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REVIEW

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 an underexplored topic 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.

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 organisational 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, extracted relevant data on team, work environment, and organisational factors, and measures of quality and/or safety, in arterial procedures.

Results: Twelve papers met the 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 common 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, although 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 heterogenous studies have evaluated the relationship between system factors and quality or safety in arterial surgery. There is some evidence of an association between system factors and patient outcomes, but there is more work to be done to fully understand this relationship. 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.

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INTRODUCTION

The outcomes of vascular surgery vary considerably between organisations and between countries but the reasons for this are not fully understood.[1—3] A relationship between annual caseload and patient outcome is now well established for many arterial procedures. Robust evidence

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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 (centralisation) 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 the 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, although contributory factors are likely to include differences in formalised training programmes, 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 organisational 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 other 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 often 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 organisation and management factors. Further details of these themes are provided in Table 1.

Information sources

The following databases were systematically searched: Medline (Ovid Medline 1946 to July 1, 2016), Embase (Embase 1947 to June 30, 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 January 29, 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 organisational 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 10% of

Table 1. Factors influencing surgical quality and safety.

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

citations. Reviewers were blinded to each other's results. Cohen's kappa demonstrated good agreement between reviewers ($\kappa = .87$, $p < .001$). Both reviewers screened all papers selected for full text review to identify 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 among team, work environment, and/or organisational factors, and quality or safety measures in elective arterial surgery during the peri-operative period. Original research papers investigating interventions to optimise team, work environment, and/or organisational factors, that also used safety or quality measures, were additionally included.

Exclusion criteria

Studies investigating the impact of patient risk factors, surgical techniques, or pharmacological interventions (e.g. cardioprotective 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.

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 organisational factor(s) investigated, and measure(s) of quality or safety used, and details of intervention if applicable, were extracted using a standardised 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 and 3). Two reviewers (RL and ADG) independently scored case control and cross sectional papers, with satisfactory agreement between assessors for quality scoring ($\kappa = .56$, $p = .01$). As a small number of papers was retrieved from the search, low quality papers were included in the review. The only randomised 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 the selection criteria (PRISMA diagram, Fig. 1). Seven of these were undertaken in the 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 randomised 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 organisational 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 intra-operative errors or procedural problems, and operating time).[19,22,25,26]

Quality assessment

Eight of twelve papers reported single centre 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 USA had large sample sizes of more than 10,000 cases.[20,30] Only one of the studies was a randomised controlled trial,[23] which reported outcomes on an intention to treat basis, but researchers and patients could not be blinded to the allocation groups because of 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 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.

Factors influencing quality and safety in arterial surgery

Relevant findings from included papers are organised into the following three themes: team, work environment, and

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[20]	658 nationwide hospitals, USA	16,732	Cross sectional	4	2	3	High (9)	Multicentre study with large sample size Patient and hospital level variables controlled for in regression model Self report method, 50% response rate
Cantlay 2006[21]	Single centre regional vascular unit, UK	234	Cross sectional	4	0	0	Low (4)	Single centre study Comparison of mortality rates pre- and post-intervention provided for AAA repairs only. Patient risk factors/other confounders not controlled for
Catchpole 2008[22]	Single centre regional vascular unit, UK	22	Cross sectional	3	1	2	Low (6)	Small sample size Single centre study Tools used to evaluate teamwork and surgical errors were previously validated
Feo 2016[27]	Single centre, university hospital, Italy	221	Retrospective cohort	4	2	2	High (8)	Single centre study Patient and peri-operative variables controlled for in regression model Retrospective control group
Murphy 2007[24]	Single centre regional vascular unit, UK	60	Cross sectional	3	0	3	Low (6)	Single centre study Demographics briefly described for each group, although not controlled for with statistical methods
Patel 2012[25]	Single centre regional vascular unit, UK	15	Case control	4	0	3	Medium (7)	Small sample size Single centre study Descriptions of demographics for each group not sufficiently detailed to judge comparability Observer and assessors not blinded to whether case was pre- or post-intervention
Sheetz 2016[30]	National data from Medicare Provider Analysis and Review (MEDPAR) files, USA	188,849 AAA repairs 681,078 LL BG	Cross sectional	4	2	3	High (9)	Large sample size Multi-centre study Restricted to Medicare population Hospital characteristics were self reported Patient and 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.
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.

Table 3. Quality assessments for four descriptive studies and one randomised controlled trial.

First author year	Study setting	Sample size	Study design	Critical appraisal of factors likely to influence interpretation of findings
Albayati 2012[19]	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 experience judged intra-operative failures Non-significant correlations between patient age and ASA grade, and failure rate (as potential confounders) are described
Soane 2014[26]	Single centre regional vascular unit, UK	12	Descriptive pilot study	Small sample size Single centre study Observational method to capture intra-operative errors: previously validated, structured approach with independent verification by two vascular surgical experts Self report method to evaluate the role of team working Attempts made to reduce Hawthorne effect prior to study Data analysed to examine trends — statistical analysis not performed because of small sample size
Muehling 2009[23]	Single centre, Germany	101	Randomised controlled trial[a]	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 and detection bias:* blinding not feasible because of 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[28]	Multicentre, USA	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[29]	Multi-centre, UK	185	Descriptive	Multicentre study (10 sites) Structured, self report method to report intra-operative system failures Training period to standardize structured, self reporting method across sites Between group differences for patient outcomes not adjusted for multiple comparisons

[a] Quality of the RCT was assessed using the Cochrane Collaboration tool for assessment risk of bias in randomised trials.

organisational factors. Table 4 provides a summary of these study characteristics.

Team factors. Five papers — all from the UK - examined the relationship between team factors and 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 multicentre study of system failures in 185 aortic procedures demonstrated that major intra-operative failures (defined as failures that caused significant intra-operative delay or endangered the patient) were associated with unplanned return to theatre ($p = .011$), major complications ($p = .029$), and in hospital mortality ($p = .027$), independent of patient age, gender, or ASA grade.[29] In this study, a significant proportion (22%) of major intra-operative failures were categorized as errors in communication. Smaller, single centre studies examining team factors used process measures to evaluate markers of quality or safety, including intra-operative errors and procedural problems[19,22,25,26] without measuring patient outcomes. 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, although the tools that they

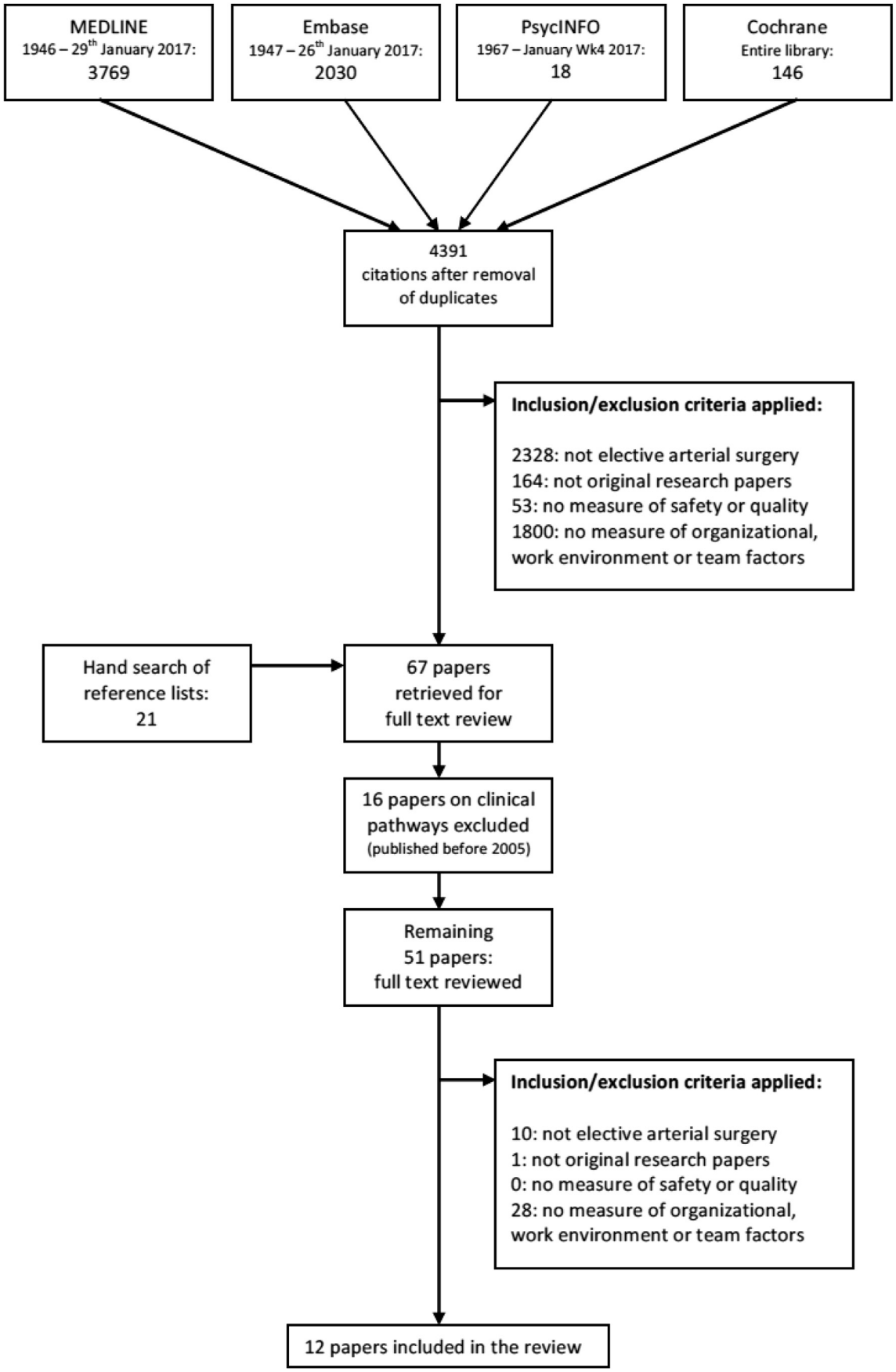

Figure 1. PRISMA diagram for study selection.

Table 4. Characteristics of included studies.

First author year	Operation type(s)	Intervention	Organisational factors assessed	Work environment factors assessed	Team factors assessed	Measures of quality and safety assessed	Findings
Albayati 2012[19]	TAAA repair AAA repair (open and 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 common failures related to equipment 5.2% of failures had high danger/delay scores
Brooke 2012[20]	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, and had lower in hospital mortality rates for most high risk procedures, but not for AAA repair, compared with hospitals with partial safe practice compliance
Cantlay 2006[21]	AAA repair-open and 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

Continued

Table 4-*continued*

First author year	Operation type(s)	Intervention	Organisational factors assessed	Work environment factors assessed	Team factors assessed	Measures of quality and safety assessed	Findings
Catchpole 2008[22]	CEA	N/A	N/A	N/A	1. Leadership and management 2. Teamwork and cooperation 3. Problem solving and decision making 4. Situational awareness	Errors in surgical technique Other procedural problems	Aspects of team performance strongly correlated with errors and procedural problems Teamwork interventions could improve technical performance and patient outcomes
Feo 2016[27]	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 and mortality ICU admission rate Time to functional recovery Length of stay Readmission rate	ERP had fewer complications and fewer ICU admissions than traditional care, although mortality was comparable between groups Functional recovery and discharge from hospital were achieved earlier in the ERP group, with no readmissions reported
Krajcer 2016[28]	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[29]	Open and 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 intra-operative system failures were associated with unplanned return to theatre, major complications, and death
Muehling 2009[23]	Open AAA repair	Implementation of fast track recovery program	1. Multi-component intervention along clinical pathway (post-operative)	N/A	N/A	Morbidity and mortality Length of stay and readmission rate	Post-operative complications and hospital stay significantly reduced in fast track group compared traditional treatment group, with no readmission within 30 days of discharge
Murphy 2007[24]	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 and readmission rate	Median hospital stay reduced from 9 to 5 days following implementation of the pathway, with only one readmission
Patel 2012[25]	Combined open and endovascular TAAA and 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	Intra-operative error rates Delay scores Danger scores	Error rates were significantly higher during the endovascular phase compared with open Error rates, danger and delay scores were significantly lower after the intervention

Continued

Table 4-*continued*

First author year	Operation type(s)	Intervention	Organisational factors assessed	Work environment factors assessed	Team factors assessed	Measures of quality and safety assessed	Findings
Sheetz 2016[30]	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 and LL BG. Hospital and patient characteristics accounted for 19% of variability in FtR rates for AAA repair, and 12% of variation for LL BG
Soane 2014[26]	CEA LL BG	N/A	N/A	N/A	1. Team orientation 2. Coordination and leadership style 3.Communication 4. Error management 5. Task distribution	Intra-operative 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.

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 surgical literature,[31–33] while Soane and colleagues developed their own assessment tool for the purposes of their study[26], based on T^{2}EAM tool approach used to assess team skills in air traffic control, which has been described elsewhere.[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," that is were perceived to have a major effect on 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 occurred intra-operatively 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 intra-operative failures relating to equipment were common during arterial operations.[19,29] Equipment failures (unavailability, configuration, workspace/equipment management, malfunction) were the most commonly observed category of intra-operative 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 intra-operative 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); $p = .140$) and not adjusted for potential confounders.[25]

The impact of staffing levels on patient outcomes following AAA repair was 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, the authors reported that hospitals with increased nurse to patient ratios had lower failure-to-rescue rates in patients undergoing AAA repair and lower limb bypass graft.[30] Another large, multicentre cross sectional study investigated US healthcare organisations' adherence to 27 hospital safety measures comprising a comprehensive set of evidence based hospital process measures and standardised practices endorsed by the National Quality Forum (NQF).[20] Included in these safety measures were standards to ensure safe nurse 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% vs. 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 (OR 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.

Organisational factors. A total of seven papers investigated organisational 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 revascularisation.[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 organisational changes to optimise allocation of resources. Four studies evaluated the implementation of a fast track or enhanced recovery programme for AAA repair.[23,24,27,28] However, only one of these studies was a randomised controlled trial (RCT) that adhered 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 pre-operative fasting, no bowel preparation, patient controlled epidural anaesthesia, enhanced post-operative feeding, and early mobilisation.[23] Patient characteristics, surgical procedure, and clamping time were comparable between the two groups ($p > .05$ 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% vs. 36%; $p = .039$), and length of stay was significantly shorter with no readmissions within 30 days (10 days vs. 11 days; $p = .016$) in patients entered into the fast-track programme compared with the treatment group. Cantlay et al. describe their experiences of introducing a pre-operative assessment

clinic (PAC) led by vascular consultant anaesthetists, 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, although the authors reported that introduction of the PAC took place at the same time as centralisation of arterial services within this organisation.

DISCUSSION

This is the first systematic review to adopt a systems approach to understanding quality and safety in arterial surgery. Team, work environment, and organisational 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 incidents are rarely the result of a single error with direct consequences - rather, patient harm is often 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, although 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 intra-operative errors and procedural problems, although one large study from the UK demonstrated an association between major intra-operative communication failures and patient outcomes for patients undergoing aortic procedures. In other surgical specialties, failures of 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 standardised 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, anaesthetists, and nurses in open surgical procedures. Certainly in the UK, current training programmes in vascular surgery do not routinely include training in non-technical skills, although 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 with 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 Organisation's Surgical Safety checklist, which includes an equipment check prior to knife to skin.[43] We suggest that the WHO checklist could be tailored to specific arterial operations, to further improve preparation and use 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 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 centre studies with limited generalisability, and some of the studies used methodologies, such as self reporting, 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 revascularisation.[30] However, this study was limited to Medicare beneficiaries in the USA. Future research should replicate this study in other countries to further understand organisational factors that influence patient outcomes. Many further aspects of the work environment that might 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 h a week and provide emergency cover more often than is considered safe according to a recent workforce evaluation in the UK[44] and in the USA, 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 organisation 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 generalisable 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 1. SEARCH TERMS FOR MEDLINE, EMBASE AND PSYCINFO.

1. (adverse adj2 event$).ab,ti.
2. Post-operative Complications/ep, mo [Epidemiology, Mortality]
3. patient safety indicator$.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

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COUP D'OEIL

Gastric erosion by abscess 15 years after mesenteric bypass surgery

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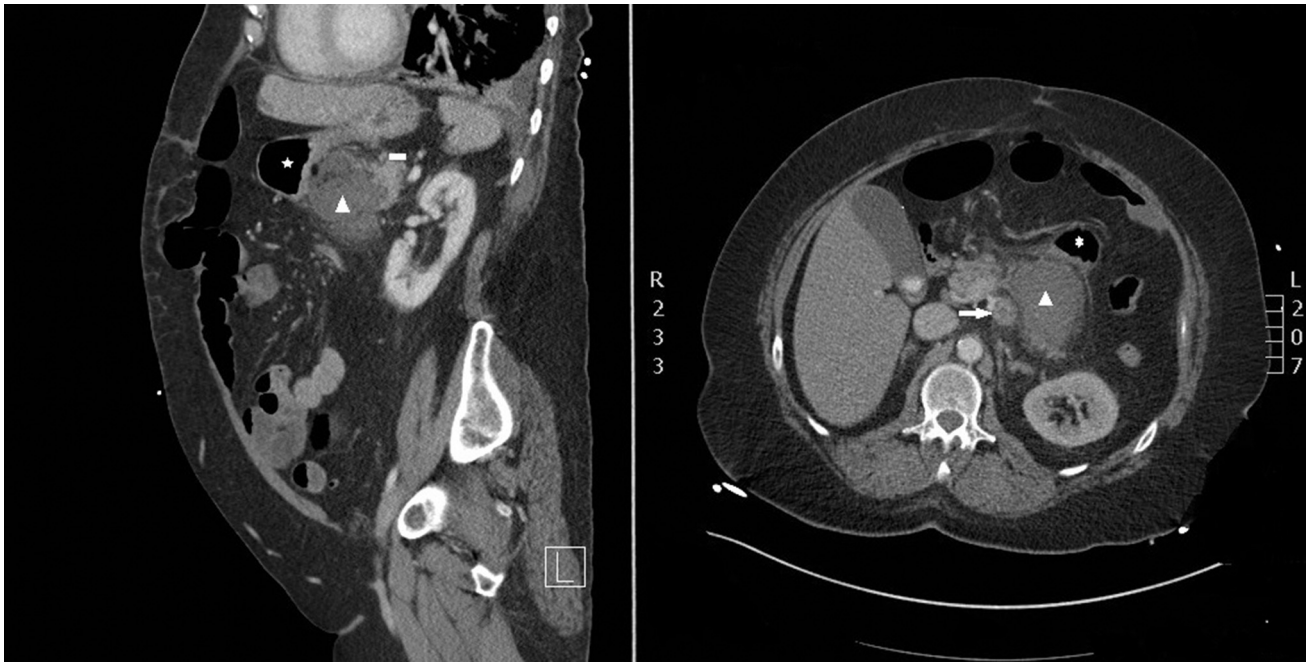

A 59 year old woman presented with fever, urinary frequency, and lower backache. A contrast enhanced abdominal computed tomography scan revealed a mass (arrow head) between the stomach (asterisk), pancreas (rectangle), and a thrombosed aorto-mesenteric Dacron graft (arrow), which had been created 15 years previously for abdominal angina. Radiologists of different subspecialties could not reach consensus on the aetiology. Intra-operatively, despite omental covering during the last operation, a thick walled abscess with gastric erosion was seen. The graft was successfully removed without the need for replacement thanks to a second patent retrograde mesenteric bypass that was created 8 years previously without visible signs of infection.

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