Risk stratification and early outcome prediction in Endovascular Aortic Aneurysm Repair. The creation of a short stay aneurysm repair program.

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Declaration

I declare that the work produced and presented in this thesis is the product of my own original work.

[redacted]

Mr James Budge

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Dedication

To my wife, Catriona. Without your ongoing and unending support and love the process of undertaking this PhD would have been impossible.

To my parents, Kate and John Budge, along with my sisters Emma and Amanda. Thank you for you continued and unwavering support. As ever I am incredibly thankful to call you my family.

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Thesis Abstract

Introduction

Day case and short stay surgery pathways are becoming increasingly prevalent. They offer advantages including reducing cost, while improving resource utilisation. Endovascular Aneurysm Repair (EVAR) and Fenestrated EVAR (FEVAR) with their low peri-operative mortality and morbidity could allow a short stay aneurysm repair pathway in select patients.

Aims

This thesis sets out to create and trial a short stay endovascular program to ascertain its safety and applicability.

Methods

A systematic review of the short stay EVAR and FEVAR studies to date was performed. A novel short stay EVAR (SS-EVAR) and FEVAR (SS-FEVAR) criteria was created and retrospectively validated. Qualitative and quantitative methods were used to identify and address the barrier to a safe and effective short stay model of care. The criteria created where tested in a pilot SS-EVAR and SS-FEVAR program using an bundle of care informed by the other studies in this thesis.

Results

Systematic literature review revealed that SS-EVAR programs to date are associated with good patient satisfaction and modest cost savings. The retrospective validation showed the selection criteria allowed up to 60% of EVAR and 65% of FEVAR patients to be safely enrolled with minimal readmissions. Qualitative and Quantitative data collection identified barrier to SS-FEVAR and SS-EVAR that were addressed in a bundle of care and pathway.

Nineteen EVAR patients and Fourteen FEVAR patients were included in a prospective short stay aneurysm repair program, with an average length of stay of 34.8 and 80.7 hours respectively. Both programs were shown to have good eligibility, complication and readmission rates.

Conclusion

SS-EVAR and SS-FEVAR programs can offer a safe and cost-effective pathway, with good acceptability in selected patients. With the ongoing efficiency reforms in the NHS and internationally the ability to offer these treatments at lower cost and equivalent safety is paramount to their ongoing success.

1. Introduction

1.1 Abdominal Aortic Aneurysms overview

The abdominal aorta is the lower portion of the largest artery in the human body, the aorta, which arises from the heart and runs through the thorax and onwards into the abdomen. Here it is responsible for the blood supply to the organs of the abdomen and lowers limbs (see Figure 1).

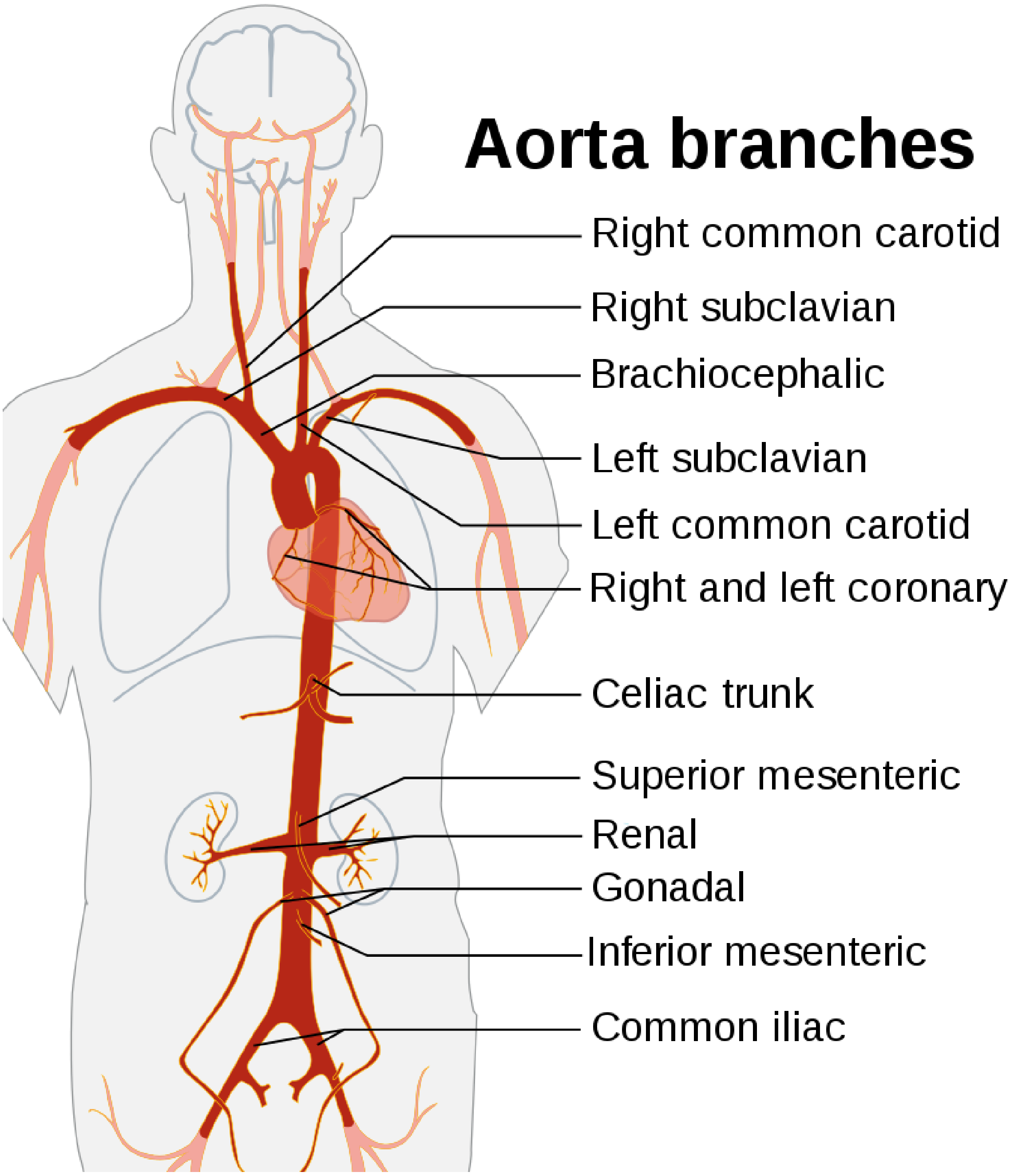


Figure 1: Diagram of the course of the aorta and its branches.

It is possible for this artery to swell over time, and when it exceeds one and half times its normal size it is deemed to be aneurysmal.

As an aortic aneurysm continues to grow, the wall of the aorta becomes thinner, which risks the artery wall tearing, leading to internal bleeding. This is referred to as an aortic aneurysm rupture and carries a mortality rate of 80%(1), with only half of those that do undergo emergency surgery surviving to 30 days.

Aortic aneurysms are dividend anatomically by their location and extent. Those that occur within the abdominal aorta are termed Abdominal Aortic Aneurysms (AAA). These are often further divided depending on where the aneurysmal component starts relative to the renal arteries into supra-, juxta- and infra-renal AAAs. Supra-renal AAAs are those that start above at least one renal artery, but below the coeliac axis. Juxta-renal start adjacent to or including the lower margin of the lowest renal artery origin. Infra-renal AAAs are below the lowest renal artery.

1.2 Diagnosis of AAA

AAAs are often asymptomatic and are often detected either incidentally or via a national screening program.

When patients do develop symptoms from a AAA, these are often severe and may include abdominal, back or leg pain. The first two are often a product of pressure on adjacent structures but can also be a product of ischemic abdominal viscera due to emboli from aneurysmal sac thrombus. These emboli can also cause lower limb ischemia resulting in leg pain.

The triad of abdominal or back pain, a pulsatile mass and a patient with haemodynamic instability is often taught as the classical presentation of a ruptured AAA, but these patient presentations are often less clear.

It is for this reason that imaging has a pivotal role in the diagnosis of AAA, both in the emergency and non-emergency setting. The major two modalities that are used are ultrasound and computed tomography (CT). In the non-emergency setting, ultrasound has good specificity and sensitivity and does not require the patient to undertake the risks of radiation and intravenous contrast that CT angiogram (CTA) entails. It is for this reason that US has become the main stay of imaging in national screening programs for AAA around the world.

CTA however does play a key role in the emergency diagnosis of AAAs. It is also commonly used when a decision has been made to repair an aneurysm as it obtains detailed anatomical information required for operative planning. Due to the resolution that modern CT allows, with slice thicknesses of less than 1mm, coupled with the availability of computers able to generate multiplanar reconstruction, detailed operative planning is possible and often necessary in the setting of endovascular repair.

1.3 AAA Screening

Since 2009, the UK has undertaken a screening program for AAA. This involves a single US scan for men of 65 years or older. If an aneurysm is identified in the screening program, it is then followed up by sequential scans until a treatment threshold is met.

1.4 Risk factors and pathophysiology

The aetiology of aneurysmal formation is not fully understood, but it is thought to be the product of a degenerative process.

Although the mechanism by which AAAs develop is not fully understood the risk factors for their development are well known. The major risk factors for the development of an aortic aneurysm include smoking, male sex and a family history of AAAs(2).

1.5 Management

Once an asymptomatic AAA is detected the decision to offer surgical repair is based on the patients' medical comorbidities and the size of the AAA. In AAA's less then 5.5cm in diameter surgical repair is often deferred in preference for medical optimisation and on-going periodic imaging surveillance. This is due to the risk of rupture being comparatively small (<1% annual risk of rupture) up to this point, as shown by the UK Small Aneurysm Trial, the Aneurysm Detection and management (ADAM) trial and the veterans Affairs Cooperative Study(3–5).

Once an aneurysm has grown to larger than or equal to 5.5cm, or is larger than 4.0 cm and has grown by more than 1 cm in 1 year, it is National Institute for Health and Care Excellence (NICE) guidance to consider repair (6).

Operative management of infrarenal AAA is generally either Open Surgical Repair (OSR) or Endovascular Aneurysm Repair (EVAR). National guidance from NICE is that OSR should be offered to unruptured AAA patients meeting the size guidance described above unless there are contraindications because of abdominal copathology, anaesthetic risks, and/or medical comorbidities. In the setting of patients who meet the size guidance above but have abdominal copathology then EVAR should be considered. Finally in the setting of patients that comply with the above size guidance but have anaesthetic risks or medical comorbidities then either EVAR or conservative treatment should be considered.

In the setting of ruptured AAA, the treatment modality of choice is EVAR unless this is precluded by unfavourable anatomy.

1.6 Open Surgical Repair

Open Surgical repair of a AAA involves the exposure of the aorta and common iliac arteries and the physical replacement of the aneurysmal segment with a synthetic graft. OSR typically is associated with a higher perioperative mortality, morbidity, critical care bed usage and length of stay when compared to EVAR(7). It is however likely to be definitive a repair and has been shown to be associated with excellent durability(1,8).

1.7 Endovascular repair of AAA

Endovascular Aneurysm Repair (EVAR) involves advancing a graft through small incisions in the arteries of the groin under the guidance of X-rays to the level of the aneurysm where it is placed (see Figure 2). This seals off the swollen segment of the artery thus repairing the defective segment.

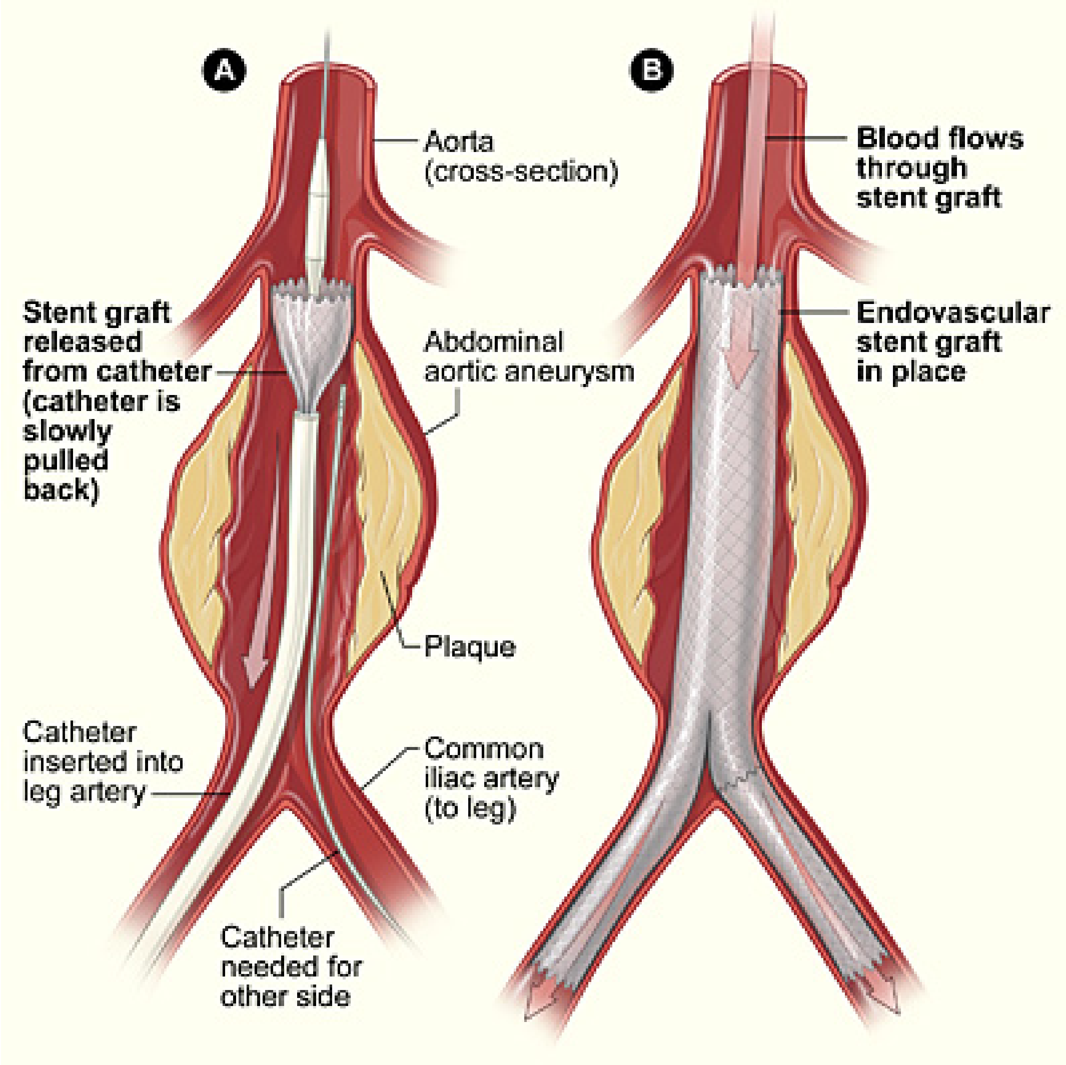


Figure 2: Placement of an EVAR; plate A: during deployment, plate B: post deployment

Although EVAR is associated with decreased procedural risks when compared to open surgical repair(9), it does have complications not seen in open AAA surgery. One of the most important of these is endoleaks; an ongoing perfusion of the excluded aneurysmal sac following repair. These endoleaks can either be from incomplete sealing by the stent (type 1), reversed flow though small arteries that enter the sac (type 2), tears or dislocation of stent components (type 3 endoleak), graft porosity (type 4) or leaks of unknown origin (type 5).

To allow EVAR repair to be durable, a sufficient length of straight walled aorta is required at the top (proximal) end of where the stent is to be landed; this region is termed the aneurysm neck. Most endovascular grafts commercially available require a minimum length of 10mm to create a durable seal. Where this aneurysm neck is less then this minimal length, but the aneurysm is still infra-renal, the AAA is termed juxta-renal. In this setting, traditional infra-renal EVAR devices alone would not provide a durable repair. One endovascular repair technique available in this setting is Fenestrated EVAR (FEVAR), this technique makes use of stents with holes cut through the stent fabric to allow the passage of blood into the visceral vessels Coeliac Axis (CA), Superior Mesenteric Artery (SMA) and the left and right renal artery. This allows the seal zone to include aortic wall that is above the lowest renal artery.

1.3 Short stay surgical pathways

Short Stay (SS) and day surgical pathways have become the norm for many surgical procedures in the UK, with 66% of surgical admission in the UK in 2019 being undertaken as day cases (10). The ongoing development in short stay and day case pathways has allowed for an increase in the complexity of the procedures and the range of patients included. Much of the success of these pathways is down to the effective pre-operative preparation and protocol driven discharge pathways (11).

Part of the appeal of short stay pathways is that they allow for a cost and resource efficient delivery of healthcare that is not only satisfactory to patients but is often preferable.

In recent years length of stay has become a major focus for GIRFT (Getting It Right First Time) and other organisations both within vascular surgery (12) and surgery more generally(10).

1.4 Aims and objectives

The aims and objectives of this thesis are laid out below.

1.4.1 Aims

1. To identify the factors determining length of stay and early readmission in patients undergoing EVAR.

2. To trial a SS-EVAR and SS-FEVAR program and prospectively collect data to analyse its safety and acceptability.

1.4.2 Objectives

1. To evaluate the present evidence for SS-EVAR and SS-FEVAR programs.

2. To develop and validate an objective and safe SS-EVAR and SS-FEVAR selection criterion.

3. To identify institutional barriers and patient concerns for short stay aneurysm programs.

4. To review the role of pre-discharge imaging in prediction of early complications.

5. To analysis the type and timing of readmission in EVAR.

6. To instigate and analyse a local SS-EVAR and SS-FEVAR program.

2. Methods

2.1 Methodological rationale and thesis structure

This thesis is split into seven experimental chapters, addressing each of the specific objectives as below:

- Chapter 3 reviews the literature to date to provide the current evidence for short stay (SS) aneurysm surgery programs, in both EVAR and FEVAR; this aims to address objective 1.

- Chapter 4 describes the developmental of a novel short stay endovascular aneurysm repair pathway criterion for EVAR and FEVAR and quantifies its applicability and safety through retrospective validation. This aims to address objective 2.

- Chapter 5 reviews the current use of Experience Based Design (EBD) in elective medical and surgical pathways to identify best practice that is then applied to the current AAA program. This aims to address objective 3.

- Chapter 6 expands and develops the patient concerns over educational material raised in Chapter 5 and highlights the diversity in quality of education material available to patients for EVAR using the EQIP tool. This aims to address objective 3.

- Chapter 7 quantifies the rates of in-patient complications after EVAR and examines any relationship to post-procedural imaging. This was undertaken to quantify any risk in the removal of routine in-patient duplex prior to discharge. This aims to address objective 4.

- Chapter 8 quantifies the timing for post-discharge readmissions and defines the reasons for readmission to inform when targeted early follow up should take place to prevent emergency readmissions in any adopted SS pathway. This aims to address objective 5.

- Chapter 9 utilised the information from stake holders gleaned from Chapter 5 to create a bundle of care involving pre-education (informed by Chapter 6) and early targeted telephone follow up (with timing information from Chapter 8). This bundle of care was then used for patients selected by the criteria laid out in Chapter 4 to pilot a short stay EVAR and FEVAR program and to quantify the feasibility and safety of such a programme. This aims to address objective 6.

2.2 Systematic Review of Short Stay Aneurysm repair programs

2.2.1 Overview

The following methods pertain to chapter 3 which reviews the literature to provide the current evidence for short stay (SS) aneurysm surgery programs.

2.2.2 Systematic review strategy

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRSIMA) guidelines were used for study selection. A database search of Ovid Medline(R) (1996 to March 2019), Embase (1974 to March 2019) and Cochrane Library (to March 2019) was completed using the terms "FEVAR", "Fenestrated Aneurysm repair", "EVAR", "aneurysm repair", "endovascular aneurysm repair", "abdominal aortic aneurysm", "outpatient", "short stay", "day case", "fast track", "ambulatory" and "length of stay".

Search term query used:
((("EVAR") OR ("endovascular aneurysm repair") OR ("abdominal aortic aneurysm")) OR ("FEVAR") OR ("fenestrated endovascular aneurysm repair") AND (("outpatient") OR ("short stay") OR ("day case") OR ("ambulatory") OR ("length of stay")))

References of the eligible studies were reviewed and if relevant included. Studies not in the English language, or studies investigating open aneurysm repair were excluded. Abstracts were screened and those that were deemed relevant were screened in full.

Abstracts that fulfilled the below inclusion criteria were read in full:

- those addressing LOS
- those that had >10 cases,
- included AAA EVAR (simple or complex)

Papers were excluded if:

- The study was investigating open aneurysm repair
- The study was not reported in English

Retrospective and review articles were included.

Variables such as patient demographics, short-stay protocol uptake, operative details, failed early discharge, and cost-analysis were extracted and collated.

No further data was requested from study authors.

2.3 Short Stay Aneurysm Program selection criteria

2.3.1 Overview

The following methods pertain to chapter 4 and describes the developmental of a novel short stay criteria for EVAR and FEVAR and its retrospective validation.

2.3.2 Development of selection criteria for SS-EVAR

Chapter 3 systematically reviewed the SS-EVAR literature revealed that the primary reasons for SS-EVAR pathway non-completion consisted of a mixture of medical concerns, unanticipated technical factors, and social issues. The respective proportions varied between studies; potentially due to the different selection criteria and pathway protocols employed. For example, Dosluoglu et al.(13) had higher rates of medical factors preventing same day discharge (64% of non- discharges; including severe respiratory disease, ischaemic heart disease, advanced age, urinary retention and poor renal function) than Hanley et al.,(14) who encountered more technical issues (61% of non-discharges; including haemostasis difficulties, conversion to aorto-uni-iliac graft, concurrent procedures and endoleaks).

Three studies specifically sought to determine the factors associated with SS-EVAR pathway non-completion(13–15). Pre-operative factors that were heterogeneously identified as being associated with pathway non-completion included advanced age(13), ASA class ≥4(13), home oxygen therapy(13), presence of heart failure(15), smaller external iliac artery diameter(15) and larger aneurysm size(13).

Subsequently, with this information and a knowledge of the co-morbidities that have previously been shown to effect outcomes following EVAR(16–18), a local expert working group meeting by consensus agreed a set of low and high risk criteria. The low-risk criteria were essentially designed to ensure that it would be safe for a relatively fit and healthy individual to undergo SS-EVAR. The high-risk criteria, however, were thought to represent the characteristics of the more commonly encountered comorbid aneurysm patient that could still be realistically enrolled onto an SS-EVAR pathway. The two criteria were then separately applied to the retrospective dataset described in section 2.3.4.

2.3.3 Development of selection criteria for SS-FEVAR

A review of the literature was performed to ascertain if there were any previous published SS-FEVAR programs, as described in section 2.2. As none were identified, SS-EVAR was felt to represent a similar patient population and thus our previous published SS-EVAR criteria were selected for this study(19).

As per the methodology stated in section 2.3.2, this represented a low and high-risk criterion, which was based upon a review of previous selection criteria and input from a local expert working group. These two criteria were then separately applied to our retrospective dataset as described in section 2.3.5.

2.3.4 SS-EVAR selection criteria testing

This was a retrospective study performed at a single tertiary vascular unit. All patients undergoing elective EVAR for infrarenal AAA over a three-year period between January 2013 and January 2016 were included. Patients were identified from the NVR, and these records were validated with local hospital records to ensure all cases were included. Although our centre did not provide an SS-EVAR service over this period, we wanted to elucidate when perioperative complications occurred in our elective EVAR patients, so that we could then determine whether patients specifically selected with our novel criteria for a theoretical SS-EVAR pathway would have good early outcomes.

Any patients with symptomatic, ruptured, or inflammatory aneurysms were excluded from the study. Furthermore, any patients with who underwent a complex abdominal aortic aneurysm repair including FEVAR, BEVAR or CHIMPS procedures were excluded. Those undergoing revision EVAR or having additional procedures to EVAR (including iliac branch devices) were also excluded from the study.

Patients were not excluded based on their anaesthetic type, vascular access approach or graft device used.

In addition to data derived from the NVR, individual patient case notes and discharge summaries were used to obtain information regarding patient demographics, co-morbidities, aneurysm characteristics, operative details, post-operative course/complications and 30-day outcomes.

Demographic data collected was:

- Age in years
- Sex
- Distance from St George's Hospital in kilometres

Distance from the hospital was calculated using the google maps distance matrix application programming interface (API): https://developers.google.com/maps/documentation/distance-matrix

The API was accessed using a custom coded Python 3 script (See appendix 4)

This was used with the St George's post code and that of the patient's home address listed on the electronic health records. Distance was calculated as the shortest journey by car between the two points.

Comorbidity data collected was:

- AAA size in mm
- ASA grade
- BMI
- Presence of diabetes, hypertension, chronic lung disease, severe COPD (FEV1 <50% predicted), ischemic heart disease, myocardial infarction past 6 months, chronic heart failure, chronic renal disease, cerebrovascular disease, hypercholesterolaemia and history of cancer
- If known the Ejection Fraction (EF) was also documented
- Smoking status was also collected

Complications where identified, were recorded. The type of complication was recorded along with the time of the complication.

Length of stay was recorded for all patients, as well as the date of their operation to allow total length of stay and post-operative length of stay to be calculated.

2.3.5 SS-FEVAR selection criteria testing

This was a retrospective study performed using data from a single high volume tertiary vascular unit. Patients undergoing FEVAR between January 2017 and January 2020 were identified from the National Vascular Registry and validated against locally held records to ensure all cases were included. All symptomatic, ruptured, and inflammatory aneurysms were excluded, along with those that FEVAR was performed in a staged manner or as part of TAAA repair.

All case notes were then screened to identify when peri-operative complications occurred and to collect baseline demographic information, operative information, and co-morbidities in this patient population.

As there was not a concurrent short stay FEVAR program during the studied period the above early outcome data allowed us to judge the possible success of the proposed SS-FEVAR selection criteria.

Demographic data collected was:

- Age in years
- Sex
- Distance from St George's Hospital in kilometres

Distance from the hospital was calculated using the google maps distance matrix API: https://developers.google.com/maps/documentation/distance-matrix

The API was access using a custom coded Python 3 script (See appendix 4)

This was used with the St George's post code and that of the patient's home address listed on the electronic health records. Distance was calculated as the shortest journey by car between the two points.

Comorbidity data collected was:

- AAA size in mm
- ASA grade
- BMI

- Presence of diabetes, hypertension, chronic lung disease, severe COPD (FEV1 <50% predicted), ischemic heart disease, myocardial infarction past 6 months, chronic heart failure, chronic renal disease, cerebrovascular disease, hypercholesterolaemia and history of cancer
- If known the Ejection Fraction (EF) was also documented
- Smoking status was also collected

Complications where identified, were recorded. The type of complication was recorded along with the time of the complication.

Length of stay was recorded for all patient, as well as the date of their operation to allow total length of stay and post-operative length of stay to be calculated.

2.3.6 Statistical Analysis

All statistical analysis was conducted in R version 4.0.3(20) using the RStudio(21).

All continuous variables are reported as mean ± standard deviation. Where categorical data was compared these were presented as count and percentage.

Where categorical variables were compared a Chi-squared test was performed.

2.4 Identification of patient and system factors limiting early discharge in EVAR patients using Experience Based Design.

2.4.1 Overview

The following methods pertain to chapter 5 which reviews the current use of Experience Based Design (EBD) in elective medical and surgical pathways, which has yet to be done in the literature. This review allowed for the creation of pragmatic guidance on the use of EBD in elective medical and surgical pathways. This guided the local application of EBD for the established local endovascular aortic repair pathway to identify issues affecting stakeholders.

EBD is a novel strategy that relies on patient and staff narratives about their experiences and interactions to collectively guide changes a service. Whilst the majority of quality improvement revolves around analysing a specific outcome measure, the principles of EBD are to analyse the entire experience of care. This enables identification of which key service interactions, known as 'touchpoints' that users of the service have identified as emotionally significant. Thus EBD can provide a platform to target interventions at these specific points of patient, carer or staff concern, called touch points.

2.4.2 EBD review

2.4.2.1 Search Strategy

A literature search was conducted on PubMed and Embase databases using the search terms "experience-based co-design" and "experience-based design". The literature search was done in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines. The last date for the search was 22nd August 2019.

Search query used:
("experience based co-design") OR ("experience based design")

2.4.2.2 Study Selection

Titles were screened independently by two investigators (James Budge and Shruti Jayakumar) to identify those that were original articles on EBD approaches. Then abstract screening was performed to identify articles that met the inclusion/exclusion criteria (Table 1), followed by full-text screening. Articles not clearly meeting the inclusion/exclusion criteria were further evaluated (J.B and S.J) and a consensus on article inclusion was reached following discussion amongst all investigators.

Inclusion criteria
- Elective based pathway - Experience based design use - Requiring staff and/or patients to take part - Prospective - Had to be administered pre, during and post (or multistage) intervention
Exclusion criteria
- Palliative pathways - Any emergency admissions - Non-traditional use of experience-based design - Papers not written in English

Table 1: inclusion and exclusion criteria for EBD review

2.4.2.3 Critical Appraisal

Two investigators (J.B. and S.J.) performed critical appraisal of included studies using the Critical Appraisal Skills Programme (CASP) qualitative studies checklist(22,23). This checklist was used as a framework for assessing the adequacy of the identified studies. Any studies deemed inadequate by both authors were excluded.

2.4.2.4 Data Extraction

The following information was independently extracted from all eligible studies by two investigators (J.B. and S.J.): type of participants (patients, carers and/or staff), number of participants (total number and by participant type), number of times EBD was administered through the pathway, timepoints of care that EBD was administered (pre-admission, during admission, pre-discharge and/or post-discharge), specialty and pathway studied, EBD techniques used including if pre-defined wording scales were used. Data was also collected on analysis techniques and use of word clouds, thematic analysis, and use of modified rating scales. Where applicable, changes to pathways resulting from EBD were also extracted.

2.4.3 Local Experience Based Design Exercise

2.4.3.1 Patient EBD

A total of 15 patients were included in the patient experience-based co-design exercise. After informal discussions with patients and staff prior to the start of this program six key touch points were identified. These were:

1. The first clinic appointment
2. The optimisation clinic appointment
3. The second clinic appointment
4. The day of admission
5. The day of discharge
6. The first follow up clinic

At each of these defined touch points patients were asked three questions. The first was to circle one of six words that most encompassed their feelings at that time. These were chosen from a list of validated words with good positive and negative connotation agreement(24).

The second question aimed to ask why the patient felt that way and the third looked at if anything could be improved. There was also a free text area for other comments.

The above questionnaire was based on the resources available through NHS improvement hub and in keeping with the best practices outlined in the review of the EBD literature. The questionnaire used can be seen in appendix 1.

The validated words were analysed by overall group (positive or negative) by touch point. The open questions were to collet themes which were presented by tally.

Interim analysis was planned after the first 15 cases comparing the final five open question thematic results against the first ten to establish if ground truth had been met, according to grounded theory(25). If new thematic areas were discovered in this cohort, then a further five cases would be included and re-analysed, until no new themes were identified.

2.4.3.1 Staff EBD

The wider multidisciplinary team at St George's that have contact with EVAR patients were approached as part of the EVAR EBD study. Structured sampling was performed to allow a range of staff groups to be involved. A total of 10 members of the wider MDT were chosen, they included three doctors, a consultant vascular surgeon, a vascular surgery registrar and a vascular surgery foundation year 1 doctor. Three nurses, an aortic clinical nurse specialist, a nurse in charge of a vascular ward and a nurse based on a vascular ward. Four allied health professionals where also approached, a vascular scientist, a physiotherapist, a physician associate and a pharmacist.

Each participant was asked to complete a structured questionnaire (see appendix 1) based upon the resource available through the NHS improvement hub. The questions addressed patient feelings, the MDT member's feelings regarding providing the patient's care and identification of what was thought to be working well and not well, with the current EVAR program. Staff were also asked to identify any barriers to early discharge in this patient population and any key points that could be learnt from the experience.

Each question was reviewed to look for thematic trends, which where appropriate were tallied.

2.5 Systematic analysis of the quality of patient information on the management of elective Abdominal Aortic Aneurysm repair on the internet using the modified 'Ensuring Quality Information for Patients' (EQIP) tool.

2.5.1 Overview

The following methods pertain to chapter 6. It expands on the patient concerns over educational material raised in Chapter 5 and highlights the diversity in quality of education material available to patients for EVAR using the ensuring quality information for patients (EQIP) tool.

The EQIP tool is a 36-point checklist which has been used extensively in other fields of medicine to assess online patient education material. It has been validated to assess the content, identification and structure of patient material and assign an overall score. This allowed the identification of high quality material towards which patients were directed.

2.5.2 Search term selection

A series of presumed patient search terms were created by discussion with a local expert group and were tested using 'Google Trends' (https://trends.google.com/) to identify those that had significant past search volume regardless of geographical location. The identified terms were *'Triple A Surgery', 'EVAR', 'Aortic aneurysm', 'Endovascular aneurysm surgery', 'Endovascular aneurysm repair', 'Endovascular aneurysm operation', 'Aorta Surgery', 'Aorta repair', 'Aorta operation', 'Aneurysm surgery', 'Aneurysm repair' and 'Aneurysm operation'*. The term *'AAA'* was excluded due to the high degree of non-relevant and non-vascular domain sites that it identified.

These search terms were used to collect the first 10 pages of search items on Google (Search date March 2020). The first 10 pages of websites were selected as per previously published methodology (26,27) with the rational that patients are unlikely to go beyond this point in the search log.

2.5.3 Eligibility of website inclusion

All websites identified using the above search criteria were screened before further assessment. Before eligibility screening all duplicates from the above search strategy were identified and removed. The remaining websites were screened with academic journals and marketing material being removed. Finally, all articles not written in English where also removed.

2.5.4 Data collection

All websites identified after filtering and screening were assessed using the MEQIP tool. Each website was assessed by two reviewers. Any disagreement in results where rectified via consensus discussion. The 36 item MEQIP criteria was applied to each website and results collected (see 36 items total comprised of Content (items 1–18), Identification (items 19–24), and Structure domains (items 25–36). Number of sites scoring for each item given, with the number and percentage of "yes" answers for high and low scoring websites for each item, as well as statistical significance between these.
Table 20 for full MEQIP criteria). The checklist items covered 3 domains, Content (item 1-18), Identification (item 19-24) and Structure (item 25-36). All items where answerable with (i) yes, (ii) no or (iii) not applicable, this was felt to increase objectivity and follows previous studies published methodologies (26–29). Websites which obtained an MEQIP score of greater than 21 (75th percentile score) were deemed to be high-score websites as per previous used methodology in multiple studies (26–31).

2.5.5 Statistical analysis

Statistical analysis was performed using R version 3.6.0 (20), in R Studio version 1.3.1056 (R Studio PBC. Boston, MA. 2020) (21).

All continuous variables were reported as median (interquartile range (IQR)) and categorical variables as numbers with proportions in percentage. Proportions were compared with the Fisher's exact test and continuous variables were compared the Kruskal–Wallis test. All p values were two-tailed and considered statistically significance when p = ≤0.05.

2.6 Peri-operative imaging and reintervention rates in EVAR

2.6.1 Overview

The following methods pertain to chapter 7 which aims to quantify the rates of in-patient and 30 days complications after EVAR and examines any relationship to post-procedural imaging. This was undertaken to quantify any risk in the removal of routine in-patient duplex prior to discharge.

2.6.2 Data collection

All patients undergoing infrarenal EVAR at St George's Hospital between the 1st of March 2010 and the 1st of March 2019 were identified using the National Vascular Registry. The patients were divided into 3 groups: asymptomatic, symptomatic and ruptured, regarding the presenting state of their aneurysm.

All complex aneurysm repairs were excluded in this study including FEVAR, BEVAR, CHIMPS procedures and EVAS.

In all cases the electronic patient records were screened to see if they had undergone an USS as an in-patient. Where this was the case the USS report was examined to look for any endoleaks or EVAR related complications including access issues (pseudo aneurysm or haematoma). Complications where found, were recorded.

The hospital PACS (Picture Archiving and Communication System) was also screened for each patient to look for a CT occurring during their in-patient stay. Where present any EVAR related complications were noted and recorded.

Each completion angiogram was reviewed on the hospital's PACS to look for any documented evidence of complication and the operative note was screened to look for mention of any identified endoleak or other complication.

The electronic patient notes were also reviewed including any discharge summaries for any evidence of re-interventions (either open or endovascular) where these were found, they were also recorded. The type of intervention performed as well as the date of this intervention was recorded.

2.6.3 Data analysis

All continuous variables are reported as median and range. Where categorical data was compared these were presented as count and percentage.

Statistical analysis was performed using R version 3.6.0 (20), in R Studio version 1.3.1056 (R Studio PBC. Boston, MA. 2020) (21).

2.7 Timing and reason for readmission in elective EVAR

2.7.1 Overview

The following methods pertain to chapter 8 which aims to identify the time pattern of readmissions and their reasons.

This is being performed to identify if there are any patterns to readmissions that could inform when targeted early follow up should take place to prevent emergency readmissions in a short stay aneurysm pathway. This would not only possibly reduced readmissions but may also increase the safety of these pathways.

2.7.2 Data collection

All EVAR cases performed at St George's Hospital from January 2013 to January 2020 were identified using the National Vascular Registry. All complex EVAR cases were identified and excluded, as were ruptured or symptomatic aortic aneurysm cases.

Complex repair was defined as any case involving the use of a fenestrated or branched device, as well as those that required chimney, snorkels or periscopes (CHIMPS approaches). It did include cases that underwent iliac embolization or the use of iliac branch devices.

All identified cases were screened using data contained in the NVR and local electronic patient records for any readmissions within 30 days post discharge. Where cases were identified, their notes were screened to confirm this readmission and to collect the reason and timing.

For each complication identified, the reason was documented. Once data collection was complete these complications were reviewed, and natural groupings were identified. These groupings were:

- Access complications
- Back pain
- Gastro-intestinal
- Renal
- Respiratory
- Sepsis

- Visceral ischemia
- Unknown

The timing of all the complications collected was plotted as a histogram to identify if there were any temporal patterns in the rates of complications.

This was also performed for each of the groups mentioned above, to identify if these groups had temporal patterns that could inform interventions to reduce readmissions or improve the pathway safety.

2.7.3 Statistical analysis

All continuous variables are reported as median and range. Where categorical data was compared, these were presented as count and percentage.

Statistical analysis was performed using R version 3.6.0 (20), in R Studio version 1.3.1056 (R Studio PBC. Boston, MA. 2020) (21).

2.8 Short stay Aneurysm prospective pilot study

2.8.1 Overview

The following methods pertain to chapter 9. Section 2.8.2 and 2.8.3 set out to prospectively test the feasibility and safety of a SS-EVAR and SS-FEVAR program. This program utilised the patient selection criteria laid out in chapter 4 along with a bundle of care informed by chapters 5-8.

This bundle of care addresses the concerns raised by the EBD process in chapter 5, including high quality pre-education information identified in chapter 6 and early targeted telephone follow up whose timing was informed by chapter 8.

2.8.2 SS-EVAR prospective pilot study

2.8.2.1 Criteria and study population

All elective EVAR cases for a six-month period from 1st January 2021 to 1st July 2021 were identified at the first or optimisation clinic. All cases were checked against an objective previously validated SS-EVAR criteria (see Table 2 below and chapter 4 for full development). Those deemed suitable for SS-EVAR, as assessed by the criteria in Table 2, and by the clinical team, were entered into the SS-EVAR pathway.

	Criteria
Social	Transport available Adult observer available for 24 h post-discharge Absence of significant immobility
Distance	< 100km
Age	<90 years
Body mass index (kg/m2)	<35
ASA grade	<=3
Advanced liver disease	Absent
Cognitive impairment	Absent
eGFR (mL/min/1.73m2)	>= 45
Ischemic heart disease	No myocardial infarction in past 6 months
Cerebrovascular disease	No stroke in past 1 year
Heart failure	No severe heart failure (ejection fraction <40%)
Chronic lung disease	No severe COPD (FEV1 <50%) or other severe respiratory disease.
Diabetes	No insulin-dependent diabetes

SS-FEVAR: short-stay fenestrated endovascular aneurysm repair; ASA: American Society of Anaesthesiologists; eGFR: estimated glomerular filtration rate; COPD: chronic obstructive pulmonary disease; FEV1: forced expiratory volume in 1 s.

Table 2: SGVI Short stay aneurysm criteria

2.8.2.2 SGVI Short stay aneurysm care bundle

The SS-EVAR pathway includes the St George's Vascular Institute (SGVI) short stay aneurysm care bundle (outlined in appendix 2), in addition to the current standard of care (SoC) components. A timeline comparison of the SoC EVAR pathway and the SS-EVAR pathway can be seen in Figure 3.

This bundle of care involved the following components:

- Pre-operative education including enrolment in the surgery school

- Short stay in-patient protocol (covering day of admission, discharge paperwork and to-take-home medications)
- Early telephone follow-up
- Early out-patient imaging

Pre-operative education and assessment was already performed as part of the SoC EVAR pathway. The current SoC practice involved two clinical appointments, an optimisation clinic and a pre-operative clinic. The optimisation clinic is run by the aortic nurse specialist and involves assessments of lung function through spirometry, echocardiography and blood tests as necessary.

The pre-operative clinic involves a physician associate, an aortic clinical nurse specialist and a vascular pharmacist. This process allows a pre-clerking to be performed by the physician associate, medication check and peri-operative advice to be given by the vascular pharmacist and peri-operative advice to be given by the aortic clinic nurse specialist.

In the SS-EVAR program the advice by the clinical nurse specialist was augmented to include:

- The recommended patient information including offers of written and internet options (as informed by the findings of chapter 6).
- Post-operative symptoms, pain and self-treatment, including simple analgesia.

In addition to the above, all patients were offered attendance at the St George's surgical school "Get Set 4 Surgery" program. Full details of this program's content can be seen in appendix 3.

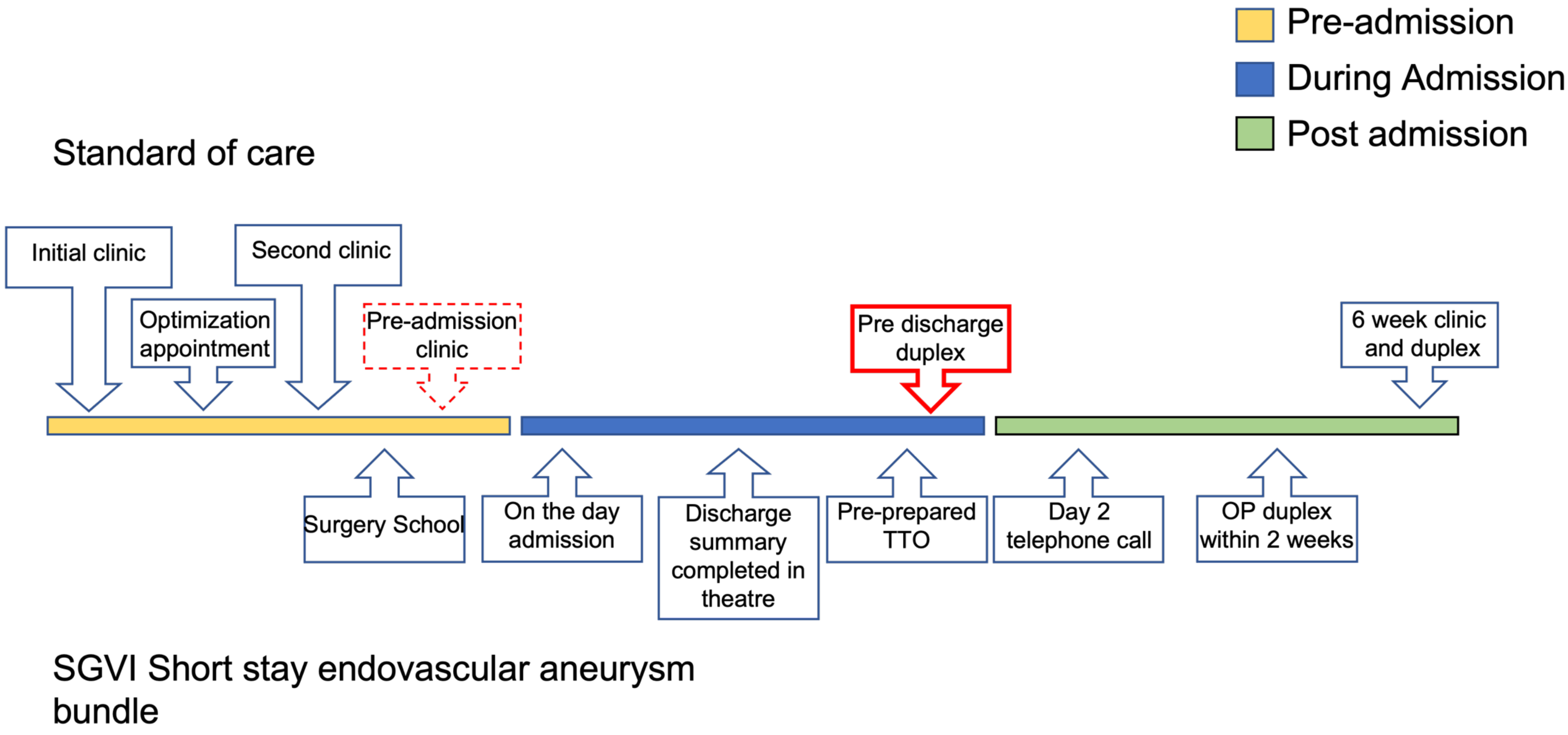
The Get Set 4 Surgery team is made up of the following clinical staff; Clinical Nurse Specialist, Consultant Anaesthetist, Consultant Surgeon, Dietician, Clinical Psychologist and Physiotherapist.

This program was originally designed to run as in person small to medium group events but during COVID-19 pandemic it has been run as a webinar. In addition, online videos and a booklet were made available.

The session covers prehabilitation topics and general pre and post admission advice. The topics covered are:

- Improving diet
- Smoking cessation advice
- Alcohol intake advice
- Increasing activity level
- Day of surgery advice regarding medication, location, time and starving.
- Post discharge preparation including supervision, at home food stock and analgesia.
- Mental preparation

The program also covered the normal patient journey and provided the opportunity to patients to ask further questions in a peer supported environment.



All components of the standard of care pathway occurred in the SS-EVAR pathway, bar those in red, as discussed below.
Dashed red outline: The pre-admission clinic was augmented in the SS-EVAR pathway.
Red outline: The Pre-discharge duplex did not take place in SS-EVAR pathway if the patient was discharged the same day.

Figure 3: Comparison of standard of care and SGVI SS-EVAR pathway

2.8.2.3 Data collection and analysis

Demographic data and past medical history were collected on all patients in the cohort.

Demographics collected included:

- Age
- Sex
- Distance from the hospital

Distance from the hospital was calculated using the google maps distance matrix API: https://developers.google.com/maps/documentation/distance-matrix

The API was accessed using a custom coded Python 3 script (See appendix 4)

This was used with the St George's post code and that of the patient's home address listed on the electronic health records. Distance was calculated as the shortest journey by car between the two points.

Comorbidities were collected to adequately rate the patient against the short stay criteria listed in Table 2. In addition to this, the following information and comorbidities were collected:

- ASA score
- Current and past smoking status
- Diabetes
- Hypertension
- Hypercholesterolemia
- History of myocardial infarction and if this was greater than 6 months ago
- History of ischemic heart disease
- Previous TIA or stroke and if this was greater than 1 year ago
- Chronic lung disease
- Heart failure
- Ejection fraction (%)
- Chronic kidney disease
- eGFR
- History of cancer and if this was treated, under surveillance or active.

Chronic kidney disease where present was rated by stage:

- Stage 1: normal function eGFR >90
- Stage 2: mild loss of function eGFR 89-60
- Stage 3a: mild to moderate loss of function eGFR 59-45
- Stage 3b: moderate to severe loss of function eGFR 44-30
- Stage 4: Severe loss of kidney function eGFR 29-15
- Stage 5: kidney failure eGFR less then 15

Ejection fraction was collected preferentially from Simpson's biplane method were stated. Where estimated ejection fraction results were stated with a range the mean value in the range was recorded.

Perioperative data collection included hospital length of stay, critical care admission and length of stay, operative complications, post-operative complications, reintervention and readmission or unplanned review up to 30 days post discharge.

Length of stay was compared to the historic cohort used to validate the SS-EVAR criteria. Only those that were selected by the pragmatic criteria were compared to with the trial population. Statistical testing was performed to compare these groups, this included testing of variance with Levene's test. Where this was significant a Mann-Whitney U test was performed and if not a two tailed independent T-test was performed.

Continuous data was presented as median and range with categorical data being presented as count and percentages.

Difference between the demographics and co-morbidities of those who successfully completed the SS-EVAR pathway (LOS of less then or equal to 36 hours) were compared. Continuous data was compared with the Mann-Whitney U test while categorical data was tested with the Chi squared test.

The project was registered as a local quality improvement project, registration number SE0014.

All statistical analysis was conducted in R version 4.0.3(20) using the RStudio(21).

Non-risk adjusted cumulative sum of failure analysis was performed to look at learning curve analysis using the 'cusum' package in R; cusum: Cumulative Sum (CUSUM) Charts for Monitoring of Hospital Performance (32). The failure state was set to be either a in hospital stay of greater then 36 hours or a stay of greater than one night. This was deemed to allow a single night stay with time allowable after this for the processing of the patient's discharge.

2.8.2.4 Staff pathway and bundle education

At the launch of the SS-EVAR program the clinical team including:

- Vascular Surgery Consultants
- Vascular Surgery Registrar
- Vascular Surgery ward doctors (Senior House Officers and Foundation year 1 doctors)
- Vascular Surgery ward physicians associates
- Vascular Surgery ward Nurse in charge
- Vascular Surgery ward Nurses
- Vascular Surgery ward Pharmacists
- Vascular Scientists

Were invited to attend an educational presentation on the SS-EVAR pathway and bundle of care ahead of its start.

This educational event was also run a second time due to concern over non-adherence with the pathway.

2.8.3 SS-FEVAR prospective pilot study

2.8.3.1 Criteria and study population

All elective FEVAR cases for a six-month period from 1st January 2021 to July 2021 were identified at the first or optimisation clinic. All cases were checked against an objective previously validated SS-FEVAR criteria (see Table 3 below and chapter 4 for full development). Those deemed suitable for SS-FEVAR, as assessed by the criteria in Table 3, and by the clinical team, were entered into the SS-FEVAR pathway.

	Criteria
Social	Transport available Adult observer available for 24 h post-discharge Absence of significant immobility
Distance	< 100km
Age	<90 years
Body mass index (kg/m2)	<35
ASA grade	<=3
Advanced liver disease	Absent
Cognitive impairment	Absent
eGFR (mL/min/1.73m2)	>= 45
Ischemic heart disease	No myocardial infarction in past 6 months
Cerebrovascular disease	No stroke in past 1 year
Heart failure	No severe heart failure (ejection fraction <40%)
Chronic lung disease	No severe COPD (FEV1 <50%) or other severe respiratory disease
Diabetes	No insulin-dependent diabetes

SS-FEVAR: short-stay fenestrated endovascular aneurysm repair; ASA: American Society of Anaesthesiologists; eGFR: estimated glomerular filtration rate; COPD: chronic obstructive pulmonary disease; FEV1: forced expiratory volume in 1 s.

Table 3: SGVI short stay aneurysm criteria (SSFEVAR).

2.8.3.2 SGVI Short stay aneurysm care bundle

The SS-FEVAR pathway includes the short stay aneurysm care bundle outlined in appendix 2 and described in section 2.8.1.3 in addition to the current standard of care (SoC) components of the current pathway. A timeline-based outline of the program when compared to SoC can be seen in Figure 4 below.

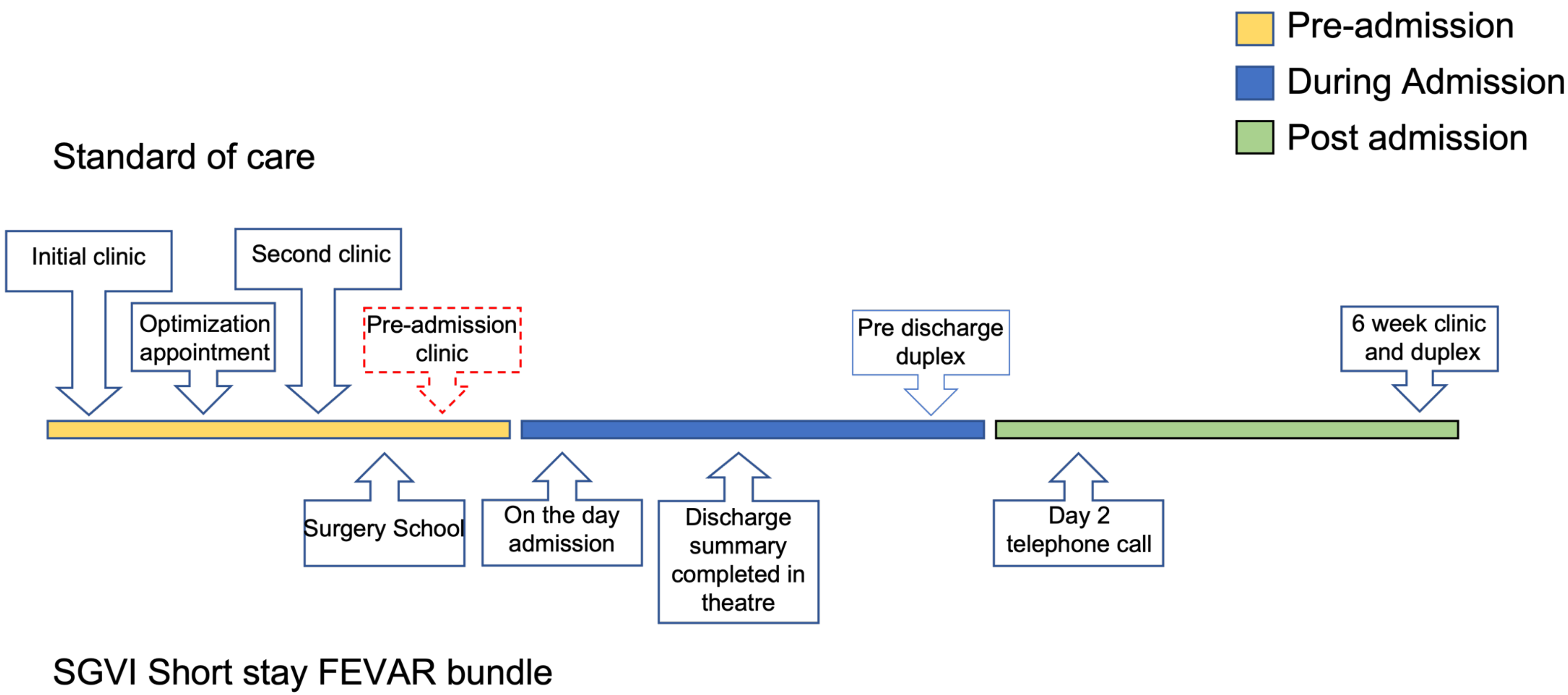


Figure 4: Comparison of standard of care and SGVI SS-FEVAR pathway

2.8.3.3 Data collection

Demographic data and past medical history were collected on all patients in the cohort.

Demographics collected included:

- Age
- Sex
- Distance from the hospital

Distance from the hospital was calculated using the google maps distance matrix API: https://developers.google.com/maps/documentation/distance-matrix

The API was accessed using a custom coded Python 3 script (See appendix 4)

This was used with the St George's post code and that of the patient's home address listed on the electronic health records. Distance was calculated as the shortest journey by car between the two points.

Comorbidities were collected to adequately rate the patient against the short stay criteria listed in Table 2. In addition to this the following information and comorbidities were also collected:

- ASA score
- Current and past smoking status
- Diabetes
- Hypertension
- Hypercholesterolemia
- History of Myocardial infarction and if this was greater than 6 months ago
- History of ischemic heart disease
- Previous TIA or stroke and if this was greater than 1 year ago
- Chronic lung disease
- Heart failure
- Ejection fraction (%)
- Chronic kidney disease
- eGFR
- History of cancer and if this was treated, under surveillance or active.

Chronic kidney disease where present was rated by stage:

- Stage 1: normal function eGFR >90
- Stage 2: mild loss of function eGFR 89-60
- Stage 3a: mild to moderate loss of function eGFR 59-45
- Stage 3b: moderate to severe loss of function eGFR 44-30
- Stage 4: Severe loss of kidney function eGFR 29-15
- Stage 5: kidney failure eGFR less then 15

Ejection fraction was collected preferentially from Simpson's biplane method were stated. Where estimated ejection fraction results were stated with a range the mean value in the range was recorded.

Perioperative data collection included hospital length of stay, critical care admission and length of stay, operative complications, post-operative complications, reintervention and readmission or unplanned review up to 30 days post discharge.

Length of stay was compared to the historic cohort used to validate the SS-EVAR criteria. Only those that were selected by the pragmatic criteria were compared to with the trial population. Statistical testing was performed to compare these groups, this included testing of variance with Levene's test. Where this was significant a Mann-Whitney U test was performed and if not a two tailed independent T-test was performed.

Continuous data was presented as median and range with categorical data being presented as count and percentages.

Difference between the demographics and co-morbidities of those who successfully completed the SS-EVAR pathway (LOS of less than or equal to 36 hours) were compared. Continuous data was compared with the Mann-Whitney U test while categorical data was tested with the Chi squared test.

The project was registered as a local quality improvement project, registration number SE0014.

All statistical analysis was conducted in R version 4.0.3(20) using the RStudio(21).

Non-risk adjusted cumulative sum of failure analysis was performed to look at learning curve analysis using the ‘cusum’ package in R; cusum: Cumulative Sum (CUSUM) Charts for Monitoring of Hospital Performance (32). The failure state was set to be stays of greater then 72 hours. As no previous SS-FEVAR criteria have been previously published 72 hours was chosen as it represents a LOS that is shorter than the median LOS currently within the UK(33).

2.8.3.4 Staff pathway and bundle education

At the launch of the SS-FEVAR program the clinical team including:

- Vascular Surgery Consultants
- Vascular Surgery Registrar
- Vascular Surgery ward doctors (Senior House Officers and Foundation year 1 doctors)
- Vascular Surgery ward physicians associates
- Vascular Surgery ward Nurse in charge
- Vascular Surgery ward Nurses
- Vascular Surgery ward Pharmacists
- Vascular Scientists

Were invited to attend an educational presentation on the SS-FEVAR pathway and bundle of care ahead of its start.

This educational event was also run a second time due to concern over non-adherence with the pathway.

3. Systematic review of short stay Endovascular Aneurysm Repair programs

3.1 Abstract

3.1.1 Introduction

Short stay endovascular aneurysm repair pathways (SS-EVAR) provide potential advantages to both healthcare providers and patients. However, these benefits must be carefully balanced against the inherent risks to patient safety and tariff penalties associated with unplanned readmissions.

3.1.2 Methodology

A literature review was performed using the databases MEDLINE, Embase and Cochrane Library up until March 2019. Search terms used included "endovascular aneurysm repair", "aneurysm repair", "EVAR", "FEVAR", "fenestrated endovascular aneurysm repair", "abdominal aortic aneurysm", "day case", "short stay", "fast track" and "ambulatory".

3.1.3 Results

Nine relevant articles (including one prior review on the topic) were identified. This early data suggests that SS-EVAR is associated with good patient satisfaction and modest cost savings for healthcare providers. Patient selection, preoperative preparation and supported discharge with early follow-up are essential components of a SS-EVAR pathway.

Increasingly, SS-EVAR tends to be delivered via bilateral percutaneous access and loco-regional anaesthesia. Over 70% of patients enrolled onto SS-EVAR pathways successfully complete the pathway. Long procedures with excessive blood loss are associated with pathway non-completion. All serious complications occur within 6 hours of the procedure and the mortality (0-1%), morbidity (8-58%) and readmission rates (0-6%) associated with SS-EVAR remains acceptably low. SS-EVAR pathways can be safely and effectively implemented in both teaching and non-teaching hospitals.

3.1.4 Conclusions

Short-stay EVAR pathways are safe and acceptable to patients. With appropriate selection of motivated patients, successful expedited discharge can be achieved with

limited readmissions, thus facilitating increased resource efficiency and cost savings for healthcare providers.

3.2 Introduction

Since the introduction of short-stay surgical protocols, improvements in anaesthetic and surgical techniques, combined with positive patient outcomes and satisfaction, have resulted in an increasingly complex variety of procedures being delivered through this format(34).

However, the concept of applying this technique to abdominal aortic aneurysm (AAA) surgery is novel to clinicians, especially given the length of stay typically associated with traditional open surgical repair.

Nevertheless, with growing experience of endovascular aneurysm repair (EVAR) and the recent introduction of new technologies such as percutaneous vascular access, this concept has now become a reality. EVAR is associated with lower perioperative mortality rates compared with open repair(9) and currently in the UK, 68% of elective infrarenal AAA repairs are undertaken using this technique(35). Median length of stay following EVAR is 2 days, and 13 of the 77 (16.9%) trusts included in the National Vascular Registry reported a median length of stay of 1 day(35).

However, whilst short stay EVAR is clearly a feasible undertaking, unlike the patients typically identified as suitable for currently routine day-case procedures (e.g., laparoscopic cholecystectomy), the typical vascular patient undergoing aneurysm repair is often burdened by a higher degree of comorbidity and frailty. Whilst comorbidity alone should not be viewed as an absolute contraindication for enrolment onto short-stay pathways (as these patients often do very well with limited hospital stays),(36,37) increased frailty has been shown to enhance the length of stay and complications following EVAR(38,39).

Therefore, whilst short stay procedures are associated with good patient satisfaction and healthcare budget utilization, it is unlikely that all EVAR patients are suitable for enrolment onto these pathways. Unplanned readmission of these patients can prove costly as they often invoke tariff penalties that could potentially negate any cost savings initially made. The current overall 30-day readmission rate following EVAR in the UK is 5.8%, with an in-hospital mortality rate of 0.7%(35).

This literature review will provide clinicians with an overview of the current data analysing short stay EVAR (SS-EVAR) pathways. The potential advantages such protocols offer to patients and resource utilization will be explored, whilst also highlighting the current controversies and theoretical risks these pathways pose.

3.3 Methodology

Methods were as described in 2.2

3.4 Results

3.4.1 Search Results

A total of 570 papers were identified via the described search terms, with an additional 3 being added through review of screened paper references. Nine articles relevant to the topic were identified (see Figure 5). These articles were comprised of one prior review on the safety and cost-effectiveness of SS-EVAR pathways(40), five studies (13–15,41,42) prospectively analysing short-stay pathways and two theoretical studies(43,44) retrospectively assessed the feasibility of SS-EVAR by retrospectively analysing a historical EVAR cohort. The remaining study represented a *post hoc* analysis of one of the original prospective studies(45).

No papers were identified dealing with short stay models of care for FEVAR.

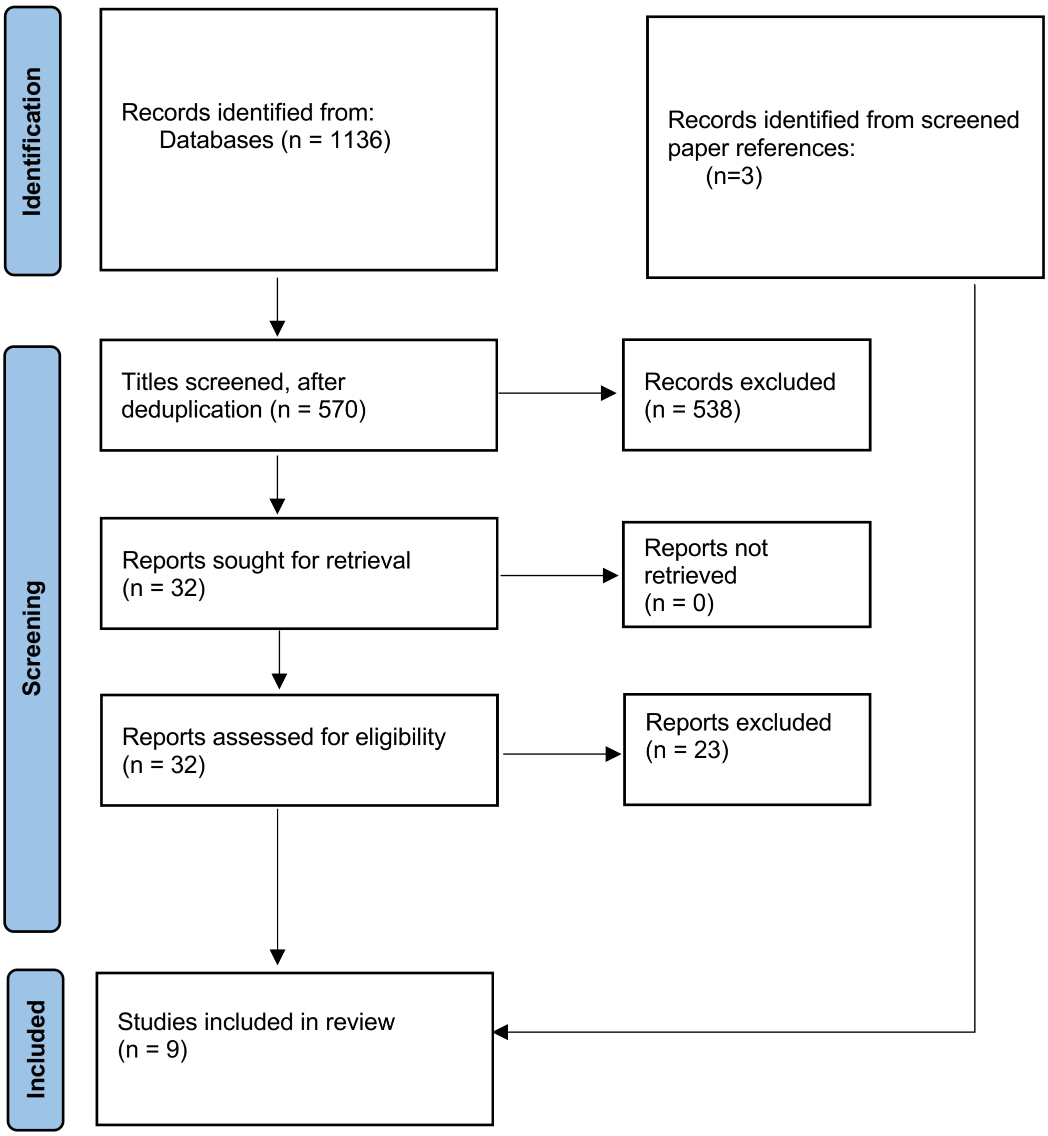


Figure 5: Literature review data collection flow diagram

3.4.2 Shorty stay program designs

The SS-EVAR protocols employed by the seven original studies currently describing this technique are laid out in Table 4. Of the studies included, three aimed for discharge on the same day as the surgery (14,42,46), two aimed for same or next day (13,43) and two aimed for discharge on the first postoperative day(15,41).

Of the prospective studies, four described a specific short stay pathway to allow preselected low risk patients to be discharged on day 0 or 1 (13,41,42), and included additional arrangements to facilitate this early charge including modified follow up arrangements (details can be seen in Table 4).

3.4.3 Prospective study program outcomes

The total number of patients that successfully underwent same or next day discharge across all prospective studies was 471/557 (85%). This represents 471/911 (52%) of the total EVAR cases assessed amongst these studies as can be seen in Table 5.

3.4.4 Retrospective study program outcomes

The total number of patients that were thought to be able to successfully undergo same or next day discharge in the reviewed retrospective studies was 85/184 (46%) as can be seen in Table 5.

3.4.5 Patient selection criteria

Patient selection criteria varied widely between the different studies (Table 4). Inclusion criteria were those mainly thought to be associated with operative success as well as good social networks to facilitate early discharge.

Exclusion criteria were able to be divided into patient comorbidities and technical factors increasing the risk of procedural complication.

In all studies, operations on ruptured or symptomatic aneurysms were excluded. Furthermore, many studies relied on intra-procedural exclusion criteria.

3.4.6 Operative technique

Choice of anaesthetic technique varied between studies (as can be seen in Table 4), representing difference in practice between different centres. In studies that examined the effect of different anaesthetic techniques, no strong significant relationship was found between anaesthetic type and length of stay(13).

Choice of vessel access varied between different studies from some studies opting for open access in all cases to mandatory percutaneous access in others. In one study, the effect of choice of access on LOS was found to be significant (p=0.016) , in the same study all the patients who were discharged on the same day as the operation underwent percutaneous access(13).

	Al-Zuhir et al (2012)(41)	Lachat et al (2013)(42)	Dosluoglu et al (2014)(13)	Moscato et al (2015)(43)	Krajcer et al (2018)(15)	Hanley et al (2018)(14)	Sylvestre et al (2019)(44)
Short-stay protocol	Next day discharge	Same day discharge	Same or next day discharge	Same or next day discharge (retrospective)	Next day discharge	Same day discharge	Same day discharge (retrospective)
Eligibility criteria	Favourable anatomy ASA Grade ≤3 BMI < 35 Dyspnoea grade ≤2 No MI past 6 months Angina classification ≤2 No CVA/TIA past 1 year Non-Diabetic (excluding diet controlled) No significant renal impairment (eGFR > 60 ml/min) No advanced liver disease No significant cognitive impairment Transport & carer support available post-operatively	Favourable anatomy No acute cardiac conditions or any other acute or unstable clinical condition or disease Not on haemodialysis Travel time to hospital ≤60 minutes & adult observer present for 24 hours Procedure duration ≤4 hours with no significant complications	Favourable anatomy Good renal function with no plans for intravenous hydration postoperatively Not medically high risk (COPD on home oxygen or CCF) Age < 80 years Good functional capacity & lives independently Adult supervision for night of surgery & live within 50 miles of hospital	Depending on postoperative course the following were relative complications: Age >80 years Presence of congestive heart failure, severe COPD, renal insufficiency Independent ambulatory status Lives near a hospital (including local community hospital)	AAA >5.0 cm with anatomy suitable for Ovation Prime Stent-graft & Percutaneous access Absence of the following: Unstable angina Unstable PAD CCF (NYHA III or IV) MI/stroke past 3 months Surgery past 30 days Connective tissue disease Bleeding disorder Haemodialysis or serum creatinine >2.0 mg/dL BMI ≥40 Home oxygen use Nursing home resident Life expectancy <1 year	Favourable anatomy Low surgical risk (based on comorbidities) Caregiver for first 24 hours after discharge No medical comorbidities Anticoagulation requiring in-hospital bridging	Favourable anatomy Normal surgical risk (according to French High Health Authority [HAS] or Society for Vascular Surgery [SVS] score), ASA ≤3 Lives within 1 hour of hospital & available carer
Operative strategy	Bilateral open common femoral artery cutdown was used in all cases	Ideally local anaesthesia with sedation used, but general anaesthesia possible	Preferred percutaneous access but surgical groin access allowed.	Percutaneous closure or surgical groin access	Mandatory bilateral percutaneous access using the 14-F Ovation	No restriction on access technique, anaesthesia technique, type of	Ideally percutaneous access but potentially surgical groin access possible if ambulatory

	All patients had a general anaesthetic & urinary catheterisation was avoided	Percutaneous access unless vessel calcification Urinary catheter for those having general anaesthesia only	Predominantly general anaesthesia. Urinary catheter placed in all patients and removed in operating room after completion	Majority underwent general anaesthesia & urinary catheterisation	stent-graft & Proglide closure. No general anaesthesia or intensive care unit admission permitted	endovascular device or use of urinary catheters	
Postoperative monitoring & Discharge plan	Single night in hospital and discharged following morning review on vascular ward	Several hours in intermediate care unit & then outpatient clinic recovery room. Examined prior to discharged & provided with complication hotline number & information	2h observation in post-anaesthesia unit before ward transfer Discharged after 6h bed rest if procedure uneventful and patient happy & ambulating Next day discharge if not	N/A (retrospective feasibility review of non-short stay pathway)	Not detailed	4 hours of bed rest in the post-anaesthesia care unit before ambulation and discharge Provided with patient information booklet	N/A (retrospective feasibility review of non-short stay pathway)
Post-discharge plan	Early telephone follow-up by vascular nurse specialist Clinic follow up at 6 weeks	Clinic appointment on first & fifth postoperative days with surgeon. Bloods, ankle/brachial index & CT performed. Further CT at 3 months	If uneventful EVAR (no type I or III endoleak) - clinic visit 2 weeks after surgery with CT imaging at 6 months	N/A (retrospective feasibility review of non-short stay pathway)	30-day follow-up	Postoperative review and imaging at 30 days	N/A (retrospective feasibility review of non-short stay pathway)
ASA; American Society of Anaesthesiologists, BMI; Body Mass Index, MI; Myocardial infarction, CVA; Cerebrovascular accident, TIA; Transient ischaemic attack, eGFR; Estimated glomerular filtration rate, CT; Computed tomography, COPD; Chronic obstructive pulmonary disease, CCF; Congestive cardiac failure, AAA; Abdominal aortic aneurysm, PAD; Peripheral arterial disease, NYHA; New York Heart Association score							

Table 4: Overview of previously employed short stay EVAR protocols

	Al-Zuhir et al (2012)(41)	Lachat et al (2013)(42)	Dosluoglu et al (2014)(13)	Moscato et al (2015)(43)	Krajcer et al (2018)(15)	Hanley et al (2018)(14)	Sylvestre et al (2019)(46)
Short-stay protocol	Next day discharge	Same day discharge	Same or next day discharge	Same or next day discharge (retrospective)	Next day	Same day	Same day (retrospective)
Successful completion of short stay pathway	101 patients assessed for SS-EVAR 33 (33%) met criteria for SEVAR 27 (81%) successfully discharged one day post-operatively	104 patients assessed for SS-EVAR 100 enrolled on pathway 96 (96%) completed same day discharge	64 patients had elective EVAR 21 (33%) discharged same day 24 (37%) on day 1 16 (25%) on day 2 or 3 3 (5%) stayed ≥4 days	67 elective EVAR (non-SS-EVAR retrospective cohort) 48 patients 72% discharged on postoperative day one	376 patients assessed for SS-EVAR 250 enrolled in SS-EVAR pathway 216 (86%) completed protocol	266 patients assessed for SS-EVAR 110 (41%) met criteria 87 (79%) successfully discharged on same day of surgery	Of 117 patients undergoing EVAR, 37 - 49% could theoretically have achieved same day discharge
Post-operative complication rate	3 patients (9%): x2 Difficulty with graft implantation x1 urinary retention and haematuria	8 patients (8%)	26 patients (41%): x1 Buttock claudication x1 Hematoma x4 Urinary retention x1 Inguinal neuritis x1 Prolonged ileus x1 Arrhythmia x1 Haematuria x1 Heart failure exacerbation x15 Post Implantation Syndrome	39 patients (58%): Respiratory failure (1.5%) Congestive heart failure (1.5%) Myocardial infarction (3.0%) Urinary retention (4.5%) Alteration in blood pressure or heart rhythm (37%)	Not described	11%	Not described

				Transient hypertension (13%) Hypotension (6%) Arrhythmia (22%)			
Mortality rate	None	None	None	None	x1 (0.4%) patient from acute respiratory failure following completion of SS-EVAR protocol	1%	Not described
30-day readmission rate	None	4 patients (4%): x2 access vessel stenosis x2 false aneurysm	1 patient (2%) for severe post-implantation syndrome	6% (not detailed)	1.6%	2% readmission rate However, 15% attended emergency department with concerns regarding access site, constitutional symptoms, urinary retention, fever, and vascular complications (deep venous thrombosis and limb occlusion)	Not described

Table 5: Outcomes of short stay EVAR pathways

3.5 Discussion

3.5.1 Current SS-EVAR protocols

A prior review on the topic revealed that most serious complications following EVAR occur within 6 hours of the procedure (40). Therefore, given this concept, all the studies included would theoretically have been able to screen for these within their post-operative observational periods. Three of the studies aimed to discharge patients on the same day of surgery following several hours of observation and ensuring appropriate recovery with regard to ambulation, urination etc(14,42,44). Two of the studies aimed for next day discharge(15,41) and the remaining two allowed for either(13,43).

3.5.2 Patient Satisfaction

There is currently a paucity of data analysing patient experiences of SS-EVAR pathways. However, very few patients specifically refused to either be enrolled onto a short stay pathway (4 of 104 patients)(42) or refused to be discharged once already participating on one (1 of 62 patients)(13), suggesting good acceptability amongst patients.

Lachat et al were the only study to report the results of a patient satisfaction survey that was provided to patients at both 5 days and 3 months post-operatively(42). This consistently showed that 97% of patients would undergo SS-EVAR again and would recommend the experience to other patients. It should be noted, however, that this study employed an intensive follow-up protocol with clinic attendance on the first & fifth postoperative days. It is, therefore, imperative that patient satisfaction is reassessed in trials utilizing a more pragmatic follow-up schedule.

3.5.3 Cost-effectiveness

Two prospective studies(41,42) and two retrospective reports(43,44) have conducted preliminary costing analysis of their SS-EVAR pathways.

It is known that the operative costs (especially endograft cost) account for a large proportion of the inpatient costs associated with an admission for EVAR(47). As a result of these high operative costs, in their retrospective study, Moscato et al felt that significant cost savings would likely be unattainable by implementing a same-day discharge pathway(43). Indeed, they found the total costs for patients staying <20, 21-24 and >24-36 hours were \$28,063, \$27,575, and \$26,554 (p=0.51), respectively.

However, Al-Zuhir et al showed that the costs associated with their SS-EVAR pathway was significantly lower than standard care (£9844 v £13,360, p<0.0001)(41). Furthermore, with increased adoption of SS-EVAR within their institution over the course of the study (from 30% to 45%), they found that the average total EVAR cost decreased from £12,102 to £10,330 (p<0.0001). Similarly, Lachat et al found similar modest cost savings when comparing 21 of their same-day discharge EVARs to 21 patients not enrolled onto a SS-EVAR pathway (€13732 v €15903, p=0.05)(42). Sylvestre et al also showed in their retrospective feasibility study that the potential costing mark-up of implementing an ambulatory EVAR pathway would be +7.5%(44).

On a national level, in their previous review, Shaw et al hypothesised that if the UK conducted half of its EVARs using a next-day discharge pathway, for the 2900 elective EVARs performed annually, approximately £1.8 million could be saved by reducing bed occupancy rates(40).

Ultimately therefore, whilst it is likely that short-stay pathways may provide some cost savings, this is expected to be specific to the individual tariffs and reimbursement rates of various healthcare providers.

3.5.4 Pathway completion

The completion rates for patients enrolled onto SS-EVAR pathways in these early, feasibility studies are encouraging. For the two trials offering same-day discharge, the successful completion rate was 79-96%(14,42), which was similar to the two studies analysing next-day discharge, where the completion rate was 81-86%(15,41) (see Table 5). In their study comparing either approach, Dosluoglu et al were successful in discharging 33% patients on the same day, with a further 37% returning home the next day(13).

In all studies, the reasons for failure to successfully complete all stages of the SS-EVAR pathway primarily consisted of acute deterioration of medical conditions, unexpected technical factors during the EVAR and a range of unanticipated social and logistical factors. The proportions of each vary between trials and are likely explained by differential patient selection criteria and pathway protocols. For example, Hanley et al had a relatively higher proportion of technical reasons (61%) than medical (35%) and social (4%) factors(14), in comparison to the Dosluoglu et al group who had a far higher rate of medical complications (technical 18%, medical 64%, and social 18%)(13).

Several studies have attempted to elucidate the factors associated with non-completion of SS-EVAR pathways(13–15). Interestingly, all three studies found that patients who did not complete the pathway had significantly longer procedure times and more blood loss. This emphasizes the dynamic monitoring required on SS-EVAR pathways, such that a low threshold maintained for removing enrolled patients from the pathway should their procedure become unexpectedly complicated intraoperatively. Other factors heterogeneously reported to be associated with non-completion included smaller external iliac artery diameter(15), presence of heart failure(15), older age(13), larger aneurysms(13), ASA class ≥4(13), home oxygen therapy(13), general anaesthesia use(14) and unexpected use of operative adjuncts(14).

3.5.5 Patient Safety

The in-hospital complication, mortality and 30-day readmission rates are shown in Table 5. Whilst these early studies have, understandably used somewhat conservative patient selection criteria(41) and follow-up protocols(42), encouragingly there were no mortalities in all but two studies(14,15). Furthermore, the mortality rate remained very low in both of these series (0.4% and 1%).

Post-operative complications for the studies prospectively assessing SS-EVAR protocols ranged from 8 to 41%(13,42), which was lower than the rates seen in studies that retrospectively assessed series of non-SS-EVAR patients (58%)(43). A previous review identified that all serious complications requiring intervention occurred within six hours of the EVAR, hence making same-day discharge a feasible option following a period of observation(40).

Unexpected readmissions represent a crucial factor in the success of SS-EVAR pathways. As discussed earlier, whilst a modest cost saving can likely be made through SS-EVAR, many global healthcare providers will refuse to reimburse tariffs associated with unexpected readmissions. Therefore, a high readmission rate could negate any potential cost savings, or even increase overall EVAR expenditure for units, and will need to be taken into account in future cost-effectiveness trials. The readmission rate for the studies using a next-day discharge protocol was 0-2%(15,41), slightly lower than the 2-4%(13,14,42) for same-day discharge trials. Whilst this was lower than the 5.8% readmission rate reported in the United Kingdom National Vascular Registry(35), it should be noted that in one same-day discharge study, 15% of patients returned to the emergency department for a range of complaints(14). Whilst most did not actually require admission, this extra workload would need to be considered by any units considering implementing SS-EVAR pathways.

3.5.6 Patient Selection

A considerable proportion of patients undergoing aneurysm repair are known to have an element of frailty, which has been shown to increase 30-day morbidity and mortality following EVAR(39). Therefore, the traditional patient selection criteria used for standard short-stay procedures may not be appropriate for SS-EVAR pathways(36).

The selection criteria used in the current SS-EVAR studies are detailed in Table 4. Indeed, note can be made of how heterogenous the criteria employed by the various studies are. Generally, all criteria consist of an array of medical, surgical/technical, and social/logistical criteria. No consistent differences are noted in the criteria of same- or next-day discharge studies. Ultimately, most studies stress the importance of a employing a personalised approach when enrolling individual patients on SS-EVAR pathways and highlight the importance of clinical opinion in addition to selection criteria when determining appropriateness for selection. However, the degree of criteria subjectivity varied between trials. For example, whilst certain studies define exact exclusion criteria for certain co-morbidities(41), others simply suggest the avoidance of "any acute or unstable clinical conditions"(42).

When selecting which elective infrarenal EVAR patients are suitable for SS-EVAR, the main reasons for non-selection included medical (34%), technical (49%), and social (17%) explanations in one study(14). Al-Zuhir et al found that 67% (n = 68) elective patients were not suitable for SS-EVAR again for similar reasons with 41% due to medical factors (unstable cardiac, pulmonary and renal disease), 34% resulting from anticipated technical reasons (adjunctive procedures required) and 25% due to social and logistical issues (transport and pre-assessment clinic problems)(41). In the one trial that mandated specific endograft use (the low-profile 14F Ovation stent-graft), 46%

were excluded for anatomical unsuitability for either the endograft or percutaneous closure device(15).

Whilst each vascular unit will likely require a unique set of selection criteria tailored to the SS-EVAR programme, more research needs to be invested into determining whether a specific set of selection criteria can optimize the equilibrium between including a good proportion of elective cases whilst limiting complications and unplanned readmissions.

3.5.7 Operative and peri-operative strategy and care

Following the appropriate selection of patients for enrolment onto SS-EVAR pathways, an important aspect of short stay surgery is pre-procedural preparation to educate patients and their family about the operation and to manage any specific expectations or concerns they have regarding same or next day discharge following their EVAR(36). This is also an opportunity to identify any potential areas for health promotion and pre-habilitation(48) and can be conducted several weeks prior to the procedure by either appropriately trained surgeons or vascular nurse specialists who are familiar with the SS-EVAR pathway.

On the day of surgery, the SS-EVAR case should take priority on the operating list and be completed as soon as possible in order to allow for appropriate monitoring prior to discharge. Ideally, it would be sensible if a hospital bed could be isolated and 'ring-fenced' for streamlined SS-EVAR patients; as bed shortages during times of high bed occupancy rates will likely result in delayed operative starts and make the successful achievement of SS-EVAR more difficult.

The specific operative strategies used in the studies are detailed in Table 4. Whilst the initial study on the topic used surgical groin exposure for vessel access(41), percutaneous EVAR has been viewed as an important factor in the ability to delivery SS-EVAR by reducing operative time, length of stay, access complications, discomfort and cost(49). For subsequent trials, percutaneous access was preferred in suitable patients, however, surgical access is generally not deemed as an absolute contra-indication to SS-EVAR.

Only one study specified the use of the specific low-profile 14F Ovation stent-graft as part of the Least Invasive Fast-Track EVAR (LIFE) registry(15). The remaining studies either did not specify the endograft type used or employed a variety depending on individual anatomy etc. This pragmatic approach of using various graft types would likely make far more patients suitable for SS-EVAR rather than mandating a specific endograft type. Clinicians should be aware of the potentially higher rates of post-implantation syndrome (PIS) noted with the use of polyester endografts (e.g. Dacron) when compared to polytetrafluoroethylene grafts(50,51). Dosluoglu et al confirmed in their SS-EVAR cohort that PIS was more prevalent in patients who had Dacron grafts implanted (31-60% vs 10-12%) and this resulted in increased length of stay in five (8%) patients with one subsequent (2%) unexpected readmission(13).

Three studies predominantly used general anaesthesia(13,41,43), whilst the other four opted for loco-regional techniques(14,15,42,44). This likely reflects local expertise and supports the concept that the use of general anaesthesia need not be a contraindication to SS-EVAR. However, in their same-day discharge study, Hanley et al did recognise use of general anaesthesia to be associated with pathway non-completion(14). Of note, both prospective studies aiming for same-day discharge preferred the use of loco-regional anaesthesia, percutaneous access and avoidance of urinary catheters(14,42).

Urinary retention is a common problem following EVAR and was noted in up to 6% of patients in some of the SS-EVAR studies(13). It was also noted as the cause of post-operative emergency department attendance in 2% of patients in another study(14). Therefore, urethral catheters tended to either be avoided(41,42) or removed early(13) in the studies. Any centre attempting SS-EVAR should have a well-defined ambulatory urinary retention protocol to prevent patient harm and hopefully avoid admission should patients attend the emergency department with this problem post-operatively.

As alluded to earlier, longer procedures with excessive blood loss were consistently associated with unsuccessful completion of the pathway(13–15). Therefore, clinicians should have a low threshold for removing patients from the pathway if the EVAR is more complex than initially expected, especially if new to the process of SS-EVAR.

Following EVAR, nearly all serious complications requiring immediate reintervention or intensive care unit admission occur within six hours of the procedure(40). Therefore, all patients should be carefully monitored over this period, ideally in a post-anaesthesia recovery unit for at least 2-4 hours(13,14). If aiming for same-day discharge, patients can then be transferred to a ward or recovery area where an assessment of ambulation, eating and urination can be made.

For those implementing next-day discharge; patients can be monitored overnight and then discharged within a '23 hour' protocol, whereby the patient is discharged early the following morning so a bed can be made available for another patient to commence the pathway. All patients must be examined by the surgical team prior to discharge to ensure the patient is well post-operatively with no access site complications.

Prior to discharge, patients and their carers (who should be present with the patient for at least 24 hours) should be made aware of the possible signs of post-operative complications and provided with appropriate contact details. Providing patients with appropriate post-operative support is crucial and may help prevent unnecessary emergency department attendances and even unexpected readmissions(14).

The authors would recommend early telephone follow-up of patients by surgeons or nurse specialists on day one post discharge and several days following this, with patients being able to contact the vascular team easily if required. The patient should then be reviewed in clinic 4-6 weeks post-operatively with appropriate imaging.

3.5.8 Centre Selection

Prior studies have suggested improved outcomes, such as reduced length of stay, for EVARs performed at major teaching hospitals(52). Therefore, as a *post-hoc* analysis of the aforementioned LIFE registry, Rajasinghe et al compared the outcomes of fast-track EVARs conducted at teaching (n = 186) versus non-teaching (n = 64) hospitals(45).

Whilst more procedures were performed in operating rooms in non-teaching hospitals rather than specialized hybrid or radiological suites, procedural and room times were similar in both groups. Overall completion of the various components of the SS-EVAR pathway was significantly lower in the non-teaching hospital group, mainly because of higher intensive care usage (1% vs 16%). However, no significant difference was noted in next-day discharge achievement rate (94% vs 88%). Furthermore, there was no difference in the incidence of major adverse events, secondary interventions, mortality or 30-day readmissions (1% vs 3%). These findings remained following propensity score matching. Therefore, it would appear that SS-EVAR can be provided safely in both teaching and non-teaching hospitals(45).

Due to the centralisation of vascular surgery services especially in regard to aortic procedures in the UK, it is unlikely that any centre performing endovascular aneurysm repair would be poorly placed to provide SS EVAR pathways.

3.6 Conclusions

As laid out in this chapter there is a growing body of evidence suggests that short-stay EVAR pathways are both safe and acceptable to patients. With the potential for healthcare providers to increase resource efficiency and reduce expenditure, an expansion of this technique should be strongly considered.

Of patients enrolled onto these SS-EVAR pathways, over 70% complete all parts of the protocol. The success of SS-EVAR pathways likely stems from the selection of appropriate patients who are subsequently motivated and educated towards achieving expedited discharge.

Competent operating with primarily percutaneous access, followed by supported discharge ensures that patient safety is maintained and limits unexpected readmissions. Further research should be conducted to elucidate exactly which patients are most appropriate for inclusion, in addition to more detailed analysis of patient satisfaction and pathway cost-effectiveness.

4. Short Stay Endovascular Aneurysm repair criteria formation

4.1 Introduction

Length of stay has become a major concern for many healthcare providers not only due to its effect and relationship on patient experience and outcomes, but also because of the fiscal effect that it has on the cost of operations. It is for these reasons that that many operations are now conducted on an ambulatory basis(36). This is also in keeping with efficiency reforms that have been ongoing since the turn of the millennium(53).

4.1.1 Short stay EVAR program context and current limitations

Infrarenal Endovascular Aortic Aneurysm Repair (EVAR) is one such procedure where short stay (SS) models of care have been previous published (40). Part of the development of these pathways was due to the advances in experience with the technique coupled with new technology including percutaneous vascular access(54). As well as the significant lowered short term mortality that EVAR affords over open surgical repair(9).

In the UK, 68% of elective infra-renal AAA repairs are performed via an endovascular approach, and the median length of stay for these cases is 2 days(35). Currently, 13 of the 77 (16.9%) trusts included in the National Vascular Registry (NVR) reported a median length of stay of 1 day.

Although an apparently attractive option to improve efficiency, the potential benefits of implementing SS-EVAR pathways must be closely considered against the inherent risks to patient safety and tariff penalties. The 30-day readmission rates following elective EVAR in the UK are 5.8%(35), double that cited for other operations routinely undertaken as day-case procedures (e.g. laparoscopic cholecystectomy)(55). Whilst the necessity for readmission is concerning for patient safety and experience, it also has significant implications for clinical costing since certain healthcare providers have reduced tariff reimbursement for unplanned readmissions within 30 days(56).

The selection of appropriate patients is, therefore, likely to be an important factor in the success of any SS-EVAR pathway. Although medically comorbid patients can achieve excellent outcomes with traditional day case procedures(34), certain risk factors such as advanced age and frailty are known to predispose patients undergoing elective EVAR to increased perioperative complications and slower recovery(39,57,58).

The few preliminary studies assessing SS-EVAR have used various specific criteria to select patients for their pathways(13–15,41–43,46). However, the criteria used thus far have been heterogeneous and occasionally contain either narrow inclusion criteria or somewhat subjective factors (see Table 4). Ultimately, in several of these studies, this has either resulted in the inclusion of a small proportion of elective EVAR patients or high rates of complications with low rates of successful SS pathway completion (see Table 5).

4.1.2 Short stay FEVAR program context and current limitations

Although the advantages of short stay EVAR programmes have been described since 2012 no such selection criteria have been published for FEVAR.

Between January 2017 to December 2019, 1303 Fenestrated Aortic Aneurysm Repairs (FEVAR) were performed in the UK with a median length of stay of 4 days (33).

As with EVAR it must be noted that FEVAR has a much higher rate of readmission (5.7% for EVAR and 7.6% for FEVAR(33)) than many other operations that are undertaken as day case operations (e.g. laparoscopic cholecystectomy)(55). Thus, as discussed with EVAR above, it is imperative that cases that are of low risk for readmission can be easily and objectively identified if a SS-FEVAR program is to be safe and cost effective. This is not only important from a patient's point of view but also has large ramifications on the cost of delivery of FEVAR as many healthcare providers have reduced or no tariff reimbursement for unplanned readmission within 30 days(56).

Due to the similarity of the disease process of infra and juxta-renal aneurysms and the endovascular treatment of each, especially when undertaken in a completely percutaneous manner, we believe that the application of a shared SS-EVAR and SS-FEVAR criteria would translate well to elective FEVAR outcomes.

4.1.3 Chapter aims

The aim of this chapter was to determine whether the implementation of a novel set of high-risk pre-operative patient selection criteria for a theoretical SS-EVAR and SS-

FEVAR pathway could facilitate an expansion of the proportion of patients suitable for both, whilst maintaining patient safety and limiting unplanned emergency readmissions. Section 4.2 will address this question in SS-EVAR and section 4.3 will do so for SS-FEVAR.

4.2 Development of novel patient selection criteria for a short stay endovascular aneurysm repair pathway.

4.2.1 Abstract

4.2.1.1 Objectives:

A short-stay endovascular aneurysm repair (SS-EVAR) pathway for infrarenal abdominal aortic aneurysms offers the potential to improve service efficiency and patient satisfaction by reducing the hospital length of stay. This study aimed to determine whether the implementation of a novel set of patient selection criteria for a theoretical SS-EVAR pathway could facilitate an expansion of the proportion of suitable patients, whilst maintaining patient safety and limiting unplanned emergency readmissions.

4.2.1.2 Methods:

Two SS-EVAR selection criteria (conservative and pragmatic) were generated based upon patient pre-operative comorbidities. The conservative criteria essentially selected fit and healthy individuals, whereas the pragmatic criteria included patients with a range of comorbidities that could still theoretically enable enrolment onto a SS-EVAR pathway. Via retrospective analysis both criteria were applied to all elective EVARs recorded in the National Vascular Registry between 2013 and 2016 at a single tertiary vascular unit. Rates and timings of postoperative complications, reinterventions and unplanned readmissions for patients meeting each criterion were assessed.

4.2.1.3 Results:

In total, 188 patients were included (92% male, mean age 75.4 ± 7.2 years). Twenty-nine patients (15%) met the conservative criteria. Two (7%) of these experienced an inpatient complication which were both detected within 24 hours of operation (including one who required reintervention), no patients in this group had an unplanned readmission within 30 days. One-hundred and ten patients (59%) met our pragmatic criteria and 19 (17%) experienced an inpatient complication, with 4 (4%) of these occurring beyond 24 h post-EVAR (three urinary problems and one acute on chronic kidney injury). Six (6%) of these patients required a reintervention; however, all these complications were detected within 24 h. Two (2%) pragmatic cohort patients required

unplanned readmission within 30 days for a femoral pseudoaneurysm and musculoskeletal back pain.

4.2.1.4 Conclusions:

With the pragmatic patient selection criteria and appropriate post-operative safeguards, up to 60% of infrarenal abdominal aortic aneurysms patients could be safely enrolled onto a next-day discharge SS-EVAR pathway with minimal readmissions, thus allowing more effective resource utilisation.

4.2.2 Methodology

Methods were as described in 2.3

4.2.3 Results

Throughout the study period, a total of 615 EVARs were performed and 188 of these met the inclusion criteria; 248 patients were excluded for complex aortic procedures, 25 EVARs were revision interventions, 84 patients had symptomatic or ruptured aneurysms and 70 patients underwent combined procedures as planned (see Figure 6).

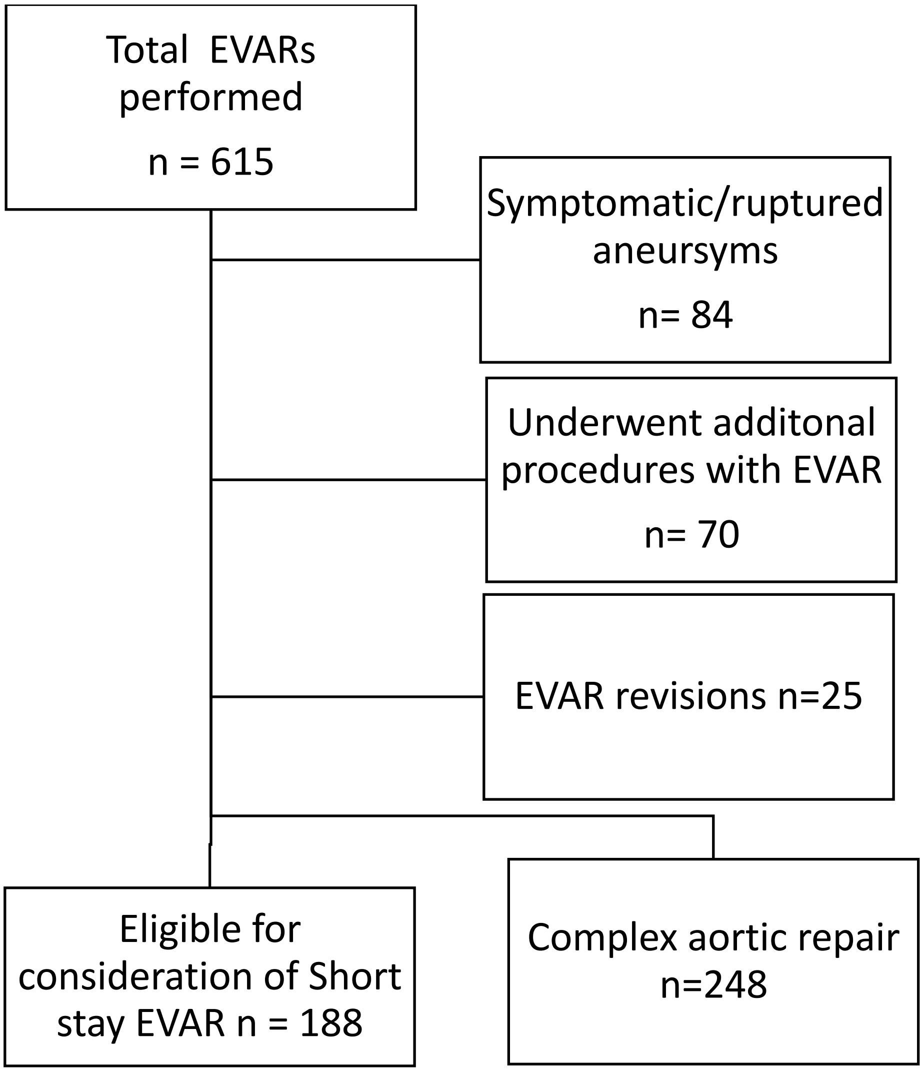


Figure 6: Exclusion of patients who were not deemed to be eligible for consideration of enrolment into a SS-EVAR pathway.

Of the 188 included patients, 77% were performed with a total percutaneous approach and 23% required surgical groin exposure. Overall, 29 (15.4%) patients fulfilled the conservative criteria and 110 (58.5%) met the pragmatic criteria. Criteria as laid out below in Table 6.

	conservative criteria	pragmatic criteria
Social	Transport available Adult observer available for 24 h post-discharge Absence of significant immobility	
Distance	<100km	< 100km
Age	<80 years	<90 years
Body mass index (kg/m2)	<35	<35
ASA grade	<=3	<=3
Advanced liver disease	Absent	Absent
Cognitive impairment	Absent	Absent
eGFR (mL/min/1.73m2)	>60	>= 45
Ischemic heart disease	No history of ischemic heart disease	No myocardial infarction in past 6 months
Cerebrovascular disease	No history of stroke or transient ischemic attack	No stroke in past 1 year
Heart failure	No heart failure	No severe heart failure (ejection fraction <40%)
Chronic lung disease	No chronic lung disease	No severe COPD (FEV1 <50%) or other severe respiratory disease.
Diabetes	No history of diabetes	No insulin-dependent diabetes

SS-FEVAR: short-stay fenestrated endovascular aneurysm repair; ASA: American Society of Anaesthesiologists; eGFR: estimated glomerular filtration rate; COPD: chronic obstructive pulmonary disease; FEV1: forced expiratory volume in 1 s.

Table 6: Patient selection criteria for SS-FEVAR.

The proportion of patients excluded from each group is detailed in Table 7. The demographics and medical comorbidities for the cohort are detailed in Table 8.

Of the patients excluded from the two groups in this study, in our pragmatic cohort, low glomerular filtration rates, severe respiratory disease and high American Society of Anaesthesiologists (ASA) scores resulted in most criterion exclusions (accounting for

13, 9 and 21% patients, respectively). For the conservative cohort, in addition to these criteria, patient age, ischaemic heart disease, heart failure, diabetes mellitus and cerebrovascular disease also accounted for a large number of exclusions from the SS-EVAR pathway (see Table 7).

Criteria	Conservative criteria (n=29)	Number patients excluded due to criterion	Pragmatic criteria (n=110)	Number patients excluded due to criterion
Distance from hospital	<100 km	3 (1.6)	<100 km	3 (1.6)
Age	<80 years	63(33.5)	<90 years	0 (0)
Body mass index (kg/m2)	≤35	7 (3.7)	≤35	7 (3.7)
ASA grade	≤3	40 (21.3)	≤3	40 (21.3)
Advanced liver disease	Absent	0 (0)	Absent	0 (0)
Cognitive impairment	Absent	5 (2.7)	Absent	5 (2.7)
eGFR (mL/min/1.73m^2)	>60	58 (30.8)	>45	25 (13.3)
Ischemic heart disease	No history of IHD	81 (43.1)	No MI in past 6 months	0 (0)
Cerebrovascular disease	No history of stroke or TIA	21 (11.1)	No stroke in past year	1 (0.5)
Heart failure	No HF	36 (19.1)	No severe heart failure (EF <40%)	3 (1.6)
Chronic lung disease	No Chronic lung disease	52 (27.7)	No severe COPD (FEV1 <50%) or other severe respiratory disease	16 (8.5)
Diabetes	No history of diabetes	28 (14.9)	No insulin-dependent diabetes	1 (0.5)

All values in parentheses are percentages of total EVAR population (n=188).

ASA: American Society of Anaesthesiologist; eGFR: estimated Glomerular filtration rate; COPD: Chronic Obstructive Pulmonary Disease; FEV1: Forced Expiratory Volume in 1 second.

Table 7: Number of patients excluded from the conservative and pragmatic SS-EVAR criteria.

	Total cohort (n = 188)	conservative criteria cohort (n= 29)	pragmatic criteria cohort (n= 110)
Demographic			
Mean age (years) [a]	75.4 (±7.2)	69.8 (±6.0)	74.7 (±7.6)
Sex ratio (M:F)	173 : 15	29 : 0	104 : 6
Mean distance from hospital (km) [a]	15.0 (±29.1)	11.8 (±8.9)	11.7 (±8.1)
Comorbidities			
AAA size (mm) [a]	62.0 (±9.2)	61.8 (±8.8)	61.3 (±9.1)
ASA Grade[a]	3.1 (±0.6)	2.7 (±0.5)	2.8 (±0.4)
Obesity	49 (26)	7 (24)	23 (21)
Diabetes	28 (15)	0 (0)	15 (14)
Hypertension	151 (80)	20 (69)	84 (76)
Chronic lung disease	52 (28)	0 (0)	27 (25)
Severe COPD	16 (9)	0 (0)	0 (0)
Ischemic heart disease	81 (43)	0 (0)	0 (0)
Myocardial infarction past 6 months	0 (0)	0 (0)	0 (0)
Chronic heart failure	36 (19)	0 (0)	6 (5)
Ejection fraction (%)[a]	57.6 (±6.3)	59.3 (±5.3)	57.9 (±5.0)
Chronic renal disease	44 (23)	0 (0)	15 (14)
Cerebrovascular disease	21 (11)	0 (0)	9 (8)
Hypercholesterolaemia	138 (73)	18 (62)	85 (77)
Current smokers	52 (28)	9 (31)	36 (33)
History of cancer	31 (17)	6 (21)	16 (15)

Values in parentheses are percentages unless otherwise stated.

[a]Values are mean (±standard deviation).

AAA: abdominal aortic aneurysm; ASA: American Society of Anaesthesiologists; COPD: chronic obstructive pulmonary disease.

Table 8: SS-EVAR Demographics and comorbidities.

4.2.3.1 Length of stay

The total cohort had a median length of hospital stay of 4 (±3) days, with a postoperative stay of 3 (±2) days as patients were routinely admitted the evening prior to operation during the study period. Forty-eight patients were admitted to critical care post-operatively with a median stay of 1 (±1) day. For the conservative group, median length of hospital stay was 3 (±1) days and three patients were admitted to critical care post-EVAR with a median stay of 1 (±0.5) days. In the pragmatic cohort, median length of hospital stay was 4 (±2) days, and 25 patients were admitted to critical care post-operatively and remained there for 1 (±1) day.

4.2.3.2 Complications

In the entire cohort, there were no deaths during hospital admission, nor at 30 days post-EVAR. Overall, 38 inpatient complications developed in 31 (17%) patients, with 21 (68%) patients having their complication recognised within 24 h of EVAR. The proportions of complications occurring in each patient group and their time to recognition are detailed in Table 9.

Inpatient complications occurring beyond 24 h post-EVAR (and hence following discharge if on a SS-EVAR pathway) only occurred in the pragmatic cohort. In total, there were four of these complications; two were urinary retention, one was a urinary tract infection treated with oral antibiotics and the final case was a patient with chronic kidney disease (baseline glomerular filtration rate 55mL/kg/1.73m2) who developed an acute kidney injury on day 2 post-operation who was treated with rehydration. In addition to these cases, six further patients in the total cohort developed complications over 24 h post-EVAR and included one stroke, three urinary tract infections and two chest infections.

	Total cohort	Conservative criteria cohort	Pragmatic criteria cohort
Total number of patients who had complications	31 (17)	2 (7)	19 (17)
Number of complications occurring within 24 h post-EVAR	21 (68)	2 (100): 1x vasovagal episode (found to have groin haematoma) 1x return to theatre for ischemic leg secondary to femoral artery dissection	15 (79): 1x vasovagal episode (found to have groin haematoma) 1x return to theatre for ischemic leg secondary to femoral artery dissection 3x Urinary retention 3x Myocardial infarction 1x Bradycardia requiring medical management 1x Stroke 3x Iliac Limb Stenosis requiring further endovascular intervention 2x Femoral Pseudoaneurysm (requiring thombin injection)
Number of complications occurring after 24 h post-EVAR	10 (32)	0 (0)	4 (21): 1x Acute on chronic kidney injury 1x Urinary tract infection 2 x Urinary retention
Inpatient reinterventions	7 (4)	1 (3)	6 (6)
Unplanned 30-day readmissions	4 (2)	0 (0)	2 (2): 1x Femoral Psuedoaneursym 1x Musculoskeletal back pain (treated conservatively)

Values in parentheses are percentages

Table 9: Post-operative complications and unplanned readmissions.

Seven patients required reintervention during the post-operative period; however, all these complications were identified within 24 h post-EVAR. Six of the patients were in the pragmatic group and included two femoral pseudoaneurysms, one femoral artery dissection and three cases where EVAR limb extension was required for kinking/stenosis. The remaining case not included in the pragmatic group was a patient with a type 1b endoleak who required stent relining and extension.

Following discharge, four patients were readmitted within 30 days; two of these patients were in the pragmatic cohort and included one patient with a femoral pseudoaneurysm that was not present on predischarge duplex ultrasound and another patient with musculoskeletal back pain that was managed conservatively following normal investigations. The remaining two patients (included in neither cohort) both had groin infections that required surgical drainage and antibiotic therapy.

4.2.4 Discussion

This study has shown that the implementation of a novel pragmatic patient selection criteria may identify a good proportion of elective EVAR patients (59%) who can be safely enrolled onto a next day discharge SS-EVAR pathway. Using these criteria, potentially serious complications were identified during inpatient stay and unplanned readmissions minimised.

Naturally, the first study investigating SS-EVAR implemented relatively stringent selection criteria which limited the proportion of elective EVAR patients suitable for enrolment onto pathways (33% – see Table 5). In the two subsequent studies, the exclusion criteria were relaxed(13,42); however, this was associated with an increase in the rates of postoperative complications (up to 41%(13)) and unplanned readmissions (up to 4%(42)).

Of the 110 (59%) patients in this study that met the pragmatic criteria, 19 (17%) developed post-operative complications. Importantly, 15 (79%) of these occurred within 24 h post-operatively and hence would have been detected if enrolled on a SS-EVAR pathway. This included the six patients who required reintervention and thus supports the previously described idea that the most serious immediate EVAR complications occur within the first six hours of the procedure(40).

Of the four complications occurring beyond 24 h post-EVAR in the pragmatic criteria cohort, three were urinary problems that could potentially have been managed on an ambulatory basis, meaning that only one patient (0.9%) would have likely required readmission. In addition to the two patients who had unplanned readmissions within 30 days (despite not actually being on a SS-EVAR pathway), this combination represents a 2.7% readmission rate (or 5.4% if including the three minor urinary complications) which reflects well compared to the 5.8% national average(35). This is crucial to the success of an SS-EVAR pathway due to the financial penalties now associated with the non-reimbursements of tariffs for unplanned readmissions. Of the previous prospective SS-EVAR studies, readmission rates ranged from 2 to 4%(13,42). However, in the recent study by Hanley et al.,(14) in addition to the 2% of patients readmitted, 15% of patients attended the emergency department within 30 days of their EVAR for various postoperative complications(14).

The more liberal criteria employed in our pragmatic cohort allowed a far higher proportion of patients to be included on the SS-EVAR pathway than with the conservative criteria (59 vs. 15%). Importantly, patient safety was maintained with these pragmatic criteria, with nearly all complications being detected within 24 h and only 2.7% of patients likely requiring readmission. Therefore, it is likely that patients up to the age of 90 with a range of relatively controlled comorbidities (no myocardial infarction within past six months, no stroke within past 1 year, no severe heart failure with ejection fraction <40%, no severe respiratory disease with FEV1<50% or non-insulin dependent diabetes) can be safely enrolled onto SS-EVAR pathways. However, we must emphasize that the personal opinion of the consulting physician is also an imperative factor in deciding whether each patient is suitable for inclusion.

From this finding it would seem reasonable that the patients fulfilling both our criteria would be suitable for telephone follow-up (nurse or surgeon led) within the week of discharge before routine outpatient follow-up six weeks postoperatively. Some of the earlier studies employed more intensive outpatient follow-up following discharge. For example, Lachat et al.(42) organised outpatient follow-up on the first and fifth days postoperatively, and whilst this regimen still proved to be popular with patients, this may be logistically difficult for other healthcare providers to deliver.

The inclusion criteria in this study did not specify the usage of a specific endograft, anaesthetic type or vascular access technique. This is to allow the maximise the number of patients suitable for our SS-EVAR pathway and was deemed reasonable as previous studies have had acceptable results with general anaesthesia and surgical groin access(41).

However, percutaneous EVAR was predominantly adopted in this study (77%) and should be viewed as an important tool for SS-EVAR pathways, given its ability to reduce operative time, length of stay, access complications, discomfort and cost(49). It should be noted that one study did report general anaesthesia usage to be associated with pathway non-completion(14), and indeed, the two most recent prospective SS-EVAR studies have predominantly employed loco-regional anaesthetic techniques(14,15).

The recent multicentre least invasive fast-track EVAR registry mandated a percutaneous approach and the use of the low-profile 14 F Ovation Prime Abdominal Stent Graft System (Endologix Inc., Irvine, CA, USA)(15). Any patients requiring general anaesthesia, critical care admission or surgical groin access were excluded. The outcomes for next-day discharge were good with 92% of patients successfully discharged on post-operative day one and an overall 30-day readmission rate of 1.6% with only one death in the cohort. However, of the 126 patients who did not meet the inclusion criteria, 58 (46%) of these were due to anatomic unsuitability for either the Ovation stent graft or Perclose closure device.

A further recent prospective study assessing same day discharge following EVAR included patients deemed to have a low perioperative risk based on their comorbidity profile(14). Ultimately, 41% of all AAA patients assessed were included and 79% of these were successful in completing the same-day discharge. Short-term outcomes were good with an 11% complication rate, 1% mortality rate and only 2% of patients requiring readmission. However, as previously mentioned, 15% of these conservative criteria patients subsequently attended the emergency department within 30 days of their procedure for a host of post-operative complications. Although there are benefits in reducing length of stay, this increased workload would have to be accounted for by any surgical unit considering implementing an SS-EVAR pathway. Furthermore, it also suggests that there is still scope for further optimisation of patient selection and post-operative support with respect to SS-EVAR pathways.

It has been previously estimated that by reducing the length of stay from four to one days for EVAR patients, expenditure related to admission could be reduced from £13,360 to £9844(40). Therefore, if all 110 pragmatic criteria patients completed the SS-EVAR successfully without readmission, over the study period, this would result in a spending reduction from £2,511,680 to £2,124,920 (£128,290 annual saving) in addition to the increased EVAR throughput.

Therefore, given the frugality of SS-EVAR and its inherent benefits to patient satisfaction(42), we believe that the pragmatic criteria detailed in this chapter has the potential to allow the safe delivery of SS pathways to a broader range of patients.

The main limitation of this study is its retrospective nature whereby criteria were applied to non-SS EVAR pathway. As a result of this methodology, it is possible that patients who are included in our criteria would actually not have been suitable for SS-EVAR. Though it has been shown that the pragmatic selection criteria can ensure safe outcomes for a larger proportion of patients, subjective clinical opinion regarding patient fitness for SS-EVAR should still be taken into account.

Furthermore, this study was conducted using data from a high-volume aortic centre and may not reflect national practice. However, the outcomes in this study such as length of hospital and critical care stay, postoperative complications and reinterventions were similar to national values(35). Finally, 48 patients in this study went to intensive care post-operatively for monitoring. Therefore, it is feasible that without the more intensive monitoring, more patients may have experienced complications.

4.2.5 Conclusions

This study has shown that a novel set of pragmatic patient selection criteria can allow carefully selected co-morbid patients to be enrolled safely onto short stay EVAR pathways. A good proportion of elective EVAR patients (58.5%) will be deemed eligible for inclusion onto SS pathways with these criteria, and only 2–3% of patients are estimated to require readmission to hospital following their EVAR, with all serious complications being identified within 24 h of the procedure. This would improve resource efficiency for healthcare providers whilst maintaining appropriate levels of patient safety.

4.3 Development of novel patient selection criteria for a short stay fenestrated endovascular aneurysm repair pathway.

4.3.1 Abstract

4.3.1.1 Objectives:

Short Stay (SS) Endovascular Aneurysm Repair pathways offer the potential to improve service efficiency and patient satisfaction by reducing length of stay. This study aims to assess previously validated SS-EVAR criteria in fenestrated endovascular aneurysm repair (FEVAR).

4.3.1.2 Methods:

Pragmatic and conservative criteria based on patient comorbidities (see Table 10), were applied retrospectively to cases between January 2017 and 2020 at a tertiary centre. Rate and timings of postoperative complications, reinterventions and unplanned readmissions were assessed.

4.3.1.2 Results:

Sixty-two patients were identified (92% male, mean age 73.1 ± 7.39). Twelve (19.4%) met the conservative criteria. Three (25%) had an in-patient complication, one (8.3%) occurred post 24 hours (haematuria requiring irrigation), which would have required readmission. Forty (64.5%) met the pragmatic criteria. Ten (25%) had an in-patient complication with five occurring after 24 hours, two (5%) would have required readmission (haematuria and abdominal pain requiring diagnostic angiogram). There were no readmissions in either cohort.

4.3.1.3 Conclusions:

The application of the pragmatic patient selection criteria allows patients with limited co-morbidity to be safely selected, in good number, for SS-FEVAR, without exposure to greater than national average rates of readmission. Adoption of this pathway could improve resource efficiency, whilst maintaining patient safety.

4.3.2 Methodology

Methods were as described in 2.3

4.3.3 Results

A total of 125 complex endovascular aneurysm repairs were conducted during the study period of which 62 met the inclusion criteria (see Figure 7); 2 patients were excluded for revision interventions, 22 had intrarenal EVAR with adjuncts of which 19 where IBDs and 3 where Chimney EVARs and 39 were excluded for TAAA requiring BEVAR or TEVAR.

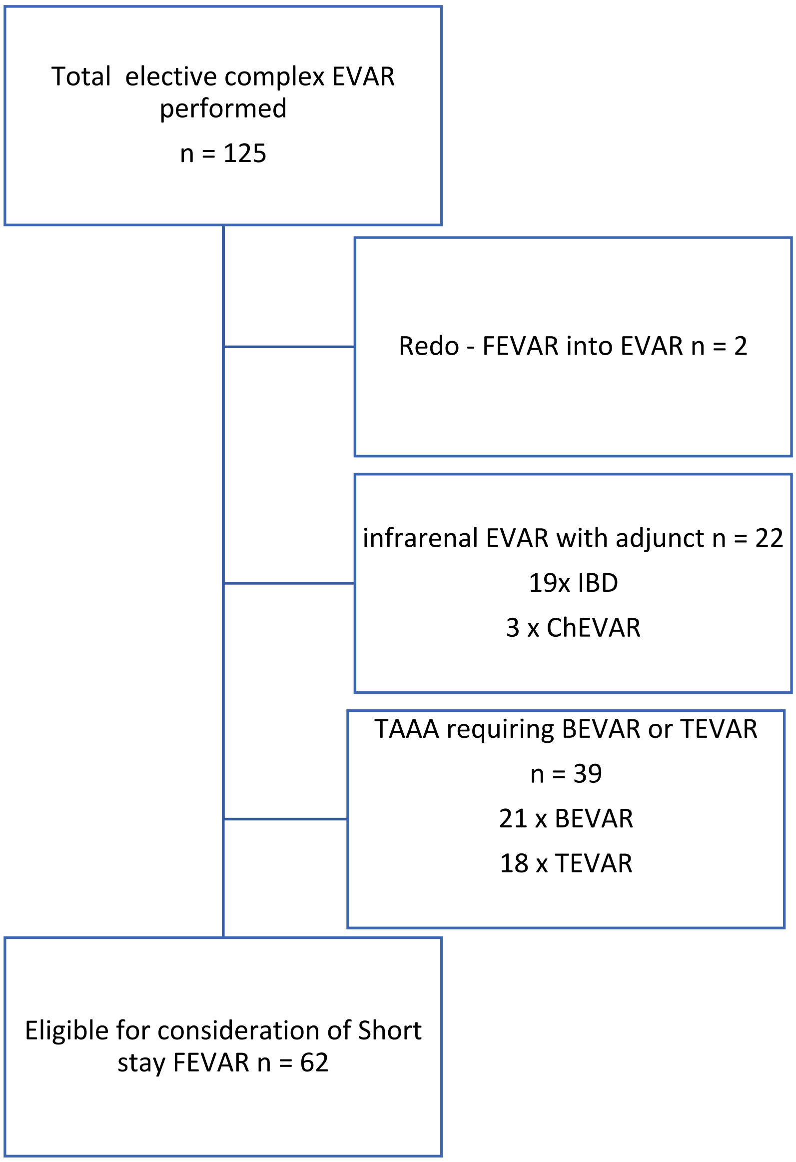


Figure 7: Retrospective SS-FEVAR patient identification flow chart.

Of the 62 patients included in the study 56 (90%) underwent a totally percutaneous approach with 6 (10%) requiring surgical vessel exposure. Overall, 12 (19.4%) patients fulfilled the conservative criteria and 40 (64.5%) met the pragmatic criteria (as per the criteria listed in Table 10). The proportion of patients excluded from each group by each criterion is laid out in Table 11. The demographics and medical comorbidities can be seen in Table 12.

	Conservative criteria	Pragmatic criteria
Social	Transport available Adult observer available for 24 h post-discharge Absence of significant immobility	
Distance	<100km	< 100km
Age	<80 years	<90 years
Body mass index (kg/m2)	<35	<35
ASA grade	<=3	<=3
Advanced liver disease	Absent	Absent
Cognitive impairment	Absent	Absent
eGFR (mL/min/1.73m2)	>60	>= 45
Ischemic heart disease	No history of ischemic heart disease	No myocardial infarction in past 6 months
Cerebrovascular disease	No history of stroke or transient ischemic attack	No stroke in past 1 year
Heart failure	No heart failure	No severe heart failure (ejection fraction <40%)
Chronic lung disease	No chronic lung disease	No severe COPD (FEV1 <50%) or other severe respiratory disease.
Diabetes	No history of diabetes	No insulin-dependent diabetes

SS-FEVAR: short-stay fenestrated endovascular aneurysm repair; ASA: American Society of Anaesthesiologists; eGFR: estimated glomerular filtration rate; COPD: chronic obstructive pulmonary disease; FEV1: forced expiratory volume in 1 s.

Table 10: SS-FEVAR patient selection criteria.

Criteria	Conservative criteria (n=12)	Number patients excluded due to criterion	Pragmatic criteria (n=40)	Number patients excluded due to criterion
Distance from hospital	<100 km	2 (3.2)	<100 km	2 (3.2)
Age	<80 years	14 (22.6)	<90 years	0 (0)
Body mass index (kg/m2)	≤35	4 (6.5)	≤35	4 (6.5)
ASA grade	≤3	14 (22.6)	≤3	14 (22.6)
Advanced liver disease	Absent	1 (1.6)	Absent	1 (1.6)
Cognitive impairment	Absent		Absent	
eGFR (mL/min/1.73m^2)	>60	15 (24.2)	>45	4 (6.5)
Ischemic heart disease	No history of IHD	24 (38.7)	No MI in past 6 months	0 (0)
Cerebrovascular disease	No history of stroke or TIA	4 (6.5)	No stroke in past year	0 (0)
Heart failure	No HF	6 (9.7)	No severe heart failure (EF <40%)	1 (1.6)
Chronic lung disease	No Chronic lung disease	14 (22.6)	No severe COPD (FEV1 <50%) or other severe respiratory disease	1 (1.6)
Diabetes	No history of diabetes	9 (14.5)	No insulin-dependent diabetes	2 (3.2)

All values in parentheses are percentages of total EVAR population (n=62).

SS-EVAR: short-stay FEVAR; ASA: American Society of Anaesthesiologists; eGFR: estimated glomerular filtration rate; COPD: chronic obstructive pulmonary disease; FEV1: forced expiratory volume in 1 s.

Table 11: Number of patients excluded from the conservative and pragmatic SS-FEVAR criteria

	Total cohort (n = 62)	conservative criteria cohort (n= 12)	pragmatic criteria cohort (n= 40)
Demographic			
Mean age (years) [a]	73.1 (±7.39)	67.2 (±5.08)	73.1 (±7.57)
Sex ratio (M:F)	57:5	10:2	37:3
Mean distance from hospital (km) [a]	20.2 (±26.2)	15.7 (±11.6)	14.6 (±9.7)
Comorbidities			
AAA size (mm) [a]	64.8 (±7.76)	62.3 (±4.42)	64.7 (±7.51)
ASA Grade[a]	3.11 (±0.58)	2.75(±0.45)	2.85 (±0.36)
Obesity	4 (6.5)	0 (0)	0 (0)
Diabetes	9 (14.5)	0 (0)	4 (10)
Hypertension	45 (72.6)	8 (66.7)	25 (62.5)
Chronic lung disease	14 (22.6)	0 (0)	7 (17.5)
Severe COPD	1 (1.6)	0 (0)	0 (0)
Ischemic heart disease	24 (38.7)	0 (0)	15 (37.5)
Myocardial infarction past 6 months	0 (0)	0 (0)	0 (0)
Chronic heart failure	6(9.7)	0(0)	3 (7.5)
Ejection fraction (%)[a]	58.5 (±6.25)	60.0 (±4.26)	59.0 (±5.5)
Chronic renal disease	5 (8.1)	0 (0)	2 (5)
Cerebrovascular disease	4 (6.5)	0 (0)	1 (2.5)
Hypercholesterolaemia	29 (46.8)	3 (25)	16 (40)
Current smokers	13 (21)	4 (33)	8 (20)
History of cancer	7 (11.3)	2 (16.7)	7 (17.5)

Values in parentheses are percentages unless otherwise stated.

[a]Values are mean (±standard deviation).

AAA: abdominal aortic aneurysm; ASA: American Society of Anaesthesiologists; COPD: chronic obstructive pulmonary disease.

Table 12: SS-FEVAR demographics and co-morbidities

Of the patients excluded from the pragmatic criteria, American Society of Anaesthesiologists (ASA) score, low glomerular filtration rate (eGFR) and High Body Mass Index (BMI) were the major reasons for criterion exclusion (accounting for 22.6, 6.5 and 6.5% respectively). In the conservative criterion in addition to the above, Age, Ischemic heart disease, Cerebrovascular disease, Heart failure, chronic lung disease and Diabetes also lead to >5% being excluded. Full details of reason for criterion exclusion can be seen in Table 11.

4.3.3.2 Length of stay

The total cohort has a median length of stay of 4 ± 2.8 days, with a postoperative length of stay of 3.5 ± 2.7 days. During the earlier part of the trial period patients were routinely admitted the night before the operation. 57 (92%) patients were admitted to critical care post-operatively with a median length of stay of 1 ± 0.87 days.

For the conservative group, median length of hospital stay was 5 ± 3.2 days with 10 of 12 patients being admitted to critical care with a 1 ± 1.2 day length of stay.

In the pragmatic criteria cohort median length of stay was 4 ± 2.8 days with 35 of 40 patients being admitted to critical care for a length of 1 ± 0.81 days.

4.3.3.3 Complications

There was one in-patient death in the cohort, this patient did not meet the parameters for either of the conservative or pragmatic criteria. There were no other deaths at 30 days within the cohort.

Overall, there were 25 in-patient complications in 21 patients (33.9%), 17 of these complications occurred within 24 hours and 8 occurred after. Table 13 outlines the proportions of these complications and their when they were recognised.

	Total cohort (n = 62)	Conservative criteria cohort (n=12)	Pragmatic criteria cohort (n= 40)
Total number of patients who had complications	21 (33.9)	3 (25)	10 (25)
Number of complications occurring within 24 h post-FEVAR	17 (27.4)	3 (25) 1x Pain that was investigated by DSA (NAD) 1x return to theatre for hepatorenal bypass 1x Bradycardia that spontaneously resolved	7 (18.5) 1x Pain that was investigated by DSA (NAD) 1x return to theatre for hepatorenal bypass 3x Bradycardia that spontaneously resolved 1x Pain investigated by CT NAD 1x AKI
Number of complications occurring after 24 h post-FEVAR	8 (12.9)	1 (8.3) 1x haematuria requiring 3-way catheter	5 (12.5) 2x urological (1x urinary retention, 1x heamaturia) 1x thrombocytopenia

			1x constipation, mild AKI and raised inflame markers 1x Abdo pain, CT, and angiogram (Nil abnormality found)
Inpatient reinterventions	4 (6.5)	2 (16.7) 1x diagnostic angiogram with no abnormality found 1x hepatorenal bypass	3 (7.5) 2x Diagnostic angiogram with no abnormality found 1 x hepatorenal bypass
Unplanned 30-day readmissions	1 (1.6)	0 (0)	0 (0)
Unplanned A&E review without admission	8 (12.9)	0 (0)	5 (12.5) 1x eye infection 1x mild haemoptysis 1x abdominal pain, CT no abnormality found. 1x back pain 1 x LRTI

Values in parentheses are percentages.

Table 13: post-operative complications and unplanned readmissions in SS-FEVAR.

Only one complication post 24 hours was noted in the conservative cohort (haematuria requiring irrigation). Five complications occurred in the pragmatic cohort; two urinary (one retention and the above-mentioned haematuria requiring irrigation), two thought to represent post implantation syndrome and one haematological. In addition to these cases, three other complications were noted within the total population after 24 hours.

These where one further episode of urinary retention requiring catheterisation, one patient with an acute on chronic renal failure, treated with supportive measures only, and a patient who developed abdominal pain which was found to be caused by a small renal infarct.

A total of 4 patients required an in-patient re-intervention. In all but one of these patients this was recognised within 24 hours. Within the conservative cohort there were 2 patients, one of which underwent a hepatorenal bypass and one who underwent a diagnostic angiography to eluate the cause of abdominal pain, which did not find anything of note and no aortic complication. Both of these were recognised within 24 hours of the procedure. In the pragmatic cohort in addition to the above cases there was one further case of abdominal pain being investigated by diagnostic angiogram which once again did not find any cause of the pain related to the procedure or any technical complication with the aortic repair. This reintervention however did occur after 24 hours post operatively. The final reintervention occurred within 24 hours but did not meet the criteria for either the conservative or pragmatic cohort and represented a post procedure haemorrhage which ultimately although controlled after a laparotomy lead to the patient's death.

Following discharge only one patient was readmitted within 30 days within the studied cohort. This patient did not fall within either the pragmatic or conservative criteria. The patient presented 14 days post discharge with an occluded right limb of his endograft requiring embolectomy.

In addition to the patients that where readmitted a total of 8 patients were reviewed in A&E within 30 days post discharge, 5 of which were part of the pragmatic cohort. None of these patients fell within the conservative criteria. All these patients were able to be treated in an ambulatory manner and were discharged to routine follow up.

4.3.4 Discussion

This study has shown that the implementation of a pragmatic patient selection criteria allows for the inclusion of the majority of patients that undergo elective FEVAR (64.5%), with a inclusion rate comparable to previously published short stay EVAR selection criteria(19).

Of the pragmatic criteria patients that were included, ten patients representing 25% of the cohort had a complication, with seven complications within 24 hours and five after this point. Of the complications that occurred after 24 hours post operatively, all but two (one haematuria requiring bladder washout and one patient requiring a diagnostic angiogram) only required blood tests, imaging, or basic medical interventions (catheterisation) and thus may well have been able to have been managed in an ambulatory manner. Therefore, as there were no unplanned readmissions in this group if a short stay model of care had been adopted, the overall readmission rate in this cohort would have been 5%. This is a favourable rate when compared with the national average readmission rate of 7.6% for elective FEVAR in the UK(33) in the absence of defined short-stay pathways. The pattern of complications also appear to mirror that seen in EVAR(40), with the most serious complications occurring within the first 6 hours post operatively.

These favourable readmission rates are crucial to the success and safety of the implementation of a short stay FEVAR program due to the financial penalties associated with non-reimbursement of tariffs for unplanned readmission(56). Adoption may however create extra demand on the service as it is likely that the four cases of complications occurring after 24 hours, projected not to require admission, would nonetheless require review and ambulatory management plans to be put in place.

As with published SS-EVAR criteria(19), it is thought that a SS-FEVAR program would be best implemented with an early (within seven days post discharge) telephone follow-up with a member of the vascular team. This would then be followed by routine follow up at six weeks post operatively with further imaging.

The more liberal pragmatic criteria suggested in this study allowed a far higher proportion of the study group to be included then with the conservative criteria (64.5% vs. 19.4%). Importantly this increase in eligibility did not come at the cost of patient safety with no serious complications in either group post 24 hours. There was however a difference in probable readmission rate with the pragmatic criteria cohort being 5% compared with 8.3% in the conservative criteria cohort, though this difference was not statistically significant (p= 0.664). These values are however is comparable to the national FEVAR average of 7.6%(33). Therefore, we feel that patients up to the age of 90 with well controlled medical comorbidities as laid out in Table 10 could be safely served by a SS-FEVAR program. However due to the complexities of these repairs we still believe it to be imperative that the decision should be made by the consulting physician supported by the local multidisciplinary team.

The inclusion criteria of the study did not specify a particular endograft, anaesthetic type or vascular access to allow maximal applicability between centres. It should however be noted that all patients in the study had Cook endografts and all cases were performed under general anaesthesia. Furthermore, the vast majority of cases performed utilised percutaneous access (56 patients (90%)), with only 6 (10%) requiring open vascular access. It is likely that the advantages of a total percutaneous approach (59) would be beneficial to allowing a short stay model of care.

It has been previously estimated that reducing the length of stay from four days to one day in EVAR patients could results in a cost saving of 3,516 pounds per case(40). Therefore, if all forty patients in the pragmatic group where to have undergone successful SS-FEVAR, assuming a similar level of saving in FEVAR as EVAR, a total of 140,640 pounds could have been saved. Though the actual cost savings could be higher if some of these saved bed days were in critical care.

The major limitation of this study is its retrospective design. This methodology could allow patients to been included in our criteria that would not have been suitable for SS-FEVAR if assessed prospectively as it does not allow for subjective assessment of patient fitness for a short stay model of care. Furthermore, as this study has been conducted using data from a single high-volume centre it is possible that it may not reflect national practice.

4.3.5 Conclusion

This study has shown that the novel pragmatic patient selection criteria can allow patients with limited co-morbidity to be safely selected, and in good number, for a short stay model of care FEVAR. The patients within the group seemingly would not be exposed to greater than national average rates of readmission whilst capturing all serious issues within the allotted SS-FEVAR timeframe. Adoption of this model of care could improve resource efficiency, whilst maintaining appropriate levels of patient safety.

5. Identification of patient and system factors limiting early discharge in EVAR patients using Experience Based Design.

5.1 Chapter overview

The following chapter is split into two halves, the first reviews the current use of Experience Based Design (EBD) in elective medical and surgical pathways. There is no currently published review article on this area in the literature.

This review will serve to outline best practices in the use of EBD, which can then be used to guide its local application. This local application constitutes the second half of this chapter.

5.2 Systematic review of Experience Based Design in Elective Medical and Surgical Pathways

5.2.1 Abstract

5.2.1.1 Introduction

Patient involvement has been shown to be beneficial to the design of elective care pathways. Experience based design has been used in many aspects of medicine already and allows the emotional concerns of the patient at each stage to be gauged and acted upon. No review of EDB in elective medical pathways exists. This study aims to review the literature to date and propose best practice guidelines in this area.

5.2.1.2 Methodology

A systematic review was conducted using the search terms "experience-based design" and "experience-based co-design" on PubMed and Embase according to the PRISMA guidelines. Results were screened to identify studies that met the inclusion and exclusions criteria.

5.2.1.3 Results

Six studies were identified that reported on EBD pathways and outcomes following elective medical or surgical interventions. There was an average number of 45 (3-117) participants. Four studies collected data via interviews, one utilised a combination of direct observation, interviews, focus groups and questionnaires and the final study utilised questionnaires alone. Patient selection strategy was poorly defined in all studies and group size was chosen arbitrarily. Data analysis was performed by thematic analysis in 5 of the 6 studies with the final study utilising pre-defined words to identify positive and negative emotion at each touch point. 5 of the 6 studies lead to service changes.

5.2.1.4 Conclusions

EBD offers an effective way to conduct quality improvement in elective services. Studies in EBD should ideally include patients, carers and staff members across different teams and allied health specialties. Multiple methodologies can be used but all should be prospective to ensure reproducibility and validity of results.

5.2.2 Introduction

Seeking feedback from patients is fundamental to improving care and ensuring patient satisfaction. In recent years, there has been a growing push amongst medical professionals to involve patients in strategic planning and include suggestions from patients and relatives when developing care pathways(60). Increasing the role and input of patients in the service can improve the quality of care and lead to better health outcomes(61,62). Such feedback has been traditionally sought via patient surveys which often consist of 'tick box' questions. These can be rigid in their nature of questioning and do not capture the emotional responses of service users. Evidence suggests that factoring in patients' thoughts and feelings when designing care pathways can lead to improved recovery and lead to improved satisfaction(63).

Experience based design or co-design (EBD) is a novel strategy that relies on patient and staff narratives about their experiences and interactions to collectively guide changes to the service and ongoing care(64). Whilst the majority of quality improvement revolves around analysing a specific outcome measure and seeks to improve a particular pre-set target, the principles of EBD are to analyse the entire experience of care through an interdisciplinary approach, relying on specific patient and staff feedback, providing a platform to target interventions at specific patient, carer or staff concerns(65). This enables identification of which key service interactions, known as 'touchpoints' that users of the service have identified as emotionally significant. Additionally, the co-design aspect of the method enables healthcare professionals to work with patients and carers to 'co-design' or develop service improvements. This can subsequently lead to creation of appropriately structured care pathways. When used in conjunction with other service improvement methods, EBD provides an opportunity to account for the value in the emotional or psychological aspect of care pathways. In particular, its use in guiding patient pathways has been shown to reduce anxiety and increase satisfaction with the service. Therefore, EBD can be particularly useful when planning service changes or improvements to pre-existing pathways.

Techniques used in the EBD approach has been well established in other customer service-oriented industries both through formal and informal approaches(66,67). However, EBD has been adapted by the UK National Health Service (NHS) Elect and further developed in conjunction with the King's Fund for assessment of healthcare pathways(68,69). EBD was first piloted in patients with head and neck cancers in Luton and Dunstable hospitals(70). Since then, its use in healthcare has gradually increased within the last 10 to 15 years and there is growing interest in its application to various fields of medicine, as well as in a variety of settings ranging from mental health units, the emergency department, intensive care, inpatient wards and hospice(71–73).

The benefits of EBD include empowering service users and health care professions to actively engage with and impact improvement processes. This ultimately results in the creation of a service that is tailored to the emotional, psychological, and physical needs of staff and patients at each step of the journey.

5.2.2.1 Experience Based Co-Design Techniques

The EBD approach consists of four broad steps – capturing the experience, understanding the experience, improving the experience, and measuring the experience. Capturing the experience can be done through interviews, questionnaires, diaries or journals, observation, shadowing, focus groups, compliments, or complains, or a combination of any of the above. Understanding the experience involves identifying the touchpoints and emotions, then mapping each of the touchpoints to an emotion. The identified touchpoints are then analysed to characterize areas to improve the experience through the co-design process, which involves working with patients, carers, and other members of staff to redesign services and make service improvements. Finally, the impact of the changes needs to be measured, which may be done through subjective methods such as experience gathering or objectively measurable results or targets(69).

The traditional method of EBD involves structured one-to-one interviews and focus group discussions to obtain information on patient experiences of a specific care pathway. The pathway is broken down into different components, each of which are emotionally significant points, known as 'touch points.' Each identified touch point is emotion-mapped through association with a particular feeling - to either a positive or negative emotion based on their connotation. These positive or negative words are then stratified by intensity to rank the feelings experienced at each touch point from best to worst. Additionally, the patient interviews may be combined and shown to staff to inform them about patient experiences. Staff subsequently engage with patients through interdisciplinary group discussions to identify ways to improve pathways.

However, these approaches can be modified to include carers in addition to patients, particularly when administered in intensive care, mental health, or palliative care settings. Additionally, surveys can be used in lieu of interviews where patients may be asked to qualify their emotions from a choice of pre-set words at each stage of their care(74). This can further be adapted to different situations including vulnerable patients, those with dementia or those with mental health problems for whom the standard approach may not work.

Alternative sources of data for EBD include complaint letters or documented patient feedback, observations of care by an external member of the EBD improvement team, or informal patient stories.

5.2.3 Aims

The EBD approach has been used in a variety of clinical pathways and its most common applications involve emergency admissions as well as palliative care. However, its use in elective care pathways is less established and evidence is still emerging. Our aims were to identify different EBD techniques used in elective medical and surgical pathways and evaluate the service changes and improvements implemented as a result of EBD. By doing so we hope to identify a robust and ideal manner to deliver EBD in elective surgical pathways like SS-EVAR.

5.2.4 Methods

Methods as were described in section 2.3.1.

5.2.5 Results

5.2.5.1 Identification of studies

A total of 111 studies were identified using the screening methodology laid out in 2.4.2. Six studies were included in this review, the flow diagram of their identification can be seen below in Figure 8.

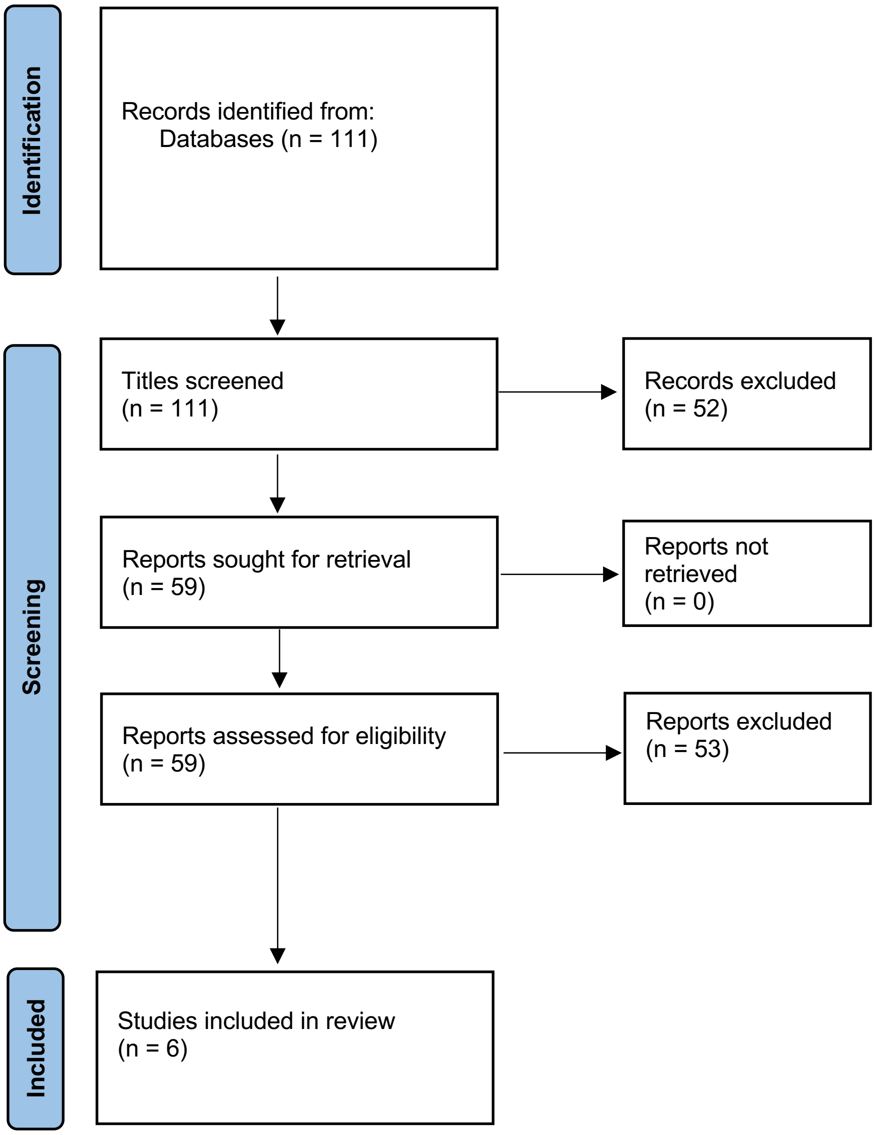


Figure 8: Study identification for elective medical and surgical pathway EBD review.

5.2.5.2 Study Population

6 studies reported on EBD pathways and outcomes following elective medical or surgical interventions (Table 14)(75–80). Areas of specialty ranged from obstetrics, colorectal surgery, plastic surgery, oncology, and an orthodontic service. 5 of the 6 studies directly

involved patients, 1 study involved carers or the responsible parent, and 3 studies incorporated members of staff into the EBD process. The average number of patients or carers per study was 45 (3 - 117). In the two studies that specified numbers of staff included, roles of staff members were not clearly defined nor was there a selection criterion that include members of the wider medical team.

5.2.5.3 Participant Selection

In the majority of studies (4 out of 6), no clearly defined sampling method for participant selection was stated within the study. One study specified that patients were recruited by a clinical nurse specialist who selected patients to include a variety of backgrounds and age groups. In the study on pancreatic cancer pathways, all patients going through the service were retrospectively sent surveys to complete.

5.2.5.4 Experience Based Design Techniques

One study used the original four-step approach to EBD, though most studies had modified this to suit their patient cohort and intervention. The most common types of EBD used were structured or semi-structured interviews (n = 4) which were conducted by an appropriately trained healthcare or psychological professional involved in the study. One study used open-ended interviews in combination with direct observation which were less rigid in their format, enabling patients to focus on the points most important to them, in addition to questionnaires which were created based on themes identified during the interviews. The remaining study relied solely on questionnaires. In most cases (n = 3), the interviews were filmed or recorded with the consent of the participant. Short clips from the videos were then compiled into a film to highlight the recurring themes or emotional issues identified by patients. These videos were then shown to members of staff and their responses were recorded.

EBD was most commonly administered once or twice during the patient journey. In all cases it was administered by a healthcare professional involved in the study. However, their roles were not specified within the text. In one study alone, EBD was recorded at 7 different time points during the care pathway. EBD was usually only studied retrospectively once the patient had reached the end of their intervention or pathway, or in oncology care, after their treatment was decided on.

Author & Year	Area of Specialty	Involved Members	Total participants	Patients (n)	Staff (n)	EBCD Technique	Number of Times EBCD administered	Pre-admission	During admission	Post discharge	Wordings Used	Analysis Technique
Kenyon 2016	Obstetrics (elective Caesarean Section)	Patients and Staff	25	15	10	Structured interview	1	0	0	1	None predefined	Thematic analysis
Haddow 2015	Colorectal (cancer)	Patients	3	3	0	Semi-structured interview	1	0	0	1	None predefined	Thematic analysis of interview
Coy 2019	Plastics (burns)	Carers and Staff	3	3 (parents)	0	Original – Semi-structured Interviews of carer and structured interviews of staff; and joint staff/carer focus event	1	0	0	1	None predefined	Thematic analysis of interview and identification of improvement areas
Ellis 2014	Orthodontics (general appointment)	Patients	95	20 (pilot) then 75	0	Questionnaire	7	2	4	1	Anxious, nervous, unwelcome, relieved, relaxed, welcome	Word cloud, bar chart with word-scales
Tsianakas 2012	Oncology (breast and lung)	Patients and Staff	99	36	63	Original – Semi-structured Interviews of patient and structured interviews of staff; and joint staff/carer focus event	2	0	0	2	None predefined	Thematic analysis

Hagensen 2016	Oncology (pancreatic)	Patients and Staff	117	117 completed questionnaires; 58 attended interviews	Not specified	1) Direct observation 2) Open-ended interviews of patients, carers, and staff 3) EBD Questionnaire from touch points identified 4) Focus group	2	0	0	2	Validated list of emotion words	Thematic analysis, graph of % using negative descriptive words

Table 14: EBD Studies included.

5.2.5.5 Data Analysis Techniques

Group sizes were arbitrarily chosen in all studies. One study retrospectively invited all patients who experienced the pancreatic cancer pathway in the preceding one-year period to take part. In another study on orthodontic clinics, surveys were initially piloted on 20 patients, then expanded to include a further 75 patients.

Data was analysed by thematic analysis in 5 out of the 6 studies. Thematic analysis was performed in all the studies which carried out patient interviews. One study used a combination of word clouds and a bar chart-based scale where different pre-defined words were associated with different levels of positivity or negativity. These were subsequently plotted on to a stacked pie chart which was a scaled from highly negative words to highly positive emotion words. Another study plotted the percentage of negative experiences at each of the 9 points in their treatment that patients retrospectively commented on. One study grouped the negative responses at each touch point for all patients and demonstrated the patient journey through a graphical representation, reporting the temporal outcomes of the satisfaction of their service users across the various touch points surveyed.

5.2.5.6 Changes Implemented

In 5 of the included 6 studies, the use of EBD highlighted the need for improvement, and instigated change, enabling the development of the service (Table 15). These changes varied from simple interventions such as training reception desk staff to greet patients to restructuring entire care pathways. The most common type of change implemented was improved information delivery methods which included processes to receive results of any diagnostic tests or procedures, thereby minimizing the anxiety associated with the waiting times for results delivery. Key strategies altered as a result of EBD programmes included creation of new short-stay pathways including day surgery pathways and more efficient referrals to endoscopy.

Study	Service Improvements	Resultant Changes and Outcomes
Kenyon 2016(80)	New pathway created	
Haddow 2015(77)	- New pathway created	- Shortened time for referral to endoscopy
Coy 2019(75)	*None specified*	- Ongoing research with families
Ellis 2014(79)	- More welcoming reception with waiting room 'distractions' (computer/TV/radio), - What to expect" information videos and illustrated booklet on dental x-rays	
Tsianakas 2012(78)	Breast: Day surgery pathway improved, new appointment process with pre-agreed dates for results and interventions (minimising anxiety), increased communication, HCA assessed for communication skills, hair loss support Lung: braking bad news room, junior doctors trained on information regarding diagnostic procedures, patient information leaflets and increased advertisement of information available, link nurse for care continuity, out of hours access, cross-site visibility of results	
Hagensen 2016(76)	- Pancreatic care pathway redesigned with new MDT approach - New information delivery technique with individual and accessible care plans for each patient	- Reduced anxiety amongst patients

Table 15: Service Improvements Implemented from Experience Based Design

5.2.6 Discussion

5.2.6.1 Patient and Staff Selection and Sampling Methods

No clear sampling methods were identified in any of the studies. Though patients, carers and staff alike may often be interested in taking part in service improvement, identifying the appropriate individuals for involvement is important. A wide range of patients should be sampled, in a method that is most representative of users of the service. Convenience sampling is most commonly used for qualitative research, due to its simplicity. This involves selecting participants for inclusion based on availability and willingness to take part. This, however, runs the risk of excluding major groups of patients, for instance those with cognitive impairment who may likely have a significantly different response to hospital admission or procedures. Future EBD programs may wish to use quota sampling where the key demographic characteristics of the service user cohort are identified and represented in invited participants. Alternatively, consecutive patients can be sampled throughout a predefined period, or until the required sample size has been reached.

While it is not possible to power EBD studies as there is no specific outcome studied, a minimum sample size will be required to ensure the themes and touchpoints identified are meaningful. Grounded theory is a powerful tool which suggests collecting more data until no new themes emerge from the answers[29]. All answers are grouped into categories and assigned codes. As long as new themes are appearing from participants answers, more participants are required as other unidentified themes could still be present. Once no new themes appear, then the sample size is deemed adequate.

Additionally, no study utilized the full multidisciplinary team when collecting experiences or planning interventions and service improvements from the EBD. This process may be aided by use of the King's Fund Experience Based Design Toolkit, which has recommendations on whom to include in various roles and at different points of the EBD process(81). The cohort of staff members sampled should represent the full multidisciplinary team to employ a holistic approach to service improvement.

In all studies, EBD interviews or questionnaires were conducted retrospectively rather than around the time of the touchpoint. Particularly as emotional responses are subject to significant biases including hindsight bias when evaluated retrospectively, prospective evaluation is fundamental to documenting accurate responses. Evidence also suggests that retrospective evaluation of subjective aspects of care are often influenced by the eventual outcome or final satisfaction and lack specificity for feelings at a particular time point or 'touchpoint'. Therefore, at least partial evaluation of perceptions at various standout events, i.e. admission, post-procedure and discharge, is important(82).

5.2.6.2 Tools for EBD

Given that research using principles of EBD is entirely qualitative, creation of the structured interviews and questionnaires is particularly important to ensuring validity of results. Such tools should avoid bias in their questioning strategy and should be worded to elicit the emotional responses to specific events. Structuring of questionnaires and interviews in the included studies were ambiguous, though in 3 studies, the development of questionnaires was based on themes elicited in initial structured or semi-structured interviews. However, this method may lack reproducibility and impair the ability to administer the EBD at various time points. A pre-set questionnaire with a simple scale of positive and negative words is quantifiable and can be reliably administered at various time points in a reproducible manner.

Additionally, the use of questionnaires also permits larger sample sizes as it requires fewer staff and resources to administer, and can be done on a more widespread basis, and easily reproduced at multiple different time points. Requiring less staff, and not requiring highly-trained professionals who are able to conduct interviews, questionnaires are more cost-effective(74). Questionnaires can allow for easier analysis of plain text instead of requiring transcription of interviews which may also be subject to more interpretation. However, interviews do have the advantage of accounting for non-verbal responses such as body language as well as receiving a more individualized set of verbal responses as the content may be tailored to the individual.

Ultimately, EBD is a broad tool that can be modified to suit different services, pathways, and patient cohorts, as well as designed to be feasible in a variety of financial situations.

5.2.6.3 Structuring of Interviews

Interviews should take place in a separate room where the patient feels comfortable, as opposed to open bays or waiting areas lacking privacy. All patients should be asked to consent to the recording of the interviews as these will need to be transcribed or edited into a shorter film for focus groups if using the traditional EBD model. Interviews should be structured but also allow for participants to share their narratives and experiences in their own words and focus on the portions they feel were most critical or memorable. The interview should be structured into sections including referral, tests and investigations, diagnosis, treatment, discharge and follow up(82). Questions should be open-ended in nature but focus on reactions, notable or unforgettable points during the steps in the patient journey, and important memories about each step. Specific experiences, particularly revolving around diagnosis and treatment, should be elicited. Patients may also be asked to list the best and worst part of their care, and any issues as well as their overall satisfaction. A sample list of questions can be found on the Point of Care Foundation website but this should be tailored to the service pathways being studied(81).

5.2.6.4 Development of Questionnaires

Capturing emotions, particularly from questions with predefined answers instead of free text, can be problematic. This is not least due to the infinite list of words that can be used to portray emotions, and the lack of formal criteria in defining emotion itself(83). In order to reliably identify and measure emotional responses to a touch point, questionnaires must utilise appropriate and validated words which have consistent connotations across different patient groups and invoke similar perceptions. This allows for the creation of a spectrum of negative, neutral, or positive emotions of varying levels.

Russ and colleagues undertook a study to identify a set of reliable emotion words which can then be employed in EBD questionnaires(24). They described a series of words which had at least 80% agreement on emotional description amongst all participants with a consistent meaning amongst different ages and genders. These words were broken into positive, negative, and neutral categories. Positive words included compassion, confident, empowered, enjoyment, enthusiastic, great, grateful, happy, hopeful, joyful, loyal, optimistic, peaceful, pleased, safe, satisfied, secure, sense of accomplishment, successful and valued. Negative words included afraid, angry, disrespected, disgusted, depressed, frustrated, guilty, hatred, hopeless, ignored, insecure, jealous, resentful, and sad. The only neutral word was okay. Utilising these evidence-based words in the development of questionnaires can minimise the innate biases that may be associated with eliciting subjective reactions and improve reproducibility of answers.

Patient experience questionnaires should cover all the different points in a care pathway in order to study the temporal relationship of patient experience and correlate it to key events to identify specific areas for improvement. Ideal time points for delivering EBD questionnaires include the initial appointment, any pre-operative or pre-admission clinics, on admission, post-procedure (if applicable), on discharge, and then at follow-up appointments following discharge. Comment boxes should also be included to identify any problems or issues elicited through the initial questions.

Questionnaires may also be easily administered to staff and should be designed to capture their experiences of delivering a service and encourage them to reflect on different aspects of service delivery. When administered to staff, these should include questions that may be answered by the entire multidisciplinary team rather than including questions focused on clinical aspects of care which may be better studied with other forms of quality improvement projects. Questionnaires should focus on both the positive and negative aspects in order to provide constructive feedback using their opinions and feelings.

5.2.6.5 Analysis of Results

Analysis of results in most studies were conducted by thematic analysis. Thematic analysis focuses on examining recurrent themes within data and can be useful for open-ended questions in interviews or free-text answers in questionnaires. Explicit and implicit ideas within text are identified and coded into themes, which are then analysed. Recurrent themes are reviewed, and the responses may be classified further to characterize any issues or points that underlie the identified themes(84).

Other graphical ways to present data include assigning each identified touchpoint to an emotion which has been quantitatively depicted on the basis that some words have stronger emotional connotations than others either negatively or positively. Modified bar charts or linear scales depicted using a temporal scale can be used to graphically display the quantitatively analysed emotional response at each touchpoint. This can provide an indication of the overall perceptions of each of the critical points during the studied care pathway and allow service modifications to be targeted at negative touchpoints.

Less common ways to display results include creation of word clouds, or edited films which contain clips from patient interviews.

5.2.7 Conclusion

EBD appears to be a valid and effective way to conduct quality improvement in elective services. Studies in EBD should ideally include patients, carers and staff members across different teams and allied health specialties. Multiple methodologies can be used but all should be prospective to ensure reproducibility and validity of results.

5.3 Local application of EBD

5.3.1 Abstract

5.3.1.1 Introduction

Patient involvement has been shown to be beneficial to the design of elective care pathways. Experience based design as detailed in 5.1 has been used in many aspects of medicine already and allows the emotional concerns of the patient at each stage to be gauged and acted upon. This study aims to use the pragmatic best practice guidance from 5.1 to perform EBD on a newly formed short stay aortic aneurysm repair pathway.

5.3.1.2 Methodology

A total of 15 patients undergoing elective EVAR and 10 members of the wider MDT were surveyed using a structured EBD questionnaire. The views of staff and patients were then analysed to look for touch points where the program may be improved.

5.3.1.3 Results

Patient cohort mood analysis showed that the areas of greatest concern where the early pre-op period and shortly after discharge. A desire for access for information and greater contact where thematic areas for improvement identified.

Similar themes were seen in the staff EBD exercise issues including those around medication, social support and the completion of a robust pre-clerking proforma that could stop on the day delays as well as aiding in identifying barriers to discharge.

5.3.1.4 Conclusions

The use of EBD at our centre has outlined a need for access to pre-operative support and education. It has also highlighted the need for early post-operative contact to enhance the experience of this patient cohort.

5.2.2 Introduction

As discussed in the above section EBD offers a structure by which the views and feeling of patient and the wider treated multi-disciplinary team can input into changes in a service. These views and feelings can help top identify key steps in the patient pathway and highlight those that require further development.

Unlike other quality improvement approaches that focus on comparing care to a known, or golden standard, EBD attempts to look at care pathways as a whole through the lens of all of that that part of it and use it.

Although EBD has been used in a variety of elective surgical and medical service development projects it used in vascular surgery has yet to be seen in the published literature.

This local application of EBD aims to identify areas within the patient journey of EVAR patients at St George's that can be improved to facilitate a SS model of care in this patient population.

5.2.3 Methodology

Methodology as described in section 2.4.2.

5.2.4 Results

5.2.4.1 Patient EBD exercise

A total of 15 patients were included in the patient EBD exercise. Interim analysis was performed after the 15th case to see if the last five cases identified any further thematic areas, as per our methodology. As none were identified recruitment was stopped.

Cohort mood was assessed at each time point using summed cohort positive and negative validated word selection. These are presented in Figure 9, overall mood at all points of the EBD cycle were found to be low. However, the first clinic appointment, admission and discharge appointment appeared to be the lowest results in this study.

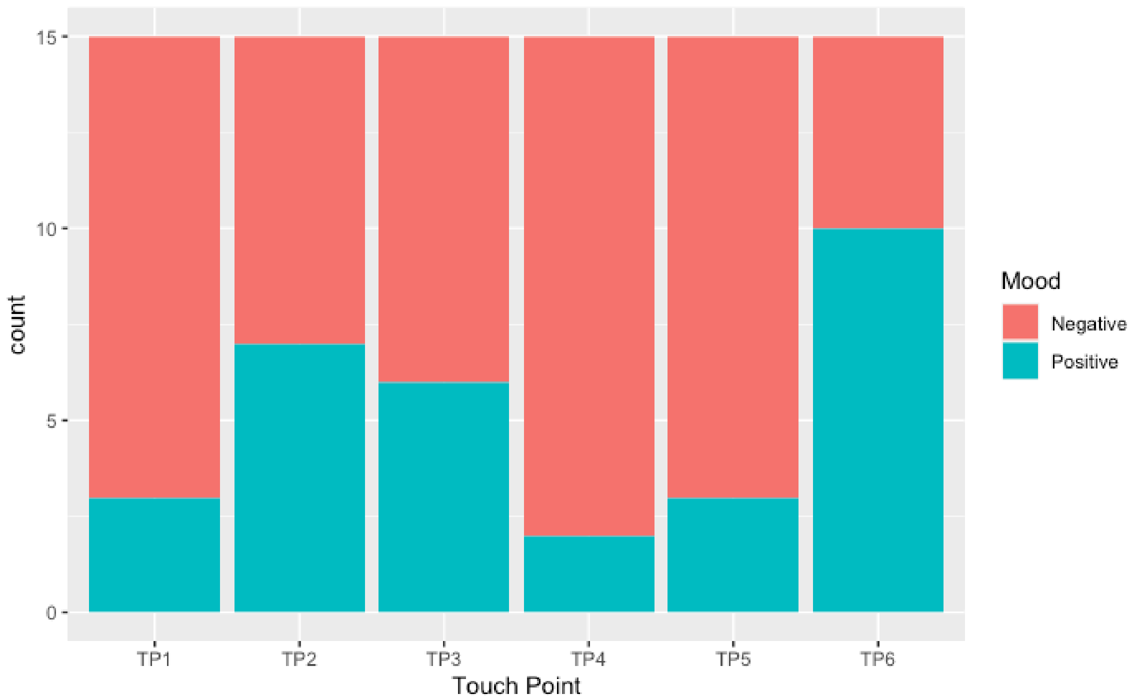


Figure 9: Stacked bar graph of 'positive' or 'negative' validated word selection by touch point. TP1: First clinic appointment, TP2: Optimisation Clinic, TP3: Second clinic appointment, TP4: Admission, TP5: Discharge, TP6: Follow up clinic.

The responses to question 2 can be seen in Table 16, where the main theme per touch point is tallied. As can be seen from this table, the main concern in the earlier part of the patient's journey is focused on the outcome and the operation, with support being provided by family, staff, and information. Later in the patient journey, concern is focused on fear due to the uncertainty of the post-operative period. Support by family and staff once again remains important during this phase.

Touch Point	Fear of outcome	Fear of operation	Fear for family	Fear of the unknown	Relief AAA found	Supported by family	Supported by staff	Supported by information given	Pleased with outcome
1	9	7	4	0	1	2	0	0	0
2	3	4	0	1	1	2	4	2	0
3	2	4	0	3	0	0	3	3	0
4	4	9	0	0	0	1	1	0	0
5	2	0	1	9	0	2	1	0	0
6	3	0	0	1	0	1	1	0	8

Table 16: EBD question 2 tally of main thematic areas

Responses to question 3 which focuses on areas for improvement can be seen in Table 17. As can be seen below, in the early phase and later phase of the patient journey desire for more information and direct contact was high. The 'direct contact' theme was defined as any desire to have the ability to contact the vascular service between formal patient contact. The 'more information' theme was defined as desire to have access to further information but not personalised. During the in-patient phase there was expressed desire to have better access to family and friend visiting however this must be understood in the context that the study was partly run during times of limited visiting due to the COVID pandemic. It should be noted that at times an answer to this question was often not given by patients.

Touch Point	*More information*	*Direct contact*	*Family support*	*Visiting*	*Help at home*	*Nil*	*Shorter waiting time*
TP1	5	4	1	0	0	2	2
TP2	3	6	0	0	0	5	1
TP3	6	6	0	0	0	3	1
TP4	0	2	0	4	0	6	3
TP5	2	6	2	0	1	5	0
TP6	2	3	0	0	0	10	0

Table 17: EBD question 3 tally of main thematic areas

5.2.4.1 Staff EBD exercise

A total of 10 members of the wider MDT were approached to be part of this staff component of this EBD program. These included a consultant vascular surgeon, a vascular registrar, a vascular house officer, an aortic clinical nurse specialist (CNS), a senior sister in charge of a vascular ward, a nurse on a vascular ward, a physician associate, a physiotherapist who covers the vascular ward, a vascular scientist and a pharmacist who covers a vascular ward.

Observations of EVAR patients' emotional state was recorded from each staff participant's point of view in question 1 of the staff EBD questionnaire. Some participants chose to comment on patient mood at varying time points over their clinical journey. The binary coded results of this question can be seen in Table 18 below.

Staff member	Pre-Admission	In-patient Pre-operative	In-patient post-operative	Early post discharge
Vascular Consultant	Negative	Negative	Positive	
Vascular Registrar		Negative		
Vascular House Officer		Negative	Positive	
Aortic CNS	Negative	Positive	Positive	Negative
Nurse in Charge		Positive/Negative	Positive/Negative	
Ward nurse		Positive	Positive	
Physician associate		Negative	Positive	
Physio therapist			Positive/Negative	
Pharmacist			Positive	
Vascular Scientist	Positive		Positive	

Table 18: Binary coded staff reported patient emotion

As can be seen in Table 18 there is a general trend of greater negative emotions pre-admission and in the pre-operatively in-patient period. This trend reverses in the post-operative in-patient period. Only one staff member commented on the early post-operative period.

The responses from this question were also thematically coded and can be seen in Table 19 below.

	Negative Emotions			Positive Emotions		
Time point	Concerned	Anxious	Pain	Supported	Relieved	Calm
Pre-admission	2			1		
In-patient pre-operative	3	2		2		1
In-patient post-operative			2	1	7	1
Early post discharge		2				

Table 19: Thematic coding tally by time point in Staff EBD Question 1.

In question 2 of the Staff EBD questionnaire, participants were asked to describe what their feelings were while treating these EVAR patients. All but one response was positive, with comments that participants felt pride, or that they had “done good” for the patient. The only negative response what from the ward pharmacist that they felt pressure to get the patient’s medications to go home rapidly.

Question 3 of the staff EBD questionnaire focused on what currently does and does not work well within the EVAR pathway.

Participants stated that currently effective parts of the pathway were:

- Pre-clerking/pre-assessment with pharmacy lead medication reconciliation.
- Patient often very motivated.
- Team approach

Current issues identified were:

- Occasional missed social support issues that delayed discharge.
- Delays to post-operative scans or discharge paperwork or medication.

- Those that came from out of network or urgent patients who didn't have the standard pre-operative work up.
- Lack of post-operative critical call bed
- COVID issues

Question 4 of the staff EBD questionnaire focused on specifically identifying any barrier to early discharge.
The issues identified were:

- Medical comorbidities that require higher level care post op (critical care)
- Decrease in mobility post-operative and deconditioning.
- Delay in discharge paperwork and home medication.
- Delays in getting post-operative imaging
- Delays in therapists' reviews
- Changes to list order.
- Operation date delays leading to expired blood samples or COVID tests.
- Changes in-patient social circumstance
- Vascular access for EVAR issues

Finally Question 5 of the staff EBD questionnaire focused on Key points that could be learnt from this patient experience. The points identified were:

- Need for early discharge paperwork including medication prescriptions.
- The importance of robust pre-operative assessment and advice, including:
    - Medication recording and pre-operative advice
    - Social support including in post-operative period
    - Pre-clerking
- The need and timing for post-operative imaging
- In-patient post-operative complications and their management in a short stay pathway
- The effect of current COVID restrictions
- The identification of patient more likely to require higher levels of support, either medical or physical.

5.2.5 Discussion

From the patient EBD exercise, we can see that there are three major touch points that cause concern for patients. This is the pre-admission, the early admission and early discharge period. The concerns raised in the pre-admission period are fear around the outcome and the operation itself. Targeted education in this area may reduce peri-operative concerns with a low risk of undesirable outcome (85). This would also address some of the themes of requests for direct contact with the clinical team between formal appointments and information during this period.

The later time period within the study also show patient concern over what happens next, most clearly seen in touch point 5 (as patients are discharged). Early contact during this period may allow for better patient outcomes and perhaps reduction in readmission, thus the inclusion of an early post-operative contact with patients on a short stay model of care may be beneficial.

This is perhaps even more important with the knowledge that older patients are more likely to be readmitted, with 15% of over 65-year-olds in England being readmitted within 28 days post being discharged from a hospital(86). Various studies have shown that telephone call follow up post discharge can reduce admission in at risk populations by up to 50% (87–90). It should be noted that this is not without cost, with up to 66% of all patient contacted receiving an extra in person clinical appointment (out-patient or home visit) following these telephone consultations(90).

The staff EBD exercise showed that staff generally feel positive in their involvement in this patient pathway as seen in the question 2 answers above. It is also interesting to note that the themes of patient reported concern being greatest in the pre-admission and early post-operative period also tallies with the observed patterns reported in staff EBD question 1.

Questions 3-5 in the staff EBD exercise have highlighted the need for a robust pre-operative assessment and educational intervention. This could address many staff raised issues including those around medication, social support and the completion of a robust pre-clerking proforma that could stop on the day delays as well as aiding in identifying barriers to discharge.

This intervention could also include patient pre-admission education which may alleviate the patient reported concerns in this period. It has also been shown to reduced length of stay in certain patient populations(91).

In-patient duplex scanning delaying discharge was raised within the staff EBD exercise. The need for this and its potential to be moved into the early post-operative period will be examined in section 7.

5.2.6 Conclusions

The EBD process is a valuable way to garner pathway satisfaction and success information from both patients and the wider MDT.

The use of EBD at our centre has outlined a need for access to pre-operative support and education. It has also highlighted the need for early post-operative contact to enhance the experience of this patient cohort. The process has raised the need to examine the utility of in-patient post-operative duplex and if it would be possible to move to this to the early post-operative period to aid in early discharge of this patient population.

6. Systematic analysis of the quality of patient information on the management of elective Abdominal Aortic Aneurysm repair on the internet using the modified 'Ensuring Quality Information for Patients' (EQIP) tool.

6.1. Abstract

6.1.1 Introduction

The internet is a major source of medical information for patients. However, little is known about the quality of websites regarding Abdominal Aortic Aneurysm (AAA) repair. The ensuring quality information for patients (EQIP) tool, a 36-point checklist, has been used extensively in other fields of medicine to assess online patient material. The EQIP tool has been validated to assess the content, identification and structure of patient material and assign an overall score.

The EQIP tool has never been used in vascular surgery and this study aims to assess the quality of patient literature on AAA repair on the internet.

6.1.2 Methods

The 12 most used search terms relating to AAA repair were identified using Google trends, with the first 10 pages of websites retrieved for each search term. After removal of duplicates and application of inclusion and exclusion criteria, websites were EQIP scored. The presence of accurate mortality, complication rates and emergency guidance were also recorded.

The ranking of each page by the search engine was collected, with a ranking of one representing the first displayed link by the search engine.

6.1.3 Results

1297 viable websites were identified with 235 (18%) eligible for analysis after removal of duplicates and the application of the inclusion and exclusion criteria. The median EQIP score for all websites was 18 (IQR 14-21). 78% of the websites originated in the USA with a median EQIP score of 17, while 13% came from the UK with a median score of 22. Only 18% of the websites provided mortality rates, 12% complication rates and 20% emergency guidance. No clear correlation of search engine ranking and EQIP score could be ascertained.

6.1.4 Conclusions

The quality of most websites concerning AAA repair is low, which is in keeping with other studies using EQIP within other surgical and medical fields. We have also shown that search engine ranking is not a reliable measure of the quality of patient information material. Thus, health practitioners should be aware of this issue and the location of high-quality material to which patients can be directed.

6.2 Introduction

For many patient groups the internet has become the most sought and used resource for medical treatment education(92,93). However previous studies have demonstrated that the quality of these resources can be variable(26,94). The utilisation of this information however can be associated with improved compliance and can affect health outcomes(95,96), so as a resource it should not be ignored by medical practitioner. Furthermore, it has been shown that patients often wish to have guidance from their physicians on reliable resource of information, both traditions written information and internet resources(97,98).

Due to the asymptomatic nature and current age restrictions on screening protocols, the true prevalence of Abdominal Aortic Aneurysms (AAA) is difficult to estimate. However, studies suggest a prevalence of 1.1% to 11% depending on age, country and the criteria used to define a AAA(99–104), with a trend of decreasing rates in more contemporary datasets. The elective repair of these can be either undertaken with Open Surgical Repair (OSR) or with Endovascular Aneurysm Repair (EVAR). Currently EVAR accounts for 61% of elective infra-renal AAA repairs in the UK (33).

Various methods have been described to assess the quality of patient information materials, most of these where originally designed for printed patient information(105,106). The EQIP(105) tool (Ensuring Quality Information for Patients) has been expanded since its conception to satisfy guidelines from the British Medical Association and the International patient decision aids standards (107,108). It is current form as the MEQIP it is a 36-item checklist that assess the quality of content (18 points), identification of the publishing persons or body (6 points) and structure (12 points). It has been already been used to assess the quality of patient information material in a wide variety of surgical and medical fields (26–31) but has yet to be used to assess patient information within vascular surgery.

Previous studies that have looked at the quality of patient information available to vascular surgery patients have found it to be generally poor quality(109–111) . Only one of these studies used a recognised analysis tool(109), all only analysed a maximum of 50 results, and none used more than a single search term to identify websites. This study aims to address the limitations of these previous studies in assess the quality of patient information on the management of elective AAA repair.

6.3 Methods

The methodology used for this study is described in section 2.5.

6.4 Results

6.4.1 Results of web search and screening.

All 12 search terms described in section 2.4 were used to collect a total of 1297 websites according to the specified methodology. After duplicates were filtered a total of 726 websites were screened using the eligibility criteria described in section 2.5. A total of 235 websites were then assessed using the MEQIP tool, a flow diagram of this selection process can be seen in Figure 10.

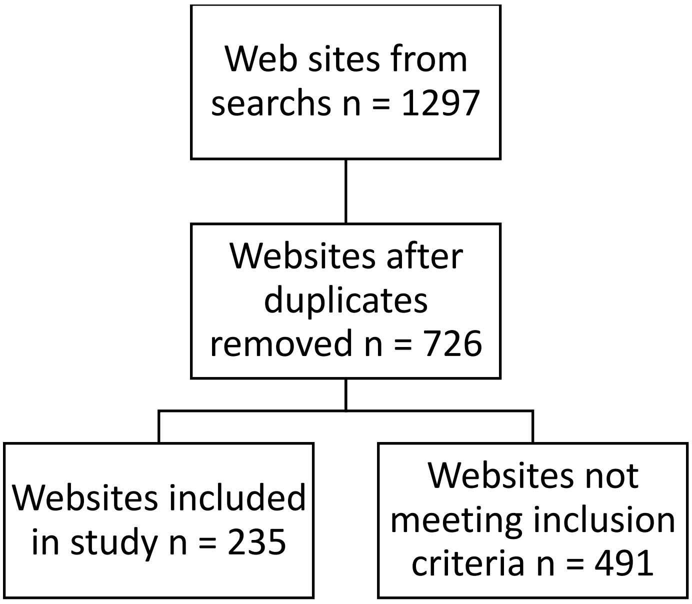


Figure 10: Flowchart of included websites

The median overall EQIP score in the websites studied was 18 (IQR 14-21), with the 75th percentile score being 21 (Table 21).

6.4.2 EQIP results from surveyed sites

The figures for each domain of the EQIP questionnaire as well as how large the difference is between high and low scoring websites can be seen in 36 items total comprised of Content (items 1–18), Identification (items 19–24), and Structure domains (items

25–36). Number of sites scoring for each item given, with the number and percentage of "yes" answers for high and low scoring websites for each item, as well as statistical significance between these.

Table 20.

	Item	Yes (n, %)	No (n, %)	N/A (n, %)	High-scoring websites (n, %)	Low-scoring websites (n, %)	p
Content Data	1. Initial definition of which subjects will be covered	158 (67%)	77 (33%)	0 (0%)	50 (89%)	108 (60%)	<0.001
Content Data	2. Coverage of the previously defined subjects (NA if the answer is "no" for item 1)	152 (65%)	7 (3%)	76 (32%)	50 (89%)	102 (57%)	<0.001
Content Data	3. Description of the medical problem/treatment/procedure	227 (97%)	8 (3%)	0 (0%)	56 (100%)	171 (96%)	0.2
Content Data	4. Definition of the purpose of the interventions	215 (91%)	20 (9%)	0 (0%)	56 (100%)	159 (89%)	0.005
Content Data	5. Description of treatment alternatives (conservative management)	147 (63%)	88 (37%)	0 (0%)	42 (75%)	105 (59%)	0.03
Content Data	6. Description of the sequence of the interventions and surgical procedure	195 (83%)	40 (17%)	0 (0%)	54 (96%)	141 (79%)	0.001
Content Data	7. Description of the qualitative benefits for the patient	153 (65%)	82 (35%)	0 (0%)	53 (95%)	100 (56%)	<0.001
Content Data	8. Description of the quantitative benefits to the patient	15 (6%)	220 (94%)	0 (0%)	11 (20%)	4 (2%)	<0.001
Content Data	9. Description of the qualitative risks and complications	93 (40%)	142 (60%)	0 (0%)	48 (86%)	45 (25%)	<0.001
Content Data	10. Description of the quantitative risks and complications	33 (14%)	202 (86%)	0 (0%)	18 (32%)	15 (8%)	<0.001
Content Data	11. Addressing quality-of-life issues	94 (40%)	141 (60%)	0 (0%)	52 (93%)	42 (23%)	<0.001
Content Data	12. Description of how complications are handled	45 (19%)	190 (81%)	0 (0%)	30 (54%)	15 (8%)	<0.001
Content Data	13. Description of the precautions that the patient may take to avoid complications	90 (38%)	145 (62%)	0 (0%)	42 (75%)	48 (27%)	<0.001

Content Data	14. Mention of alert signs that the patient may detect	86 (37%)	149 (63%)	0 (0%)	35 (63%)	51 (28%)	<0.001
Content Data	15. Addressing medical intervention costs and insurance issues	15 (6%)	220 (94%)	0 (0%)	7 (13%)	8 (4%)	0.05
Content Data	16. Specific contact details for hospital services (NA if not hospitals)	125 (53%)	42 (18%)	68 (29%)	31 (55%)	94 (53%)	0.5
Content Data	17. Specific details of other sources of reliable information/support	67 (29%)	168 (71%)	0 (0%)	34 (61%)	33 (18%)	<0.001
Content Data	18. Coverage of all relevant issues for the topic (summary item for all content criteria)	43 (18%)	191 (81%)	1 (0%)	30 (54%)	13 (7%)	<0.001
Identification Data	19. Date of issue or revision	82 (35%)	153 (65%)	0 (0%)	35 (63%)	47 (26%)	<0.001
Identification Data	20. Logo of the issuing body	231 (98%)	4 (2%)	0 (0%)	56 (100%)	175 (98%)	0.5
Identification Data	21. Names of the persons or entities that produced the document	128 (54%)	107 (46%)	0 (0%)	43 (77%)	85 (47%)	<0.001
Identification Data	22. Names of the persons or entities that financed the document	90 (38%)	144 (61%)	1 (0%)	28 (50%)	62 (35%)	0.08
Identification Data	23. Short bibliography of the evidence-based data used in the document	43 (18%)	192 (82%)	0 (0%)	23 (41%)	20 (11%)	<0.001
Identification Data	24. Statement about whether and how patients were involved/consulted in the document's production	0 (0%)	234 (100%)	1 (0%)	0 (0%)	0 (0%)	0.2
Structure Data	25. Use of everyday language and explanation of complex words or jargon	215 (91%)	20 (9%)	0 (0%)	56 (100%)	159 (89%)	0.005
Structure Data	26. Use of generic names for all medications or products (NA if no medications described)	63 (27%)	3 (1%)	169 (72%)	27 (48%)	36 (20%)	<0.001

Structure Data	27. Use of short sentences (<15 words on average)	195 (83%)	40 (17%)	0 (0%)	53 (95%)	142 (79%)	0.007
Structure Data	28. Personal address to the reader	158 (67%)	77 (33%)	0 (0%)	53 (95%)	105 (59%)	<0.001
Structure Data	29. Respectful tone	231 (98%)	4 (2%)	0 (0%)	56 (100%)	175 (98%)	0.5
Structure Data	30. Clear information (no ambiguities or contradictions)	226 (96%)	9 (4%)	0 (0%)	56 (100%)	170 (95%)	0.1
Structure Data	31. Balanced information on risks and benefits	92 (39%)	143 (61%)	0 (0%)	51 (91%)	41 (23%)	<0.001
Structure Data	32. Presentation of information in a logical order	210 (89%)	25 (11%)	0 (0%)	56 (100%)	154 (86%)	<0.001
Structure Data	33. Satisfactory design and layout (excluding figures or graphs; see next item)	201 (86%)	34 (14%)	0 (0%)	56 (100%)	145 (81%)	<0.001
Structure Data	34. Clear and relevant figures or graphs (NA if absent)	77 (33%)	8 (3%)	150 (64%)	31 (55%)	46 (26%)	<0.001
Structure Data	35. Inclusion of a named space for the reader's notes or questions	13 (6%)	221 (94%)	1 (0%)	6 (11%)	7 (4%)	0.1
Structure Data	36. Inclusion of a printed consent form contrary to recommendations (NA if not from hospitals)	2 (1%)	165 (70%)	68 (29%)	2 (4%)	0 (0%)	0.08

36 items total comprised of Content (items 1–18), Identification (items 19–24), and Structure domains (items 25–36). Number of sites scoring for each item given, with the number and percentage of "yes" answers for high and low scoring websites for each item, as well as statistical significance between these.

Table 20: Modified EQIP tool

6.4.3 EQIP content questions

The median EQIP score for the content questions (items 1-18 36 items total comprised of Content (items 1–18), Identification (items 19–24), and Structure domains (items 25–36). Number of sites scoring for each item given, with the number and percentage of "yes" answers for high and low scoring websites for each item, as well as statistical significance between these.

Table 20) was 8 (IQR 6-11) with the 75th percentile score being 5. The total possible score for this domain was 18. 97% of the websites provided a description of the medical issues (item 3) and the 91% explained the purpose of the intervention (item 4). However only 63% mentioned conservative management as an option (item 5). 83% of sites described the steps in the surgical procedure or procedures discussed (item 6). Only 65% discussed the benefit to the patient in a qualitative manner (item 7) and even less (6%) quantitatively (item 8), and 60% did not mention quality of life issues (item 11). Risks and complications were equally poorly covered with only 40% discussing them in a qualitative manner (item 9) and 14% in a quantitative one (item 10), with only 19% addressing how these complications are addressed (item 12). Very few sites (29%) also provided any details of other reliable sources (item 17).

6.4.4 EQIP identification questions.

The median score for the EQIP identification questions was 3 (IQR 1-3) out of a total of 6, with the 75th percentile score of 3 (see Table 21). Almost all (98%) sites provided an identification logo (item 20), though far fewer provided the date, or identified who produced or funded the website (item 21, 22 and 23, with 35%, 54% and 38% respectively). In only 18% of the sites a bibliography was provided on the data used (item 23), and none of the sites stated if or how patients were involved or consulted in the document's creation (item 24).

EQIP Data Properties				
	Overall EQIP	**Content Data**	**Identification Data**	**Structure Data**
Median:	18	8	3	7
Minimum:	6	1	0	2
Maximum	33	17	5	12
Quartile 1:	14	6	1	6
Quartile 3:	21	11	3	9

IQR:	7	5	2	3
75th Percentile	21	11	3	9

Table 21: Overall and domain EQIP scores

6.4.5 EQIP structure questions

The median score for the EQIP structure questions was 7 (IQR 6-9) out of a possible 12, with the 75th percentile score being 9. Most websites were found to use everyday language (91%, item 25), short sentences (83%, item 27) with a respectful tone (98%, item 29) and thus felt to provide clear information according to the EQIP criteria (item 30, 96%). A clear layout and a logical order were also found to be present in most sites too (items 33 and 32 with 86% and 89% respectively). Of note 64% of sites did not contain any figures or graphs but where they were present, they were generally clear and relevant with only 3% not being so (item 34).

6.4.6 Country of origin

The breakdown of the country of origin of the websites included in the study can be seen in * Wikipedia's head office is based in America, but the site is moderated and updated by an international team.
Table 22. Many of the websites included in the study were from America (78%) followed by the UK (13%), other countries made up the remaining 9% as seen in * Wikipedia's head office is based in America, but the site is moderated and updated by an international team.
Table 22. Websites originating from the USA had a median EQIP score of 17, while those from the UK has a median score of 22.

Country	Articles n (%)	Average EQIP Score
USA	183 (78%)	17.16
UK	30 (13%)	21.77
Australia	5 (2%)	19.4
Canada	4 (2%)	21.75
New Zealand	3 (1%)	15.67
Germany	2 (1%)	18
Republic of Ireland	2 (1%)	16.5
Austria	1 (0%)	24
India	1 (0%)	20
International website*	1 (0%)	21

Israel	1 (0%)	19
Netherlands	1 (0%)	13
Switzerland	1 (0%)	20

* Wikipedia's head office is based in America, but the site is moderated and updated by an international team.

Table 22: Number of included websites by site's country of origin.

6.4.7 Sources of patient information

The organisation type that provided the websites reviewed can be seen in Table 23. It should be noted that the vast majority (67%) of the websites identified were from hospitals with an average score of 17.29. Though the next most prevalent were professional societies with score an average of 20.33.

Source of information	Articles n (%)	Average EQIP Score
Hospital	157 (67%)	17.3
Professional society	18 (8%)	20.3
Industry	16 (7%)	17.2
Academic Centre	10 (4%)	17.4
Encyclopaedia	9 (4%)	21.6
News service	9 (4%)	20.2
Health department	6 (3%)	21.5
Charity	5 (2%)	20
Practitioner	3 (1%)	17.7
Others	2 (1%)	11.5

Table 23: Included site results by organisation type.

6.4.8 EQIP score and search ranking

No relationship was noted between EQIP score and search engine ranking (see Figure 11). There was however a difference seen between different sources of patient information and their search engine ranking (see Figure 12).

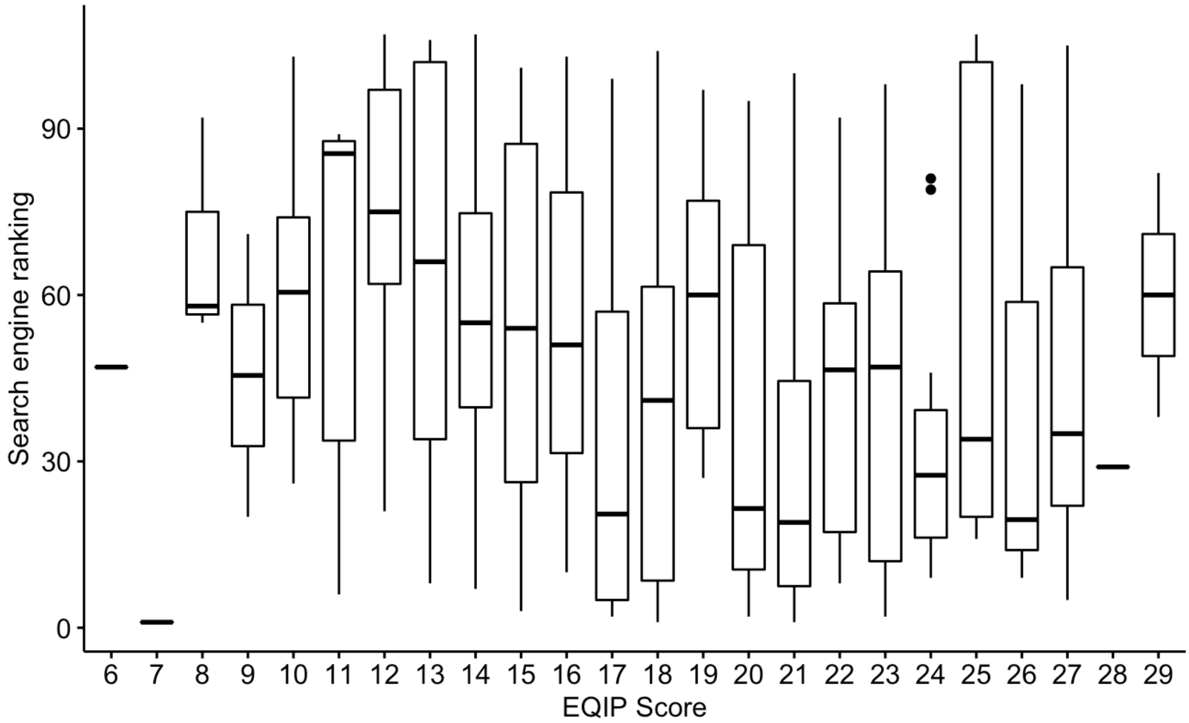


Figure 11: Box plot showing search engine ranking by EQIP score

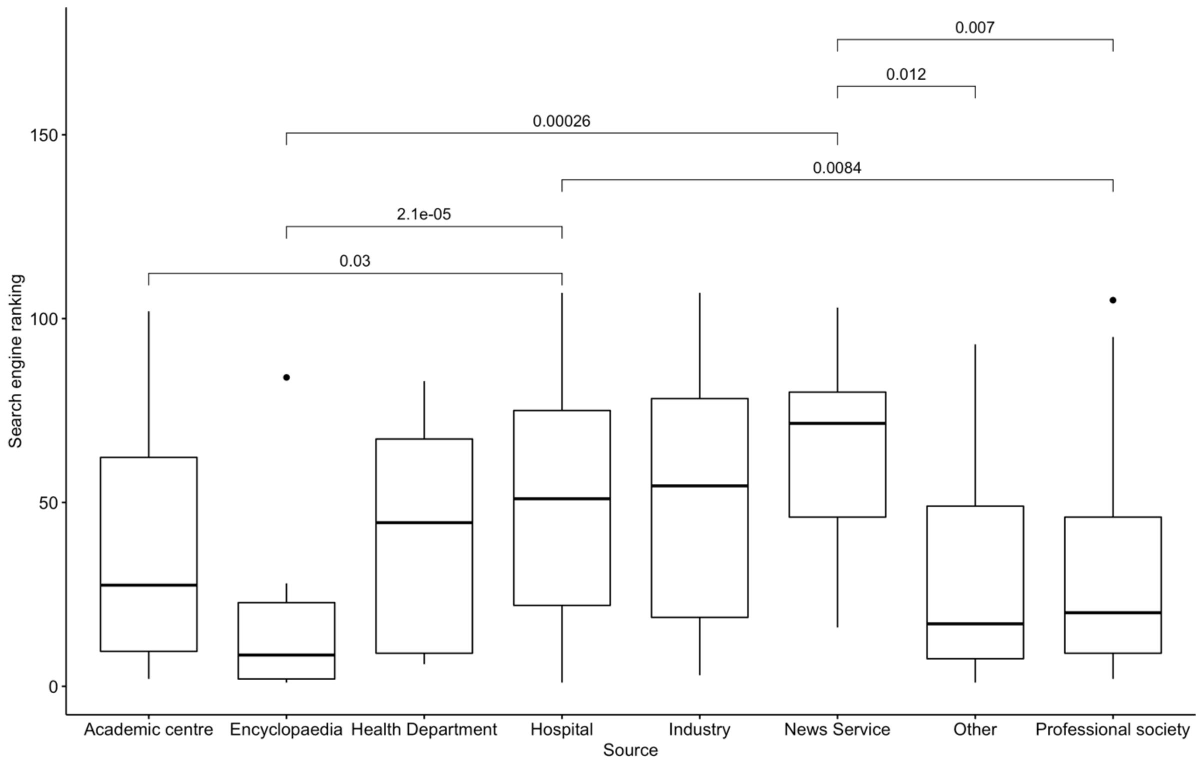


Figure 12: Box plot of Searching engine ranking by website category. All statistically significant differences between group are shown with associated p values.

6.4.9 Top rated websites

The websites that were rated to be in the 99th percentile using the overall EQIP score are listed in Table 24.

Websites with an EQIP Score >27 (99th percentile)	Score
1. Dudley group NHS foundation trust AAA patient information leaflet. URL: https://www.dgft.nhs.uk/leaflet/abdominal-aortic-aneurysm-aaa-treatment-v1/	33
2. North Bristol NHS Trust Endovascular Aneurysm Repair (EVAR) Leaflet. URL: https://www.nbt.nhs.uk/sites/default/files/attachments/Endovascular%20Aneurysm%20Repair%20%28EVAR%29_NBT002075.pdf	29
=3. US department of health and human Services Abdominal Aortic Aneurysm information site. URL: https://health.gov/myhealthfinder/topics/health-conditions/heart-health/talk-your-doctor-about-abdominal-aortic	28
=3. Patient and family guide to Endovascular Aneurysm Repair (EVAR) at Toronto General Hospital. URL: https://www.uhn.ca/PatientsFamilies/Health_Information/Health_Topics/Documents/EVAR_TGH.pdf?utm_source=EndovascularAneurysmRepair&utm_medium=Click&utm_campaign=EndovascularAneurysmRepair-EVARTGH	28
=3. East Kent Hospitals University NHS foundation trust patient information leaflet. URL: https://www.ekhuft.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=88494	28
=3. Abdominal Aortic Aneurysm (AAA): Causes, Symptoms, & Management. Information site by news-medical.net. URL: https://www.news-medical.net/health/Abdominal-Aortic-Aneurysm-(AAA)-Causes-Symptoms-Management.aspx	28

Table 24: 99th percentile scoring websites

6.5. Discussion

The internet is an important resource for patients looking for health information and this study focuses on the quality of patient information for the treatment of abdominal aortic aneurysms. Overall, this study found that the average EQIP score for all sites included was 18 out of a possible 36 points. This demonstrates that a whole the quality of the available information is poor when assessed using the EQIP toolkit. This is in keeping with previous studies that have reported a median EQIP score between 15-19 in various fields of medicine(26–31,112). As well as in keeping with smaller studies that have examined vascular surgery patient information in the past(109–111).

However as seen in table 5 within the search results the 99th percentile in this study achieved scores greater than 27. Therefore, it is clear from our findings that good patient resources are available, and physicians should be aware of these.

Out of the three major components of the EQIP (content, identification, and structure), and in keeping with previous studies, the identification score was the lowest (median 3 out of a possible 9, 33% of total possible). Due to the unregulated nature of the internet this should be concerning to physicians as it may mean that data with strong bias is hard for patients to identify. The structure section achieved the highest median percentage of the best possible score at 58% and the content section achieved a median of 44% of the maximum possible score. This is again in keeping with studies in other areas of medicine(26,27,29,113).

Along with the poor quality of the data as assessed by EQIP it is concerning to note the limited information on the risk provided by the reviewed sites. As assessed using the EQIP tool in item 9 and 10 only 40% had any qualitatively discussion of risks and complications with even less (14%) quantifying these either for the procedure or condition. This is extremely important as the risk profile of both EVAR and OSR are part of the reasons a patient may opt for a type of repair or conservative management.

As can be seen in Figure 11 no relationship was seen between the search ranking of websites by the search engine and their EQIP score in the searches performed. This is important to note as patients may not continue to search though more than the first few websites recommended by a search and thus, they may not come across high quality pages without direction.

Several limitations have been identified in this study, firstly due to the ever-changing nature of the internet the results presented are only accurate for the time that the search was produced. However, the authors believe that the trends presented are likely to continue to be true and the importance of being able to direct patients to reputable sources of information is likely to become increasing important over time. Secondly the searches for this study where only performed using the Google search engine, therefore other search engines may rank webpages differently or give different pages all together. However in April 2020 86% of searches performed on the web were done so using Google, thus the authors feel that even if there were difference with other search engines this would only affect a small number of the overall patient population(114).

The EQIP tool was originally designed for use with printed patient information leaflets though in the form of the MEQIP it has been used in a variety of medical field for the assessment of internet patient information. Furthermore, EQIP has been designed as a general tool for the assessment of patient information and is not specifically validated for the assessment of AAA patient information. However, as a general tool it does highlight the large discrepancy in quality of the sources identified in this study.

6.6 Conclusions

The internet has become an important source of patient information and vascular physicians must have an awareness of the benefits, risk, and limitations of this resource. This study shows that the average quality of patient information in the surgical management of AAA when assessed by the EQIP is poor. This is in keeping with findings in other areas of medicine. However, there are pockets of high-quality information that vascular surgery physicians should be aware of to be able to direct their patients towards.

The importance of physicians to direct patient to reliable and accessible information is especially important because of the effect it can have on patient attitude, compliance and health outcomes(97).

7. Peri-operative imaging and reintervention rates in EVAR

7.1 Abstract

7.1.1 Introduction

National and international guidance on EVAR surveillance post operatively do not explicitly advise the need for post-operative pre-discharge imaging. Published literature to date does show that post-operative pre-discharge ultrasound duplex scans do pick up EVAR complications that cannot be seen on the completion angiogram. The effect that this has on management of this patient population however is unclear as many of these findings are self-resolving.

7.1.2 Methodology

All patients undergoing EVAR at St George's Hospital between March 2010 and 2019 were identified and screened for those that were infrarenal asymptomatic repairs. For each patient the electronic patient records were screened to identify those that had undergone an inpatient USS and CT, and if any complication were noted on these. All completion angiograms and operative notes were screened to look for complications. All in-patient post-operative reinterventions were collected from the hospital's PACS system and the patient's electronic notes.

7.1.3 Results

A total of 650 asymptomatic infrarenal EVARs were performed with a 3.5% in-patient reintervention rate. 2.3% were Aortic related reinterventions and 1.2% were non-Aortic. 27 patients were noted to have abnormalities on their completion angiogram. 7.4% of those that had an abnormal completion angiogram went on to have an in-patient reintervention compared with 3.4% of those that had a normal completion angiogram. 93.2% of those studied had a post procedure in-patient duplex. 75% were normal and 24% discovered an abnormality, of those that were normal 1.5% had an intervention compared with 9.4% of those with an abnormal scan. Of those that had a normal completion angiogram 1.36% had a normal duplex but underwent an in-patient re intervention compared with 9.2% with an abnormal duplex. Of those that had an abnormal completion angiogram 4.2% had a normal duplex but underwent an in-patient re intervention compared with 12.5% with an abnormal duplex.

7.1.4 Conclusions

Duplex ultrasound and the completion angiogram have good discriminatory potential to diagnose early post-operative issues in EVAR that require re-interventions. Many of the reinterventions undertaken could be safely delayed, thus performing the post-operative duplex in the early outpatient period is safe and allow greater program efficiency.

7.2 Introduction

The role of in-patient post-operative imaging and its relationship to in-patient reintervention in EVAR poorly studied, with no guidelines in either the 2020 NICE or 2019 ESVS report. Both however are clear on the need for post procedure follow up.

In the NICE guidelines there is recommendation for enrolment into a surveillance imaging protocol. The ESVS report is more prescriptive in outlining the need for imaging in the first 30 days post operatively. This is recommend to be in the form of a contrast enhanced CT angiogram, for which there is reasonable evidence (115–118).

Pre-discharge ultrasound duplex scans have been shown to detect new endoleaks not seen on the completion angiogram(119). In this study Sandford et al showed that only 17% of the endoleaks found by pre discharge duplex ultrasound were seen on the completion angiogram. However, 53% of these where type 2 endoleaks, of which only 18% went on to have an intervention at any point in their patient journey. Of the remaining patients 33% were found to have a type 1 endoleak of which 29% spontaneous resolved, and 15% were found to have a type 3 endoleak 75% of which also resolved. It is therefore unclear if the routine use of ultrasound duplex as an in-patient is needed in all patients who undergo infrarenal EVAR.

7.3 Methodology

Methodology as per section 2.6.

7.4 Results

7.4.1 Data identification

A total of 1102 infrarenal aneurysm repairs in the study period were identified. Of these 650 cases represented asymptomatic infrarenal EVAR cases (see Figure 13, plate A). Of these 650 cases 623 (95.8%) were noted to have satisfactory completion angiograms (see Figure 13, plate B)

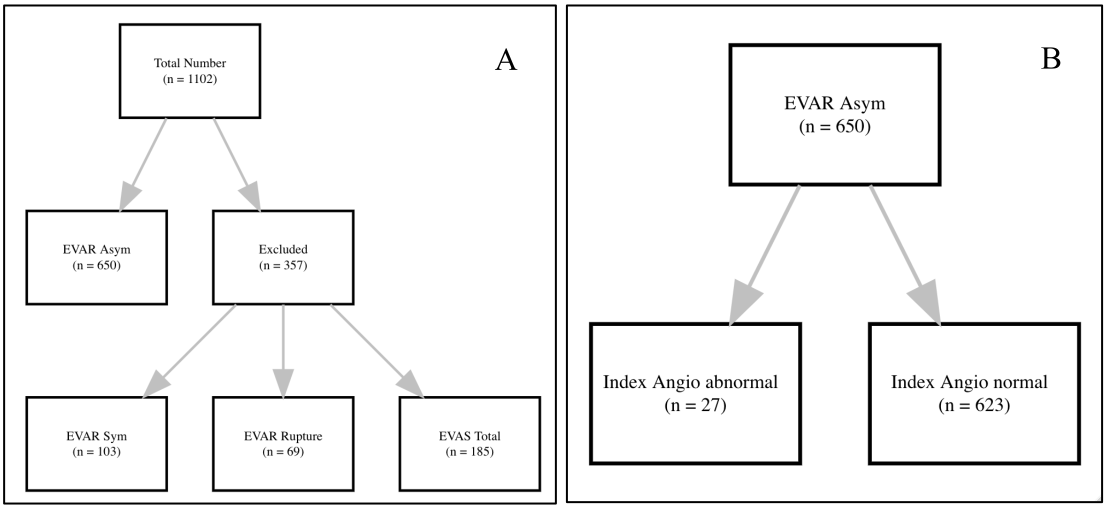


Figure 13: Flow chart of included cases.

The imaging modalities and in-patient interventions undergone in the two groups identified in Figure 13 plate B can be seen in Figure 14 and Figure 15 for those that had normal and abnormal procedural angiograms respectively.

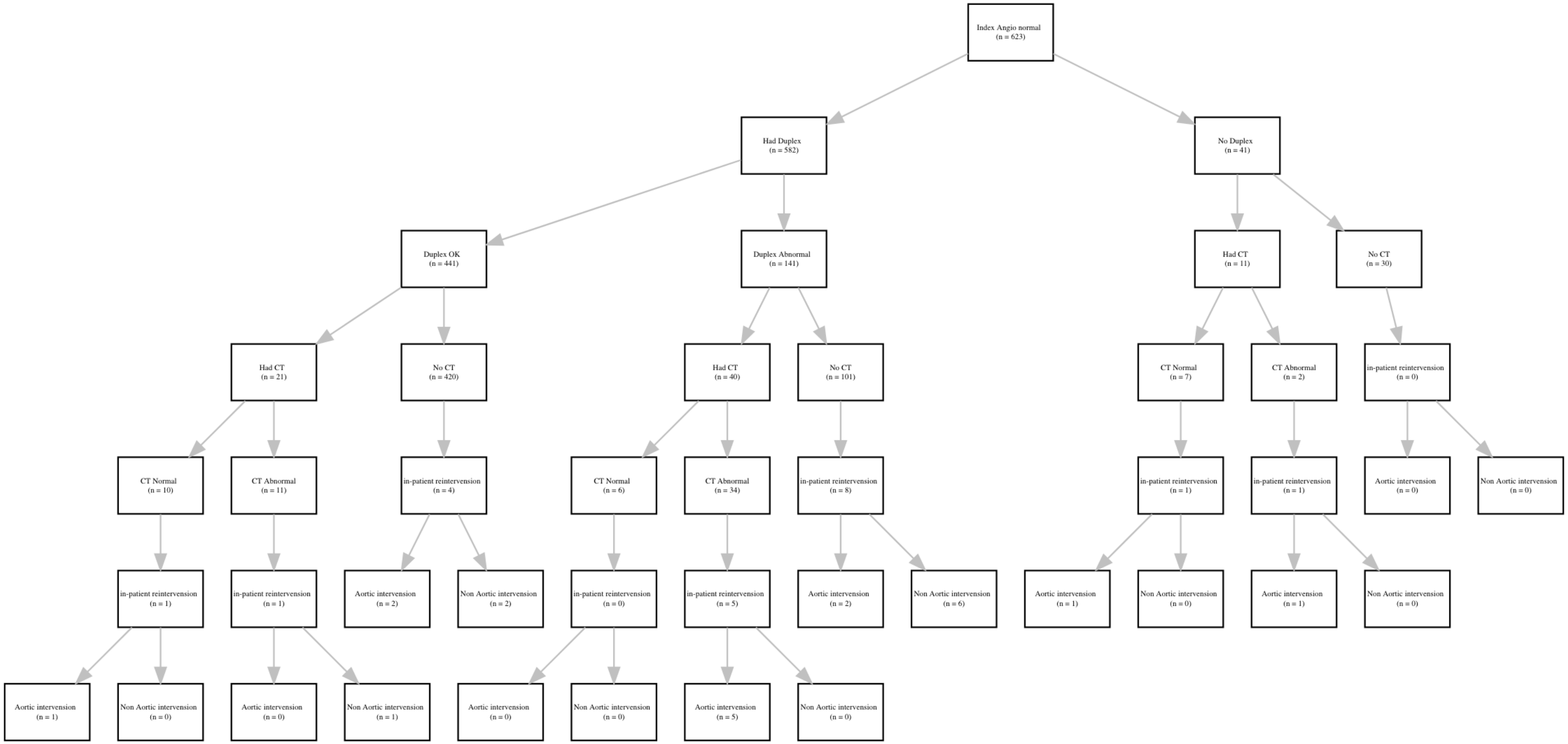


Figure 14: Flow chart of EVAR patients with normal procedural angiograms.

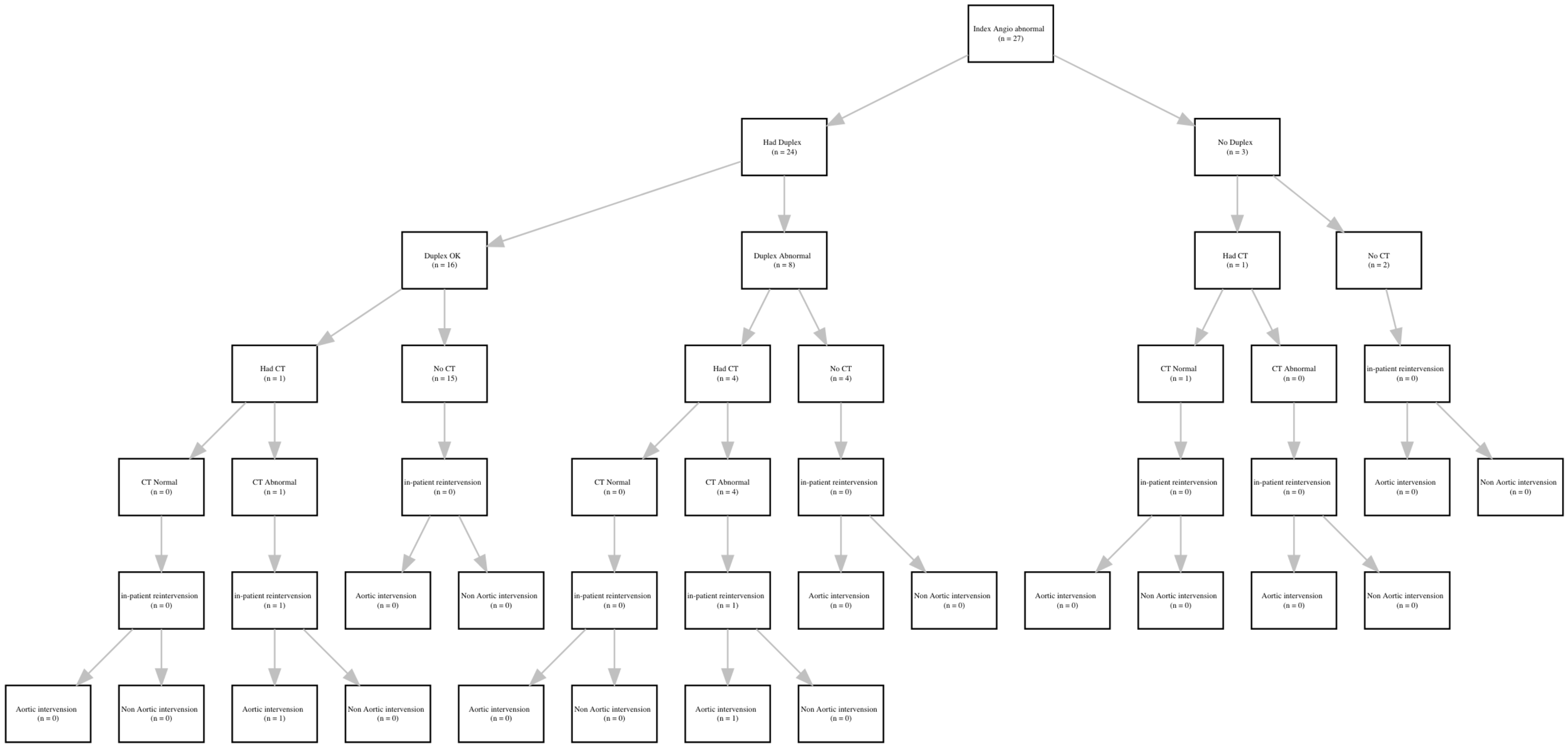


Figure 15: Flow chart of EVAR patients with abnormal procedural angiograms

7.4.2 Duplex usage

The vast majority of the patients in this study underwent an in-patient duplex, 606 (93.2%). Within the normal procedural angiogram group 93.4% underwent duplex ultrasound and 88.9% of those in the abnormal angiogram group. Overall 75% (457) of all the duplex scans performed were normal and 26% (149) showed an abnormality.

Of those that had a normal post-operative duplex 7 (1.5% of the 457 that had a normal duplex) had an intervention as an in-patient compared with 14 (9.4% of the 149 that had an abnormal duplex) of those with an abnormal duplex scan.

7.4.2 Reinterventions

There were a total of 23 (3.5%) in-patient re-interventions in the studied asymptomatic EVAR patients. Eight of these were non-graft related, and fifteen were graft related, as seen in Table 25.

Procedural completion angiogram	In-patient duplex	Number of patients (Percentage of total cohort)	Interventions undertaken (Percentage of cohort)	
			Graft Related	Non-graft related
Normal	Normal	441 (67.8%)	3 (0.7%)	3 (0.7%)
Normal	Abnormal	141 (21.7%)	7 (5%)	6 (4.2%)
Normal	No duplex	41 (6.3%)	2 (4.9%)	Nil
Abnormal	Normal	16 (2.5%)	1 (6.3%)	Nil
Abnormal	Abnormal	8 (1.2%)	1 (12.5%)	Nil
Abnormal	No duplex	3 (0.5%)	Nil	Nil

Table 25: Interventions performed by procedure angiogram and duplex result.

7.4.4 Abnormal procedural angiogram group

In the abnormal procedure angiogram group (27 patients), 16 (66.7%) of these patients' duplex scans were normal, 8 (29.6%) were abnormal and 3 (11.1%) did not undergo an in-patient duplex. Although these may have been performed after reintervention in some cases.

Two interventions (7.4% of this cohort) occurred in the cohort of patients who were noted to have abnormalities on the completion angiogram, all of these were graft related interventions. As a percentage this was higher than the 3.4% (21 patients) interventions that occurred in patients who had no abnormalities seen on the procedural completion angiogram. The interventions undertaken can be seen in Table 26 below.

Stent related interventions	**number**
EVAR relining for type 3 endoleak	1
Palmaz stent for type 1a	1

Table 26: In-patient interventions undertaken in those with an abnormal completion angiogram.

Only one patient with an abnormal angiogram but normal duplex (4.17%) underwent an in-patient procedure. Furthermore only one patient who had an abnormal angiogram and abnormal duplex scan (12.5%) underwent an in-patient procedure.

7.4.4 Normal procedural angiogram group

In the normal procedural angiogram group, 440 (75.6%) has a duplex scan that was normal, with six (1.36%) of these patients undergoing an in-patient procedure. In those that had an abnormal duplex scan thirteen (9.2%) underwent an in-patient intervention. The interventions undertaken can be seen in Table 27 and Table 28 below.

As can be seen in these tables, patients who had a normal duplex scan during their in-patient stay but had a reintervention (both graft and non-graft related) all had these ultrasound scans performed after or on the day of their reintervention.

In all those that had an abnormal duplex after a normal completion angiogram, the duplex was performed before in intervention took place.

Intervention type	**Ultrasound**		
	Normal duplex	Abnormal duplex	No duplex
Graft related			
Limb extension ± embolization of internal iliac artery	1: Left internal iliac artery embolization: duplex after intervention.	5: 2x EVAR limb stenting for stenosis: duplex before intervention. 1x EVAR limb stenting for stenosis and type 2: duplex before intervention. 1x IIA embolization and EVAR limb extension for unknow type 2 or type 1b: duplex before intervention. 1x EVAR limb extension for Ib endoleak: duplex before intervention.	1: Iliac rupture requiring limb extension.
Fem-fem cross over for occluded limb	1: Fem-Fem cross over: duplex performed after intervention.		1: Fem-Fem cross over for occluded EVAR limb.
EVAR relining		1: Relining for type 3: duplex before intervention	
EVAR Ballooning for type 1a		1: Proximal ballooning for 1a endoleak: duplex before intervention.	
Open CIA repair	1: Open CIA repair for rupture, duplex after intervention.		

Table 27: In-patient, graft related reinterventions undertaken in those with normal completion angiogram.

Intervention Type	**Ultrasound**		
	Normal duplex	Abnormal duplex	No duplex
Non graft related			
CFA endarterectomy or repair	1: CFA repair for iatrogenic dissection: duplex performed on day of intervention.	1: CFA endarterectomy for occlusion: duplex performed before intervention.	
Pseudo-aneurysm treated with thrombin		4: 4x Pseudo-aneurysm treated with thrombin: duplex before intervention	
Popliteal artery embolectomy	1: Emergency popliteal embolectomy: duplex performed after intervention.		
EIA rupture and stent	1: 1x EIA rupture and stent; Duplex performed after.		
EIA dissection		1: 1x: EIA stent for dissection. Duplex before intervention.	

Table 28: In-patient non-graft related reintervention in those with normal completion angiograms.

7.4.5 Temporal patterns in intervention

When the number of interventions (both graft and non-graft related) are examined by year no clear patterns of complication rate change can be seen. The graft related and non-graft related interventions by year can be seen in Table 29 below.

It should be noted that the department had an active endovascular aneurysm sealing (EVAS) program between 2013 and 2016. As EVAS cases were excluded from this study the volume of cases during this time is decreased.

	% Graft related interventions	N	% Non-graft related interventions	N
2010	0	0 of 62	0	0 of 62
2011	3.73	5 of 134	1.49	2 of 134
2012	2.94	3 of 102	1.96	2 of 102
2013	0	0 of 64	1.56	1 of 64
2014	0	0 of 39	5.13	2 of 39
2015	2	1 of 50	0	0 of 50
2016	4	2 of 50	0	0 of 50
2017	1.61	1 of 62	0	0 of 62
2018	2.63	2 of 76	2.63	2 of 76
2019	0	0 of 11	0	0 of 11

Table 29: Complication rate by year

7.5 Discussion

Post procedure duplex ultrasound is a routine part of many centres' post-operative EVAR pathway, this is due to it low risk and perceived ability to pick up serious early complication of EVAR both stent and access related. It can however be a barrier to early discharge if it is not readily available.

When we compare the rates of in-patient reintervention in those with normal vs abnormal completion angiograms, 2.01% vs 7.4% respectively, we can see that this allows triage of high-risk cases that would be worth considering in-patient follow up imaging. Though it is worth noting that only 27 patients in our study population had a documented issue identified in the post procedural imaging and thus most patients fell outside of this group.

Our study did show that duplex does have a good ability to pick up post-operative issues that require intervention. With only 1.5% of patients who had a normal post-operative duplex undergoing an in-patient reintervention compared with the 9.4% seen in those that had an abnormal duplex.

However, when these interventions undertaken are examined in detail, as seen in Table 26, Table 27 and Table 28, all the serious or immediately life threatening described would generally present with symptoms. This would be in keeping with Shaw et al's review (40) that showed that a serious complication across a series of SS-EVAR trials to date have occurred within 6 hours post operatively within 6 hours post EVAR.

The safety that in-patient duplex provides in this study population is best shown by the cohort of patients who have a normal completion angiogram and go on to have an abnormal duplex and undergo an intervention. This is because it would be expected that if an abnormality was seen on the completion angiogram, then the complication would be known and could be triaged appropriately. In our study 141 (23.3% of those that had a duplex) had a normal completion angiogram but an abnormal duplex with 13 having an re-intervention as an in-patient as seen in Table 27 and Table 28.

Of these 13 re-interventions 6 were for access related complications, 4 of which were pseudo-aneurysms. These may well be safely treated in an ambulatory manner by thrombin injection if robust measures were in place to have a duplex scan performed within 2 weeks post operatively. The remaining two non-graft related complications were a CFA endarterectomy and EIA dissection. If these conditions were flow limiting it would be expected that they would be symptomatic.

Regarding the remaining 7 re-interventions in those with a normal completion angiogram but abnormal duplex scan these were graft related and comprise of; 2 EVAR limb stenosis, 2 EVAR limb stenosis and type 2 endoleak, 1 EVAR limb extension and IIA embolization for endoleak, 1 EVAR limb extension for type 1b endoleak, 1 EVAR relining for type 3 endoleak and 1 balloon moulding for type 1a endoleak.

It is likely that any stent-related technical problems not known about at the time of completion angiogram would either present with symptoms or were adequately screened with an expedited scan.

Furthermore this delay in imaging may in fact reduce the number of reintervention needed, as some endoleaks may only be transitory (120,121). Sandford et al. showed in their paper (119) that of the endoleaks identified on post procedural duplex only 18% of the type 2 endoleaks ever underwent an intervention, while 29% of the type 1 endoleaks and 75% of the type 3 endoleaks spontaneously resolved. This is in keeping with other papers and meta-analysis that also show that in the setting of low flow endoleaks that are most likely to be missed on completion angiograms conservative treatment may allow these to seal (118,120,122).

It is however impossible to predict from the data and its analysis presented in this chapter, as well as the literature presented, what the benefit of a post-operative pre discharge duplex would be in a particular patient's case. It is thus imperative that any short stay model of care that would aim to routinely remove this should allow for it to be available if the treating clinician deems it to be necessary, and for a robust audit process to be in place to re-implement it if concerns are raised.

This study is limited in the retrospective nature of its data collection. This may have affected its ability to understand the patient journey and the timings of the scans and interventions undertaken. The retrospective nature of the data collection and the time span that it covers, during which the hospital used a variety of electronic health note systems, may also mean that known complications seen on the completion angiogram or other imaging methods may not have been recorded.

7.6 Conclusions

Duplex ultrasound has good discriminatory potential to diagnose issues in EVAR that require re-interventions. Many of the reinterventions undertaken could be safely delayed and thus a robust post-operative short stay EVAR program that involves an early post discharge ultrasound as well as clear exit criteria for high-risk cases could allow select patient to undergo SS-EVAR with a good degree of safety.

There are however risks to this approach and the tolerance to such risk would need to be made on a unit, physician and individual patient basis.

8. Timing and reason for readmission in elective EVAR

8.1 Abstract

8.1.1 Introduction

Understanding readmission after EVAR is important not only for the affect that it has on patients but also its fiscal effect. By understanding the pattern of readmission, it may also be possible to introduce steps to reduce these events which may lead to safer and more cost-effective EVAR programs.

8.1.2 Methodology

All elective asymptomatic EVAR cases performed at St George's Hospital from January 2013 to January 2020 were identified using the National Vascular Registry. All identified cases were screened using data contained in the NVR and local electronic patient records for any readmissions within 30 days of discharge. Where cases were identified, their notes were screened to confirm this readmission and to collect the reason and timing.

8.1.3 Results

A total of 964 cases were identified with 21 readmissions within 30 days post discharge. Median readmission was 10 days post discharge with a bimodal pattern of readmission being noted. These peaks were at day 4 and day 19 respectively, with a skew toward the early peak. 62% of readmission occurred in the first 10 days.

The most common cause of readmission was back pain most of which occurred within the first 5 days post discharge.

8.1.4 Conclusions

30-day readmission rates in this study follow a bimodal distribution with a skew toward to the early peak. Any readmission reduction program produced would need to take this into account.

8.2 Introduction

Hospital readmission within 30 days is an increasingly scrutinised variable, with recommendations being made in the vascular GIRFT report to reduce these with improved perioperative care and follow up (12). This issue is combined with the fact that it has been shown in the USA that vascular surgery patients represent a disproportionate number of readmissions amongst surgical specialities. It was estimated in this study that readmissions cost the Medicare system 17 billion US dollars in 2004 (123).

Within vascular surgery it has also been shown that readmission after four common vascular surgery procedures adds an additional 39% to the cost of the index hospitalisation(124), without even counting the loss of tariff this incurs in the UK.

In regards to EVAR, national 30 day readmission rates in UK NVR in 2020 were 4.9%(125). There are a few large-scale studies that have examined the timing and cause of readmission after EVAR, with Chen et al. doing so in 3886 patients from the American College of Surgeons National Surgical Quality Improvement Program Targeted Vascular database in 2012 to 2013(126). In this study it was found that median time to readmission was 12 days, with an overall readmission rate of 8.2%. The major causes of readmission were found to be surgical site infections (26%), peripheral vascular complications (10%), GI complications (9%), bleeding complications (8%), renal complications (8%) infections (7%), cardiac complications (7%) and pulmonary complications (7%). The timing of each of these complications was not studied.

This data is similar to that of Dua et al., who used the US National Readmission Database to identify 120646 patients who underwent elective EVAR between 2012 and 2014(127). The unplanned readmission rate in this study was 11.6%. It did not examine the time of the readmission during the 30-day period but did once again find that the largest single cause of readmission was surgical site infection. It should be noted that both studies had low rates of percutaneous access which was in keeping with practice at the time.

This study hopes to add to the literature by examining the timing of readmission within the first 30 days post discharge to look for patterns that can help to reduce readmission post elective EVAR within a contemporary UK practice.

8.3 Methodology

Methodology as per section 2.7.

8.4 Results

A total of 964 patients were identified as having undergone EVAR for asymptomatic infrarenal aortic aneurysm in the time period studied.

From this population a total of 21 (2.2%) readmissions up to 30 days post discharge were identified. The median age was 77 (62-89) with 3 females and 18 males.

Readmission appeared to follow a bimodal distribution, with a skew toward the earlier peak. Thirteen of the twenty-one (61.9%) cases occurring in the first 10 days post discharge. The pattern of readmission can be seen in Figure 16 below. The mean readmission day was day 10.

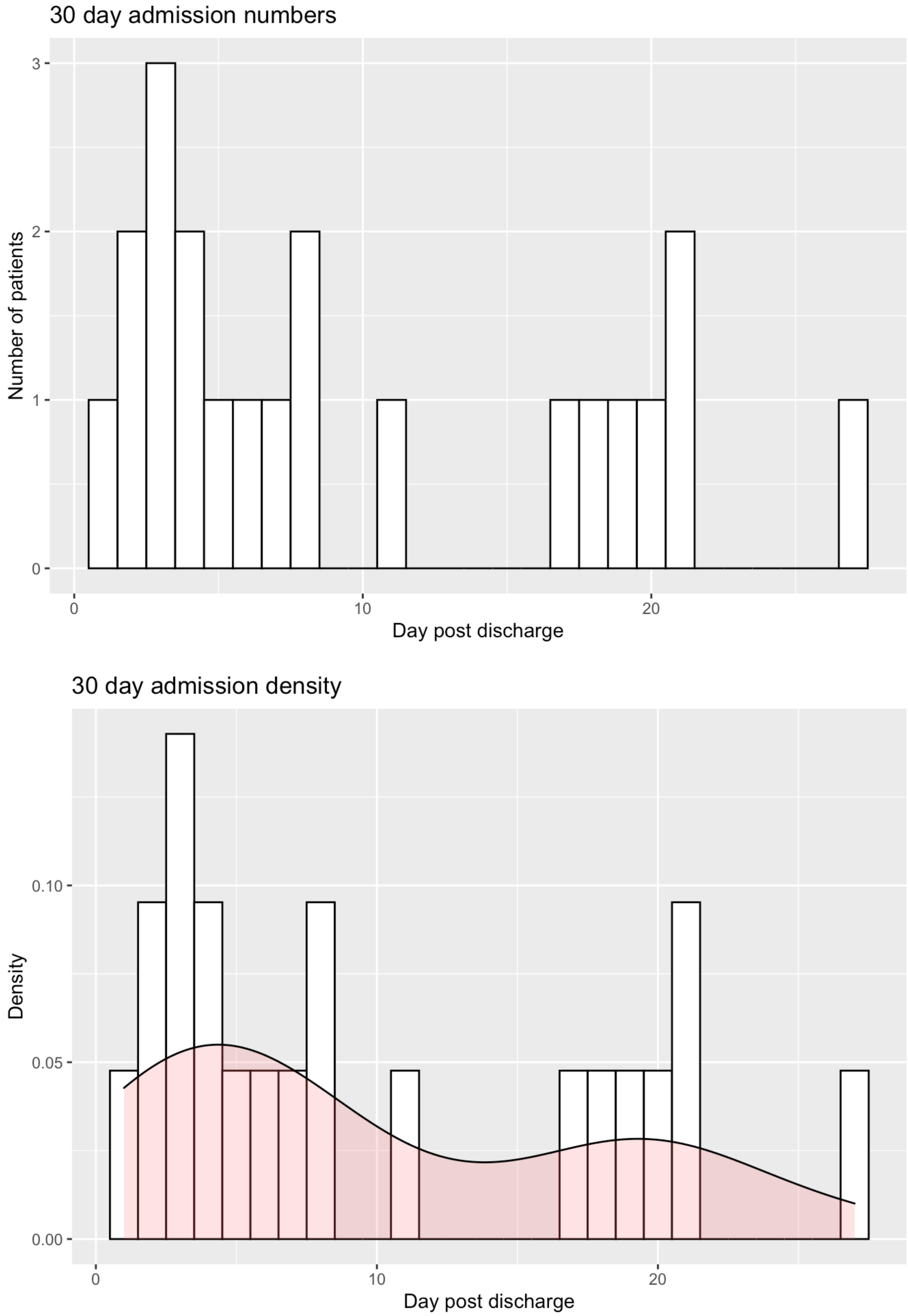


Figure 16: 30-day readmission timing, by count (top) and by density (bottom).

The reason for the readmission was also examined, with a brief description being available in Table 30 below. As discussed above, the first 10 days post discharge was associated with a greater number of admissions than the remaining 20 days. Respiratory complication, sepsis and visceral ischemia were noted to only occur within this first peak while other complications were distributed between this early and later phase. The distribution of each type of complication can be seen in Figure 17 below.

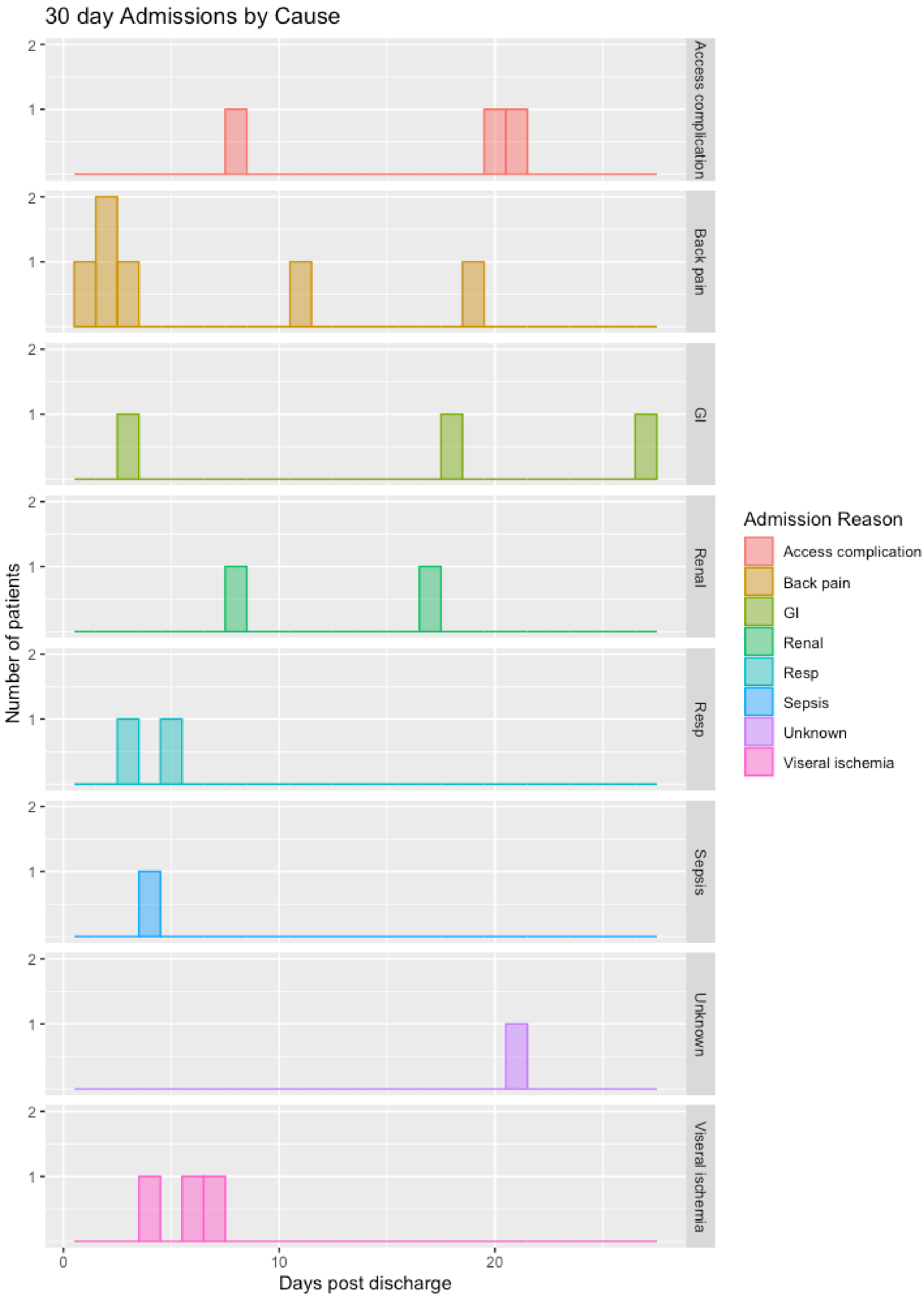


Figure 17: 30-day EVAR readmission by type and time

Patient	Readmission timing (number of days post discharge)	Length of readmission stay (days)	Reason for readmission	Reason group
A	1	1	Leg weakness and abdomen pain with no clear cause found post investigation	Back pain
B	2	2	Abdomen and back pain investigated and thought to be PIS	Back pain
C	2	3	Back pain that settled, nil on investigations	Back pain
D	3	3	Pneumonia	Respiratory
E	3	5	Abdominal pain and constipation, treated conservatively after investigations.	Gastro intestinal
F	3	2	Back pain with nil cause found on investigations	Back Pain
G	4	2	Abdominal pain found to be due to splenic infarct.	Visceral ischemia
H	4	3	Sepsis of unknown cause	Sepsis
I	5	1	Pneumonia	Respiratory
J	6	1	Mortality due to visceral ischemia	Visceral ischemia
K	7	8	Back pain with renal infarcts noted on the CT	Visceral ischemia
L	8	1	AKI treated conservatively	Renal
M	8	12	Groin infection from access site	Access complication

N	11	4	Back pain with no cause found	Back pain
O	17	6	AKI needing change in medication and intravenous fluids	Renal
P	18	1	Epigastric pain, thought to be from gallstones	GI
Q	19	3	Abdominal pain with no cause found	Back pain
R	20	11	Access site pseudo aneurysm which required open repair	Access complication
S	21	3	Nil documentation available for review	unknown
T	21	11	Access site collection requiring drainage and outpatient IV antibiotics	Access complications
U	27	3	Nausea and vomiting, due to constipation	GI

Table 30: Reason, timing and length of readmission by patient.

8.5 Discussion

The readmission rate in the studied population was 2.2% at our centre, this is significantly lower than the 5.7% national readmission rate (33). This is also substantially less than many studies in published literature(126,127). Part of this difference is likely due to the increasing prevalence of percutaneous access, as groin infections were a major reason for readmission in these historic cohorts.

The mean day of readmission in this study was the 10th day post operatively, which is in keeping with the 11th day mean seen in other studies(126). However, as over half (61.9%) of these happen in the first 10 days it would be important that any readmission avoidance program consider this front loading of complications and design interventions accordingly.

Due to the retrospective nature of this study, it is not possible to discern if any of the recorded readmissions could have been avoidable. However, of the readmission categories recorded, those that were admitted for back pain (seven patients (33.3%)) could be targeted with support and an ambulatory pathway, possibly reducing readmission. Once again as with the overall early peak seen in Figure 16 this persists with patients presenting with abdominal pain with five occurring in the first 10 days. It would therefore be prudent that any intervention was designed to cover this early peak.

8.2.6 Conclusions

30-day readmission rates in this study follow a bimodal distribution with a skew toward to the early peak. Any readmission reduction program would need to take this into account.

9. Prospective Short Stay Aneurysm Trials

9.1 Prospective SS-EVAR trial

9.1.1 Abstract

9.1.1.1 Objectives:

Short Stay (SS) Endovascular Aneurysm Repair (EVAR) pathways offer the potential to improve service efficiency and patient satisfaction by reducing length of stay. This study aims to assess a previously retrospectively validated SS-EVAR criteria in a prospective population.

9.1.1.2 Methods:

A validated SS-EVAR criteria based on patient comorbidities (see table 1), was applied prospectively to all EVAR cases between 1st January – 1st July 2021 at a tertiary centre. Postoperative complications, length of stay and readmissions were recorded.

9.1.1.3 Results:

Nineteen patients were included (95% male, mean age 74 ± 6.41). Median length of stay was 35 ± 21.5 hours. Six (26.3%) patients had in-patient complications, four within 8-hours (Two groin haematoma's, one respiratory infection and one urinary retention). One occurred post 24-hours (pseudo-aneurysm). There were two readmissions within 30 days, one requiring renal artery stenting and one cholecystitis. There was no in-patient or 30-day deaths in the studied population.

9.1.1.4 Conclusions:

The pathway used allows for the safe inclusion and adequate uptake of patients with limited co-morbidity for SS-FEVAR. Without greater than national average rates of readmission. Wider adoption of this pathway could improve EVAR resource efficiency, whilst maintaining patient safety.

9.1.2 Introduction

As discussed in chapter 3, SS-EVAR programs have been previous shown to be possible and safe. Previous studies however have been limited but either being device specific, retrospective, having limited inclusion or require intraoperative values for selection into the program. This led us to developing our own SS-EVAR and SS-FEVAR guidelines that have been retrospectively validated.

We have also identified barriers to short stay EVAR in our local centre through EBD and the issue of lack of easy access to appropriate educational materials to patient in chapter 6. This has led us to develop a peri-operative bundle of care consisting of a pre-operative surgery school and early telephone based follow up of SS-EVAR patients to reduce readmission and review, as well as addressing areas of anxiety identified within our EBD process.

Using the selection criteria discussed above and with the bundle of care developed, this chapter aims to prospectively test the SGVI SS-EVAR and SS-FEVAR program at our local centre.

9.1.3 Methodology

The methodology used for this study is described in section 2.8.1

9.1.4 Results

9.1.4.1 Demographics of study population

A total of 19 consecutive elective EVAR patients were identified during the study period with a median age of 74 years old (Range 63 to 86 years) with 18 being male (94.7%) and 1 female (5.3%). The median travel distance to the hospital in this cohort was 14.1km (Range 2.3- 31.6) see Table 31.

	>36hr stay (N=7)	≤36 hr stay (N=12)	Overall (N=19)	P-value
Demographics				
Age				
Median [Min, Max]	77.0 [67.0, 83.0]	73.0 [63.0, 86.0]	74.0 [63.0, 86.0]	0.553
Gender				
Male	6 (85.7%)	12 (100%)	18 (94.7%)	0.179
Female	1 (14.3%)	0 (0%)	1 (5.3%)	
Distance from hospital (km)				
Median [Min, Max]	18.4 [4.10, 25.3]	9.90 [2.30, 31.6]	14.1 [2.30, 31.6]	0.536

Table 31: SS-EVAR cohort demographics

All patients underwent infrarenal bifurcated grafts (Medtronic endurant).

9.1.4.2 Comorbidities of study population

The comorbidities of the studied population can be seen in Table 32 below. In those that had a history of cancer these were either curatively treated, under surveillance or prostate cancer under long term stable hormonal treatment. Three were prostate cancer (two on hormonal treatment, one surveillance), two were skin cancer (both treated with resection), one bowel cancer (hemicolectomy) and the final case was a bladder cancer treated with BCG.

As can be seen in the table the only variables that were found to be significant were ASA grade (p=0.047), a history of hypertension (p=0.047) and a history of chronic lung disease (p=0.05)

	>36hr stay (N=7)	≤36hr stay (N=12)	Overall (N=19)	P-value
Comorbidities				
BMI				
Median [Min, Max]	30.1 [19.1, 34.3]	25.2 [20.4, 34.7]	27.1 [19.1, 34.7]	0.902
ASA grade				
2	0 (0%)	5 (41.7%)	5 (26.3%)	**0.047***
3	7 (100%)	7 (58.3%)	14 (73.7%)	
Current smoker				
No	4 (57.1%)	8 (66.7%)	12 (63.2%)	0.678
Yes	3 (42.9%)	4 (33.3%)	7 (36.8%)	
Previous smoker				
No	0 (0%)	3 (25.0%)	3 (15.8%)	0.157
Yes	4 (57.1%)	5 (41.7%)	9 (47.4%)	
Current smoker	3 (42.9%)	4 (33.3%)	7 (36.8%)	
Type 2 diabetes				
Yes	3 (42.9%)	1 (8.3%)	4 (21.1%)	0.075
No	4 (57.1%)	11 (91.7%)	15 (78.9%)	
Hypertension				
Yes	7 (100%)	7 (58.3%)	14 (73.7%)	**0.047***
No	0 (0%)	5 (41.7%)	5 (26.3%)	
Hypercholesterolaemia				
Yes	6 (85.7%)	5 (41.7%)	11 (57.9%)	0.061
No	1 (14.3%)	7 (58.3%)	8 (42.1%)	
Myocardia infarction greater then 6 months ago				
No	4 (57.1%)	10 (83.3%)	14 (73.7%)	0.211
Yes	3 (42.9%)	2 (16.7%)	5 (26.3%)	
Any ischemic heart disease				
No	4 (57.1%)	11 (91.7%)	15 (78.9%)	0.075
Yes	3 (42.9%)	1 (8.3%)	4 (21.1%)	
Previous TIA or stroke > 1 year ago				
Yes	1 (14.3%)	1 (8.3%)	2 (10.5%)	0.683
No	6 (85.7%)	11 (91.7%)	17 (89.5%)	
Chronic lung disease				
No	5 (71.4%)	12 (100%)	17 (89.5%)	**0.05***
Yes	2 (28.6%)	0 (0%)	2 (10.5%)	
Congestive cardiac failure				
No	6 (85.7%)	12 (100%)	18 (94.7%)	0.179
Yes	1 (14.3%)	0 (0%)	1 (5.3%)	
Ejection fraction (%)				
Median [Min, Max]	62.0 [43.0, 65.0]	59.0 [50.0, 72.0]	60.0 [43.0, 72.0]	1
Chronic kidney disease				
CKD 2	4 (57.1%)	7 (58.3%)	11 (57.9%)	0.707
CKD 3a	3 (42.9%)	4 (33.3%)	7 (36.8%)	
None	0 (0%)	1 (8.3%)	1 (5.3%)	
History of cancer				
Yes	2 (28.6%)	5 (41.7%)	7 (36.8%)	0.568
No	5 (71.4%)	7 (58.3%)	12 (63.2%)	

Table 32: SS-EVAR cohort comorbidities

No cases were excluded by the SS-EVAR criteria laid out in Table 2.

9.1.4.3 Length of hospital stay including historic comparison

Median length of stay was 34.8 hours (range 9.75 - 124 hours). 12 (63.2%) patients were discharged in less than or equal to 36 hours. The length of stay (LoS) over the course of the trial period can be seen in Figure 18.

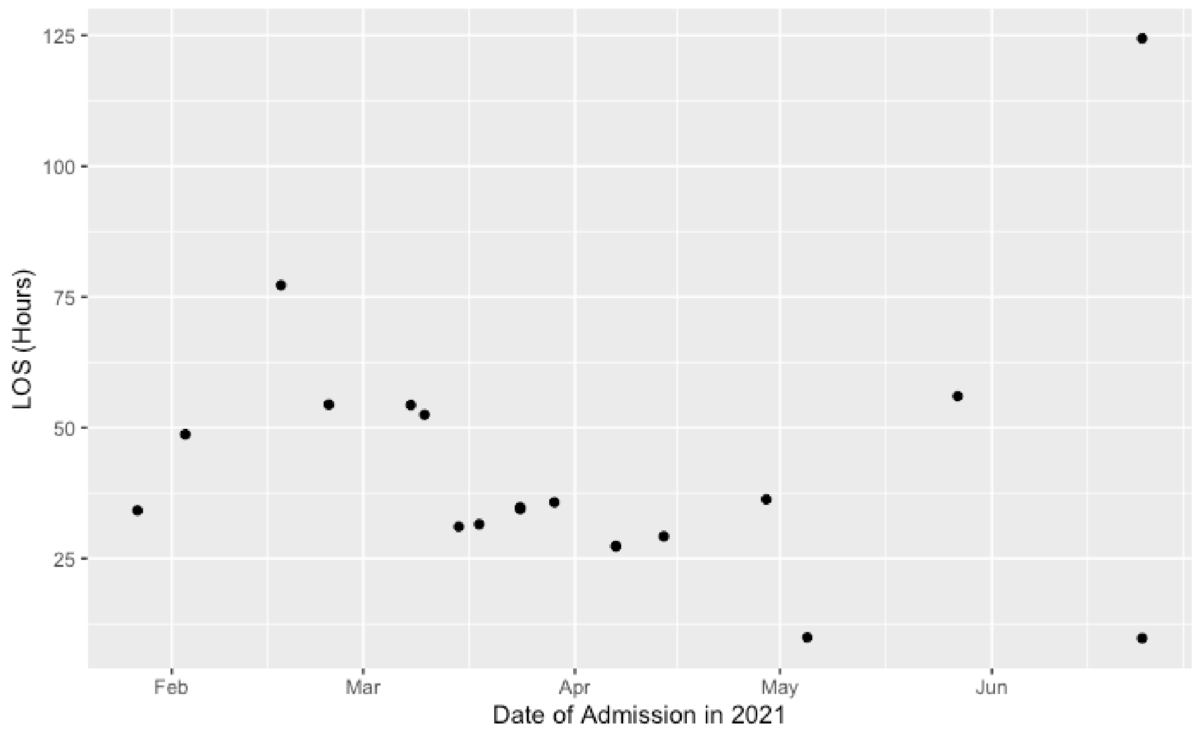


Figure 18: LOS in SS-EVAR trial

Due to the small number of cases in this study a single outlier can have a large effect, thus if the outlying case with a LOS of 124 hours is removed the median length of stay was 34.6 hours (range 9.75 – 77.2 hours). Although this has little effect on the median, the range is heavily affected with this exclusion.

When compared to the historic cohort (2013-2018) used in chapter 4 to validate the SGVI SS-EVAR criteria, we can see that there is significant difference in the length of stay. This difference between patients in this historic cohort that were selected with the pragmatic criteria and the SS-EVAR population can be seen in Figure 19 below.

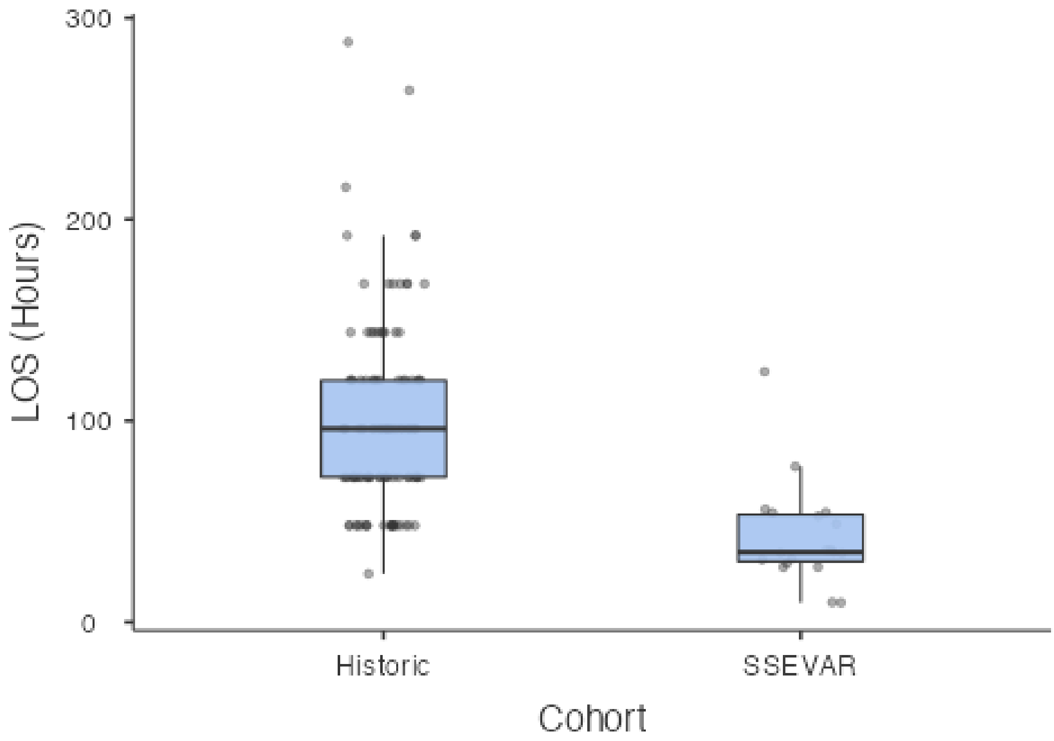


Figure 19: Length of stay (hours) in the historic 2013-2018 cohort selected using the pragmatic criteria and the SS-EVAR trial cohort.

Equal variance testing using Levene's test was significant (p <.05) suggesting violation of the assumption of equal variance and thus a Mann-Whitney U test was performed to test the significance of this difference, this was significant with a p-value of <.001.

All but one case was admitted on the day of surgery, with the remaining case having a pre-operative length of stay of >24 hours caused by a same-day cancelation of their operation due to institutional issues.

9.1.4.4 Learning Curve

Using non risk adjusted CUSUM (see Figure 20) we can see after one success the next 5 cases do not meet our SS-EVAR aim of discharge within 36 hours. However, after this, there are 11 out of the remaining 13 that do successfully achieve this status. The reasons for this, and learning taken from it, are drawn out in the discussion.

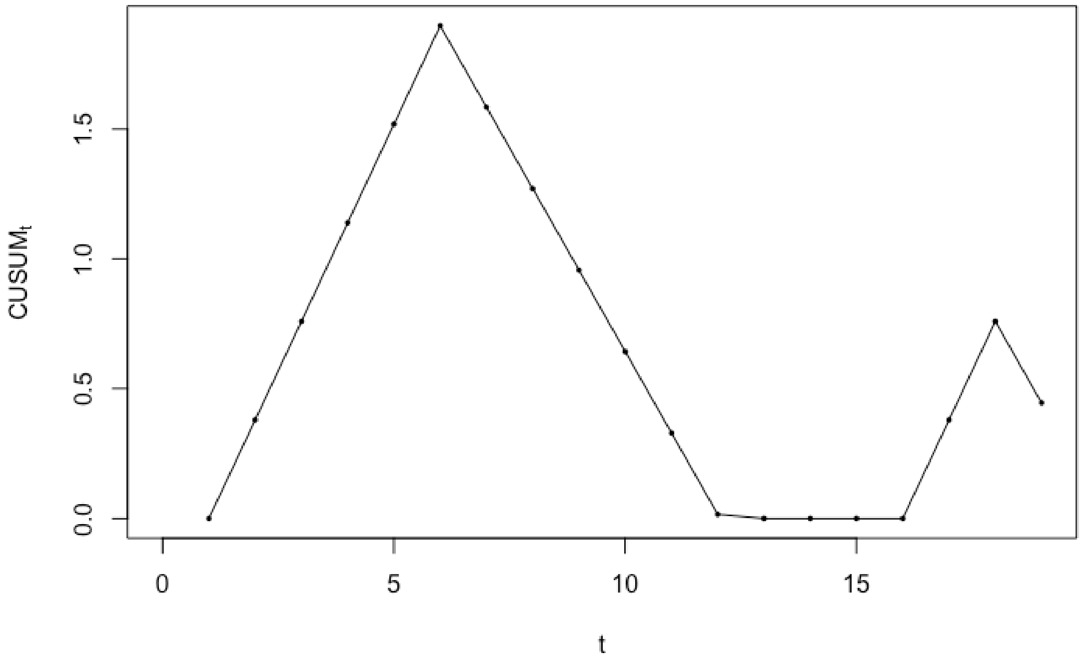


Figure 20: CUSUM for SS-EVAR cohort

After the 5th cases, and due concerns over staff adherence to the SS-EVAR pathway contributing to failure achieving 36 hour targeted in select cases a second educational event for the clinical team was performed.

9.1.4.5 In patient and 30 days complications and deaths

There were no in-patient or 30-day deaths in the studied population.

A total of six (26.3%) patients had in-patient complications. Four of these were within 8-hours post operatively and included two groin haematomas which were treated conservatively after duplex imaging to exclude pseudo-aneurysm, one respiratory infection treated with IV antibiotics and one patient with urinary retention treated with a catheter. One complication that occurred 24-hours post-operatively was an asymptomatic pseudo-aneurysm noted on a post-operative duplex. This was treated with a thrombin injection which represents the only in-patient reintervention noted in this population (5.2%).

There were two readmissions within 30 days. The first patient presented on the 6th day post discharge with abdominal pain and after CT imaging, underwent renal artery stent placement due to concern over shuttering one renal from the EVAR although renal function was unaffected. The other presented 3 weeks post discharge with abdominal pain and was found to have cholecystitis which was initially treated conservatively with a plan for day case laparoscopic cholecystectomy in the future. Therefore the aneurysm and EVAR related readmission only occurred in one patient (5.2%).

There was one unscheduled emergency department review in the study period which occurred on the same day as discharge due to concern from the patient over oozing from the groin, they were discharged with advice and did not need imaging, treatment or reintervention.

9.1.4.6 SS-EVAR Care bundle performance

All patients attended the surgery school online events or stated they had watched the online materials or the booklet provided.

All patients were phone at 48 hours post discharge. None of these calls prompted review or readmission.

9.1.5 Discussion

9.1.5.1 Safety

In the study population, a total of six patients (26.3%) had an in-patient complication, with 5 of the 6 occurring (83.3%) within 8 hours. This is in keeping with previous findings that the vast majority of serious complications occur withing the first 8 hours post operatively(40). It should be noted that this later complication did result in the only in-patient re-intervention in the study group with a thrombin injection for a small groin pseudoaneurysm. This in-patient complication rate is within the range seen by previous prospective SS-EVAR programs (8-41%)(13,14,41,42), while allowing for a more lenient selection criteria.

The readmission rate (5.2%) and mortality (0%) rates were also in keeping with previous published studies, between 1.6%-4%(13–15,42) and 0-1%(13–15,41,42) for readmission and mortality respectively.

9.1.5.2 Successful completion of the program

Overall, 12 (63.2%) where discharge in less than or equal to 36 hours. This is lower than previous published prospective SS-EVAR programs who had completion rates between 96-70%. This must be taken in the context of the enrolment percentage which was 100% in this study and between 33-66%(14,15,41) of the selection criteria that did not utilise intra-operative findings. Although the level of enrolment seen in this study is unlikely to continue to be as high if the case mix is similar that of our retrospective study(19), in which 59% of elective EVAR cases were eligible.

9.1.5.3 Learning curve

The CUSUM analysis performed shows signs of an institutional learning curve, with 5 of the first 6 cases not being discharged within 36 hours. Thus, due to the limited time period that this study has run it may be that over a longer time horizon the successful completion percentage may increase.

Due to the concerns that in selected cases this unsuccessful completion of the SS-EVAR pathway may be due to unfamiliarity with the new SS-EVAR pathway a second interim educational event took place after the 5th case in this series. Although it is not possible to assert that the improvement seen after this point is due to this educational event, centres who wish to start a SS-EVAR pathway should be mindful of the possible effect of staff familiarity with the program.

9.1.5.4 Limitations

This pilot period of the St George's SS-EVAR program ran for a period of 6 months during which case mix and throughput was affected by the ongoing COVID pandemic. It is therefore likely that the results may have been affected by these external factors. However the study, along with our previous published retrospective study, does appear to show that the selected criteria are safe and objectively applicable from pre-operative factors.

9.1.6 Conclusions

This study has continued to build on the work of our previously published retrospective validation study. This study has prospectively tested the SS-EVAR criteria which has been shown to have excellent eligibility while maintaining a similar safety to previous published studies.

A longer study period would be required to show statistical significance of LoS reduction and the cost implications of this to be modelled with accuracy.

The trial has highlighted the importance of staff education, and re-education, as a key part of the SS-EVAR bundle.

9.2 Prospective SS-FEVAR trial

9.2.1 Abstract:

9.2.1.1 Objectives

Short Stay (SS) Fenestrated Endovascular Aneurysm Repair (FEVAR) pathways offer the potential to improve service efficiency and patient satisfaction by reducing length of stay. This study aims to assess a previously retrospectively validated SS-FEVAR criteria in a prospective population.

9.2.1.2 Methods

A validated SS-FEVAR criteria based on patient comorbidities, was applied prospectively to all FEVAR cases between 1st January – 1st July 2021 at a tertiary centre. Postoperative complications, length of stay and readmissions were recorded.

9.2.1.3 Results

Fourteen patients were assessed with eleven included (91% male, median age 72 (62-83)), two were excluded for severe respiratory disease and one for an MI within the last 6 months. Mean length of stay was 96.9 ± 70 hours. Six (54.5%) patients had in-patient complications, five within 8-hours (Two patients with puncture site bleeds, one high BP, one abdominal pain of unknown cause, and one 1b endoleak). One occurred post 24-hours (CIA stent for asymptomatic duplex diagnosed disrupted plaque). There were three readmissions within 30 days, two for abdominal pain without clear cause and one access complication treated conservatively. There was no in-patient or 30-day deaths in the studied population.

9.2.1.4 Conclusions

The pathway used allows for the good uptake of patients with limited co-morbidity for SS-FEVAR. Wider adoption of this pathway could improve EVAR resource efficiency, whilst maintaining patient safety.

9.2.2 Introduction

Short Stay (SS) Fenestrated Endovascular Aneurysm Repair (FEVAR) pathways offer the potential to improve service efficiency and patient satisfaction by reducing length of stay.

As discussed in section 3 there have been no reported SS-FEVAR trials in the literature to date.

This study aims to assess a previously retrospectively validated SS-FEVAR criteria in a prospective population.

9.2.3 Methods

The methodology used for this study is described in section 2.8.2

9.2.4 Results

9.2.4.1 Study demographic and co-morbidities

A total of 14 Elective FEVAR were identified during the study period with eleven being included within the study. Of those that were excluded, two were for severe respiratory disease and one for a myocardial infarction within the last 6 months pre-operatively, all excluded patients were also categorised as ASA 4. The demographics and comorbidities of those included in the study can be seen in Table 33 and Table 34 below.

	Excluded (N=3)	Included (N=11)	Overall (N=14)	p-value
age				
Median [Min, Max]	70.0 [68.0, 72.0]	72.0 [62.0, 83.0]	72.0 [62.0, 83.0]	0.35
Gender				
Male	3 (100%)	10 (90.9%)	13 (92.9%)	
Female	0 (0%)	1 (9.1%)	1 (7.1%)	
distance from hospital (km)				
Median [Min, Max]	16.6 [6.70, 42.2]	11.5 [4.60, 45.7]	14.1 [4.60, 45.7]	1

Table 33: Demographics of those included and excluded in the SS-FEVAR program

	Excluded (N=3)	Included (N=11)	Overall (N=14)	p-value
BMI				
Median [Min, Max]	28.6 [23.6, 30.3]	26.1 [22.9, 34.1]	27.1 [22.9, 34.1]	0.885
ASA				
3	0 (0%)	11 (100%)	11 (78.6%)	**<0.001***
4	3 (100%)	0 (0%)	3 (21.4%)	
Current smoker				
No	3 (100%)	10 (90.9%)	13 (92.9%)	0.558
Yes	0 (0%)	1 (9.1%)	1 (7.1%)	
Previous smoker				
Yes	3 (100%)	6 (54.5%)	9 (64.3%)	0.188
No	0 (0%)	4 (36.4%)	4 (28.6%)	
Current smoker	0 (0%)	1 (9.1%)	1 (7.1%)	
Type 2 Diabetes				
Yes	0 (0%)	3 (27.3%)	3 (21.4%)	0.308
No	3 (100%)	8 (72.7%)	11 (78.6%)	
Hypertension				
Yes	3 (100%)	6 (54.5%)	9 (64.3%)	0.145
No	0 (0%)	5 (45.5%)	5 (35.7%)	
Hypercholesterolaemia				
Yes	2 (66.7%)	7 (63.6%)	9 (64.3%)	0.923
No	1 (33.3%)	4 (36.4%)	5 (35.7%)	
Myocardial infarction greater then 6 months ago				
No	2 (66.7%)	8 (72.7%)	10 (71.4%)	0.837
Yes	1 (33.3%)	3 (27.3%)	4 (28.6%)	
Ischemic heart disease (inc MI)				
No	2 (66.7%)	9 (81.8%)	11 (78.6%)	0.571
Yes	1 (33.3%)	2 (18.2%)	3 (21.4%)	
Previous TIA or stroke > 1 year				
No	2 (66.7%)	11 (100%)	13 (92.9%)	0.047
Yes	1 (33.3%)	0 (0%)	1 (7.1%)	
Chronic lung disease				
No	1 (33.3%)	10 (90.9%)	11 (78.6%)	**0.03***
Yes	2 (66.7%)	1 (9.1%)	3 (21.4%)	
Heart failure				
No	3 (100%)	11 (100%)	14 (100%)	n/a
Ejection fraction				
Median [Min, Max]	65.0 [55.0, 65.0]	60.0 [56.0, 67.0]	61.0 [55.0, 67.0]	1
Chronic kidney disease				
CKD 2	2 (66.7%)	9 (81.8%)	11 (78.6%)	0.519
CKD 3a	1 (33.3%)	1 (9.1%)	2 (14.3%)	
Normal	0 (0%)	1 (9.1%)	1 (7.1%)	
History of cancer				
No	1 (33.3%)	11 (100%)	12 (85.7%)	**0.003***
Yes	2 (66.7%)	0 (0%)	2 (14.3%)	

Table 34: SS-FEVAR comorbidities by inclusion status

9.2.4.2 Length of stay

Median length of stay of those included by the SS-FEVAR criteria was 80.7 (Range 30.5 – 237). As can see Table 35 this was longer than the median length of stay for the excluded patients (median 71 hours). This difference however was not statistically significant. Five (45.5%) patients were discharge in less than or equal to 72 hours.

	Excluded (N=3)	Included (N=11)	Overall (N=14)	p-value
Length of Stay (Hours)				
Mean (SD)	117 (94.2)	96.9 (70.0)	101 (72.2)	
Median [Min, Max]	71.0 [53.9, 225]	80.7 [30.5, 237]	75.9 [30.5, 237]	0.769

Table 35: Length of Stay (SS-FEVAR)

The length of stay for patients included by the SS-FEVAR criteria over the course of the trial period can be seen in Figure 21.

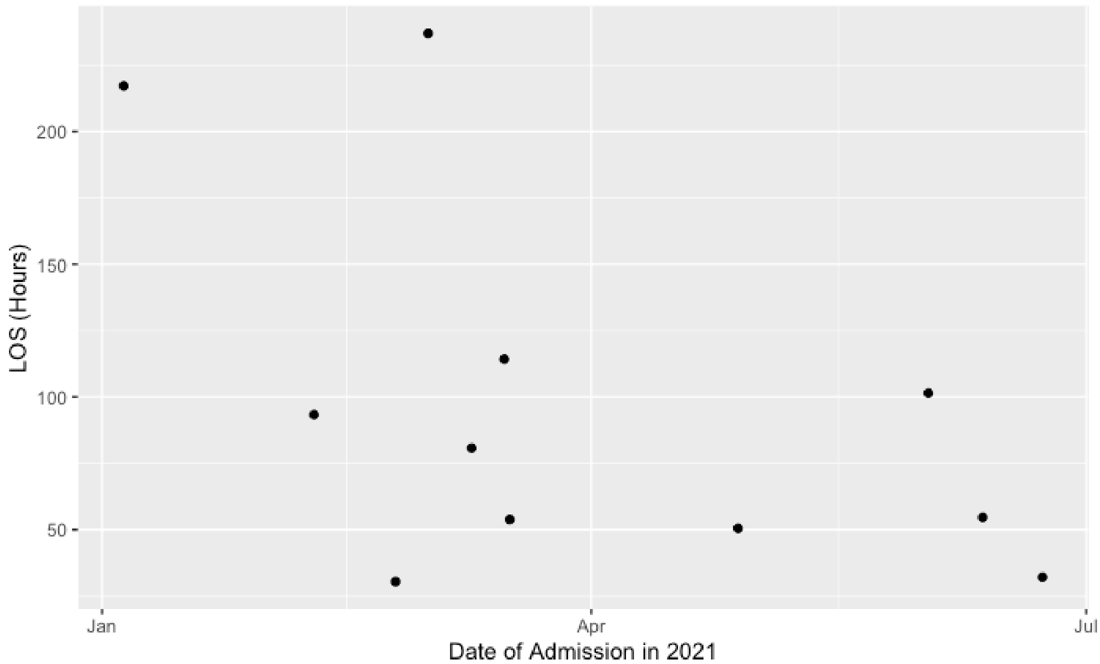


Figure 21: Length of stay for patients included in the SS-FEVAR program.

The demographics and comorbidities of those that were successfully discharged within 72 hours can be seen in Table 36 and Table 37 below.

	>72 hour LoS (N=6)	<72 hour LoS (N=5)	Overall (N=11)	p-value
age				
Median [Min, Max]	74.5 [62.0, 82.0]	71.0 [64.0, 83.0]	72.0 [62.0, 83.0]	0.647
Gender				
M	5 (83.3%)	5 (100%)	10 (90.9%)	0.338
F	1 (16.7%)	0 (0%)	1 (9.1%)	
distance from hospital (km)				
Median [Min, Max]	10.5 [8.70, 45.7]	17.5 [4.60, 41.0]	11.5 [4.60, 45.7]	0.931

Table 36: Demographics of SS-FEVAR cohort divided by length of stay.

	>72 hour LoS (N=6)	<72 hour LoS (N=5)	Overall (N=11)	p-value
BMI				
Median [Min, Max]	27.1 [22.9, 34.1]	26.0 [23.0, 30.5]	26.1 [22.9, 34.1]	0.931
ASA grade				
3	6 (100%)	5 (100%)	11 (100%)	n/a
4	0 (0%)	0 (0%)	0 (0%)	
Current smoker				
No	6 (100%)	4 (80.0%)	10 (90.9%)	0.251
Yes	0 (0%)	1 (20.0%)	1 (9.1%)	
Previous smoker				
Yes	4 (66.7%)	2 (40.0%)	6 (54.5%)	0.598
No	2 (33.3%)	2 (40.0%)	4 (36.4%)	
Current	0 (0%)	1 (20.0%)	1 (9.1%)	
Type 2 Diabetes				
Yes	3 (50.0%)	0 (0%)	3 (27.3%)	0.064
No	3 (50.0%)	5 (100%)	8 (72.7%)	
Hypertension				
Yes	4 (66.7%)	2 (40.0%)	6 (54.5%)	0.376
No	2 (33.3%)	3 (60.0%)	5 (45.5%)	
Hypercholesterolaemia				
Yes	4 (66.7%)	3 (60.0%)	7 (63.6%)	0.819
No	2 (33.3%)	2 (40.0%)	4 (36.4%)	
Myocardial infarction greater then 6 months ago				
No	5 (83.3%)	3 (60.0%)	8 (72.7%)	0.387
Yes	1 (16.7%)	2 (40.0%)	3 (27.3%)	
Ischemic heart disease				
No	5 (83.3%)	4 (80.0%)	9 (81.8%)	0.887
Yes	1 (16.7%)	1 (20.0%)	2 (18.2%)	
Previous TIA or stroke > 1 year				
No	6 (100%)	5 (100%)	11 (100%)	n/a
yes	0 (0%)	0 (0%)	0 (0%)	
Chronic lung disease				
No	5 (83.3%)	5 (100%)	10 (90.9%)	0.338
Yes	1 (16.7%)	0 (0%)	1 (9.1%)	
Heart Failure				
No	6 (100%)	5 (100%)	11 (100%)	n/a
EF (%)				
Median [Min, Max]	60.0 [56.0, 60.0]	65.0 [62.0, 67.0]	60.0 [56.0, 67.0]	**0.006***
Chronic kidney disease				
CKD 2	5 (83.3%)	4 (80.0%)	9 (81.8%)	0.361
CKD 3a	1 (16.7%)	0 (0%)	1 (9.1%)	
Normal	0 (0%)	1 (20.0%)	1 (9.1%)	
History of cancer				
No	6 (100%)	5 (100%)	11 (100%)	n/a
Yes	0 (0%)	0 (0%)	0 (0%)	

Table 37: SS-FEVAR comorbidities divided by length LoS stay.

9.2.4.3 Comparison to historic cohort

When compared to the historic cohort (January 2017 – January 2020) used in chapter 4 to validate the SGVI SS-FEVAR criteria, there was a lower average LoS in the SS-FEVAR cohort as compared to the historic one (see Figure 22). However, on statistical testing using a Mann-Whitney U test this difference is not found to be significant (p=0.243).

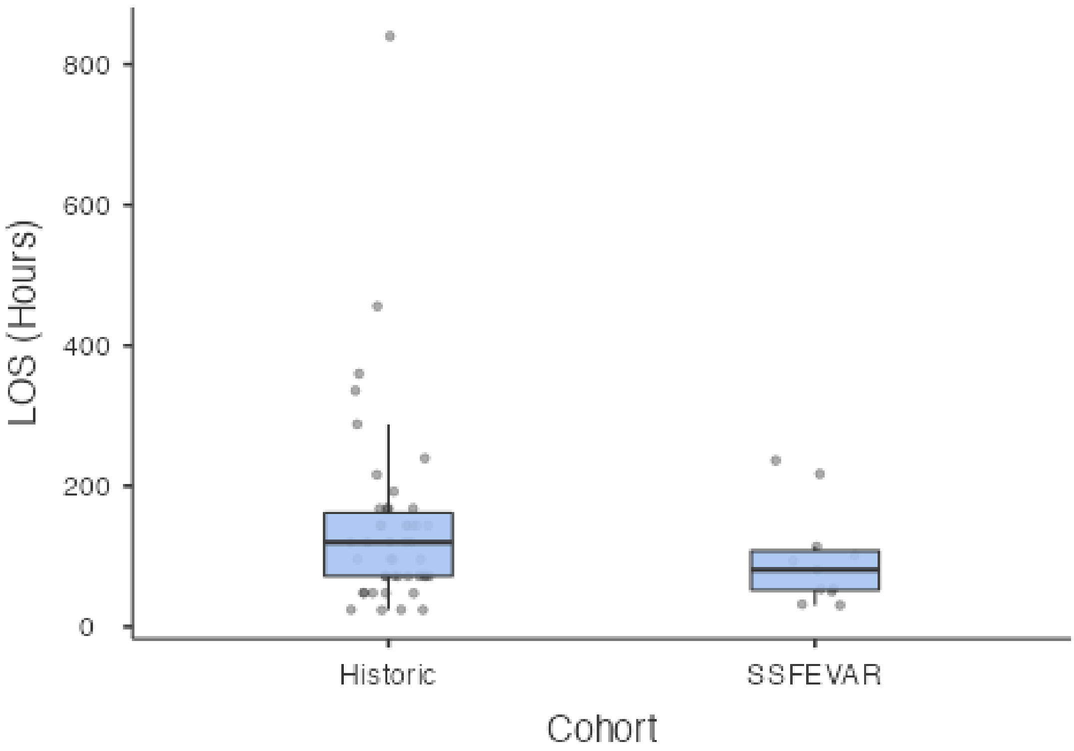


Figure 22: Length of stay (hours) in the historic January 2017- January 2020 cohort selected using the pragmatic criteria and the SS-FEVAR trial cohort

9.2.4.4 Learning curve

Using non risk adjusted CUSUM (see Figure 23) we can see a general trend over the first 6 cases of failure to discharge within the first 72 hours post operatively. However subsequent to this, 4 of the 5 remaining cases were successfully discharged within 72 hours.

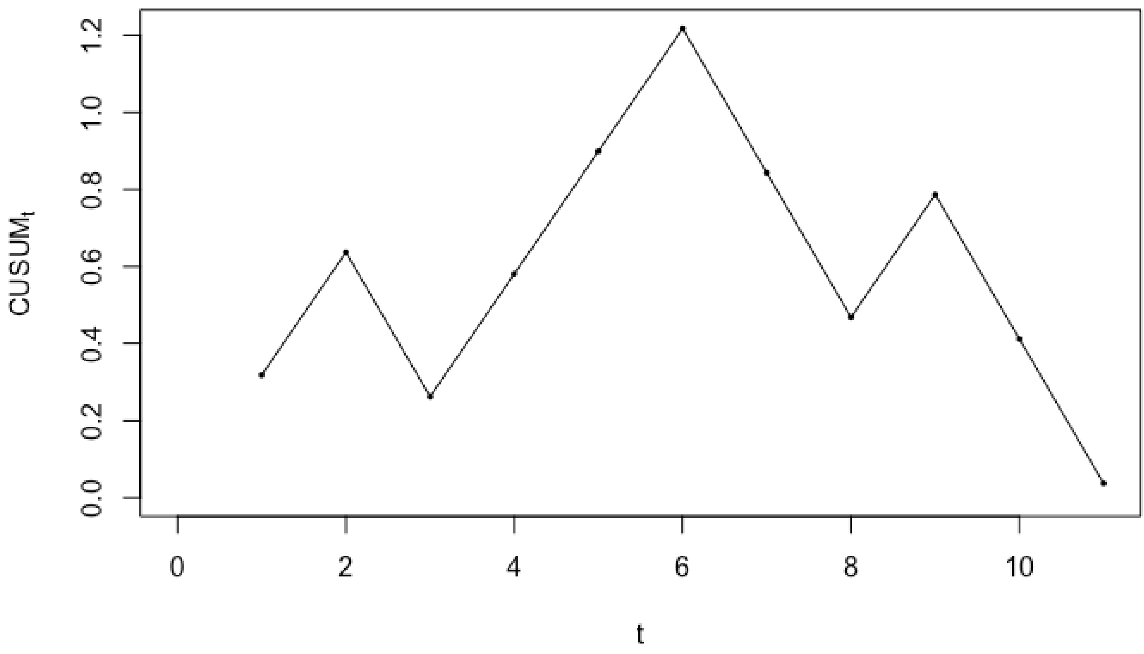


Figure 23: CUSUM for admission over 72 hours in sequential cases in the SS-FEVAR program.

Due to concerns that part of the unsuccessful completion of the SS-FEVAR pathway was due to staff unfamiliarity with the pathway a re-educational event was held just after the 7th case. This was run in conjunction with the event described in 9.1.4.4 for the SS-EVAR program.

9.2.4.5 In patient and 30 day complications and readmissions

Six (54.5%) patients in the SS-FEVAR group had in-patient medical or surgical complications. Five of these complications occurred within 8-hours post operatively. These consisted of two patients with bleeding femoral access sites both of which settled spontaneously or with simple pressure dressings. One patient had a period of hypertension which was treated medically. Another patient had abdominal pain investigated with CT but with no technical or abdominal complication identified. Finally, one patient was identified to have a type 1 endoleak noted at the time of the operation requiring further intervention the day after the index procedure. One complication occurred more than 8-hours post operatively; this was an asymptomatic disrupted plaque requiring a common iliac artery stent. These two procedures represented the totality of the in-patient reinterventions in the studied cohort.

There were two readmissions within 30 days (18.2%), one for abdominal pain without clear cause 5 days post discharge). This patient was also reviewed in in A&E 2 days post operatively for the same symptoms. Leading to a unplanned review rate of 9.1%. The other readmission was due to an access complication treated conservatively and presented on one day after discharge. There was no in-patient or 30-day deaths in the studied population.

9.2.4.6 SS-FEVAR bundle adherence

All patients attended the Surgery school online events or stated they had watched the online materials, or the booklet provided.

All patients were phone at 48 hours post discharge, apart from the one patient was admitted one day post discharge.

One of these calls prompted the unscheduled A&E review mentioned above due to the symptoms described by the patient being significant enough to warrant review.

9.2.5 Discussion

9.2.5.1 Safety

In our study population a total of six patients (54.5%) had an in-patient medical or surgical complication, with 5 of the 6 occurring (83.3%) within 8 hours. The definitions of complications used in the study were stringent, due to the effect of any deviation from normal recovery can have on LoS. These finding are in keeping with the findings earlier in this chapter for our SS-EVAR program and is also as mentioned previous in keeping with the literature(40).

As with our finding in the SS-EVAR program, the one complication that occurred after 24 hours did lead to an in-patient reintervention.

The in-patient complication rate in our study population was significantly greater than that seen in our prospective SS-EVAR program and the previously reported short stay EVAR programs discussed in chapter 3 (8-41%)(13,14,41,42). Though the definition on complications may vary from this study to others. Furthermore the readmission rate (18.2%) was greater than previous SS-EVAR programs(1.6%-4%(13–15,42)) and our own SS-EVAR study. It was also higher than the national average of 7.6%(33) reported for infrarenal EVAR. The 30 day death rate in this SS-FEVAR program was 0% compared to the national average of 2.3%(33).

These results however must be taken in the context of the small number of patients in this study, with even a single complication out of a cohort of 11, as in thus study, leading to a rate of 9%. Therefore further testing would be required to confirm the safety of this program.

9.2.5.2 Successful completion of the program

Overall, 5 (45.5%) of the patients were discharged in less than or equal to 72 hours. As there is no preceding SS-FEVAR programs there is little context beyond the national average LOS of 4 days(33). This percentage was achieved while achieving an enrolment percentage of 78.6%, which is much higher than the initial SS-EVAR studies 33-66%(14,15,41) whilst not using any intraoperative selection criteria. This is also higher than the 64.5% inclusion rate seen in our retrospective work.

9.2.5.3 Learning curve

The CUSUM analysis performed shows signs of an institutional learning curve. After the first 6 patients there was a downtrend in-patient LOS. Therefore, as in the findings from our SS-EVAR program it may be that over a longer time horizon the successful completion percentage would continue to increase.

As in section 9.1.5.3 it is unclear if the educational event can be congratulated for the improvement in the successful completion rate seen. But it would be prudent for this strategy to be promoted if the pathway and bundle were to be used in other vascular centres in the future.

9.2.5.3 Limitations

This pilot period of the St George's SS-FEVAR program ran for a period of 6 months during which case mix and throughput was affected by the ongoing COVID pandemic. It is thus likely that the results may have been affected by these external factors.

However, this study along with our previous published retrospective study does appear to show that the selected criteria allow good uptake of patients.

9.2.6 Conclusions

This study has continued to build on the work of our previously published retrospective SS-FEVAR validation study. We have shown that prospectively the criteria have excellent eligibility. A longer study period would be required to allow for statistical significance for reduction in unit level LoS and the cost implications of this to be modelled.

10. Summary and conclusions

10.1 Limitations

Although this thesis has shown that there are clear benefits to be derived from adopting SS-EVAR and SS-FEVAR programs, there are limitations. First, whilst the criteria have been validated using retrospective and prospective data, they are yet to be tested on a population outside of St George's Hospital, London. Although it is likely that the criteria and package of care would be easily translatable to other institutions, this would need to be tested if it were to be used at other centres. If such a program were to be undertaken there may have to be local iterations or alterations to the overall package of care presented to suit local practice. Clearly, local staff educational events would be required to derive the greatest benefit in the shortest time with further repeated educational interventions planned routinely to support local learning curves.

This thesis has shown that with any pathway change there is a requirement for reinforcement through on-going clinician education to ensure that novel pathways become embedded and to address any local concerns.

As the prospective data collection for chapter 9 occurred over a 6-month period, case inclusion was limited. Due to this limitation, safety and cost effectiveness of the program cannot be statistically determined at the present time.

COVID-19

As the start of the prospective study occurred during a peak of COVID-19 cases, it is unclear what effect this has had on the care that was delivered and the pathways tested. The EBD data collection exercise was similarly performed during the COVID-19 pandemic thus the results from this data may be skewed by the experiences of staff and patients during this time.

10.2 Future Work

The above pilot SS-EVAR and SS-FEVAR programs have already been developed into a larger time frame study to assess the safety and cost effectiveness of this intervention. In conjunction with this, and to allow greater application of this criteria, the SS-EVAR criteria presented in this thesis has also been planned to be validated against the Gore GREAT (Global Registry for Endovascular Aortic Treatment) registry.

If these local studies were successful, then a national application of the SS-EVAR and SS-FEVAR criteria and bundle of care could take place that could run alongside the national vascular registry which already recorded the constituent parts of the selection criteria. As the outcomes in question are all peri-operative this could be conducted over a relatively short period.

To continue to understand the availability and quality of online education resources, the EQIP methodology performed in this thesis could be applied to the FEVAR literature. This will allow a greater understanding if the issues seen in online EVAR education materials are more universal across vascular subject areas. This would have ramifications across vascular surgery and the approach taken by physicians on guiding patients to high quality and reputable source of information.

This thesis has not undertaken any prospective quality of life data collection. It is therefore unknown what affect the SS-EVAR or SS-FEVAR pathway or bundle of care have on patients. It would be prudent that any further work in this area include quality of life data collection.

Since the start of the SS-EVAR and SS-FEVAR pathway the EBD data collection exercise has not been re-performed. It may be useful for this to be done to allow any further areas for improvement to be identified.

10.3 Final conclusions

This thesis has shown that our retrospectively validated patient selection criteria for SS-EVAR and SS-FEVAR can allow patients with selected co-morbid to be safely enrolled onto a short-stay pathway of care. These selection criteria are robust and transportable due to their use of objective measures of co-morbidity that can be collected by any member of the wider MDT. Furthermore they are already part of the data collection that occurs for this patient population nationally when they are added to the National Vascular Registry.

These pathways have the ability to improves resource use, as well as clinical and cost effectiveness whilst also enhancing patient experience. With the ongoing efficiency reforms in the NHS and internationally in many healthcare systems, the ability to offer these treatments at lower cost and equivalent safety is paramount to their ongoing success.

11. References

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Appendix 1: EBD questionnaires used

Staff EBD worksheet

Staff perspectives of patient journeys

This tool has been designed to enable you, as a member of staff, to describe what a patient journey was like from your perspective.

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To start think of a particular patient journey and then of a patient who followed this

Remember this specific journey and think about what it was like for you to deliver care.

Without giving any confidential information briefly describe the patient and how they were feeling:

How did you feel as you were delivering care to this patient?
What made you feel like this?

What worked well and what didn't work so well?

Do you feel there were any modifiable barriers to early discharge in this patient's journey?

What three key points can be learnt from this experience?

1.

2.

3.

The experience based design (ebd) approach

How do you feel?

Patient experience questionnaire

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This experience questionnaire will help you think about how you feel at different stages of your journey through the service.

Please circle the words that best describe your feelings at each stage, or write your own word at the bottom of the page.

	1 First Clinic Appointment	2 Optimisation Clinic Appointment	3 Second Clinic Appointment
	How did you feel? Happy Worried Supported Comfortable Safe Lonely Good Sad Other ______	How did you feel? Happy Worried Supported Comfortable Safe Lonely Good Sad Other ______	How did you feel? Happy Worried Supported Comfortable Safe Lonely Good Sad Other ______
What was it that made you feel like this? Was it friendly staff, a nice conversation, or a long wait – whatever it is we'd like to know.	What made you feel like this?	Can you describe why you felt like this?	What made you feel like this?
We would also like to ask you a question about a specific part of our service, so that we can gather your feedback and improve this area.	Did you want any futher information?		Would anything help prepare you for your admission?

The experience based design (ebd) approach

How do you feel?

Patient experience questionnaire

continued

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4 Admision and treatment	5 Discharge	6 Follow up clinic	Other comments
How did you feel? Happy Worried Supported Comfortable Safe Lonely Good Sad Other ______	How did you feel? Happy Worried Supported Comfortable Safe Lonely Good Sad Other ______	How did you feel? Happy Worried Supported Comfortable Safe Lonely Good Sad Other ______	**Do you have any other comments or thoughts about your visit?** Please let us know so we can continue improving the service we deliver, thank you
What made you feel like this?	Can you describe why you felt like this?	What made you feel like this?	
What could we have done better?	Do you feel prepared for discharge?	Is there anything else we could have done better?	

The experience based design (ebd) approach

Appendix 2: SGVI Short Stay Aneurysm Care Bundle SSACB

Outline:

The St George's Vascular Institute (SGVI) Short Stay Aneurysm Care Bundle (SSAVB) is comprised of pre-operative education and assessment, in-patient protocol-based discharge and an early outpatient management plan.

These interventions have been guided by the work performed in chapters 3-8 to create a robust bundle of care for patients undergoing SS-EVAR or SS-FEVAR that runs along side of the current SoC pathways for EVAR and FEVAR at St George's hospital Figure 3 and Figure 4.

Pre-operative care

Alongside the SoC pathway that generally includes an initial clinic, optimisation clinic, second clinic and pre-admission clinic the SSACB also includes:

- Surgery school enrolment (see Appendix 3 for further details)
- Aortic nurse specialist delivered (performed at pre-admission clinic) operation specific pre-operative advice including targeted length of stay, education materials, post-operative follow up plan:
    - For SS-EVAR this length of stay advice is either same day or next day discharge.
    - For SS-FEVAR this length of stay advice was for discharge on or before the second post operative day.
    - Education materials were provided to patients including the "Get fit 4 Surgery" booklet (see Appendix 3) and the SGVI EVAR booklet (attached at end of the appendix).
    - The post-operative follow-up plan outlined below was also provided to the patient along with at vascular CNS contact number.

In-patient peri-operative care

All SS-EVAR and SS-FEVAR admissions are brought in as day of surgery admission to reduce their in-patient stay and to mitigate the current COVID risk.

To aid in timely discharge of patient in the SS-EVAR and SS-FEVAR pathway standardised documentation and discharge medicines packs has been created.

The post-operative documentation bundle for the the SS-EVAR and SS-FEVAR pathways are partly pre-populated operation notes, discharge summaries and discharge medication documentation designed to be completed by the operating team shortly after the operation to aid in timely discharge.

The operation note and discharge summary templates involve multiple options that are selectable to allow accurate and timely documentation. These are embedded within the hospital electronic notes system.

For discharges within 24 hours of admission a 'pain pack' discharge medication model has been adopted. This model has been successful be shown to work with other high volume short stay models of care(128). This includes paracetamol (excluded by the ward pharmacist if the patient has taken advice to obtain this preadmission) and di-hydrocodone. Where stays are beyond 24 hours then it is hospital policy that their discharge medications go through the normal discharge medication route with the patient being given, or checked to have, a full two week supply of their regular medications.

For patients that are discharged on the same day of admission no in-patient imaging (ultrasound duplex) is performed, unless clinically indicated. With those that stay beyond this on the SS-EVAR pathway and those on the SS-FEVAR pathway undergoing an in-patient duplex ultrasound prior to discharge. In cases where this period crossed public holiday or weekends, during which ultrasound duplex services are not available, then if there are not clinical concerns the patient may be discharge without an in-patient arterial duplex scan.

Post discharge care

All patients on the SS-EVAR and SS-FEVAR pathway are called at day 2 post operatively to ascertain if they have any concerns and if so the best way these can be managed.

SS-EVAR and SS-FEVAR patients that did not undergo an in-patient duplex are planned to undergo a duplex as an outpatient within 2 weeks post discharge. This has been protocolised with the vascular laboratory with any abnormality be flagged to the on call vascular surgery registrar for same day review of this scan and the patient.

All patients (SS-EVAR and SS-FEVAR) are seen in an outpatient clinic at 6 weeks post discharge with a CT Aortic angiogram either on the day or before this appointment, which is in keeping with the standard of care pathway for these patients at St George's hospital.

SGVI SS-EVAR Patient Leaflet

Your EVAR at St Georges Hospital

A patient and family guide to Endovascular Aneurysm Repair (EVAR) at St Georges Hospital.

This guide gives you important information about:

- your aneurysm and its repair
- what to expect before, during and after surgery
- what you can do to have a healthy recovery
- your need for follow-up care

Patients name:
Your Surgeon(s):
Your Operation date:

If you have any concerns in advance of your operation, please contact:

Liz Anderson Aortic Nurse Specialist on:

Email:

Phone:

About Abdominal Aortic Aneurysms and EVAR.

What is an Aneurysm?

An aneurysm is a weakened artery that has stretched and ballooned out (see figure 1). This has occurred in the main artery in your tummy called the aorta.

The wall of the artery becomes thinned by the loss of elastic tissue and the artery expands making it likely to burst (ruptured aneurysm). Rupture is commonly fatal so an operation to repair the aneurysm before it bursts is normally recommended for patients fit enough for the surgery.

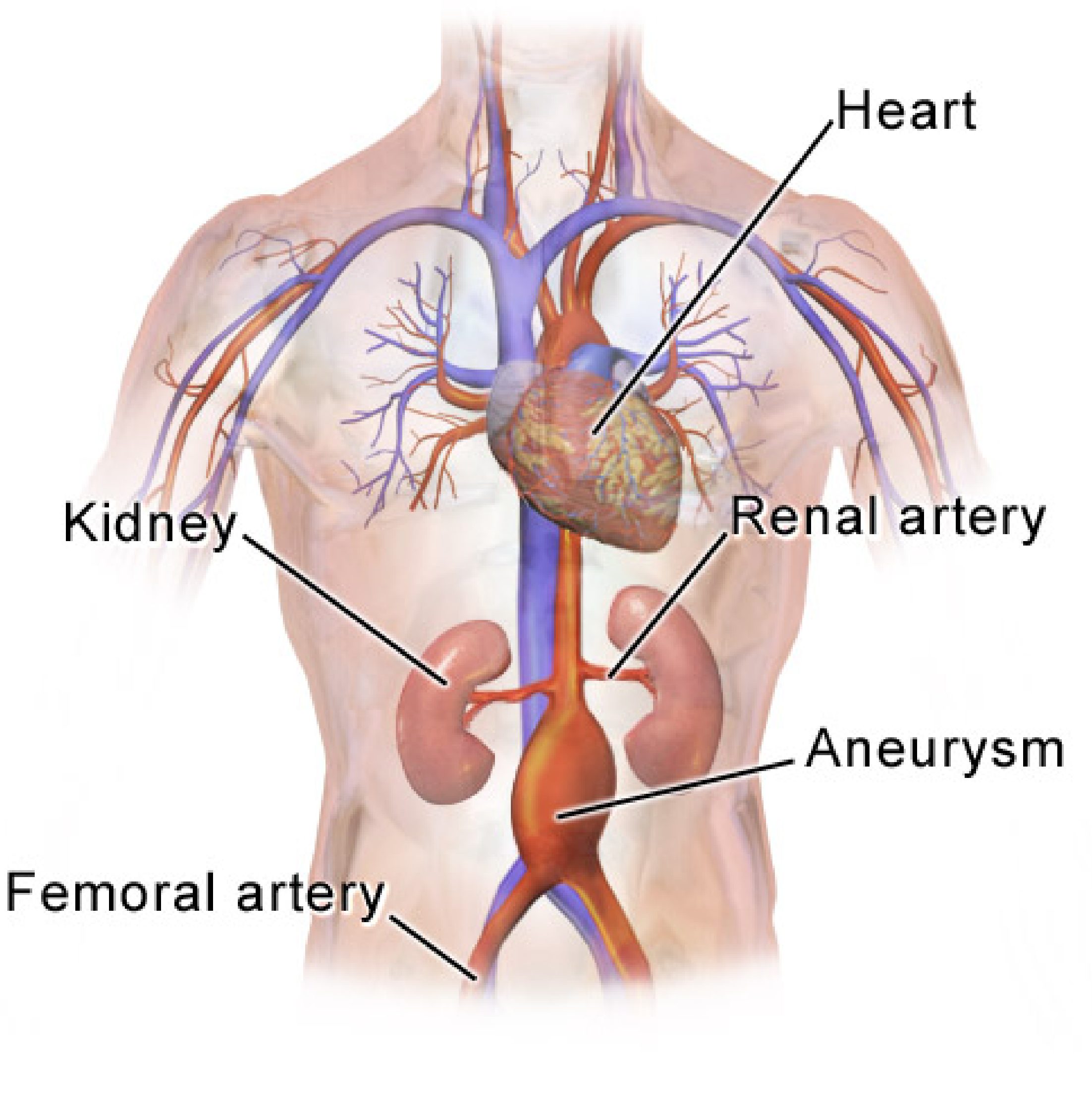

Figure 1 – AAA

What is an EVAR?

EVAR (**E**ndo**V**ascular **A**neurysm **R**epair) is an operation to repair the stretched section by placing a new inner tube inside, so that it will not burst. It is carried out in a special theatre under x-ray control and involves an injection and small cut in both your groins. A wire is passed via the artery in your leg into the aorta and the stent graft (tube of graft material -see figure 2) is passed over the wire and into position.

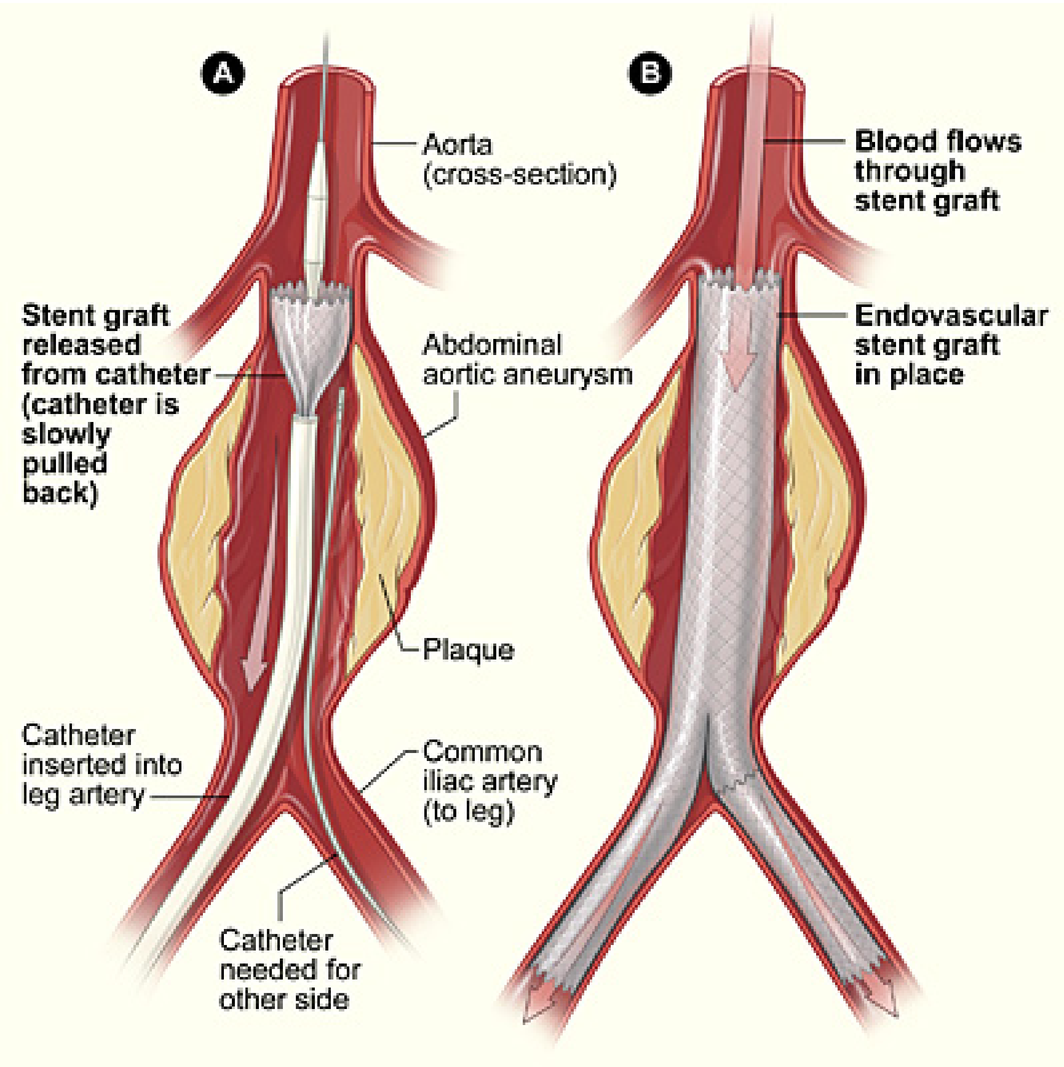

Figure 2 – EVAR

Once in place the stent is expanded and it anchors to the artery wall with small metal hooks.

What are the alternatives?
The alternatives are a more major open (direct repair via a large cut in the tummy) operation on your abdomen (tummy) or no treatment.

Is EVAR safe?
All operations carry risks. With this type of procedure there is a risk of the aneurysm rupturing during your operation, or failing to seal off the aneurysm, in which case you may need more major surgery. The main complication that can occur after the procedure is that the graft can move position. Scans can identify any potential problems which can then be rectified or monitored depending on how severe they are. The wounds in your groin can become infected and the usual treatment is antibiotics. Your wounds may also fill with fluid called lymph that may discharge through the wound, but this usually settles down with time.

With EVAR the potential complications of the traditional repair are greatly reduced as it places far less stress on your heart. There is less risk of haemorrhage (bleeding) and/or respiratory complications (chest/lung) and general conditions such as deep vein thrombosis (blood clot in leg veins). There is a risk of loss of circulation to your legs, bowel, and kidney, and further surgery is occasionally needed to restore the blood supply to your legs. There is also a risk of the graft becoming infected and to reduce the chance of this happening you are given antibiotics during the operation.

The long-term durability and success may be reduced compared to open repair. Research has shown that one in every 10 patients has to undergo a further endovascular procedure due to complications.

EVAR offers the opportunity for repair in patients who might otherwise not have been fit enough for open surgery.

Coming into Hospital

What will happen when I arrive at hospital?
On admission you will be greeted by a member of the Ward team and introduced to your named nurse. They will discuss with you the care that you will receive while you

are in hospital. You will also be seen by your consultant or one of their team to explain anything you may be unsure about before you sign a consent form for your operation.

As part of your care whilst in hospital, every effort is made to make sure you are seen by the same hospital doctors who will be part of the vascular and interventional radiology team.
You will usually be admitted early on the day of your operation. Any final tests, such as blood tests, will be completed then. Please do not shave any hair from your stomach or groins as this will be done for you in theatre before your operation. This will be discussed when you attend for the preassessment clinic.

You will meet the anaesthetist, who is a doctor with specialist training in anaesthesia and in the treatment of pain. They will visit you before your operation to talk to you about the anaesthetic and methods of pain relief, taking into consideration any other medical conditions that you have and also previous anaesthetics you have had. They may ask you about your health, look at all your test results, listen to your heart and breathing, and look at your neck, jaw, mouth, and teeth. They will be happy to answer your anaesthetic questions and discuss any worries that you have.

You will be given clear instructions about when to stop food and drink; it is important to follow this advice. If there is food and liquid in your stomach during your anaesthetic, it can get in to and seriously damage your lungs. Usually, you should have no food for six hours but water is allowed until two hours before your operation. You should continue to take all your regular medications even on the morning of the operation, except, if you are taking clopidogrel in combination with aspirin, you would have been advised to stop this if and when you attended the preassessment clinic. You must also temporarily stop anticoagulants, for example warfarin.

A physiotherapist may see you before your operation. They will advise you of exercises to perform after the operation that will help your circulation whilst lying in bed and of deep breathing exercises that will help keep your lungs clear, together with movements of your legs and feet to help prevent blood clots developing in your leg veins. It is very important that you can breathe deeply and cough effectively to help you avoid a chest infection or pneumonia.

You will be asked to have a bath or shower and put on a theatre gown on the day of your operation before you go to theatre.

The procedure will take place in St Georges Hospital.

Will I have an anaesthetic?
The operation is usually performed under a general anaesthetic, where you will be asleep during the operation.

EVAR can also be carried out with local anaesthetic injections in your groin or other forms of anaesthetic if you cannot or would be safer not to have a general anaesthetic.

What happens in the anaesthetic room?
The anaesthetist's assistant will attach machines which measure your heart rate (sticky pads on your chest), blood pressure (inflatable cuff on your arm), and oxygen levels (small peg on your finger or ear lobe). The anaesthetist will insert thin plastic tubes (cannulas) into a vein on the back of your hand or forearm (usually known as a drip) and in the artery at your wrist (arterial line to measure your blood pressure). These are attached to a bag of fluid.

You may be asked to breathe extra oxygen through a mask covering your nose and mouth.

After your operation

How will I feel afterwards?
Following your operation, you will be returned to the ward if you are well enough and free of pain.

With this type of procedure, the recovery rate is much quicker than the traditional open operation and you will be able to eat and drink immediately. The drips in your artery and vein, used to monitor blood pressure and to give you fluids, will be removed once the nurses are happy that you are stable, tolerating diet and fluids, and not feeling sick.

It is usual to experience some discomfort and numbness around your groin wounds for several weeks after your operation. It is not uncommon for men to experience some swelling to their penis and scrotum following this type of surgery. This will go down in time and should not cause you any problems with passing urine. We will aim to get you on your feet and ready for home the next day.

It is quite common to feel a bit low after having an operation; this can be caused by a number of factors such as pain, feeling tired, and not sleeping well. The nurses can help you with this so please do not hesitate to let them know how you are feeling. It may be as simple as changing your painkillers or having a light-sleeping tablet that may help to make you feel better.

How long will I be in hospital?

We aim to have you home the day after your surgery unless there are problems or concerns. Please do not leave until you have been given instructions, your medication, and discharge letters for your GP.

After Leaving the Hospital

What should I do when I go home?

You should aim to ease yourself back to normal activity within a month. You will be safe to drive when you are able to perform an emergency stop comfortably. This will normally be two weeks after your surgery, if in doubt please check with your doctor. Driving too soon after an operation may affect your insurance so we advise you to check your insurance policy details or to contact your insurance company.

It is important to keep your wound areas clean, after 48 hours this can be done with a daily bath and shower patting the area dry with a clean towel. If your wound becomes red and/or there is a discharge you should speak to the vascular team or your GP as you may need antibiotics. You will be sent home on a small dose of clopidogrel if you were not already taking it; this is to make the blood less sticky. If you are unable to tolerate clopidogrel an alternative drug will be prescribed. Also, you will be taking a statin, a drug to lower cholesterol, together with any other of your normal medications.

What do I do if I feel unwell at home?

In general, call your GP or out of hours doctor's service. If you develop sudden pain or numbness in the leg(s) that does not get better within a few hours, then contact the hospital immediately. If you experience any pain or swelling in your calves, any shortness of breath or pains in your chest, you must go to accident and emergency (A&E) immediately.

Will I have to come back to hospital?

You will be called 3 days after you have been discharged by a member of the clinical team to make sure you are no suffering from any problems.

You will also be seen in clinic in 2-4 weeks post operatively to have a follow up Jelly scan (Duplex Ultrasound) as an outpatient. During this time you will have a follow-up CT scan and, if no issues are found you will be followed up with Jelly scans after this. These are to check that the new graft is working well and has not moved.

When can I return to work?

You should be able to return to light work or jobs at home after two weeks and heavier jobs after a month. If in doubt please ask one of the vascular team or your GP.

Finally…..

Some of your questions should have been answered by this leaflet, but remember that this is only a starting point for discussion about your treatment with the doctors looking after you. Make sure you are satisfied that you have received enough information about your procedure before you sign the consent form giving us your permission to operate.

Source of information

The information within this leaflet is based on current practice undertaken by your consultant and from national guidelines. If you have any comments regarding this leaflet, we would appreciate your feedback.

Where to get further information

CNS:

Consultant Secretaries:

Useful web addresses

- National Institute for Health and Care Excellence www.nice.org.uk
- Vascular Society of Great Britain and Ireland www.vascularsociety.org.uk
- Circulation Foundation www.circulationfoundation.org.uk

Appendix 3: St George's Get Fit 4 Surgery program

The St George's Surgery School Get Fit 4 Surgery program is a non-operation specific multi-disciplinary prehabilitation program run at St George's hospital NHS trust.

It is delivered and organised by a range of professionals including:

- Administrative Co-ordinator
- Clinical Nurse Specialist
- Consultant Anaesthetist
- Consultant Surgeon
- Dietician
- Clinical Psychologist
- Physiotherapist
- Macmillan Information Centre Support Officer

The program was originally designed as face-to-face peer supported group sessions, however during the time it was used as part of the work in this thesis these were suspended due to the Covid-19 pandemic. During this time an alternative structure of weekly classes live online, via Microsoft Teams was used.

Entry into the program can be either via the clinical team caring for a patient or directly via its website (link below)

A full outline of the program including links to its written and pre-recorded sessions are provided on their patient facing website:
https://www.stgeorges.nhs.uk/service/prehabilitation/

Direct links to its web-based videos overview and advice videos and example pre-recorded session videos are below:

Overview and advice videos:

Overview of program video: https://youtu.be/wCYUNpThzOg
Pre-operative advice video: https://youtu.be/40hDlC6wZaY
Day of surgery and hospital stay video: https://youtu.be/1_n7mmnan20

Post-operative care and discharge video: https://youtu.be/d9_diZjY2lM

Pre-recorded full session videos:

Introduction to preparing for surgery and simple steps to aid recover:
https://youtu.be/Ucl6_MCI1LI
Preparing for surgery: dietary advice and eating well:
https://youtu.be/v2G2gI6uQ5A
Preparing for surgery: increasing activity:
https://youtu.be/EemMDB-eKBE

The session covers prehabilitation topics and general pre and post admission advice. The topics covered are:

- Improving diet
- Smoking cessation advice
- Alcohol intake advice
- Increasing activity level
- Day of surgery advice regarding medication, location, time and starving.
- Post discharge preparation including supervision, at home food stock and analgesia.
- Mental preparation

The program also covers the normal patient journey and gave the time to patient to ask further questions in a peer supported environment.

In addition to the above program a written booklet is also provided to each patient that covered the above areas:
https://www.stgeorges.nhs.uk/wp-content/uploads/2018/11/Surgery-booklet-final-for-upload-copy-1.pdf

Appendix 4: Distance from hospital data collection.

The below code written in Python version 3 was used to generate the distance from St George's hospital to the patient's home by car.

It does this using the google maps API.

```
#!/usr/bin/env python3
# -*- coding: utf-8 -*-
"""
Created on Sun Dec 23 17:14:25 2018

@author: James Budge
"""
import pandas as pd
import googlemaps
from datetime import datetime
import ast

#create column names and make dataframe from csv file
col_names =  ['postcode', 'hospital', 'distance_car', 'duration_car', 'status_car', 'distance_transit', 'duration_transit',
'status_transit']
df = pd.read_csv('*CSV File with post codes*', names = col_names)

# google maps api
gmaps = googlemaps.Client(key=*insert key here*)

# what time of day should it be calculated for
when = datetime.now()

#for loop for data
for i in df.index:
    # define location and hospital
    location = df.loc[i,'postcode']
    hospital = df.loc[i,'hospital']
    ####################################################
    #transit loop
    ####################################################
    map_result_transit = gmaps.distance_matrix(location,
                                hospital,
                                mode="transit",
                                departure_time=when)
    #access 'rows' part of JSON and remove sq brackets and read as dictionary,
    #do the same for 'elements'
    rows_transit = map_result_transit['rows']
    elements_transit = str(rows_transit)[1:-1]
    elements_dict_transit = ast.literal_eval(elements_transit)
    final_transit = elements_dict_transit['elements']
    final_short_transit = str(final_transit)[1:-1]
    final_dict_transit = ast.literal_eval(final_short_transit)
```

```
# just dictionary of distance duration and status left
# save out variables distance, duration and status
distance_transit = final_dict_transit['distance']['value']
duration_transit = final_dict_transit['duration']['value']
status_transit = final_dict_transit['status']


####################################################
#car loop
####################################################
map_result_car = gmaps.distance_matrix(location,
                        hospital,
                        mode="driving",
                        departure_time=when)
#access 'rows' part of JSON and remove sq brackets and read as dictionary,
#do the same for 'elements'
rows_car = map_result_car['rows']
elements_car = str(rows_car)[1:-1]
elements_dict_car = ast.literal_eval(elements_car)
final_car = elements_dict_car['elements']
final_short_car = str(final_car)[1:-1]
final_dict_car = ast.literal_eval(final_short_car)

# just dictionary of distance duration and status left
# save out variables distance, duration and status
distance_car = final_dict_car['distance']['value']
duration_car = final_dict_car['duration']['value']
status_car = final_dict_car['status']

####################################################
#save to row
```

Appendix 5: Image rights

Figure 1 and Figure 2 have been sourced from Wikimedia commons: https://commons.wikimedia.org/

Figure 1, has been granted to use under the creative commons licence. https://commons.wikimedia.org/wiki/File:Aorta_branches.jpg
Figure 2, has been stated to be in the public domain, with no restrictions to use. https://commons.wikimedia.org/wiki/File:Aneurysm_endovascular.jpg

Appendix 6: Publications and Presentations

Publications

- **Recent developments and current controversies in short-stay endovascular aneurysm repair.** Preece R, Stenson K, Shaw S, Budge J, Patterson B, Holt P, Loftus I. J Cardiovasc Surg (Torino). 2019 Aug;60(4):460-467. doi: 10.23736/S0021-9509.19.10952-4. Epub 2019 Apr 15. PMID: 30994308.
- **Development of novel patient selection criteria for a short stay endovascular aneurysm repair pathway: Improving patient selection for short stay endovascular aneurysm repair**. Preece R, Shaw S, Wiltshire J, Stenson K, Budge J, De Bruin J, Loftus I, Holt P, Patterson B. Vascular. 2020 Feb;28(1):59-67. doi: 10.1177/1708538119867523. Epub 2019 Jul 27. PMID: 31354107.

Presentations at learned society conferences

- **The effect of hybrid operating theatres on early reintervention in EVAR** - James Budge, Hadyn Kankam, Bilal Azhar, Arsalan Wafi, Kate Stenson, Ian Loftus, Peter Holt. Charing Cross Conference 2020 and Vascular Society Annual Scientific Meeting 2020
- **Quality assessment of patient information on Abdominal Aortic Aneurysm repair on the internet using the modified 'Ensuring Quality Information for Patients' tool.** James Budge, Lorenzo Lenti, Bilal Azhar, Arsalan Wafi, Ian Loftus and Peter Holt. Vascular Society Annual Scientific Meeting 2020
- **Development of novel patient selection criteria for a short stay fenestrated endovascular aneurysm repair pathway.** James Budge, Bilal Azhar, Arsalan Wafi, William Selway, Iain Roy, Ian Loftus and Peter Holt. Vascular Society Annual Scientific Meeting 2021
- **Short Stay Endovascular Aneurysm Repair pathway pilot trial**. James Budge, Bilal Azhar, Arsalan Wafi, William Selway, Oliver Rees, Iain Roy, Ian Loftus, Peter Holt. Vascular Society Annual Scientific Meeting 2021

Submitted Papers

- Systematic analysis of the quality of patient information on the management of elective Abdominal Aortic Aneurysm repair on the internet using the modified 'Ensuring Quality Information for Patients' (EQIP) tool.
- A Systematic review of the use of 'Experience Based Design' in Elective Medical and Surgical Pathways

Appendix 7: Addendum to address examiners comments

The following addendum serves to address the examiners comments from this PhD's viva voce. It is divided into four segments each addressing the four areas of clarification requested as stated in italics.

1. Selection criteria development issues

Distinguish between developing criteria for early discharge based on statistical analyses of retrospective data from the centre and developing criteria by consensus of a clinical group and testing how often they would have been applicable in a retrospective cohort.

As discussed in chapter 4 and our paper on the subject (19) the selection criteria utilised in this thesis was developed by consensus agreement of a local expert working group. The selection criterion components selected were also informed by the systematic review of the selection criterion used by previous SSEVAR studies as discussed in chapter 3.

An alternative strategy to produce a selection criterion for this study would have been to develop a criterion by mathematically identifying factors associated with length of stay and early complication using univariate then multivariate analysis. This methodological choice was not made for two reasons as discussed below.

The first was the relatively small number of cases that would have been used in to develop the criteria. The contemporary dataset used to validate the selection criteria in Chapter 4 represented 188 patients. Thus, using this smaller sized dataset may have biased the selection criteria if this 188 were not fully representative.

The second reason is that the selection criteria may well have been less generalizable to other units. This is due to the factor that it would only have been derived from data from our own center. By utilizing information from our systematic review to inform the creation of our selection criteria from studies that have taken part in SSEVAR programs in a range of countries we hoped to elucidate factors that were more applicable across a wide range of institutions.

However, we did consider this methodology and attempts were made as part of this body of work to obtain national level data that would have addressed the two above short comings. An application was made to obtain national level EVAR and FEVAR pre-operative co-morbidity and early outcome data including length of stay and complications from the National Vascular Registry (NVR) via the Healthcare Quality Improvement Partnership (HQIP) but these applications were unsuccessful. This is however an area of work we hope to revisit as part of the ongoing further work of this project.

2. Selection criteria limitations

The issue of how the selection criteria were identified, issues of bias, lack of involvement of certain professional groups and lack of PPI. The lack of usage of Frailty index

As discussed in section 1 of this addendum the methodological choices made in the development of the selection criteria discussed in Chapter 4 did come with certain limitations. Among these are the bias towards choosing factors most considered by the roles of those on the local expert work panel that selected these criteria.

To further develop the work, undertake in this thesis, it would be prudent to have a panel that is more representative of the entire MDT that cares for patients undergoing EVAR and FEVAR. This may allow for factors that affects LOS and outcome to be selected that had not been identified in this body of work.

One area not currently included in this selection criteria was clinical frailty scores. This was not included as the dataset used to retrospective test the criteria did not have clinical frailty scoring in them and there were concerns over the validity of generation of these scores retrospectively from the patient's routine healthcare notes. The production of these scores from data routinely recorded in patient records retrospectively has been validated in small populations in the UK(129), and thus perhaps this should have been considered and could be part of the future development of our SSEVAR and SSFEVAR criteria.

Furthermore, with the recent inclusion of clinical frailty scale in the National Vascular Registry data collection this is an area that will soon have good national level data and may perhaps be routinely collected by most vascular centres. It could thus also be considered for inclusion if a mathematically developed selection criteria were to be developed as discussed in section 1 of this addendum.

Additionally, the methodology used did not involve patient or public involvement in the selection criteria. This too may have improved the criterion created and could be another area in which the selection process could be improved in the future. The importance of patient and public involvement was however recognised by this body of work in the involvement of all stake holder, which included patients, in the experience-based co-design process undertaken in Chapter 5.

3. Retrospective validation of selection criteria

Provided an a-priori definition of success or failure of discharge criteria. Clarify how the selection criteria excluded group differed from those who fulfilled pragmatic criteria but not conservative.

Our study defined a successfully discharge criteria as one that was able to objectively identify individuals from pre-operative information that could undergo EVAR or FEVAR within the specified discharge time without increasing their risk of complications or readmissions.

The specified time limit for SSEVAR in this study was a single night stay, defined as an in-hospital period of equal to or less then 36 hours. For SSFEVAR this was defined as less than or equal to 72 hours. The SSEVAR time limits were designed to represent a single night stay and started when the patient was admitted to a hospital bed and ended when they left the hospital. This time could include the use of a discharge lounge or day discharge area and thus would not compromise the ability to admit a new patient into the same hospital bed the next day. Similarly, the SSFEVAR timing was designed to represent the same timings but with a 3-night bed occupancy in comparison to that of the 1-night of the SSEVAR program.

	Total cohort (n = 188)	SSEVAR (Pragmatic) criteria cohort (n = 110)	SSEVAR criteria excluded cohort (n = 78)
Total number of patients who had complications	31 (17)	19 (17.3)	12 (15.4)
Number of complications occurring within 24 h post-EVAR	21	15 (13.6)	6 (7.7)
Number of complications occurring after 24 h post-EVAR	10	4 (3.6)	6 (7.7)
Unplanned 30-day readmissions	4	2 (1.8)	2 (2.6)

Post-operative complications and unplanned readmissions in SS-EVAR. Values in parentheses are percentages.

As seen in the table above there is a slight increase in the rate of total in patient complications in those that were elected by the SSEVAR program compared to those that were not, 17.3% vs 15.4%. However, the majority of these happened in the first 24 hours (13.6% vs 7.7%) in the SSEVAR selected cohort compared to the excluded cohort. While complications occurring after 24 hours was decreased in the SSEVAR cohort compared with the excluded cohort (3.6% vs 7.7%). Therefore, the selection criteria may be able to exclude those that would be of increased risk of late complications that may occur after discharge if these patients were to have followed a SSEVAR pathway. Furthermore, the patients selected by the SSEVAR criteria had a lower unplanned 30-day readmission rate (1.8% vs 2.6%).

The selection criteria when applied to the SSFEVAR cohort performed better, selecting those at decreased risk of any in-patient complication regardless of timing (25% vs 50%) and also selected those at decreased risk of unplanned 30-day readmission (0% vs 4.5%) as seen in the table below.

	Total cohort (n = 62)	SSFEVAR (Pragmatic) criteria cohort (n = 40)	SSFEVAR criteria excluded cohort (n = 22)
Total number of patients who had complications	21 (33.9)	10 (25)	11 (50)
Number of complications occurring within 24 h post-FEVAR	17 (27.4)	7 (18.5)	10 (45.5)
Number of complications occurring after 24 h post-FEVAR	8 (12.9	5 (12.5)	4 (18.2)
Unplanned 30-day readmissions	1 (1.6)	0	1 (4.5)

Post-operative complications and unplanned readmissions in SS-EVAR. Values in parentheses are percentages.

4. Clinical pathway limitations

Discuss shortcomings of clinical pathway used (e.g. the lack of a robust method of identifying Contrast Nephropathy while pragmatic criteria included patients at moderate to high risk)

The SSEVAR and SSFEVAR pathway at time of the original submission of this thesis did not include a targeted pathway for those at increased risk of contrast nephropathy. These patients were thus identified as higher risk at their pre-operative clerking visit and advice was given on a patient-by-patient basis by the clinical team. This occurred both prior to the admission as part of the optimisation appointments including advice by a pharmacists, CNS and Doctor/PA teams, and also during their in-patient stay lead by the consultant of the week.

Measures have now been placed that automatically flag those at risk and these are discussed at the MDT to ascertain if pre-hydration would be of benefit on a patient-by-patient basis, as per the recommendations in NICE guidance NG148.

In all those that are deemed to be at increased risk, a standardised addendum is added to their discharge summary that contains the patient's last eGFR and Creatine values (and the dates these are from) and asks the GP to perform repeat blood tests in 4-7 days post discharge. This is also raised directly with the patient's GP by telephone and where this is not possible an appointment is made for the patient to have bloods at St George's hospital via the vascular surgery hot clinic.