data. Multiple imputation of missing values was undertaken, with sensitivity analyses being concordant with results from multiple imputation; however, this method remains inferior to obtaining actual data on all patients. Although the association has been demonstrated by the analyses, causation cannot be inferred without randomised data. Lastly, over 90% of the data originated from the UK, limiting international generalisability.

SSI remains a significant problem in vascular surgery and there is an inherent need to improve practice and to evaluate aspects of SSI prevention with high quality randomised studies or registry data. There are a number of interventions that require further evaluation and are yet to enter everyday clinical practice. GIVE has benchmarked SSI rates and provides a platform for future randomised trials in SSI prevention.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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DATA AVAILABILITY STATEMENT

Research data are not shared.

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SUPPORTING INFORMATION

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

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