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Title: Risk factors for ischaemic colitis after surgery for abdominal aortic aneurysm: A systematic review and observational meta-analysis.

Short title: Ischaemic colitis after aortic aneurysm repair

Category: Review

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What this paper adds: This is the first systematic review and observational meta-analysis to collate risk factors for ischaemic colitis following abdominal aortic aneurysm repair. Emergency presentation and open surgery are associated with increased risk. Factors related to hypoperfusion such as hypotension, large volume blood transfusion and prolonged operative time are also implicated.

Abstract

Background: Ischaemic colitis is an infrequent but serious complication following repair of abdominal aortic aneurysm (AAA), with high mortality rates. This systematic review set out to identify risk factors for the development of ischaemic colitis after AAA surgery.

Methods: A systematic search of the MEDLINE, EMBASE and CINAHL databases was performed. This search was limited to studies published in the English language after 1990. Abstracts were screened by two authors. Eligible studies were obtained as full text for further examination. Data was extracted by two authors and any disputes were resolved via consensus. Extracted data was pooled using Mantel-Haenszel random effects models. Bias was assessed using two Cochrane approved tools. Effect sizes are expressed as relative risk ratios alongside the 95% confidence interval. Statistical significance was defined at the level of $p<0.05$.

Results: From 388 studies identified in the initial search, 33 articles were included in the final synthesis and analysis. Risk-factors were grouped into patient (female gender, disease severity) and operative factors (peri-procedural hypotension, operative modality). The risk of ischaemic colitis was significantly higher when undergoing emergency repair versus elective (RR 7.36, 3.08 to 17.58, $p<0.001$). Endovascular repair reduced the likelihood of ischaemic colitis (RR 0.22, 0.12 to 0.39, $p<0.001$).

Discussion: The quality of published evidence on this subject is poor with many retrospective datasets and inconsistent reporting across studies. Despite this, emergency presentation and open repair should prompt close monitoring for the development of IC.

Background

Abdominal aortic aneurysm (AAA) is a common procedure in the UK with around 4,000 elective, infra-renal procedures performed each year[1]. In recent years, there has been a drive to reduce mortality following surgery and the increased use of endovascular aneurysm repair (EVAR). This has had a notable effect by reducing mortality rates from 7.5% to 2.4% in elective surgery[2]. Despite the improvement in post-operative survival, complications following surgery remain a problem, with around 41% of patients suffering a post-operative complication[3].

Ischaemic colitis **(IC)** is a recognised complication of AAA repair, which although uncommon, may vary from clinically insignificant to full-thickness infarction and necrosis. Ischaemic colitis carries a high morbidity and mortality[4].Patients who develop IC typically require either re-operation with bowel resection and stoma formation or palliation. As a complication of AAA repair, IC requires cross specialty management with the involvement of gastrointestinal surgeons.

Endovascular aneurysm repair (EVAR) techniques have revolutionised AAA repair surgery. EVAR has enabled the adoption of a minimally invasive approach, reducing post-operative mortality, morbidity and increasing the availability of surgery to those who would have previously not been considered for open surgery[5]. However, there is limited evidence surrounding the effects of EVAR on ischaemic colitis.

The aim of this systematic review was to identify risk factors associated with the development of clinically overt ischaemic colitis after surgery for abdominal aortic aneurysm.

Methods

This review was undertaken in accordance with the Meta-analysis of observational studies in epidemiology (MOOSE) guidelines and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Primary Aim

The primary aim of this study was to compare the effects of elective versus emergency repair on the risk of developing clinically significant ischaemic colitis. Clinically significant was defined as colonic ischaemia necessitating intervention or palliation.

Secondary Aim

The secondary aim of this study was to compare the effects of EVAR on the risk of post repair ischaemic colitis.

Search Strategy

We undertook a systematic review of MEDLINE, EMBASE and CINAHL databases according to a predefined protocol. The search strategy included the terms and operator as follows; 'abdominal aortic aneurysm' AND 'ischaemic colitis'. Due to advancements in screening and the introduction of EVAR, results were limited to those published after the 1st January 1990. Due to resource constraints, only studies written in the English language were included. Retrospective cohort or case-control studies, prospective cohort or case-control studies and randomised controlled trials were eligible for inclusion in the review. Case series, case reports, commentaries and editorials were excluded due to an unacceptably high risk of bias. Grey literature

such as conference proceedings were excluded due to the perceived risk of incomplete data.

Definitions

To be included in the final analysis, studies must have included patients with clinically detectable ischaemic colitis. This included patients with symptoms such as abdominal pain and bloody diarrhoea, with the diagnosis confirmed either radiologically, endoscopically or at operation. Studies which detected colitis using colonographic techniques only were excluded, as transient and inconsequential ischaemia may occur in patients during surgery, but not require any clinical action.

Study inclusion and data extraction

Abstracts were screened by two reviewers (MJL & SD), and full papers were obtained for relevant citations. Bibliographies of included studies were hand searched in order to identify further relevant primary studies.

Data extraction

Two authors extracted information from primary studies using a standardised Microsoft Excel (Richmond, WA, USA) proforma. To assist understanding of aetiology, factors related to ischaemic colitis were divided into patient, pre-operative and operative factors. Data on study design, definitions of colitis, modality of repair and identified risk factors was collected. In case of disagreement, consensus was achieved through discussion.

The quality of included studies was independently assessed by MJL and SD using the ACROBAT NRSI tool for observation studies[6] and the Cochrane tool for bias in randomised trials for RCTs[7]. Risk of bias was used to evaluate the strength of

findings of the review. Funnel plots and visual tests of asymmetry were used to assess the risk of publication bias.

Statistical Analysis

Studies included in the final synthesis were pooled using meta-analysis to construct relative risk estimates and presented using Forrest plots. Results of each study and overall pooled effects are presented as risk-ratios (RR) of developing post repair ischaemic colitis, alongside the 95 per cent confidence interval (95% CI). Two-tailed statistical significance was defined at the level of $P<0.05$. Inter-study heterogeneity was measured using the I^2 statistic. Substantial statistical heterogeneity between studies was defined as when I^2 exceeds 50 per cent or a statistically significant chi squared value ($P<0.10$). Where statistical heterogeneity occurred, further qualitative synthesis of findings were employed. Clinical heterogeneity across studies was predicted to be likely due to the range of patients that were included, thus Mantel-Haenszel (M-H) random-effects models were employed for pooled analyses. Inverse variance models perform poorly in the context of low event rates and rare complications, thus the M-H method was employed. All statistical analyses were performed using RevMan 5.3 (Nordic Cochrane Centre, Copenhagen).

Results

A total of 388 studies, excluding duplicates, were identified in the initial search. Of these, **101** full text articles were screened and of these, **32** were eligible for inclusion in the final synthesis. Two randomised controlled trials were included in the final **32**, one of which directly addressed ischaemic colitis after AAA repair by randomising to IMA re-implantation or ligation at elective repair[8]. There were two prospective studies based on post-operative surveillance with colonoscopy, and the remaining papers were retrospective observational or cohort studies. A total of 111938 patients were included, with evidence of IC in 2384. Results of the search strategy can be seen in the PRISMA flow diagram (figure 1).

Patient factors

A summary of included studies and characteristics can be seen in table 1. Female gender was associated with increased incidence of IC in two studies[9,10]. The natural logarithm of a disease severity score was recognised as positively associated with development of ischaemic colitis (mean severity score in IC 1311 vs 389 in no-IC, $p<0.001$)[9]. **This disease severity score is a proprietary measure developed by Medstat (Ann Arbor, Michigan, USA) and is based on hospital admissions and discharges in the USA. It uses fifteen common diagnoses to understand the severity of disease, in a manner analogous to Injury Severity Scoring in trauma. It uses these characteristics to stratify patients into those likely to suffer from no complications, minor complications, major complications and death.** Only one paper identified a positive association between age and IC[8].

Pre-operative factors

Nature of presentation was frequently implicated in the development of ischaemic colitis. The reported rates of ischaemic colitis after elective surgery ranged from 0% to 4.6%[11,12] versus 5% to 20.5%[13,14] after emergency surgery. Six studies looked in more depth at emergency presentations and found those who had ruptured aneurysm demonstrated a higher rate of IC compared to those who had not ruptured (3.2 to 6.4 times more likely in ruptures) [9,13,15,10,16,17]. The studies reporting this are retrospective cohort studies.

In addition to nature of presentation, pre-operative hypotension defined as systolic blood pressure <90mmHg was identified as a risk factor. The odds ratio of developing IC if hypotension lasted for 30 minutes or more ranged from 1.26-30 [16,18,15]. Dadian *et al* identified intra-operative hypotension of <70mmHg as associated with IC[19]. Three studies identified that massive transfusion was associated with increased rates of IC[19,20,15]. All of these were retrospective single-centre observational studies.

Less frequently recorded variables were also associated with an increased incidence of post repair IC. Hypothermia (OR 5.08 (0.92-27.76, p=0.61)), significant hypovolaemia (OR 11.8 (2.40-57.98)) and acidosis on arrival (pH<7.3 (OR 4.78 (1.13-20.32)) were reported as risk factors in one study[20]. Pre-operative renal impairment was identified as a significant risk factor for development of ischaemic colitis in two papers, with reported odds ratios of 2.30[14] and 4.67[10].

Operative factors

Reported rates of IC following EVAR ranged from 0.0 to 4.1%[19,21-23]. Rates of IC for open repairs ranged from 0 to 4.95%[24,25]. This included data from a randomised trial

comparing 30-day outcomes of open repair versus EVAR with event rates of 1.1% and 0.6% respectively[26].

In open surgery, Becquemin *et al* reported that an operative time of >4 hours carried odds of 5.73 (95% C.I. 2.06 to 15.9)[10]. Neary *et al* investigated this relationship in their cohort and found a non-significant association between operative duration and incidence of post-repair IC, OR 0.95(0.84 to 1.09)[13]. Extended duration of 'clamp time' was associated with a non-significant increase in IC in two studies (40 minutes versus 35 minutes, p=0.06)[27],(63 minutes versus 50 minutes, p=0.06)[8] and achieved statistical significance in another[13]. For EVAR, Toya *et a*l identified a 'shaggy aorta' as a specific risk factor for IC[28].

Seven studies reported on preoperative status of colonic blood supply. Of these one RCT reviewed the value of re-implanting the inferior mesenteric artery. This did not show a statistically significant reduction in the rate of IC (RR 0.55 (0.21-1.41)), however this study was likely to be underpowered[8]. A retrospective study suggested that ligation of a patent IMA was associated with increased rates of IC[16]. A non-pulsatile IMA at operation was associated with a 3.6 times increase in rates of IC in a small prospective study[27]. Four retrospective case series looked at the role of pre-operative unilateral or bilateral internal iliac embolization, and did not show any significant increase in rates of IC subsequent to this[28-33].

Remaining studies were observational studies of incidence, describing rates of IC specifically after emergency repair, or after aneurysm repair in general, , with no further identification of risk factors[34-40].

Risk of Bias

Risk of bias was assessed for each study; summary tables for observational studies and RCTs are presented in tables 2 and 3 respectively. These show that there is potential for a high degree of bias in the observational studies.

Meta-analysis

Meta-analysis was undertaken for emergency versus elective AAA repair. Eight studies of appropriate quality showed emergency surgery was associated with a relative risk of 7.36 (95% C.I. 3.08 to 17.58, p<0.001) (figure 2)[10,14,12,37,25,35,13,9]. In this analysis there was a high level of statistical heterogeneity. Due to this observed heterogeneity we looked closely at the included studies and found that in each study, the risk of ischaemic colitis was increased for patients undergoing emergency repair versus elective repair, although the size of this effect cannot be accurately determined.

A second meta-analysis was undertaken for EVAR versus open repair. This included three studies and showed a relative risk of 0.22 (95% C.I. 0.12 to 0.39, p<0.001), showing rates of IC were lower after EVAR than open repair (figure 3) [10,24,25].

Discussion

In this study we have presented a systematic review and meta-analysis of factors associated with the development of ischaemic colitis after surgery for abdominal aortic aneurysm. We have identified that emergency presentation is associated with a statistically significant increase in the rate of IC and that use of EVAR is associated with a statistically significant decrease in the rate of IC. In addition to these findings, the body of literature also suggests that older, female patients, with a period of hypotension, or those requiring massive transfusion, are at higher risk of IC.

Given the reported frequency of IC, the methodology of this review was designed to capture information on the only data currently available, that from observational studies. We accepted that this would result in some intrinsic bias and heterogeneity in our results. This was seen in the high level of heterogeneity in the analysis of open versus emergency surgery. Despite high statistical heterogeneity there was an increased risk of ischaemic colitis in most studies and should be considered as a risk of emergency aneurysm repair in the absence of meta analysis of randomised patients. The quality of supporting this remains very poor and should be interpreted with due caution. Differences in the patient characteristics between countries and clinical practice may be contributory to this heterogeneity. As a result, the studies identified are mostly retrospective studies with moderate levels of bias due to confounding factors and selective reporting of risk factors. Given this, we cannot categorically state that factors such as age or gender are truly predictive of the risk of IC. In addition, the only randomised controlled trial on reduction of IC through IMA re-implantation was likely to be underpowered. As such the level of evidence for this is very poor and should be addressed directly in future studies we outline below.

Despite the limitations of the paper, we have reported rates of IC following 111,938 AAA repairs and upon factors associated with 2,384 cases of ischaemic colitis. Our methodology has allowed us to draw upon a large body of literature to improve our understanding of the aetiology in a challenging condition. Data quality was sufficient to allow meta-analysis of two major factors.

Notably, studies did not report on the development or otherwise of abdominal compartment syndrome, the use of intra-operative heparin or operative and post-operative inotropic support.

The finding that EVAR is associated with a lower risk of post-procedure IC is plausible. The EVAR procedure itself probably does not cause the same degree of intra-operative disruption to visceral flow as there is no clamping of the aorta. The literature suggests that prolonged disruption to flow through cross-clamping is associated with increased rates of IC, suggesting that the aetiology may be different in the two groups[27,8]. In interpreting this data, caution should be exercised as the majority of EVAR repairs in the analysis were in elective settings. One study suggested that IC following this operation is most likely due to micro-embolisation from disrupted aortic plaques[28].

The importance of emergency presentation and peri-procedural hypotension is highly relevant. It is known that visceral circulation suffers early in shock. It is plausible that disruption to flow occurs during AAA rupture due to the loss of circulating volume and sacrifice of the viscera through vasoconstriction. Whilst permissive hypotension is advocated in the care of ruptured AAA, evidence supporting this in humans is lacking[41]. Observations from more a recent study has suggested that aggressive permissive hypotension in emergency AAA surgery is associated greater mortality[42].

A retroperitoneal haematoma may add further insult by increasing compartment pressures. The identification of patients requiring massive blood transfusion and those with pre-operative acidosis might add weight to hypoperfusion as a key aetiology. Given the relatively high rates of ischaemic colitis following emergency presentation of AAA, one might consider whether this complication belongs to the operation or the mode of presentation. The possibility that IC develops regardless of the operation and might be present at surgery, albeit not fully declared as fulminant colitis, should be considered.

If is useful to have this data aggregated into a study as a reference point. There are clearly gaps in the data describing risk factors. At present, those with a high risk of colonic ischaemia (i.e. emergency open repairs) should undergo routine post-operative surveillance with flexible sigmoidoscopy. This would allow early identification of full thickness ischaemia and appropriate intervention. It may also over-detect cases as most patients will have a degree of colonic ischaemia post-surgery.

There is a need to develop pre-operative or intra-operative strategies to predict of detect colonic ischemia. With factors identified in this study, interrogation of a prospectively maintained national vascular registry might allow us to develop a formal scoring system to identify those at high risk. If robust enough, this might indicate colectomy at time of repair to prevent a ‘second hit’ related to ischaemia. Other intra-operative techniques might be of use, such as on-table angiography to assess colonic viability at the end of a procedure. Future research on this topic may come as a secondary outcome of other studies looking at operative modality or resuscitation protocols. Using the above information we should consider what might constitute a minimum dataset for reporting of IC.

Conclusion

This systematic review and meta-analysis has shown that emergency presentation and open surgery are associated with higher rates of ischaemic colitis after surgery for abdominal aortic aneurysm. A high index of suspicion for development of the condition should be maintained in these patients. There is continuing uncertainty around the effect of female sex, age, hypotension and hypovolaemia.

Conflicts of interest:

MJL has no conflicts of interest to declare. SLD has no conflicts of interest to declare. TMD has no conflicts of interest to declare. IJA has no conflicts of interest to declare. Parts of this project have been presented to the Society of Academic & Research Surgery, the Association of Surgeons of Great Britain and Ireland and the Asia-Pacific Federeration of Coloproctology.

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Titles for figures:

Figure 1: PRISMA flow diagram showing identification and exclusion process for review.

Figure 2: Forest plot of meta-analysis showing that IC is more likely after emergency aneurysm repair

Figure 3: Forest plot of meta-analysis showing that IC is less likely after endovascular aneurysm repair.