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Study protocol for the groin wound infection after vascular exposure (GIVE) audit and multicentre cohort study

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ABSTRACT

Introduction: Surgical site infections (SSIs) following groin incision for arterial exposure are commonplace and a significant cause of morbidity and mortality following major arterial surgery. Published incidence varies considerably. The primary aim of GIVE will be to compare individual units' practice with established guidelines from The National Institute for Health and Care Excellence (NICE). Secondary aims will be to describe the contemporary rate of SSI in patients undergoing groin incision for arterial exposure, to identify risk factors for groin wound infection, to examine the value of published tools in the prediction of SSI, to identify areas of equipoise which could be examined in future efficacy/effectiveness trials and to compare UK SSI rates with international centres.

Methods and analysis: This international, multicentre, prospective observational study will be delivered via the Vascular and Endovascular Research Network (VERN). Participating centres will identify all patients undergoing clean emergency or elective groin incision(s) for arterial intervention during a consecutive 3-month period. Follow up data will be captured at 90 days after surgery. SSIs will be defined according to the Centres for Disease Control and Prevention (CDC) criteria. Data will be gathered centrally using an anonymised electronic data collection tool or secure email transfer.

Ethics and dissemination: This study will be registered as a clinical audit at all participating UK centres; research ethics approval is not required. National leads will oversee the appropriate registration and approvals in countries outside the UK as required. Site specific reports of SSI rates will be provided to each participating centre. Study results will be disseminated locally at each site, publicised on social media and submitted for peer-reviewed publication.

1. Introduction

An SSI is defined as a wound infection occurring at the site of a surgical incision. It is a major potential complication of any operation, ranging from minor superficial wound infection to deep infection [1,2]. Despite NICE recognising SSI as a leading cause of in-hospital morbidity and mortality, incidence remains high [3,4].

The groin is the most common site for an incision in vascular surgery [5,6], used to provide access to the femoral vessels. Predisposition to infection is due to the several co-morbidities that vascular patients typically have [5,7,8], the type of skin flora which reside in the groin, difficulties in decontaminating the area of skin commensals and its proximity to the anal canal and genitalia

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[5,6,9]. The incidence of SSIs following groin incision has been reported as up to 27% [10], with the highest risk associated with groin incisions for bypass surgery [11]. Re-do groin surgery is associated with even greater risk of SSI and subsequent morbidity and mortality [8,12]. Authors have developed risk scoring tools to identify vascular patients at risk of developing SSIs [2,5]. However, their value in predicting SSIs relating specifically to groin surgery is not known.

VERN was founded in 2014 and is the official vascular trainee research collaborative of the United Kingdom [13]. Its multidisciplinary structure fosters close links between trainee surgeons, nurses and vascular scientists on a national basis. VERN has successfully delivered several multi-centre audits without incurring cost using this collaborative approach [14–16].

1.1. Primary aim

To compare the performance of the local vascular unit against UK NICE guidance relating to SSIs (supplementary material 1) in the groin incisions of vascular patients.

1.2. Secondary aims

The secondary aims are:

(i) to calculate a contemporaneous rate of groin incision infections in the UK and abroad;
(ii) to identify patient, surgical and theatre risk factors associated with groin SSIs;
(iii) to examine the value of previously published tools in predicting SSIs in groin incisions;
(iv) to identify areas of equipoise which could be examined in future effectiveness trials.

2. Methods and analysis

2.1. Design

An international, multicentre audit of practice, and a prospective observational cohort study disseminated via VERN.

2.2. Setting

Hospitals providing emergency and/or elective vascular surgery in the UK and abroad, recruited via VERN. Based on current interest it is expected at least 25 centres will be enrolled.

2.3. Time frame

The GIVE audit was officially launched on 21st January 2019. The UK will close to new participating centres on 1st May 2019. Centres are encouraged to start data collection as soon as possible once appropriately registered. Data from consecutive groin incisions meeting the inclusion criteria will be collected prospectively for 3 months.

Follow up data will be captured at 90 days following surgery. The entire study period will span 6 months. Centres are required to return all data within 7 months of starting, which will allow 1 month from last data point for all data capture.

2.4. Participants

The audit will enrol consecutive patients undergoing a groin incision for access to the femoral arteries.

Inclusion criteria:

- Patients undergoing an emergency or elective groin incision(s) for arterial intervention including endarterectomy, embolectomy, thrombectomy, bypass, repair of (non-infected) traumatic injury (i.e. iatrogenic pseudoaneurysm) or exposure for an endovascular procedure.
- Groin incisions which are extended down the leg (i.e. for vein harvest) or above the groin (i.e. for iliac vessel exposure) are included, although outcomes will be limited to the incision overlying the femoral triangle.

Exclusion criteria:

- Patients undergoing groin surgery for infective complications, e.g. infected pseudoaneurysm, explantation of infected prosthetic material.
- Groin exposure for venous access only without arterial exposure or intervention, (e.g. vein harvest only).
- Groin exposure performed for cardiac procedures, e.g. Transcatheter Aortic Valve Implantation (TAVI); access for cardiac bypass.

2.5. Patient identification and data collection/management

The local study team will be responsible for contemporaneous data collection. Theatre information technology systems will be used to screen for eligible patients regularly. Datapoints consisting of key demographic, baseline variables and intra-operative variables will be collected as early as possible following surgery. Post-operative sequelae datapoints will be preferentially collected as soon as the 90-day follow up threshold is reached. Should an SSI develop, further details will be required about the extent of the infection and resultant patient outcome. Data capture tools were drafted and refined to ensure appropriate data points will be captured (supplementary material 2).

Data will be obtained using patient's notes and electronic records – including pre-operative assessment documentation, theatre information technology systems, discharge letters, clinic letters and accident and emergency department records. No changes to normal patient follow up will be made, and the patient will not be contacted to enquire about SSIs, unless this encompasses centre specific standard care.

Data will be recorded on an anonymised online data collection tool or held electronically locally, and anonymous data transferred to the GIVE Audit team via secure encrypted email. No patient identifiable information will be transferred from participating centres. Patients will be pseudoanonymised at each participating centre. The local audit lead will organise for the local centre to hold a secure database with a minimum of three patient identifiers (e.g name/hospital number/date of birth) and a 3 digit pseudoanonymised number. The pseudoanonymised number will be used to link peri-operative data and 90-day post-operative outcome data.

Data will be collated, stored and analysed by the GIVE Audit team at the Royal Gwent Hospital, Aneurin Bevan University Health Board, Newport, UK.

2.6. Primary outcome

The primary outcome will be compliance with NICE guidelines on SSI prevention.

An SSI will be defined as per the Centres for Disease Control and Prevention (CDC) criteria (supplementary material 3) [17]. These guidelines state that superficial SSIs are those presenting within 30 days of surgery, whilst deep or organ/space SSIs are those presenting within 90 days.

SSIs will be limited to those apparent to the treating vascular team within 90 days of surgery. It is recognised that this study may therefore fail to capture milder infections which are treated in the community.

2.7. Secondary outcomes

Secondary outcomes include (all for up to 90 days):

- Rate of post-operative SSI
- Rate of additional dressings used to manage SSI
- Rate of vacuum dressing therapy used to manage SSI
- Rate of antibiotics (both oral and intra-venous) used to manage SSI
- Rate of surgical and radiological re-interventions to manage SSI
- Organisms grown from samples sent to microbiology
- Rate of post-operative acute kidney injury (AKI)
- Rate of SSI resulting in sepsis
- Rate of SSI resulting in unplanned admission to a critical care setting
- Length of stay in hospital
- Mortality

AKI will be defined according to the Acute Kidney Injury Network (AKIN) criteria (supplementary material 4) [18].

Sepsis will be defined according to a definition recommended by the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) (supplementary material 5) [19].

2.8. Specific considerations

A groin incision can be extended inferiorly (e.g. for vein harvest), or superiorly onto the abdomen (e.g. for iliac vessel exposure). In these instances, the groin incision will be considered as that which overlies the femoral triangle. SSIs distant to the groin, such as in the mid-thigh, will not be captured. In cases of uncertainty, the decision of the overseeing consultant will be sought.

In the event of both groins being used simultaneously, data on each incision will be captured separately. If both groins of a patient are used sequentially (at different dates, but both within the audit timeframe) they will also be captured separately.

Should a patient already enrolled onto the GIVE audit return to theatre and require re-opening of the index groin incision for a reason other than SSI (e.g. for repair of a pseudoaneurysm arising from the original surgery), this would not be captured as a new groin incision, but rather as a return to theatre.

2.9. Data completeness and validation

Data completeness is considered essential. Data points recorded as 'unknown', where this option is available, will count as complete data. Cases with <95% of data completeness will be returned to the participating centre for completion, or if this is impossible, will be excluded from analysis, as is standard with international collaborative audits [20,21].

Certain centres will be asked to review a small number of patient data points (approximately 5%) to confirm case ascertainment and data accuracy, as is standard with international collaborative audits [20,21]. This will comprise of a review of the data collection by an individual not involved with its initial collection.

2.10. Statistical analysis

Analyses will be performed to assess overall SSI rates and examine secondary outcomes. Data will be checked for normality and the appropriate parametric or non-parametric test used. Individual unit SSI rates will be presented in funnel plot form, with lines representing ±2 and ±3 standard deviations. Individual unit rates will not be identified. Univariate and multivariate regression analyses will be used to identify significant variables predictive of SSIs. Variables reaching threshold of $p < 0.10$ on univariate analysis will be put forward to the multivariate regression analysis. $P < 0.05$ will be used to define statistical significance.

Two published risk prediction tools will be evaluated to assess their accuracy in predicting SSIs in this cohort (supplementary material 6) [2,5]. A receiver operating characteristic (ROC) curve will be plotted for each tool, with calculation of area under the curve (AUC) as the summary statistic.

2.11. Centre eligibility and team roles

The GIVE audit is open to all centres that provide an elective and/or emergency arterial vascular service. UK vascular units often comprise of a Hub and Spoke type model. A registered Hub site may be able to undertake data collection for Spoke sites, depending on practicalities and local policies, without registering the Spoke site separately. However, it is noted that the majority of arterial operations will be performed at the Hub site therefore data collection from Spoke sites is likely to be minimal.

Each centre will require the support of a supervising consultant, and a data collection team. The supporting consultant is expected to facilitate audit registration/ethical approval, provide unit support for engagement with the GIVE study, act as a guarantor to data capture and upload/transfer, provide workplace-based assessments documentation for team members, and facilitate local presentation of the audit results at an appropriate local meeting.

3. Ethics and dissemination

3.1. Ethics and registration

Decision-making tools provided by the NHS Health Research Authority (HRA) ("Is My Study Research?" [22] and "Do I need NHS Research Ethics Committee (REC) approval?" [23]) were used to determine that this study does not require approval from an NHS Research Ethics Committee.

The GIVE audit is required to be registered in each participating centre prospectively, prior to data collection. Participating centres that are situated outside of the UK will need to comply with local regulations prior to commencing, which may require prospective approval from an ethics committee. The agreement of a consultant vascular surgeon (or equivalent for non-UK centres) is required to oversee the process.

The GIVE Audit received Caldicott Guardian approval from the corresponding author's institution to store pseudoanonymised data on secure NHS computers, and undertake appropriate statistical analysis.

3.2. Dissemination and authorship

Data will be submitted for presentation at national and international meetings. A paper, or papers of the resultant data will be submitted for peer-reviewed publication. A writing team, including those involved with the design, implementation and dissemination of the GIVE audit, and those contributing to data analysis in the cohort study will be responsible for both presentation(s) and publication(s). For both presentation(s) and publication(s) a collaborative authorship model will be used. To qualify for PubMed-citable collaborative co-authorship individuals must have either:

1. had a significant role in the set up and management of the GIVE study, including audit department registration, creation of a data collection team and engagement with VERN to ensure timely upload of data (with validation as required) and completion of the questionnaire
   OR
2. captured sufficient data to warrant authorship – this would be the equivalent of collecting baseline and follow up data on approximately 10 patients, although it is appreciated individuals may participate in only baseline data collection or only follow up data capture. Data collection is expected to be complete (>95% variables completed), and submitted within 7 months of starting data collection
   OR
3. (for consultants) provide oversight and support as detailed in the "Centre Eligibility and Team Roles" section.

It is encouraged that data for each centre is presented locally. Summary data for each participating site will be provided to the local audit leads, with comparisons to the group average.

4. Discussion

This multicentre, international audit and observational cohort study will allow us to reliably determine the incidence and burden of groin SSI in this cohort. The strengths of the GIVE audit will lie in its use of contemporaneous data collection from numerous hospitals around the UK and internationally.

Compared to existing audits of vascular SSI, the protocol is designed to collect information in greater depth, due to the focus on vascular groin incisions. Previous studies have been limited by the variety of tools used to classify SSI. This audit will include the most recent CDC definition of SSI, and longer term follow up than recent audits. This will permit more information to be gathered on patient, surgical and theatre factors.

It is anticipated that the cohort study will provide impactful data for future comparisons with global practice and support the design of robust and meaningful studies. By including criteria for two published SSI prediction tools, we will be able to assess if either tool accurately predicts SSIs in this cohort. The large number of sites included will identify areas of significant variation in practice, suggesting clinical equipoise.

Limitations of the observational cohort study will include its inability to define specific causative associations between factors and incidence of SSI. Therefore, focus will be placed on factors either known to contribute to SSI, or areas with limited evidence base. Although the VERN collaborative has experience of data collection from previous studies, it will be impossible to confirm reliable consecutive patient recruitment. Finally, the data will be limited to clinically relevant SSIs that are severe enough to prompt review or referral to secondary care.

Snapshot audits of this nature have been shown to collect robust and useful data to guide national guidelines and surgical research priorities, especially in the setting of SSIs in other specialties such as colorectal surgery [24,25]. Expanding surgical audits internationally has permitted the development of research links between high, middle- and low-income countries [26,27], and we anticipate that success of the GIVE audit will support further collaboration with trainees globally, supporting the global surgery agenda and promoting good surgical practice with colleagues around the world.

Ethical approval

Decision-making tools provided by the NHS Health Research Authority (HRA) ("Is My Study Research?" and "Do I need NHS Research Ethics Committee (REC) approval?") were used to determine that this study does not require approval from an NHS Research Ethics Committee.

The GIVE Audit received Caldicott Guardian approval from the corresponding author's institution to store pseudoanonymised data on secure NHS computers, and undertake appropriate statistical analysis.

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Author contribution

Conception or design of work: AS RB RF GD ND TL JS DCB.

Contributed to data or analysis tools: BLG AS RB RF GD ND TL JS DCB.

Manuscript writing: BLG AS RB RF GD ND TL RP JS DCB.

Critical revision of the manuscript: BLG AS RB RF GD ND TL RP JS DCB.

Final approval of the version to be published: BLG AS RB RF GD ND TL RP JS DCB.

Conflict of interest statement

No conflicts of interest to declare.

Guarantor

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Appendix A. Supplementary data

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