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Identification of Patient Safety Improvement Targets in Successful Vascular and Endovascular Procedures: Analysis of 251 hours of Complex Arterial Surgery☆ CME

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Abstract *Objectives:* To investigate failures in patient safety for patients undergoing vascular and endovascular procedures to guide future quality and safety interventions.
Design: Single centre prospective observational study.
Methods: 66 procedures (17 thoracoabdominal and 23 abdominal aortic aneurysms, 4 carotid and 22 limb procedures) were observed prospectively over a 9-month period (251 h operating time) by two trained observers. Event logs were recorded for each procedure. Two blinded experts identified and independently categorised failures into 22 types (using a validated category tool) and severity (5-point scale). Data are expressed as median (range). Statistical analysis was performed using Mann—Whitney U, Kruskal—Wallis and Spearman's Rank tests.
Results: 1145 failures were identified with good inter-assessor reliability (Cronbach's alpha 0.844). The commonest failure types related to equipment (including unavailability, configuration and other failures) (269/1145 [23.5%]) and communication (240/1145 [21.0%]). A comparatively lower number of technical and psychomotor failures were identified (103 [9.0%]). The number of failures correlated with procedure duration (rho $= 0.695$, $p < 0.001$) but not anatomical site of the procedure or pathology of the disease process. Failure rate was higher in patients undergoing combined surgical/endovascular procedures compared to open surgery (median 5.7/h [IQR 4.2—8.1] vs 3.0/h [2.5—3.5]; $p < 0.001$). The severity of failures was similar (1.5/5 [1—2] vs 1/5 [1—2] respectively; $p = 0.095$). For combined procedures, failure rates

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were significantly higher during the endovascular phase (9.6/h [7.5–13.7]) compared to the non-endovascular phase (3.0/h [1.0–5.0]; $p < 0.001$).

Conclusions: Failures in patient safety are common during complex arterial procedures. Few failures were severe, although minor failures during critical stages and accumulation of multiple minor failures may potentially be important. Failures occurred especially during the endovascular phase and were often related to equipment or communication aspects. Interventions to improve procedural safety and quality of care should primarily target these specific areas.

Introduction

The increasing complexity of healthcare over the past decade has led to a corresponding rise in the number of reported adverse events, defined as unintended injuries caused by medical error rather than the disease process itself.[1] One of the first studies to quantify medical injury was the Harvard Medical Practice Study in 1991, which identified that surgical procedures accounted for 48% of all adverse events.[2,3] Later studies demonstrated rates of adverse events attributed to surgery as high as 66%.[4,5] Factors contributing to this high incidence of adverse events include rapid technological advances (with a corresponding lack of surgical training or experience), poor supervision, fatigue and communication breakdowns. Interestingly, the majority of surgical adverse events are attributed to a small number of specialties including vascular surgery, gastrointestinal surgery, urology, orthopaedic surgery, spinal surgery and obstetrics and gynaecology.[4]

Vascular surgery, in particular, is a specialty that poses many complex safety risks. In a retrospective review of over 15,000 patients including 402 cases with surgical adverse events, researchers in the early 1990s identified that abdominal aortic aneurysm repair and lower extremity bypass graft surgery carried significantly higher rates of adverse events (18.9% and 14.1%, respectively) than other major non-vascular procedures such as colon resection (6.8%).[4] Moreover, these procedures also had the highest incidence of preventable adverse events. More recent advances in minimally invasive surgical techniques have meant that the operating theatre environment has changed immeasurably. The vascular operating room is now a dynamic and complex multidisciplinary environment involving the transfer of high volumes of information between teams and highly complex surgical tasks. Prevention of surgical error presents a significant challenge in this setting, although few studies have evaluated the extent of this problem.

The aim of this study was to investigate avoidable failures in patient safety for patients undergoing vascular and endovascular procedures to guide future quality and safety interventions.

Materials and Methods

Setting and study population

Patients undergoing arterial surgery in a tertiary level regional vascular unit (St Mary's Hospital, London) over a nine-month period (September 2009 to May 2010) were studied prospectively. All elective major arterial procedures that took place whilst an observer was present in theatre were included. A direct observational methodology was employed to identify intraoperative failures during open vascular and combined (open and endovascular) procedures. Procedures performed as an emergency were not included and, in order to maintain a consistent study environment, only procedures performed within the vascular surgery operating theatre were considered. During combined procedures, the endovascular stage was performed with the interventional radiology team (interventional radiologist, radiographer and junior staff) present in addition to the vascular surgical team. The main operator during this phase is variable and decision-making during this phase is a multidisciplinary process. The World Health Organization (WHO) Surgical Safety Checklist was performed in all cases before the procedure as standard.

Study design

Full ethical committee approval was granted for this study. The methodology used in this study was designed and validated by the Centre for Patient Safety and Service Quality at Imperial College London (KM, CAV, AV).

Data on intraoperative events were collected by two observers (MAA, SRP) using contemporaneous ethnographic field notes. The observers in this study were both medical students (MAA and SRP). The documentation of the events that occurred was performed in a non-judgemental fashion, noted as a description of what occurred. An event was defined as an occurrence perceived to be a potential failure. Failure was defined as 'the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)'.[6] For each event, the time of occurrence, team members involved, precise events and any immediately visible effects were recorded.[7] If a significant planning omission or failure was identified in the WHO checklist it was considered a failure as this study was designed to identify the pattern of failures in theatre. The start and end-points of data collection were the patients' arrival on the operating table and completion of the final closing suture. Operative duration, procedure type, American Society of Anaesthesiologists (ASA) grade, patient age and the composition of the theatre teams were also documented.

A two-week preliminary phase was implemented for observer training and to reduce any improvements in performance as a result of the subjects' knowledge of being observed; the *Hawthorne effect*. The observers received training on the observation of non-technical skills, instructed directly in theatre during this phase (AV — Clinical Research Fellow for the Clinical Safety Research Unit, Imperial College London).

Analysis of events

The event log for each procedure was anonymised (to maintain anonymity and protect confidentiality) and analysed by two blinded experts (CVR — Clinical Lecturer in Vascular Surgery, MSG — Post CCT Specialist Registrar) familiar with the operating room work environment, who identified and categorised failures into 22 pre-defined types, using a validated category tool (Table 1).[8] Each identified failure was assigned a 'delay score' and a 'danger score' using a 5-point scale, based upon the impact on procedural duration and safety of the patient, respectively. A score of 0 was assigned to a failure that has a seemingly insignificant effect on the procedure and does not impact on key tasks or patient safety. A score of 3 was assigned if there was a moderate impact on the flow of the procedure or a safety issue that is easily resolved and is unlikely to cause patient harm. A score of 5 was given to a failure if there was a severe impact on the flow of the operation with major delays or if there was a significant events leading to a compromise of the safety of the patient or the quality of treatment delivered. Discrepancies in failure categorization were resolved by a third expert adjudicator (CDB — Clinical Senior Lecturer and Honorary Consultant Vascular Surgeon) and where delay and danger scores differed between experts, median scores were used (Fig. 1).

Statistical analysis

The data were analysed for both descriptive and analytical statistics. Cronbach's alpha reliability coefficient was used to measure inter-rater reliability. Correlations between failures and other variables were tested using Spearman's Rank test and the Mann—Whitney *U* test was used to compare outcomes between groups. When comparing more than two groups, a Kruskal—Wallis test was used. Statistical analysis was performed using Statistical Package for the Social Sciences version 18.0 (SPSS, Chicago) and p values < 0.05 were deemed to be significant.

Results

Study population

During the study period, 79 patients undergoing open vascular or combined vascular and endovascular intervention

Table 1 Categories and descriptions of failure types (adapted from Catchpole et al.[8]).

Failure	Description
Absence	Lack of personnel when required
Communication failure	Failures in communication and information transfer between operating team
Decision-related surgical error	Team member fails to make appropriate decision
Direct equipment failure	Intraoperative equipment failure
Equipment unavailability	Equipment that is required for the procedure is not available for use when requested
Equipment/workspace management failure	Failure in organization of workspace and equipment
Equipment configuration failure	Failure to prepare or operate equipment appropriately
External pressures	Requirements of the external organisation that impact on the operating room team
External resource failure	Failures in elements of the external organisation to provide equipment or human resources
Fatigue	Indication that operating room individuals are suffering from tiredness/lack of sleep
Fault resolution failure	Failure to identify cause of a problem or to resolve a problem
Patient-related procedural difficulties	Characteristics of the patient that make the procedure more difficult
Planning failure	Failure to anticipate or discuss task requirements prior to start of procedure
Procedure-related error	Procedural errors by operating room team members
Psychomotor error (general)	Handling errors
Psychomotor error (surgical-related)	Technical manipulation errors by surgeon
Psychomotor error (radiological-related)	Technical manipulation errors by interventional radiologist
Resource management	Failures in the organisation of available people or equipment in the operating room
Safety consciousness	Failures to observe basic elements of patient safety
Team conflict	Team members have contrasting opinions or give conflicting commands
Technical failure	Failures associated with lack of expertise or skill, usually in trainees
Vigilance/awareness failure	Failure to notice immediately important aspects in the procedure and workspace environment

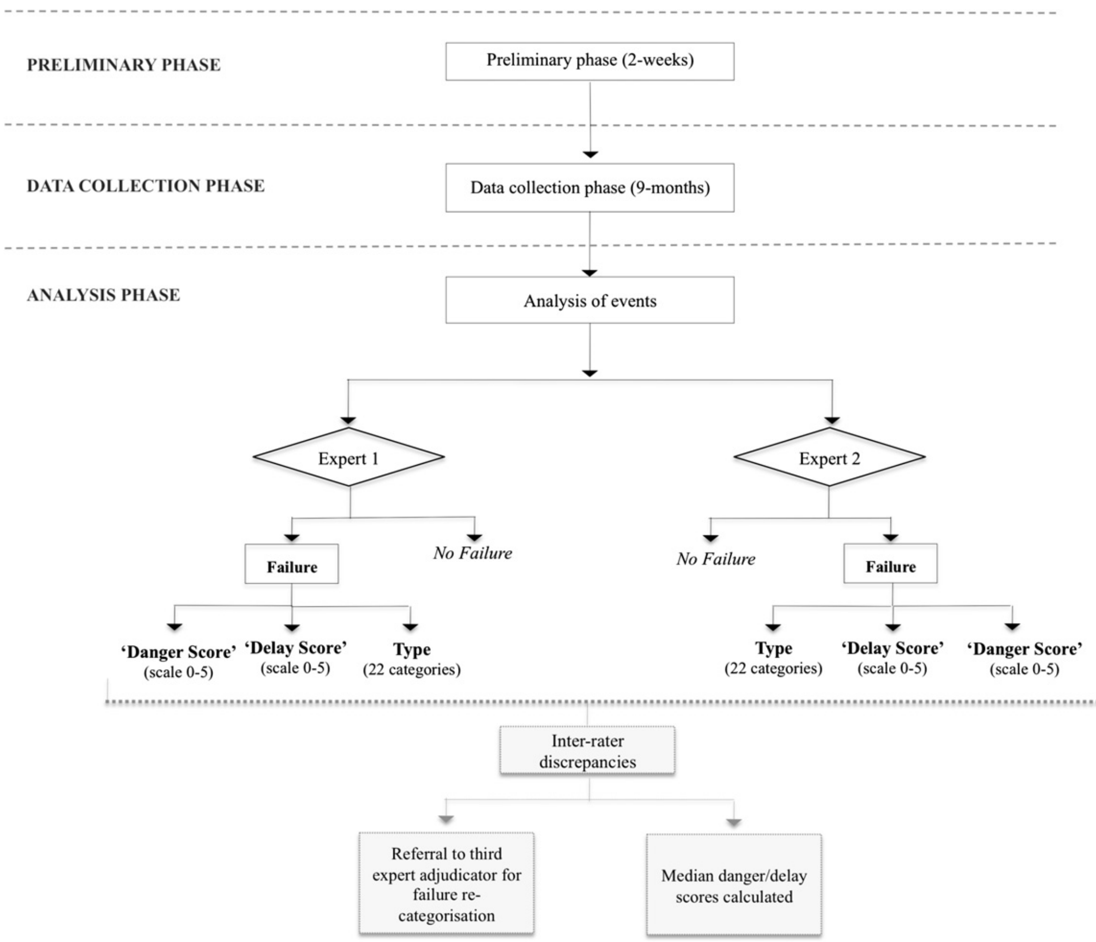

Figure 1 Process of data collection and analysis of event logs.

were assessed for eligibility. The first 10 cases, considered part of the data collection learning curve, were excluded from analysis and a further 3 emergency procedures were also excluded. The remaining 66 patients, with a total observation time of 251 h (median 173 min, interquartile range [IQR] 126–314), were included in this study. Thirty-three patients (50%) had open vascular procedures and thirty-three patients (50%) had combined procedures involving open vascular and endovascular stages. Observed procedures included 17 thoracoabdominal aortic aneurysm (TAAA) repairs (26%), 23 infrarenal aortic aneurysm (IRAAA) repairs (35%), 4 carotid artery interventions (6%) and 22 lower limb arterial reconstructions (33%). The mean age of patients was 69 years (range 13–89 years) and the mean patient ASA grade was 3 (range 1–4).

Failures identified

In the 66 procedures studied a total of 1847 events were logged by the observers. Of these, a total of 1145 failures were identified and categorised, with good inter-rater reliability (Cronbach's alpha 0.844). The overall rate of failures was 13 per procedure (IQR 8–23). Equipment-related failures were most common (equipment unavailability, equipment configuration failure, equipment/workspace management failure and direct equipment failure), responsible for 23.5% (n = 269/1145) of failures, with equipment unavailability being the most prevalent (127/1145). Communication failures were responsible for 21% (240/1145) of all failures (Fig. 2). Technical (41/1145 [3.6%]) and psychomotor (62/1145 [5.4%]) failures were less common.

3.1% (n = 36/1145) of failures were identified during the 'time-out' phase of the WHO Surgical Safety Checklist.

Failure severity — delay and danger scores

The severity of failures was largely low and similar between cases. The mediandanger and delay scores were 1.5/5 (IQR 1–2) and 1.5/5 (IQR 1–2) respectively. Only 59/1145 (5.2%) of failures had danger (n = 29) or delay (n = 30) scores of 4–5/5 and were therefore perceived to have a major effect on procedural duration and patient safety. There were 10 major technical errors leading to these failures, most commonly anastomotic construction errors (with significant blood loss or requiring major re-anastomosis) or excessive bleeding from arterial or venous injury. There were 8 major equipment-related failures, most commonly related to malfunction/misuse of imaging equipment or failure of stent graft deployment (such as snapping of the stent graft deployment mechanism). Five planning failures occurred,

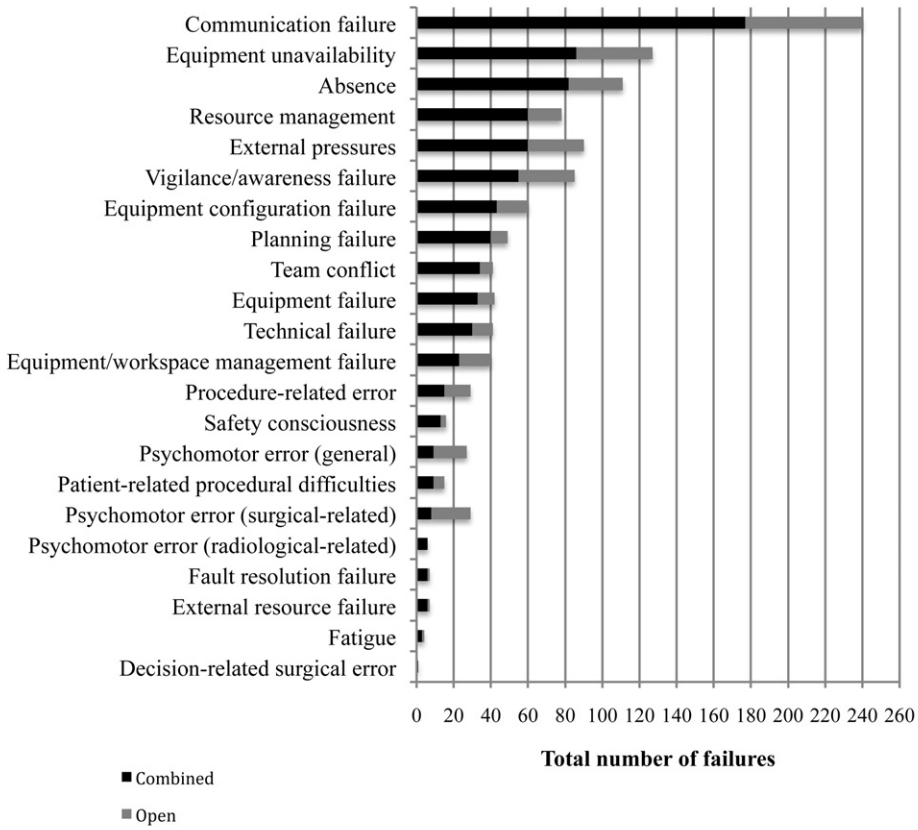

Figure 2 Failure distribution between open and endovascular groups (by type).

which included inadequate discussion of subsequent procedural steps causing significant delay, appropriate personnel not being available and there was one major delay when the side of operation required long discussion. Major communication failures (four) involved miscommunication between surgeon and circulating nurse (setting the diathermy machine to an inappropriate level during a critical stage in the procedure), between anaesthetic and surgical teams (when excessive blood loss occurred without discussion and failure of communication when critical steps of the procedure were performed, such as balloon occlusion of the aorta and when heparin not administered despite a request). Three major failures occurred secondary to absence, in each case leading to excessive delay when appropriate personnel were not available after unexpected events or complications occurred. Two psychomotor failures occurred with accidental displacement of guidewires/catheters and one psychomotor failure occurred whilst

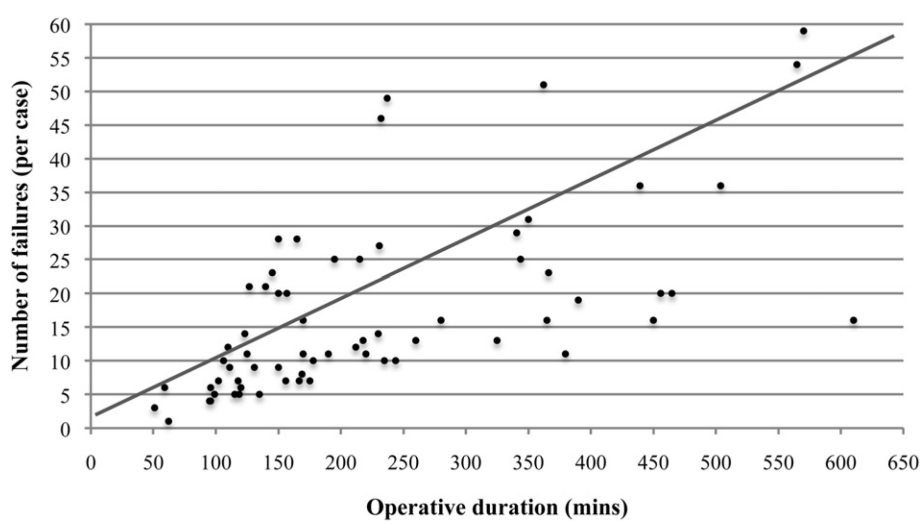

Figure 3 Scattergram demonstrating relationship between number of failures per case and operative duration.

tunnelling a femoro-popliteal bypass graft with venous injury. Other major failures included awareness, fault resolution, patient-related and team conflict errors.

This pattern in failure severity distribution was seen across the majority of failure types. Procedures featuring higher severity scores (score 4–5/5) had significantly more failures overall than procedures featuring lower severity scores (Spearman's Rank rho = 0.60; $p < 0.001$).

Factors influencing number of failures

Operative duration

A two-tailed Spearman's Rank correlation demonstrated a strong positive relationship between operative duration and the number of failures (rho = 0.695, $p < 0.001$) (Fig. 3). Failure rate per hour is therefore used for all further analyses in this study.

Patient age and ASA grade

Patient age (Spearman's Rank rho = 0.193; $p = 0.204$) and ASA grade (Spearman's Rank rho = 0.077; $p = 0.614$) did not correlate with failure rate.

Type of procedure

Failure rates between specific procedure types are shown in Fig. 4. The subgroups are too small for valid evaluation, but differences between those procedures that involved an endovascular component and those that did not can be seen and therefore these groups were compared.

Failure rates were significantly lower in open vascular compared to combined vascular and endovascular procedures (3.0/h [IQR 2.5–3.5] vs 5.7/h [IQR 4.2–8.1]) respectively; $p < 0.001$, Mann–Whitney U) (Table 2). However, failure severities were similar between the two groups (median combined danger-delay scores of 1.5/5 [1–2] and 1/5 [1–2] for open and combined groups respectively; $p = 0.095$, Mann Whitney U). Within combined procedures, the failure rate were highest during the endovascular phase of the procedure compared to the non-endovascular phase (median of 9.6/h [IQR 7.5–13.7] vs (3.0/h [1.0–5.0], respectively; $p < 0.001$).

Discussion

This study demonstrated that intraoperative failures are common during open vascular and combined vascular and endovascular procedures. There was considerable variability in the type and frequency of failures identified between cases and, although most failures were of low severity and were compensated for successfully, accumulation of these events or failures occurring at critical points in the procedure may impact on quality of care and patient safety. The majority of failures were identified in elements of the system, reflected by the finding that communication and equipment-related failures were most frequent, jointly accounting for 44.5% of all failures, with a comparatively lower number of technical (3.6%) and psychomotor (5.4%) errors. The predominance of communication failures in our study mimic the findings of the Joint Commission on Accreditation of Healthcare Organisations (JCAHO)[9] and several other research reports,[8,10–12] suggesting that this is an area in urgent need of improvement.

Although the majority of failures were low in severity and only had a small negative effect on the procedure and the patient, 5.2% were scored as potentially having a major impact on procedural flow or patient safety. Procedures containing a high number of low severity score failures also had a higher number of more major failures which may imply that frequently occurring and 'seemingly insignificant' failures predispose to more major failures. Other

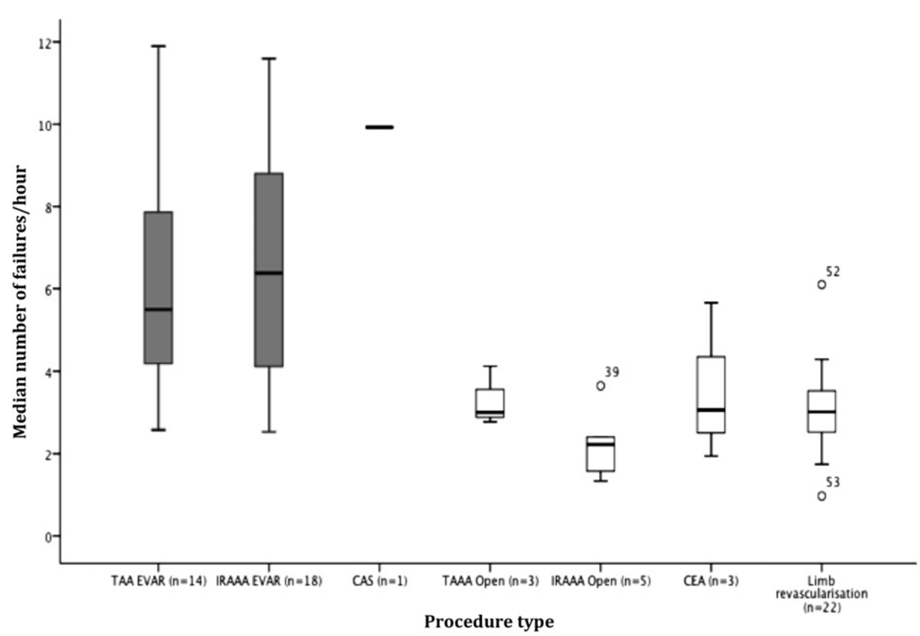

Figure 4 Box plot of median number of failures per hour by type of procedure. The box represents the interquartile range and the error bars demonstrate the range for each procedure. The central thick lines represent median value. Outliers are shown as separate dots, which are denoted by their case number.

Table 2 Comparison between open and combined open and endovascular groups.

	Open		Combined		*P* value[a]
	% (*n*)	Median per hour [IQR]	% (*n*)	Median per case [IQR]	
Number of failures	30.2[b] (346)	3 [2.5–3.5]	69.8[b] (799)	5.7 [4.2–8.1]	$p < 0.001$
Operative duration		170 [106–230]		161 [136.8–233.3]	

[a] Mann–Whitney *U* test.
[b] Calculated as percentage of total number of failures (1145).

researchers have also found the propagation of error from minor to major may occur either through the cumulative effect of a sequence of small failures or via the activation of a more serious 'latent' failure already present in the system.[8] Lengthier procedures were also more likely to generate a greater number of failures. In this cohort, failures due to fatigue were scarce. It is likely that the longer procedures were generally more complex and therefore at higher risk of failures, although further analysis is needed to understand how procedure length is affected by the number and severity of failures.

Although the numbers in the subgroups are small, there does not seem to be a difference between error rates in different open surgical procedures (the rate of error during open aneurysm repair seems to be similar to that during lower limb bypass, Fig. 4). There is, however, a striking difference between open and combined surgical/endovascular cases. Nearly 70% of failures were identified in combined open and endovascular cases, with the endovascular phase being the period of greatest risk. Communication and equipment-related failures jointly accounted for nearly half of failures in this period. This is an important finding of this study and clearly highlights this period as high-risk for intraoperative failures. This may be due to the fact that complex combined surgical and endovascular procedures have a higher reliance on technology and involve multidisciplinary teams making, often urgent, decisions on high-risk patients with vascular disease. In open surgical operations, although they may also be urgent and high-risk, there is one primary surgical operating team communicating with the nursing and anaesthetic teams and using surgical equipment that is available as standard, which may lessen the rate of error. In addition to this, the open procedures may be more familiar to scrub nurses and surgeons, highlighting the need for more effective training in endovascular processes.

It is important to recognise that the endovascular phase of combined procedures is a highly complex multidisciplinary environment involving interventional radiologists and radiography staff in addition to surgical, anaesthetic and nursing teams. Effective communication and teamwork is likely to be of even greater importance within this dynamic and complex setting. Previous reports have suggested that this weakness in communication and information transfer in the operating room may stem from a lack of standardisation and team integration.[12,13] The recently launched WHO Surgical Safety Checklist has been implemented with the aim to address such intraoperative communication deficiencies.[14,15]

Despite occupying similar proportions of total failures in both open vascular (11.8%) and endovascular (10.8%) groups, there was a twofold increase in equipment unavailability in the endovascular cases. This was largely due to equipment stock depletion and therefore highlights planning failure as a possible major root cause of this (i.e. failure to plan for procedure equipment needs). In the field of endovascular therapy, with regular technological advances, failures due to lack of familiarity with equipment are important to eradicate.

We recognise that this study has limitations particularly as assessment by observation has flaws.[8,11,16] Such methodologies always run the risk of inter-rater reliability and sampling bias,[17,18] so more sophisticated and objective observational methods should be developed and implemented in future studies. It is also important that similar future research is carried out at other centres to validate these findings. The collection of data for analysis in this study was carried out by two medical students. Although one may argue that students are less able to judge what constitutes an error in these complex procedures, the construction of an event log was performed without judgement and the decision on whether each of these events constituted a failure was that of the two blinded assessors, who had significant experience in vascular surgical procedures. It is also possible that the observers, though not involved in the surgical procedure, may have been more inclined to note events more frequently during combined procedures. However, the decision on whether this constituted an error was not theirs. The fact that approximately 40% of events were not logged as errors is testament to the fact that the observers diligently logged the operative events without attempting to make a decision on whether an error had occurred.

On the basis of the findings of this study, it may be suggested that the introduction of a second protocol, a "pre-endovascular checklist" on the arrival of the interventional radiology team may reinforce the procedural stages, verify equipment availability and potentially reduce the risk of failures. Whether this can successfully target and reduce some of the communication and planning deficiencies in the endovascular stenting phase is not currently known. A protocol-based communication tool that targeted critical stages in cardiopulmonary bypass procedures has reported significant reductions in communication breakdowns.[19] The benefits of new checklists and protocols, however, must be balanced with the disadvantages of time delays and 'checklist fatigue' that may reduce the impact of such an intervention.

In conclusion, structured observation of major vascular procedures can identify a significant number of recurrent and related failures during open and combined open and endovascular vascular procedures. It seems that the rate of failures is not increased in specific anatomical operative sites or with certain pathology but endovascular phases and combined procedures are associated with significantly higher failure rates when compared with open vascular procedures. Interventions to improve procedural safety should primarily focus on these high failure rate phases during complex vascular intervention.

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Conflict of Interest

None.

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