THE IMPACT OF SYSTEM FACTORS ON QUALITY AND SAFETY IN ARTERIAL SURGERY: A SYSTEMATIC REVIEW

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What this study adds:

This review addresses a topic that is an underexposed in vascular surgery: how system factors such as teamwork and the work environment influence quality and safety. The limited evidence collated in this review is heterogeneous in terms of definitions, methodologies and outcome measures, which makes it difficult to draw meaningful conclusions from the existing body of literature. Research in this field would benefit from consistency in terminology, the use of validated assessment tools, measurement of clinically relevant endpoints, and adherence to national reporting guidelines.

ABSTRACT

Objective

A systems approach to patient safety proposes that a wide range of factors contribute to surgical outcome, yet the impact of team, work environment and organizational factors, is not fully understood in arterial surgery. The aim of this systematic review is to summarize and discuss what is already known about the impact of system factors on quality and safety in arterial surgery.

Data sources

A systematic review of original research papers in English using MEDLINE, Embase, PsycINFO and Cochrane databases, was performed according to PRISMA guidelines.

Review methods

Independent reviewers selected papers according to strict inclusion and exclusion criteria, and using predefined data fields, they extracted relevant data on team, work environment, and organizational factors, and measures of quality and/or safety, in arterial procedures.

Results

Twelve papers met selection criteria. Study endpoints were not consistent between papers, and most failed to report their clinical significance. A variety of tools were used to measure team skills in five papers; only one paper measured the relationship between team factors and patient outcomes. Two papers reported that equipment failures were frequent and had a significant impact on operating room efficiency. The influence of hospital characteristics on failure-to-rescue rates was tested in one large study, though their conclusions were limited to the American Medicare population. Five papers implemented changes in the patient pathway, but most studies failed to account for potential confounding variables.

Conclusions

A small number of heterogeneous studies have evaluated the relationship between system factors and quality or safety in arterial surgery. There is some evidence that system factors affect patient outcomes, but there is more work to be done to fully understand these relationships. Future research would benefit from consistency in definitions, the use of validated assessment tools, measurement of clinically relevant endpoints, and adherence to national reporting guidelines.

Key words: quality; safety; arterial surgery; system factors

INTRODUCTION

The outcomes of vascular surgery vary considerably between organizations and between countries but the reasons for this are not fully understood[1–3]. A relationship between annual caseload volume and patient outcome is now well established for many arterial procedures. Robust evidence demonstrates that higher procedural volumes predict lower operative mortality for a range of arterial procedures including elective open abdominal aortic aneurysm (AAA) repair, endovascular aortic aneurysm repair (EVAR), carotid endarterectomy (CEA) and lower extremity bypass[4–6]. Such evidence has prompted major service reconfiguration (centralization) in recent years. Individual surgeon volume does not account for the entire effect of institutional volume, with the relative importance of surgeon volume varying according to operation performed[7]. Therefore, other determinants within a healthcare institution must also play a role. Alongside caseload volume and experience, emerging evidence suggests that hospital teaching status is important – with academic institutions having better outcomes, a finding which may be explained by variations in training[8]. The precise determinants of variation in outcome are yet to be established, though contributory factors are likely to include differences in formalized training programs, resource availability, specialty teams, and provision of intensive care facilities[8].

A systems approach to surgical quality and safety proposes that all aspects of the healthcare system should be considered when attempting to explain outcome[9]. A number of studies conducted in the surgical setting have implicated communication failures, fatigue, poor staffing levels and equipment problems[10–12]. This systematic review aims to summarize and discuss what is known about the impact of team, work environment and organizational factors on quality and safety in arterial surgery.

METHOD

Protocol

The protocol for this systematic review was specified in advance of the review taking place. The methodology and reporting of the review adheres to the Preferred Reporting Items for Systematic reviews and Meta-Analyses statement (PRISMA)[13].

Definitions

Elective arterial surgery

Elective arterial surgery refers to the planned open surgical or endovascular treatment of aneurysmal or occlusive arterial disease. The evaluation of factors influencing safety and quality in *emergency* surgery was deemed beyond the scope of this review.

Measures of quality and safety

The principal outcome measures were mortality, complications, length of stay and readmission rates. These were complemented by surrogate process measures, including intra-operative errors, failures or procedural problems, and unnecessary procedural delays. These surrogate process measures may provide important insights into quality and safety because they are frequently defined by their consequences (i.e. harm to patient or delays to an operation).

Factors influencing surgical quality and safety

A systems approach was adopted for the purposes of this review to take evaluation of factors influencing surgical quality and safety, beyond patient risk factors and surgical skill. This approach, which has been described in full elsewhere[9] encourages consideration of all potentially relevant factors implicated in surgical quality and safety in the perioperative period. This review considers three overarching themes informed by a previously published framework of factors influencing clinical practice[14]: team factors, work environment, and organization and management factors. Further details of these themes are provided in table 1.

- Table 1: Factors influencing surgical quality and safety -

Information sources

The following databases were systematically searched: Medline [Ovid Medline 1946 to 1st July 2016], Embase [Embase 1947 to 30th June 2016], PsycINFO [PsycINFO 1967 to June Week 5 2016], and the Cochrane Library. Reference lists of key papers were hand searched for additional citations. The last search was performed on 29th January 2017.

Search

A comprehensive list of search terms was devised in consultation with vascular and patient safety experts, identification of commonly used terms in the literature and synonyms of relevant terms (appendix 1). It was anticipated that few papers would specifically focus on investigation of team, work environment or organizational factors, therefore, the search was deliberately broad to capture papers that may include an assessment of such factors as an aspect of a wider study. Search terms were categorized into three groups: arterial disease; surgical intervention; measures of quality and safety. Within groups, search terms were linked by the Boolean operator

'OR'. Each group of search terms was linked using the Boolean operator 'AND'. MeSH (Medical Subject Headings) were used to ensure that the search was comprehensive. Limits were applied for humans, abstracts and papers in the English language.

Study selection

The primary reviewer (RL, advanced vascular nurse practitioner) screened all titles and abstracts according to predefined inclusion and exclusion criteria, with a second reviewer (ADG, clinical research fellow) screening ten percent of citations. Cohen's kappa demonstrated good agreement between reviewers ($\kappa = .87$, $p<.001$). Both reviewers screened all papers selected for full text review to select included papers ($\kappa = .84$, $p<.001$). Any disagreements between reviewers at each stage of selection were resolved by consensus.

Inclusion criteria

Studies were eligible for inclusion if they were original research papers published in a peer-reviewed journal, which addressed the relationship between team, work environment, and/or organizational factors, and quality or safety measures in elective arterial surgery during the perioperative period. Original research papers investigating interventions to optimize team, work environment and/or organizational factors, that also utilized safety or quality measures, were additionally included.

Exclusion criteria

Studies investigating the impact of patient risk factors, surgical techniques, or pharmacological interventions (e.g. cardio protective medication) were excluded. Studies solely describing the following operation types were also excluded:

emergency arterial surgery; iatrogenic arterial injury; the vasculature of the heart or the brain; type A aortic dissection; arterial closure devices.

Volume-outcome relationships have already been examined exhaustively in arterial surgery, and such studies are therefore excluded from this review. Only clinical pathway papers published within the last decade were considered to be relevant to the current state of arterial service provision. Therefore, any papers published earlier than 2005 that examined interventions along the clinical pathway were excluded. Reviews, case reports, editorials, opinions and conference proceedings were also excluded.

- Figure 1: PRISMA diagram for study selection -

Data collection process and data items

For each paper, details of the design, aim, study period, sample size, type of surgical intervention, aspect of team, work environment, or organizational factor(s) investigated, and measure(s) of quality or safety used, and details of intervention if applicable, were extracted using a standardized data extraction form. The primary reviewer (RL) extracted all preset information, which was subsequently checked and verified by the second reviewer (ADG).

Risk of bias of individual studies

Case-control studies were quality assessed using the Newcastle-Ottawa Scale, which has been described elsewhere[15]. A modified version of the Newcastle-Ottawa Scale [16] was used to assess the quality of cross-sectional studies. Studies were assessed for risk of bias, based on case selection, comparability of groups and outcome measurement and analysis. High quality case-control and cross-sectional studies attained the maximum score of 9; medium quality studies obtained a score of 7 or 8, while a score of 6 or less indicated that the study was of poor quality (tables 2 & 3). Two reviewers (RL and ADG) independently scored case-control and cross-sectional papers, with satisfactory agreement between assessors for quality scoring ($\kappa = .56$, $p=.01$). Due to the small number of papers retrieved from the search, low quality papers were included in the review. The only randomized controlled trial (RCT) identified thought the search strategy, was appraised using the Cochrane Collaboration's tool for assessment of risk of bias[17]. A critical appraisal of all included studies, guided by the STROBE checklist[18] (Strengthening the Reporting of Observational studies in Epidemiology) has been included in tables 2 and 3 to make explicit particular strengths and weakness that may influence the findings.

RESULTS

Study characteristics

Twelve studies[19–30] met selection criteria (PRISMA diagram, figure 1). Seven of these were undertaken in the United Kingdom (UK)[19,21,22,24–26,29]. There were four descriptive studies[19,26,28,29], one case-control[25], one cohort[27], five cross-sectional studies[20–22,24,30], and one randomized control trial (RCT)[23]. Seven studies measured the impact of an *intervention* designed to improve surgical quality and safety[20,21,23–25,27,28]. The most common operation studied was aortic aneurysm (AAA) repair (10/12 studies[19–21,23–25,27–30]); five of these included *endovascular* aortic aneurysm repairs (EVARs)[19,21,25,28,29]. Four papers addressed carotid endarterectomy (CEA)[19,21,22,26] and four papers included lower limb bypass graft (LL BG)[19,21,26,30]. Seven papers addressed organizational factors[20,21,23,24,27,28,30], five papers addressed work environment factors[19,20,25,29,30] and five papers addressed team factors[19,22,25,26,29]. Eight papers measured patient outcomes[20,21,23,24,27–30] and four papers measured surrogate markers of surgical quality and safety (including intraoperative errors or procedural problems, and operating time) [19,22,25,26].

Quality Assessment

Eight of twelve papers reported single-center studies[19,21–27], and of these, two had sample sizes of less than 20 cases[25,26]. Two cross-sectional studies, both undertaken in the United States (US) had large sample sizes of more than ten thousand cases [20,30]. Only one of the studies was a randomized controlled trial[23], which reported outcomes on an intention-to-treat basis, but researchers and patients could not be blinded to the allocation groups due to the nature of the intervention studied. Of the studies scored using the Newcastle-Ottawa Scale, three papers were scored as high quality[20,27,30] and three papers were deemed to be of low quality[21,22,24]. Details of the quality assessments for all papers are provided in tables 2 and 3.

- Table 2: Quality assessments for studies evaluated using the (modified) Newcastle-Ottawa Scale -

- Table 3: Quality assessments for four descriptive studies and one randomized controlled trial -

Factors influencing quality and safety in arterial surgery

Relevant findings from included papers are organized into the following three themes: team, work environment, and organizational factors. Table 4 provides a summary of these study characteristics.

- Table 4: Characteristics of Included Studies -

Team Factors

Five papers – all from the UK- examined the relationship between team factors on quality and safety[19,22,25,26,29]; all five papers addressed team factors in the operating room. One study measured the impact of these factors on patient outcomes[29]. A multi-center study of system failures in 185 aortic procedures demonstrated that major intraoperative failures (defined as failures that caused significant intraoperative delay or endangered the patient) were associated with unplanned return to theatre (p=0.011), major complications (p=0.029) and in-hospital mortality (p=0.027), independent of patient age, gender or ASA grade[29]. In this study, a significant proportion (22%) of major intraoperative failures were categorized as errors in communication. Smaller, single-center studies examining team factors used process measures to evaluate markers of quality or safety, including intraoperative errors and procedural problems[19,22,25,26] without using outcome measures. Two studies found that levels of team skills (including teamwork, leadership and situational awareness) correlated with the frequency of errors or procedural problems in arterial operations, though the tools that they used to assess team skills were not consistent. Catchpole and colleagues used the Oxford NOTECHS (NON-TECHnical Skills) tool , which is well-validated and widely used in the wider surgical literature[31–33], while Soane and colleagues developed their own assessment tool for the purposes of the study, based on T^2EAM tool approach used to assess team skills in air traffic control[34]. These two studies by Catchpole and Soane were small (sample sizes of 22 and 12, respectively), and neither tested associations between the observed errors and clinical outcomes. However, anecdotes were reported to provide insights into the impact of these errors - for example, Catchpole and colleagues describe a lapse in teamwork and communication which led to delayed heparin administration for arterial cross clamping, thus increasing the risk of embolisation[22,26]. In two further studies, two blinded experts assigned ‘danger’ and ‘delay’ scores to failures observed during arterial operations, to provide an insight into the impact of these failures on the patient and the procedure[19,26]. Albayati and colleagues found that 21% (240/1145) of all observed failures related to communication[19]. Four of these communication failures were ‘major’ – i.e. were perceived to have a major effect of procedural duration or patient safety- these occurred during critical stages of the operation but their clinical consequences are not reported. In the only study evaluating a teamwork intervention, Patel and colleagues demonstrated a non-significant reduction in the number of communication errors occurring in combined open/endovascular arterial procedures following implementation of a structured, mental rehearsal before the endovascular phase[25]. The authors reported that no major errors occurring intraoperatively after implementation of the intervention but they did not control for any confounders, such as patient risk-factors or procedural variables[25].

Work Environment Factors

Five papers addressed work environment factors[19,20,25,29,30]. Two UK studies found that investigated intraoperative failures relating to equipment were common during arterial operations[19,29]. Equipment failures (unavailability, configuration, workspace/equipment management, malfunction) were the most frequently observed category of intraoperative failures in both studies. Lear and colleagues reported that 17% of equipment failures occurring in aortic procedures either endangered the patient or caused long procedural delays, and these major failures were associated with poorer patient outcomes[29]. In the study evaluating a structured mental rehearsal intervention before the endovascular phases of combined open/endovascular procedures, the number of intraoperative equipment-related failures fell after implementation of the intervention, but these findings were not statistically significant (2.40 equipment problems/hour (0–5.33) vs. 1.01/hour (0–4.0); p=0.140) and not adjusted for potential confounders[25].

The impact of staffing levels on patient outcomes following AAA repair were assessed in two American studies using data from large, national databases[20,30]. Sheetz and colleagues investigated the impact of hospital characteristics on failure to rescue following major vascular surgery in the American Medicare population. After properly adjusting for potential confounders, authors reported that hospitals with increased nurse-to-patient ratios had lower failures-to-rescue rates in patients undergoing AAA repair and lower limb bypass graft[30]. Another large, multi-center cross-sectional study investigated US healthcare organizations' adherence to 27 hospital safety measures comprising a comprehensive set of evidenced-based hospital process measures and standardized practices endorsed by the National Quality Forum (NQF)[20]. Included in these safety measures were standards to ensure safe nursing staffing levels. Hospitals with full compliance had a lesser unadjusted rate of failure to rescue for open AAA repair compared with hospitals with partial compliance (11.71% versus 12.96%). The risk-adjusted mortality benefit conferred by full compliance with NQF safety practices was significant for most high-risk procedures but not for open AAA repair (Odds Ratio, 0.85; 95% CI, 0.71-1.03), and the findings were not presented in sufficient depth to ascertain the relative importance of individual safe practices. Of note, the level of compliance with NQF safety practices was calculated from self-report data and the survey had a 50% response rate.

Organizational Factors

A total of seven papers investigated organizational factors. In the large American Medicare study that evaluated the impact of particular hospital characteristics on properly risk-adjusted patient outcomes – hospital teaching status, lower bed occupancy and higher numbers of ICU beds, were all associated with lower rates of failure to rescue for patients undergoing AAA repair and lower limb revascularization[30]. Six further studies describe the impact of multi-component interventions along the entire clinical pathway[20,21,23,24,27,28]. Clinical pathways define the sequencing and timing of health interventions[35], and include efforts to increase the reliability of core clinical processes as well as organizational changes to optimize allocation of resources. Four studies evaluated the implementation of a fast-track or enhanced recovery program for AAA repair[23,24,27,28]. However, only one of these studies is a randomized controlled trial (RCT) that adheres to SQUIRE guidelines[36]. In this RCT, Muehling et al. piloted the safety and efficacy of a fast-track recovery pathway for patients undergoing open AAA repair, which included reduced preoperative fasting, no bowel preparation, patient-controlled epidural anesthesia, enhanced post-operative feeding and early mobilization[23]. Patient characteristics, surgical procedure and clamping time were comparable between the two groups ($p>0.05$ for all characteristics). In this RCT, which assessed outcomes on an intention-to-treat basis with a low attrition rate (5 of 101 patients excluded), the rate of post-operative medical complications was significantly lower (16% versus 36%; $p=.039$), and length of stay was significantly shorter with no readmissions within 30 days (10 days versus 11 days; $p=.016$) in patients entered into the fast-track program compared to the treatment group. Cantlay et al., describe their experiences of introducing a pre-operative assessment clinic (PAC) led by vascular consultant anesthetists, designed to evaluate and manage pre-operative risk for patients undergoing major vascular procedures[21]. While patients scheduled for a variety of arterial operations were reported to have attended the clinic, the authors report unadjusted mortality rates pre- and post-intervention for open infrarenal aneurysm repair only (14.5% and 4.8%, respectively). Patient risk factors and other confounding variables were not accounted for though the authors report that introduction of the PAC took place at the same time as centralization of arterial services within this organization.

DISCUSSION

This is the first systematic review to adopt a systems approach to understanding quality and safety in arterial surgery. Team, work environment, and organizational factors were evaluated with respect to patient outcomes and other markers of surgical quality and safety. The design and methodologies of the studies are varied and this heterogeneity makes it difficult to draw meaningful conclusions from the collected literature. Designing studies that are capable of measuring all potentially relevant determinants of patient harm in a given healthcare system is inherently challenging. When adverse events occur, these incident are rarely the result of a single error with direct consequences -rather, patient harm is frequently the consequence of multiple failures at many levels of the system[37]. The evidence collected in this review identifies various deficiencies in the systems supporting arterial surgery, though the link between these deficiencies and patient outcomes is not entirely clear. Some of the collected studies failed to measure the clinical significance of reported system failures or procedural problems. Outcomes such as in-hospital mortality or readmission within 30 days are relatively rare. For studies to establish any associations between system factors and patient outcomes, sample sizes would need to be large, and likely to be resource- and time-intensive. While the utility of endpoints holding no clinical significance may seem questionable, there is an argument for identifying deficiencies that can be pinpointed as targets for building resilience in the system. However, publication guidelines for quality improvement reporting excellence advocate assessment of a combination of process and outcome measures to evaluate quality interventions[36].

In the literature collated for this review, failures relating to teamwork and communication were consistently associated with high rates of intraoperative errors and procedural problems, though one large study from the UK demonstrated an association between major intraoperative communication failures and patient outcomes for patients undergoing aortic procedures. In other surgical specialties, failures in communication and information transfer have been directly associated with patient harm[11]. However, there is more work to be done to confirm the relationship between team factors and clinical outcomes in patients undergoing arterial surgery. Research into team skills in vascular surgery is likely to benefit from the use of standardized assessment tools which are well-validated in terms of psychometric properties and content validity. The authors advocate the use of Endo-OTAS (Endovascular Observational Teamwork Assessment for Surgery), which is a robust tool to assess teamwork skills in endovascular procedures[38]; other teamwork assessment tools – such as OTAS[39] and NOTECHS[31,40] are well-validated and can be used to assess the non-technical skills of surgeons, anesthetists and nurses in open surgical procedures. Certainly in the UK, current training programs in vascular surgery do not routinely include training in non-technical skills, though individual studies on the use of simulation to improve team performance in emergency arterial operations are encouraging[41].

The evidence collated here suggests that equipment-related failure is common during arterial operations, having a significant impact on efficiency as well as patient safety. Cardiac surgery, which also relies heavily on technology, has been shown to bear a greater burden of equipment-related errors compared to general surgery[12]. The relatively high rate of equipment-related problems may not be surprising given the rapid uptake and evolution of endovascular technology over the last two decades. Former health minister, professor Lord Ara Darzi cautioned that the introduction of new technologies must be accompanied by process innovation[42]. An example of process innovation is the implementation of the World Health Organization's Surgical Safety checklist, which includes an equipment check prior to knife-to-skin[43]. We suggest the the WHO checklist could be tailored to specific arterial operations, to further improve preparation and utilization of equipment and associated technologies in these procedures.

Team factors and equipment failures appear to be a source of risk to patient safety and affect procedural efficiency in arterial surgery. Researchers seeking to address these deficiencies should be aware of the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines[36] when designing studies to evaluate the impact of interventions. In this review, most of the studies that implemented a quality improvement intervention failed to control for patient-, hospital- and other confounding factors, making it difficult to understand the nature of the association between the interventions and the reported outcomes. These studies were also largely small, single-center studies with limited generalizability, and some of the studies used methodologies, such as self-report, which threatens the internal validity of the intervention being studied.

This review included a large, well-conducted study that found significant associations between certain hospital characteristics –including hospital occupancy, number of

ICU beds, and nurse-to-patient ratios- and failure-to-rescue rates for AAA repair and lower limb revascularization[30]. However, this study was limited to Medicare beneficiaries in the US. Future research should replicate this study in other countries to further understand organizational factors that influence patient outcomes. Many further aspects of the work environment that conceivably influence surgical quality and safety have yet to be studied in vascular surgery. For example, the majority of vascular consultants work more than 50 hours a week and provide emergency cover more frequently than is considered safe according to a recent workforce evaluation in the UK[44] and in the US, vascular surgery has been ranked the highest of 41 specialties with regards to the number of hours worked annually, but the impact of working long hours on service quality and patient outcome is not known.

There is considerable scope for more detailed examination of a range of factors that may influence surgical outcomes, as well as to evaluate interventions to enhance teamwork, the working environment and the wider organization of vascular surgery. Research in this field would benefit from studies that are properly powered to understand the relationships between system factors and clinical outcomes, and which adhere to national guidelines for reporting standards. To produce generalizable results, large studies are likely to require collaborative efforts between institutions with use of validated assessment methods and consistent endpoints.

Conflict of Interest: None

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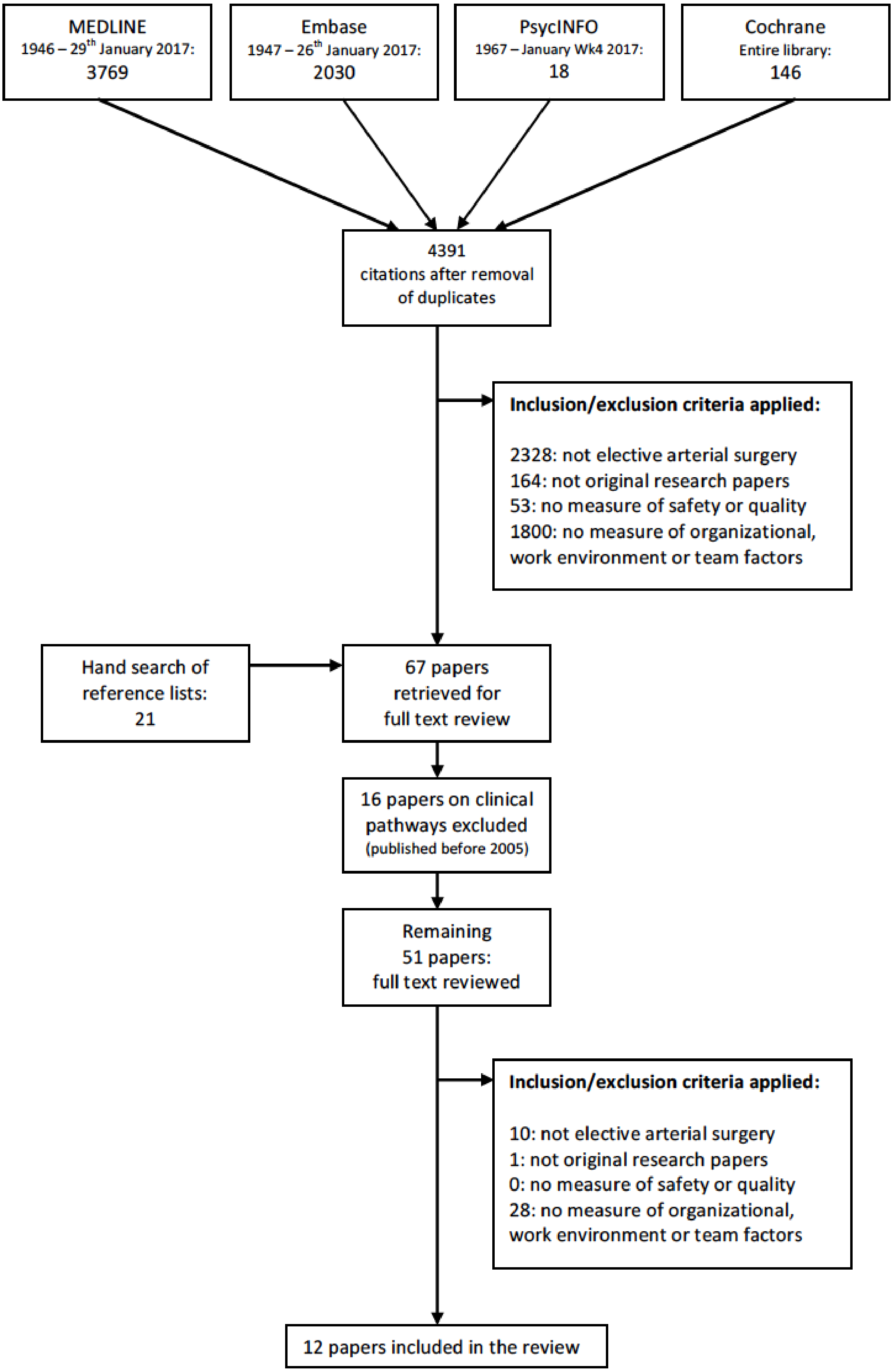
Appendix: Search terms for Medline, Embase and PsycINFO

1. (adverse adj2 event$).ab,ti.
2. Postoperative Complications/ep, mo [Epidemiology, Mortality]
3. patient safety indicator$.ab,ti.
4. harm.ab,ti.
5. error$.ab,ti.
6. morbidity/ or incidence/ or prevalence/ or mortality/ or "cause of death"/ or fatal outcome/ or hospital mortality/ or survival rate/
7. frequency.ab,ti.
8. rate.ab,ti.
9. severity.ab,ti.
10. Treatment Outcome/
11. consequence$.ab,ti.
12. avoidable.ab,ti.
13. prevent$.ab,ti.
14. operation.ab,ti.
15. intervention$.ab,ti.
16. surg$.ab,ti.
17. Arterial Occlusive Diseases/ or Peripheral Arterial Disease/
18. Vascular Surgical Procedures/ or vascular surgery.mp.
19. endovascular.ab,ti.
20. bypass.ab,ti.
21. aort$.ab,ti.
22. carotid.ab,ti.
23. Aortic Aneurysm, Abdominal/ or Aneurysm, Dissecting/ or Aortic Aneurysm, Thoracic/ or Iliac Aneurysm/ or Aortic Aneurysm/
24. Limb Salvage/ae, mo [Adverse Effects, Mortality]
25. 1 or 2 or 3 or 4 or 5
26. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
27. 14 or 15 or 16
28. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
29. 25 and 26 and 27 and 28
30. "gastric bypass".ab,ti.
31. "cardiopulmonary bypass".ab,ti.
32. "heart bypass".ab,ti.
33. "coronary artery bypass".ab,ti.
34. "coronary bypass".ab,ti.
35. "coronary intervention".ab,ti.
36. "aortic valve".ab,ti.
37. "coronary artery stenting".ab,ti.
38. (cerebral adj3 aneurysm).ab,ti.
39. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40. 29 not 39
41. limit 40 to abstracts
42. limit 41 to humans
43. limit 42 to english language

Figure 1: PRISMA diagram for study selection



- Table 1: Factors influencing surgical quality and safety -

Organization and management factors	Work environment factors	Team factors
Financial resources & constraints Organizational structure Policy standards & goals Safety culture & priorities	Staffing levels & skill mix Workload & shift patterns Availability & maintenance of equipment Administrative & managerial support	Verbal communication Written communication Supervision & seeking help Team structure (consistency, leadership etc)

Table 2: Quality assessments for studies evaluated using the (modified) Newcastle-Ottawa Scale

First Author Year	Study setting	Sample size	Study design	Selection	Comparability	Outcome	Overall quality score	Critical appraisal of factors likely to influence interpretation of findings
Brooke 2012	658 nationwide hospitals, US	16,732	Cross-sectional	****	**	***	High (9)	Multi-centre study with large sample size. Patient- & hospital-level variables controlled for in regression model. Self-report method, 50% response rate
Cantlay 2006	Single centre regional vascular unit, UK	234	Cross-sectional	****	0	0	Low (4)	Single-centre study. Comparison of mortality rates pre- & post-intervention provided for AAA repairs only. Patient risk factors/other confounders not controlled for.
Catchpole 2008	Single centre regional vascular unit, UK	22	Cross-sectional	***	*	**	Low (6)	Small sample size. Single-centre study. Tools used to evaluate teamwork & surgical errors were previously validated.
Feo 2016	Single-centre, university-hospital, Italy	221	Retrospective cohort	****	**	**	High (8)	Single-centre study. Patient- & perioperative variables controlled for in regression model. Retrospective control group.
Murphy 2007	Single centre regional vascular unit, UK	60	Cross-sectional	***	0	***	Low (6)	Single-centre study. Demographics briefly described for each group though not controlled for with statistical methods.

Table 2 continued:

First Author Year	Study setting	Sample size	Study design	Selection	Comparability	Outcome	Overall quality score	Critical appraisal of factors likely to influence interpretation of findings
Patel 2012	Single centre regional vascular unit, UK	15	Case-control	****	0	***	Medium (7)	Small sample size. Single-centre study. Descriptions of demographics for each group not sufficiently detailed to judge comparability. Observer & assessors not blinded to whether case was pre- or post-intervention.
Sheetz 2016	National data from Medicare Provider Analysis & Review (MEDPAR) files, US	188,849 AAA repairs 681,078 LL BG	Cross-sectional	****	**	***	High (9)	Large sample size. Multi-centre study. Restricted to Medicare population. Hospital characteristic were self-reported. Patient & operative variables controlled for in regression model.

Selection assesses representativeness of the sample, sample size, description of cases not included, and measurement of the exposure. Comparability assesses the extent to which confounding factors are controlled for to ensure different outcome groups are comparable. Outcome assesses the quality of outcome assessment and statistical analyses.

Table 3: Quality assessments for four descriptive studies and one randomized controlled trial

First Author Year	Study setting	Sample size	Study design	Critical appraisal of factors likely to influence interpretation of findings
Albayati 2012	Single centre regional vascular unit, UK	66	Descriptive	Single-centre study. Observational method: unstructured observations undertaken by medical students. Two blinded assessors with significant vascular surgical experienced judged intraoperative failures. Non-significant correlations between patient age & ASA grade, & failure rate (as potential confounders) are described.
Soane 2014	Single centre regional vascular unit, UK	12	Descriptive pilot study	Small sample size. Single-centre study. Observational method to capture intraoperative errors: previously validated, structured approach with independent verification by two vascular surgical experts. Self-report method to evaluate the role of teamworking. Attempts made to reduce Hawthorne effect prior to study. Data analysed to examine trends – statistical analysis not performed due to small sample size.
Muehling 2009	Single centre, Germany	101	Randomized controlled trial^	Single-centre study *Selection bias:* patients were randomly assigned to either the traditional or the fast-track treatment arm but further description of allocation not provided. *Performance & detection bias:* blinding not feasible due to nature of intervention. *Attrition bias:* Intention-to-treat analysis performed. Five excluded (2 withdrew consent, 2 suprarenal clamping, 1 EDA dysfunction) Attrition not expected to affect results. *Reporting bias:* All pre-specified outcomes were reported.
Krajcer 2016	Multi-centre, US	129	Descriptive	Post-market study of a single stent graft device. Number of participating sites not stated. Outcomes compared for completers and non-completers of fast-track protocol (no true control group)
Lear 2016	Multi-centre, UK	185	Descriptive	Multi-centre study (10 sites) Structured, self-report method to report intraoperative system failures Training period to standardize structured, self-reporting method across sites Between-group differences for patient outcomes not adjusted for multiple comparisons

^Quality of the RCT was assessed using the Cochrane Collaboration's tool for assessment risk of bias in randomized trials.

Table 4: Characteristics of Included Studies

First Author Year	Operation type(s)	Intervention	Organizational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Albayati 2012	TAAA repair AAA repair (open & endovascular) CEA LL BG	N/A	N/A	1. Team member absence 2. Equipment unavailability/ configuration/ malfunction 3. Fatigue	1. Communication 2. Team conflict	Intra-operative failure distribution	Most frequent failures related to equipment. 5.2% of failures had high danger/delay scores.
Brooke 2012	Open AAA repair	Implementation of National Quality Forum (NQF) safety practices	1. Creation of safety culture 2. Pharmacy involvement with medication-use process 3. Specialist anticoagulation service involvement 4. Protocols for prevention of complications	1. Nursing staffing levels 2. Workspaces where medications are prepared free from clutter, distraction, noise	N/A	In-hospital complications Failure to rescue (FTR) All-cause 30-day mortality	Hospitals that fully implemented safe practices were more likely to diagnose complications, had lower FTR rates, & had lower in-hospital mortality rates for most high-risk procedures, but not for AAA repair, compared to hospitals with partial safe practice compliance.
Cantlay 2006	AAA repair-open & EVAR LL BG CEA	Implementation of vascular consultant anaesthetist-led pre-operative assessment clinic (PAC)	1. Multi-component intervention along clinical pathway (pre-operative)	N/A	N/A	In-hospital mortality	In-hospital mortality for AAA repair fell from 14.5% in 2-year period before PAC to 4.8% in 2 years after introduction of PAC. Improvement likely multi-factorial but implementation of PAC played major role.

Table 4 continued:

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Catchpole 2008	CEA	N/A	N/A	N/A	1. leadership & management 2. teamwork & cooperation 3. problem solving & decision-making 4. situational awareness	Errors in surgical technique Other procedural problems	Aspects of team performance strongly correlated with errors & procedural problems. Teamwork interventions could improve technical performance and patient outcomes.
Feo 2016	Open AAA repair via retroperitoneal approach	Implementation of an Enhanced Recovery Program (ERP)	1. Multi-component intervention along clinical pathway (peri-operative)	N/A	N/A	Morbidity & mortality ICU admission rate Time to functional recovery Length of stay Readmission rate	ERP had fewer complications and fewer ICU admissions than traditional care, though mortality was comparable between groups. Functional recovery and discharge from hospital were achieved earlier in the ERP group, with no readmissions reported.

Table 4 continued:

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Krajcer 2016	EVAR	Implementation of fast-track recovery protocol	1. Multi-component intervention along clinical pathway (peri-operative)	N/A	N/A	Major adverse events Health-related quality of life measures	There was one major adverse event in the fast-track group. Completers of fast-track protocol reported improved quality of life, whereas quality of life measures remained unchanged in non-completers group.
Lear 2016	Open & endovascular AAA repair	N/A	N/A	Equipment-related failures Noise/distractions	Communication failures	Unplanned return to theatre Post-operative complications In-hospital mortality	Major intraoperative system failures were associated with unplanned return to theatre, major complications & death.
Muehling 2009	Open AAA repair	Implementation of fast-track recovery program	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	Morbidity & mortality Length of stay & readmission rate	Postoperative complications and hospital stay significantly reduced in fast-track group compared traditional treatment group, with no readmission within 30 days of discharge.

Table 4 continued:

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Murphy 2007	Open AAA repair	Implementation of fast-track goal-directed pathway	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	Length of stay & readmission rate	Median hospital stay reduced from 9 to 5 days following implementation of the pathway, with only one readmission.
Patel 2012	Combined open & endovascular TAAA & AAA procedures	Implementation of a structured, mental rehearsal before the endovascular phase		1. Intervention designed to increase efficiency in equipment use	1. Intervention designed to improve team dynamics	Intraoperative error rates Delay scores Danger scores	Errors rates were significantly higher during the endovascular phase compared to open. Error rates, danger & delay scores were significantly lower after the intervention.
Sheetz 2016	AAA repair LL BG	N/A	1. Hospital teaching status 2. Hospital occupancy 3. Number of ICU beds	1. Nurse-to-patient ratio 2. Technology	N/A	Failure-to-rescue (FtR)	Teaching status, occupancy, high hospital technology, nurse-to-patient ratio, and size of ICU significantly influenced FtR rates for AAA repair & LL BG. Hospital & patient characteristics accounted for 19% of variability in FtR rates for AAA repair, & 12% of variation for LL BG.

Table 4 continued:

First Author Year	Operation type(s)	Intervention	Organisational Factors assessed	Work Environment Factors assessed	Team Factors assessed	Measures of quality & safety assessed	Findings
Soane 2014	CEA LL BG	N/A	N/A	N/A	1. team orientation 2. coordination & leadership style 3.communication 4.error management 5.task distribution	Intraoperative error rates	Error rates were lower when there were effective teamwork measures in place. Teamwork training for vascular teams may help to prevent or mitigate errors.

N/A: not applicable, TAAA: thoraco-abdominal aortic aneurysm, AAA: abdominal aortic aneurysm, CEA: carotid endarterectomy, LL BG: lower limb bypass graft, ICU: Intensive Care Unit.