SURGICAL SYSTEM FAILURES & THEIR RELAIONSHIP WITH PATIENT OUTCOMES IN AORTIC PROCEDURES: A MULTI-CENTER, OBSERVATIONAL STUDY

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This paper is submitted in the category: **original article.**

ABSTRACT

Background:

The vascular surgical system has changed dramatically in recent years with little knowledge of the impact of system failures on patient safety. The primary aim of this multi-centre, observational study was to define the landscape of surgical system failures, errors and inefficiency (collectively termed 'failures') in aortic surgery. Secondary aims were to investigate determinants of these failures and their relationship with patient outcomes.

Method:

Twenty vascular teams at ten English hospitals trained in structured, self-reporting of intra-operative failures (phase I). Failures occurring in open/endovascular aortic procedures were reported in phase II. Error details (category/delay/consequence), demographic information (patient/procedure/team experience) and outcomes were reported.

Results:

There were strong correlations between the trainer and teams for the number/type of failures recorded during 88 cases in phase I.

In 185 aortic cases, teams reported a median of 3 failures/procedure (interquartile range 2-6). Most frequent failures related to equipment (unavailability/failure/configuration/desterilisation). Most *major* failures related to communication. Fourteen failures directly harmed twelve patients. Significant predictors of increased failure rate were: endovascular versus open repair (Incidence Rate Ratio (IRR) for open repair: 0.71; 95% confidence interval (CI) 0.57-0.88, $p=0.002$); thoracic aneurysms versus other aortic pathologies (IRR 2.07; CI 1.39-3.08, $p<0.001$; equipment unfamiliarity (IRR 1.52; CI 1.20-1.91, $p<0.001$). Major error total was associated with reoperation ($p=0.011$), major complications ($p=0.029$) and death ($p=0.027$).

Conclusion:

Failures in aortic procedures are frequently caused by team-working and equipment-related issues, and are associated with patient harm. Multi-disciplinary team-training, effective technology utilisation, and new-device accreditation are recommended to improve patient outcomes.

Key words: Error; Safety; Surgery

INTRODUCTION

It is well known that a significant number of patients come to harm while in hospital[1]. The highest rate of adverse events is in patients undergoing surgical intervention, most notably in patients undergoing major vascular procedures[2].

Sir Cyril Chantler said that, while medicine used to be “simple, ineffective and relatively safe”, it is now “complex, effective and potentially dangerous” [3]. This is certainly true for major vascular surgery. Patient and technical factors are obvious determinants of outcome, but current thinking emphasizes the role of wider aspects of the surgical system in patient safety[1]. The high-risk nature of vascular patients with complex comorbidities and the importance of technical expertise are well recognized in vascular surgery. Yet, further investigation of wider system factors is now warranted, particularly as the vascular surgical system has undergone significant changes in recent years with centralisation of services within the United Kingdom (UK) and the rapid development of minimally-invasive technologies. These minimally-invasive treatment strategies for vascular patients have undoubtedly reduced major morbidity and mortality, but to achieve consistently optimal results, we must place continuous emphasis on optimising patient safety. Single-centre exploratory studies in arterial surgery identified failures related to team communication, surgical equipment and planning[4,5], but whether these failures occur at vascular centres throughout the country and most importantly, their impact on patient outcome, remained unknown. The mechanisms of harm, the determinants of increased failure rates and the impact of system failures on patient outcomes are vital to plan strategies for safety improvement.

The LEAP study (Landscape of Error in Aortic Procedures) is a multi-centre, collaborative effort to explore patient safety in vascular surgery. The primary aim of the LEAP study was to define the landscape of surgical system failure, error and inefficiency in open and endovascular aortic surgery. Secondary aims were to investigate determinants of failure and the relationship between intraoperative failure and patient outcomes.

METHODS

Phase I was a training phase to train teams and establish the reliability of a self-reporting method. In phase II, teams self-reported failures occurring in aortic procedures, the impact of these failures, and patient outcomes. Full Research Ethics Committee (12-LO-0710) and local approvals were obtained.

Setting and participants

Participating operating teams were recruited in ten hospitals in England (September 2012-July 2014). Operating teams consisted of a consultant vascular surgeon, anaesthetists, nurses, and support staff, as well as radiology staff (radiologist and/or radiographer) for many procedures; team composition was not necessarily consistent from case to case due to shift patterns and rotation of staff. For the purposes of the training phase, all adult patients on participating vascular consultants' operating lists were eligible for inclusion in phase 1. However, in phase 2, only adult patients undergoing elective or urgent aortic surgery for aneurysmal or aorto-occlusive disease. Staff and patients provided written, informed consent to participate.

Materials

Twenty consultant vascular surgeons and their operating teams were trained by a single observer (a senior vascular nurse practitioner-RL) to report intraoperative surgical system failures, errors and inefficiencies using a validated and structured, team-based approach. The Imperial College Error Capture record (ICECAP) is a paper-based tool consisting of several prompts read aloud to structure reporting of failures; its development and validation is described in full elsewhere[5]. Primary failure categories are: equipment, communication, procedure-independent pressures (i.e. distractions, team member absence, external pressures), technical, safety awareness, and patient-related. Each of the primary categories has a number of secondary fields. For a failure to be recorded on ICECAP, the team had to come to a consensus on whether or not a failure had occurred, as well as the category of failure. For example, during one ICECAP debrief, the team reflected on intraoperative delays during an emergent bleeding event after iliac vein injury. The surgeon highlighted that there was a delay in obtaining pledgeted sutures. Following discussion, it became apparent that this event was not a failure relating to equipment unavailability, rather, the scrub nurse was unfamiliar with the use of pledgets. Consensus discussion led to this failure being document as a technical error (sub-category: equipment unfamiliarity) rather than an equipment-related failure, and the scrub nurse received training in the use of pledgeted sutures.

Definitions

A failure is as any event that prevented the procedure from progressing in an ideal manner. This broad definition was a deliberate attempt to capture all relevant safety events. The term failure encompasses different types: failures in the surgical system (system factors), human errors and sources of inefficiency. Failures were to be reported if they occurred between the patient being transferred into the operating theatre, to final closure of the wound.

Major and minor failures were defined by their immediate consequences intraoperatively. Failures that caused more than fifteen minutes' intraoperative delay, caused harm, or placed the patient at significant risk of harm, are referred to as major failures. Harm was defined as injury to the patient evidenced by a physiological response to the injury (e.g. cardiovascular instability), or by the need for further invasive intervention; harm may have occurred intra-operatively without further sequelae (lasting disability).

Procedure & data collection

Phase I:

Shift patterns and staff rotation mean that operating team composition is inconsistent; the trainer therefore undertook multiple visits to each site to capture as many operating staff as possible. The trainer (RL, Vascular Nurse Practitioner) attended a median of five cases (range 4-6) with each consultant vascular surgeon and team, to provide training to all key participating staff. At the beginning of the operating list, the trainer outlined the aims of the study, important definitions and protocol to the operating team. During the case, the trainer recorded failures that occurred. At the end of the first case with the trainer present, the trainer led the team through the ICECAP debrief and completion of the written ICECAP record. Thereafter, a member of the team to led the debrief, which took place in the same structured manner on each occasion. The trainer highlighted failures that she recorded to help teams to develop an understanding of the types of failures that should be reported. The trainer encouraged reflection and discussion between team members to enable a consensus to be reached regarding failures to be documented on the ICECAP record.

Phase II:

In the main study phase, each site aimed to independently collect data during 20 consecutive aortic cases. Sites were asked to complete an aortic case log, indicating any cases that were not recruited with reasons. For each case, patient, procedure and team demographic information were collected, and the primary operator indicated if he or she was unfamiliar with any of the equipment used. Details of each error were recorded, including whether or not the patient was harmed, any corrective measures necessary to prevent harm, and the delay caused by the error. Post-operative complications were recorded until day thirty or until discharge, whichever was sooner.

Handling of data

Case report forms were collated and entered onto a purpose-built database at the lead site. All errors were independently reviewed by two experienced clinical assessors (CB, Consultant Vascular Surgeon & CR, Clinical Lecturer) and categorised as 'major', 'minor', or excluded if they did not meet the study definition. Two independent assessors (RL Vascular Nurse Practitioner & DG, Surgical Registrar & Research fellow) graded post-operative complications using the Clavien-Dindo grading system[6]. Grades III, IV, and V are referred to as 'major' complications.

Statistical Analysis

Data were analysed with Stata version 12 by an independent statistician (EF). Agreement between assessors was measured with Cohen's kappa. Univariate and multivariable Poisson regression analysis was used to compare error rates (errors per hour) for different patient, procedure and team groups, and the clustering effect due to potential variability in reporting styles at the hospital site level was taken into account by using cluster robust standard errors. The variables included in the regression were: age; gender; American Society of Anaesthesiologists (ASA) grade; aortic pathology; procedure type (open surgical or endovascular); team member experience based on the number of similar operations performed (> 50 versus < 6 similar cases); equipment familiarity. The Wilcoxon rank-sum test was used to test for differences in the number of errors occurring intraoperatively and patient outcomes. All reported P values are two-sided. P values less than 0.05 were deemed to indicate statistical significance.

RESULTS

Phase I

Eighty-eight cases were included in phase I. The error profiles reported by the trainer and in self-report by operating teams are reported in figure 1. The correlation between the trainer and operating teams for the number of errors identified per procedure was good (Spearman's rho=0.766, p<0.001) and operating teams identified 95% (18/19) of major errors, indicating that operating teams were able to effectively follow study procedures and reliably assess error rates.

-Figure 1-

Phase II

Following a period of training, twenty consultant vascular surgeons and their operating teams reported failures occurring in 185 elective aortic cases. Only two urgent cases were recruited and were therefore excluded from analyses. The aortic case log was poorly completely and was therefore unhelpful. Teams performing open surgical procedures consisted of the following core members: consultant vascular surgeon, consultant anaesthetist, scrub nurse and support staff. For endovascular cases, core team members additionally included a consultant radiologist and a radiographer, as is common practice in the UK. 47% of open surgical cases were performed by ‘experienced’ teams (with all core team members having performed > 50 similar cases). None of the endovascular cases were undertaken by teams in which *all* core members had performed more than 50 similar cases. All cases started during daytime hours, though 16% (30/185) cases finished after 5pm. Patient, pathology and procedure characteristics are provided in table 1.

- Table 1-

Failure characteristics

The operating teams recalled 930 events in total. Independent assessment excluded 131 events that did not meet the study definition. Most errors were excluded for the following reasons: event did not occur intra-operatively (n=43) e.g. lack of intensive care bed delayed start of procedure; likely *anticipated* patient-related issue (n=72) e.g. tortuous iliac arteries identified on pre-operative imaging. Of 799 errors, operating teams identified a median of 3 errors per procedure (Interquartile range (IQR) 2-6, range 0-23). Median error rate was 1.0 per hour (IQR 0.6-2.0, range 0-6.3). Correlation between the number of errors per case and operative duration was 0.3, $p<0.001$ (Spearman’s rho).

- Figure 2-

The details of failure categorisation are shown in figure 2. Overall, most frequent failures related to equipment (33.9%), most commonly unavailability, ranging from minor issues, e.g. unavailability of the desired sheath size, to major errors, e.g. *"unavailability of the custom-made thoracic stent graft, which was believed to be on site but was found not to be available after spinal drain insertion and general anaesthesia (GA)"*. The primary operator reported unfamiliarity with equipment in eighteen procedures (open surgical n=1, endovascular n=17), of which unfamiliarity with stent graft devices was reported in eleven cases. Procedure-independent pressures (i.e interruptions and distractions, team member absence and external pressures) were also common (21.7% of all errors).

Failure consequences

The consequences of failure were varied. Nearly two thirds of failures (63%) caused intraoperative delays, and 10% of errors led to significant delays (more than 15 minutes during the operation). In total, intraoperative delays accounted for more than ninety hours unproductive operating time over the 185 cases. More than a third of failures (34%) necessitated corrective action by the operating teams.

11.6% (64/799) of all failures were classified as *major* failures. Fourteen major failures directly caused harm. Most (83%) of major errors led to significant intraoperative delay. Of the 17% of failures that posed serious risk of harm without causing intraoperative delay, communication failures were the most common. Overall though, most frequent major failures were unanticipated problems related to the patient's anatomy or phsyiology (33%), such as injury to a vessel during clamping because of calcification. Patient-related failures are therefore an important source of unanticipated delay (while the operating team address the problem), and could indicate failures in pre-operative planning or preparation. Non-patient related failures were most commonly communication failures (21.5% of major failures) *e.g. "radiology staff not informed of start time- delay in starting* *endovascular phase (45 mins) while patient under GA"*. Of the major communication failures, 65% were communication problems between operating sub-teams: between the surgical and radiology teams (38%) and between the surgical and the anaesthetic teams (23%). Of the remaining major failures: 17.2% were technical failures (e.g. *"unfamiliarity with a new* stent"/"sheath fell out"); 12.9% were equipment-related failures (e.g. *"requested stent size not available"*/*"cell saver not working"*)*;* 7% were safety awareness failures (e.g. *checks not done*), and 5% were procedure-independent pressures (*"significant intraoperative delays - radiology staff & equipment attending an emergency-patient already under GA with groins open").* Of the fourteen major failures directly led to intraoperative harm in 12 patients (6.5% of study cohort), communication failures were reported by team to have led to half of these harm-producing events (box 1). There were four technical errors that directly harmed patients (e.g. *"Iliac sheath removal led to iliac rupture. Acutely unstable requiring. immediate stenting and laparotomy"*). Three failures in which unanticipated difficulties with the patient's anatomy led to in harm (e.g. *"Difficult anatomy (unanticipated dissection in left common iliac artery) led to need for further anastamoses (jump graft). Hypotension caused by blood loss & reperfusion during this additional procedure*.) Although not a primary aim of the study, review of these failures details indicates that additional factors, such as inexperience or a lack of vigilance may also have played a role in the generation of these failures; harm was rarely a direct result of a single identifiable cause.

Box 1: Illustrative quotes from ICECAP records for major errors leading to harm

"Misleading communication led to wrong clamps being taken off the graft…substantial blood loss, which was 'hidden' and went unnoticed leading to severe hypotension in a patient with significant co-morbidity." (Hybrid open visceral artery retrograde revascularisation and endovascular thoracoabdominal aneurysm repair)

"Communication failure and discord between surgeons & scrub nurse during bleeding. Scrub nurse unfamiliar with use of pledgeted sutures to repair internal iliac vein injury. Miscommunication led to a further tear in vein as sutures were pulled out. Patient became acutely unstable." (Endovascular Aneurysm Repair (EVAR) with surgical ligation of internal iliac artery (IIA))

"Wrong sized limb placed necessitating embolization of IIA." (EVAR & left to right femoral-femoral artery crossover graft)

"Wrong incision due to lack of communication between radiology and surgical teams." (Aorto-uni-

Box 2: Case history

Case history

- 82 year old male, elective admission for aorto-uni-iliac stent & femoral- femoral artery crossover
- During the operation, the wrong size limb was placed, accidently covering the internal iliac artery (IIA) therefore putting the patient at risk of buttock claudication
- Immediate actions: embolisation of IIA & placement of extra limb (delay of 35 minutes)

Causal factors identified during the team debrief

- Unclear whether wrong limb was requested by surgeon or given by circulating nurse
- Operator (registrar under direct supervision) had not checked the limb size prior to placement
- Lack of clarity over registrar's experience & role of registrar/consultant intraoperatively
- The registrar and radiology staff had been absent from the morning briefing

Actions & changes in practice

- Incident was reported via NRLS & the potential implications discussed with the patient
- Radiology staff now attend pre-operative safety briefing
- Surgeons & radiology staff check the grafts together before the procedure
- Lead surgeon asks for vigilance in checking sizes when opening grafts

Determinants of error

Patient age, gender, ASA grade were *not* associated with increased failure rates in univariate analyses. Univariate analysis also demonstrated no significant difference between levels of experience for all professions within the multi-disciplinary vascular operating team. In multivariable regression (figure 3), thoracic/arch aneurysms in comparison to other aortic pathologies (IRR 2.07; 95% CI 1.39-3.08, $p<0.001$) were significant predictors of increased error rates. Of note, two thirds of patients with thoracic/arch aneurysms in this cohort underwent either carotid subclavian bypass and TEVAR or scalloped TEVAR.

Unfamiliarity with equipment (IRR 1.52; 95% CI 1.20-1.91, $p<0.001$), and endovascular repair compared with open surgical approaches (IRR for open repair 0.71; 95% CI 0.57-0.88, p=0.002) (figure 4). For *major* error, only unfamiliarity with equipment was significantly associated with increased error rate (IRR 2.59; 95% CI 1.51-4.28, p=0.001).

-Figure 3-

Impact of error on outcomes

152/171 procedures were technically successful with no adverse events at 24 hours post-operatively (missing data: n=14). Thirteen patients required re-operation, thirty-seven patients suffered major complications, four patients had a prolonged hospital stay (>30 days) and seven patients died. Total number of intraoperative errors was significantly higher in procedures subsequently requiring reoperation (reoperation: median 5 (IQR 4-10), vs. no reoperation: 3 (2-6), p=0.037). The number of *major* intraoperative errors was also significantly higher in those procedures subsequently requiring reoperation (reoperation: 1 (0-2), vs. no reoperation: 0 (0-1), p=0.011). Significantly higher numbers of major errors were reported during cases where the patients went onto suffer major complications (major complication: 0 (0-1.5) vs. minor or no complications: 0 (0-1), p=0.029) or death (died: 1 (0-3) vs. survived to discharge: 0 (0-1), p=0.027) (figure 5). There were no differences in the number of intraoperative errors occurring during successful procedures (successful: 3 (2-6) vs. unsuccessful: 5 (2-6), p=0.147) or between regular and prolonged hospital stays (hospital stay > 30 days: 4 (3-5) vs. hospital stay <30 days: 3 (2-6), p=0.837).

-Figure 4-

DISCUSSION

This large study in vascular surgery demonstrates that many avoidable safety failures relate to aspects of the surgical system in addition to patient factors and technical expertise. This study links intraoperative safety failure with adverse outcomes in patients undergoing aortic surgery. In line with a smaller study of safety failures in paediatric cardiac surgery[7], the present work shows that many failures leading to patient harm stem from failures in the system. Operating teams must recognise potential failures in the surgical system and endeavour to mitigate these challenges to optimise the safety of the patient.

The National Reporting and Learning System (NRLS) is voluntary system for reporting adverse events and near misses that occur in healthcare (ref). As such, it relies upon the details submitted by the reporter and is inherently under-representative of the volume of events that occur. The benefits of NRLS, in the same way as the LEAP study, come from analyzing the report to identify themes, which can be targeted for improvement. Interestingly, a retrospective study of NRLS reports to identify the causes of patient harm in aortic surgery, has demonstrated findings remarkably similar to those in the present study: there is a clear need to address communication and equipment related failures (findings presented at international meetings, manuscript in preparation). A benefit of the ICECAP debriefing approach to identifying intraoperative failures is that this approach enables learning to take place locally immediately after the case, with improvement measures such as those indicated in box 2 being implemented straight away.

Intraoperative errors appear to significantly affect operating theatre efficiency as well as patient safety. Two thirds of errors caused intraoperative delays in procedural workflow with more than ninety hours lost over 185 cases. Since the average cost of running an operating theatre exceeds €1500 per hour[8], the potential cost savings would be great for each institution by avoiding these procedural delays. Future research should consider the financial implications of intra-operative failures.

It has been previously demonstrated that error rates vary between operation types, with those procedures having a high reliance on technology, such as those in vascular or cardiac surgery, having the highest rates of total and equipment-related error[9]. The present study has expanded on the findings of previous single-centre studies[4,10], demonstrating that endovascular procedures are consistently associated with more errors compared to open surgical operations. Whilst minimally invasive surgery has undoubtedly reduced surgical morbidity and mortality, to achieve optimal, safe and efficient outcomes we must also minimise avoidable error. The increased rates of error during endovascular procedures versus open surgical procedures may be explained by the rapidly evolving nature of the endovascular field, more challenging technology and the increased number of new devices on the market, resulting in an extensive learning curve associated with these complex endovascular techniques. Thoracic/arch aortic aneurysms predicted higher failure rates than infra-renal or juxta-renal aortic pathologies, which may be explained by their relative technical difficulty. However, this leads to the question of why thoraco-abdominal aortic pathologies did not also predict higher failure rates. The TAAA repairs are performed only in centres with the experience and infrastructure to cater for these, requiring particularly meticulous planning and preparation, which may help to explain the non-significant higher rate of errors in these cases relative to those for infra-renal or juxta-renal pathologies.

In the present study, perceived unfamiliarity with equipment significantly predicted increased rates of intraoperative failures while actual experience (in terms of the number of operations performed) did not. Vascular operating teams use an increasingly wide range of stent graft devices in order to treat patients with a broad range of anatomical configurations. In a similarly honest study of adverse events during branched and fenestrated aortic stent graft procedures, the authors suggested that the number of devices being used may have contributed to unfavourable results[11]. Medical practitioners planning to introduce a new interventional device have a responsibility to ensure that the introduction of new equipment is accompanied by adequate training and fulfills safety and financial regulations within their institution. This may include gaining approval from the divisional board and new procedures committee, ensuring that protocols are in place and ensuring there is a robust structure for audit and evaluation. In reality, new devices and equipment are regularly introduced into the operating environment. Care should be taken to ensure that the process for implementation is rigorous on each occasion. Currently, it is unclear who is ultimately responsible for training endovascular operators and their teams, whether industry or healthcare institutions, when new devices become available and are being used in patients. However, it appears new device training requires attention to improve patient safety.

Communication failures represented a significant proportion of *major* errors reported in the study, and contributed to half of all intraoperative harm events. Complex aortic procedures demand precise communication and collaboration from increasingly large and multi-disciplinary operating teams. This study was undertaken in the UK, where, similar to many European institutions, surgeons and interventional radiologists commonly collaborate to perform endovascular procedures. As we endeavour to treat ever more ambitious anatomical configurations, dual consultant operating has also become routine practice. Rotation of operating staff is commonplace, and as a result, team members may not regularly work together. Consequently, effective leadership and teamwork are challenging in this high-risk environment, yet training in these essential non-technical skills is not routine practice, despite the evidence of a relationship between teamwork and patient outcomes[12,13].

This study highlights the need to address human factor skills (such as communication, team-working, leadership) and system factors (equipment planning, provision and maintenance, pressures on the operating team and their environment, provision of training) that may influence patient outcomes in aortic surgery, while continuing to optimise the patient's preoperative condition and technical expertise among surgeons. A substantial proportion of equipment failures were due to unavailability, failure or configuration, suggesting that there are clear advantages to implementing protocols to reduce equipment-related error[14,15]. The quality of the WHO checklist is more important than a tickbox exercise and time pressures often mean that it is not completed with due care and consideration [ref]. The equipment required for aortic procedures is often a long and complex list and so there is potential for error. Equipment items that may be required when the team are faced with difficulties during an operation, particularly during endovascular cases, also needs to be considered and prepared. Further procedure-specific equipment checks could be incorporated into the World Health Organisation's surgical safety checklist, specially adapted for use in aortic repair.

Clarity on training accountability for new devices is also essential to reduce the number of technical and equipment errors that occur. The provision of teamwork and leadership training for vascular operating teams is crucial to further improve patient outcomes. Team simulations have been shown to be a powerful tool to train and improve the technical and non-technical skills required to perform endovascular aortic aneurysm repair and complex cardiovascular procedures, and may be particularly useful for rehearsal of crisis scenarios[16,17].

A clear limitation of this study is self-reporting, which is likely to be influenced by cognitive biases, clinical processes (e.g. production pressure) and individual reporting styles[18]. To minimise the impact of this limitation, the ICECAP tool was used immediately after the case to structure post-operative team self-reporting of error, which has been shown to reduce 'recall bias'[5] (the propensity to remember significant or novel events), and a training period was undertaken to attempt to standardise data recording. A limitation of the ICECAP debriefing method is that, because failures are not recorded in real time, the temporality of failures cannot be established with certainty. The principles of primacy and recency suggest that operating team members were more likely to report failures occurring at the start or at the end of the procedure. Independent observation by a human factors expert and a surgeon is an alternative strategy that has been used to capture this kind of data (ref) in real-time. There are several benefits of team self-report over independent observation. In the operating theatre, various tasks may be undertaken simultaneously by different sub-teams; it may be difficult for observers to capture all failures that occur. Operating team members are uniquely placed to understand the context of intra-operative failures, which is important for establishing their significance. Different professions are likely to report different kinds of failure and it would be implausible to have every member of the multi-disciplinary team undertaking concurrent observations. In an ideal study environment consistent teams would have been necessary for consistent data reporting. Having said this, variability in team composition has been proposed as a source of communication failure in surgery. Therefore, in this study that aims to capture real world intra-operative failures, the fact that teams were inconsistent provides an honest report. Selective reporting may introduce bias into the findings. As the aortic case log was poorly completed across participating sites, it is not clear whether consecutive cases were recruited into the study. The study cohort was a heterogenous sample in terms aortic pathology and procedure performed. To address this, multivariable regression identified predictors of increased failure rates to present meaningful conclusions. Future studies may also wish to consider as possible confounding variables: treatment outside instructions for use (IFU) guidelines and operating setting (theatre/radiology suite/hybrid suite). Additional studies (as yet unpublished), undertaken in parallel with the LEAP study, have investigated pre- and post-operative system factors that may influence patient outcomes; measuring peri-operative failure was beyond the scope of the present study. A final point to note is that the number of patients with adverse outcomes was small, therefore the assessment of between-group differences for error and patient outcomes was not adjusted for multiple comparisons; further research is needed to confirm a relationship between intraoperative error and outcome.

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FIGURES & TABLES:

Figure 1: Profile of errors identified through prospective observation by the trainer & structured, team self-reporting during the training phase

Table 1: Patient & procedure demographics in the study phase

Figure 2: The landscape of error in aortic procedures (n=185) by primary category and subcategory

Figure 3: Forest plot of multi-variable incidence rate ratio for predictors of error rate.

Legend: Significant predictors ($p<.05$) of increased error rates in the univariate model were included in multivariable analyses. The variable 'errors per hour' was used to control for differences in operative duration. N indicates sample size for each group. Data points on the forest plot indicate incidence rate ratio (IRR) and 95% confidence intervals (CIs).

Figure 4: Comparison of major errors per procedure and by patient outcomes.

Legend: The box indicates the IQR divided by the median (solid line), Tukey-style whiskers extend to a maximum of 1.5 x IQR. Test used: Wilcoxon-Rank Sum. P-values (unadjusted for multiple comparisons): reoperation: p=0.011, post-operative complications: p=0.029, death: p=0.027.

Table 1: Patient & procedure demographics in the study phase

Patient demographics (n=185)		Procedure demographics (n=185)	
Mean age (SD, min-max):	73 (9.9, 37-100)	Open infrarenal AAA repair	11.4% (21/185)

Male gender:	85% (153/180)	Open juxtarenal aortic aneurysm repair/Type IV aortic aneurysm repair	4.9% (9/185)
American Society of Anaesthesiologists (ASA) grade:		Open aortoiliac bypass	3.8% (7/185)
I	1% (2/179)	Open aortofemoral bypass	3.8% (7/185)
II	26% (44/179)	Endovascular Aneurysm Repair (EVAR) (conventional)	37.3% (69/185)
III	65% (119/179)	EVAR (additional complexity*)	9.7% (18/185)
IV	8% (14/179)	Branched EVAR/ Fenestrated EVAR (conventional)	12.4% (23/185)
Primary aortic pathology:		Fenestrated EVAR (additional complexity*)	2.2% (4/185)
Infrarenal Abdominal Aortic Aneurysm (AAA)	61% (111/182)	Thoracic EVAR (conventional)	4.3% (8/185)
Juxtarenal AAA	17% (30/182)	Thoracic EVAR (additional complexity*)	3.8% (7/185)
Thoracic/arch AA	4% (8/182)	Visceral hybrid repair	1.1% (2/185)
Thoraco-abdominal AA	8% (15/182)	Other	5.4% (10/185)
Occlusive disease	5% (9/182)	* Additional complexity: endovascular procedure with additional intervention besides femoral cut down for arterial access.	
Other	5% (9/182)		