Eur J Vasc Endovasc Surg (2018) ■, 1–8

Re-interventions After Repair of Ruptured Abdominal Aortic Aneurysm: A Report From the IMPROVE Randomised Trial

Janet T. Powell [a,*], **Michael J. Sweeting** [b,#], **Pinar Ulug** [a], **Matthew M. Thompson** [c,†], **Robert J. Hinchliffe** [d], **IMPROVE Trial Investigators** [‡]

[a] Vascular Surgery Research Group, Imperial College, London, UK
[b] Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK
[c] St George's Hospital, London, UK
[d] Bristol Centre for Surgical Research, University of Bristol, Bristol, UK

WHAT THIS PAPER ADDS

The mid-term re-intervention rate after ruptured abdominal aortic aneurysm repair by endovascular or open repair appears to be twice as high as after elective repair. This suggests the need for bespoke surveillance protocols after rupture. Limb ischaemia is a frequent early reason and distal aneurysms a frequent later reason for re-intervention to indicate where quality improvement programmes might be directed. Limb amputation is uncommon but higher after open repair than after endovascular aneurysm repair.

Objective/Background: The aim was to describe the re-interventions after endovascular and open repair of rupture, and investigate whether these were associated with aortic morphology.

Methods: In total, 502 patients from the IMPROVE randomised trial (ISRCTN48334791) with repair of rupture were followed-up for re-interventions for at least 3 years. Pre-operative aortic morphology was assessed in a core laboratory. Re-interventions were described by time (0–90 days, 3 months–3 years) as arterial or laparotomy related, respectively, and ranked for severity by surgeons and patients separately. Rare re-interventions to 1 year, were summarised across three ruptured abdominal aortic aneurysm trials (IMPROVE, AJAX, and ECAR) and odds ratios (OR) describing differences were pooled via meta-analysis.

Results: Re-interventions were most common in the first 90 days. Overall rates were 186 and 226 per 100 person years for the endovascular strategy and open repair groups, respectively ($p = .20$) but between 3 months and 3 years (mid-term) the rates had slowed to 9.5 and 6.0 re-interventions per 100 person years, respectively ($p = .090$) and about one third of these were for a life threatening condition. In this latter, mid-term period, 42 of 313 remaining patients (13%) required at least one re-intervention, most commonly for endoleak or other endograft complication after treatment by endovascular aneurysm repair (EVAR) (21 of 38 re-interventions), whereas distal aneurysms were the commonest reason (four of 23) for re-interventions after treatment by open repair. Arterial re-interventions within 3 years were associated with increasing common iliac artery diameter (OR 1.48, 95% confidence interval [CI] 0.13–0.93; $p = .004$). Amputation, rare but ranked as the worst re-intervention by patients, was less common in the first year after treatment with EVAR (OR 0.2, 95% CI 0.05–0.88) from meta-analysis of three trials.

Conclusion: The rate of mid-term re-interventions after rupture is high, more than double that after elective EVAR and open repair, suggesting the need for bespoke surveillance protocols. Amputations are much less common in patients treated by EVAR than in those treated by open repair.

Article history: Received 29 November 2017, Accepted 29 January 2018, Available online XXX

Keywords: Abdominal aortic aneurysm, Morphology, Re-intervention, Rupture

INTRODUCTION

As experience with elective endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA) has increased and stent graft technology has advanced, the rate of re-interventions has reduced. In the early randomised trials, the mid-term re-intervention rates were about 3.5 per 100 person years versus 0.5 per 100 person years after open repair,[1] but, today, much lower rates are reported from more recent data.[2] Endovascular repair of ruptured AAA

† **Current address**: Endologix Inc., Irvine, CA, USA.
# **Current address**: Department of Health Sciences, University of Leicester, Leicester, UK.
‡ See Appendix S1.
* Corresponding author. Vascular Surgery Research Group, Imperial College at Charing Cross, Fulham Palace Road, London W6 8RP, UK.
E-mail address: j.powell@imperial.ac.uk (Janet T. Powell).

https://doi.org/10.1016/j.ejvs.2018.01.028

presents additional challenges: the aneurysms are larger, the emergency imaging may not be optimal, sizing for endografts may be difficult owing to hypotensive arterial collapse, the available stock of endografts may be limited and these may be used outside conservative instructions for use (IFU). Therefore, there is widespread acceptance that EVAR for rupture is likely to be associated with a higher re-intervention rate than EVAR for elective repair.

There are few studies that report mid-term re-intervention rates after either EVAR or open repair for rupture. The most comprehensive study comes from the 467 patients with repair of ruptured AAA in the Amsterdam cohort from 2004 to 2011.[3] By 5 years 45% of the EVAR patients and 40% of the open repair patients had had at least one re-intervention. The re-interventions in the primary admission and after discharge were described separately. After discharge the rate of re-interventions after EVAR was nearly four times as high as after open repair and a common reason for re-intervention after EVAR was life threatening graft infection.

The IMPROVE trial, which randomised 613 patients with a clinical diagnosis of ruptured AAA to either an endovascular strategy (EVAR if morphologically feasible, open repair if not) or open repair, included 502 patients in whom repair of rupture was commenced, and followed these patients for re-interventions for 3 or more years. It has already been reported that the overall re-intervention rates were not significantly different between the randomised groups and that any additional re-interventions incurred in the endovascular strategy group did not compromise the overall cost-effectiveness of the endovascular strategy.[4] The purpose here is threefold: (i) to provide further insight concerning the reasons for and rates of re-intervention (directly aneurysm related and other) in the 502 patients with repair of rupture started, both by randomised group and by treatment received; (ii) to investigate whether pre-operative aneurysm morphology was associated with re-intervention rates; and (iii) to assess whether major amputation (an uncommon outcome but one much feared by patients) was more common after either EVAR or open repair in an individual patient meta-analysis across the three recent European randomised trials for the management of ruptured AAA.[5–7] The first two aims will also provide important information as to whether surveillance protocols after rupture might need to be different from those after elective AAA repair.

METHODS

The design and patients of the IMPROVE trial (ISRCTN48334791), their follow-up, and assessment of baseline aortic morphology have been described previously.[8,9] Briefly, 613 patients with an in hospital clinical diagnosis of ruptured AAA were randomised to either an endovascular strategy (immediate computed tomography [CT] scan and EVAR if morphologically feasible, otherwise open repair) or to open repair (CT scan optional). Of these, 502 patients with a confirmed diagnosis of rupture had aneurysm repair or started aneurysm repair and were followed up by trained local coordinators, for all re-interventions in the first 30 days, and aneurysm related re-interventions for 3 years thereafter. The trial protocol required clinical follow-up with imaging at 3, 12, and 36 months after repair, with intermediate follow-up left to the discretion of each trial centre. A standardised protocol for the detection and management of abdominal compartment syndrome, with recording of intra-abdominal pressures, was recommended but not widely followed. The completeness of re-intervention data, including re-interventions at non-trial hospitals, was verified by cross-checking against an administrative data set for English patients (Hospital Episode Statistics) and by detailed audit for Scottish and Canadian patients. Re-interventions beyond 3 years were not collected comprehensively. Re-interventions for pre-existing conditions, for example colon cancer, which had been included for the analysis of outcomes at 30 days are excluded from the present analysis, whereas fistula formation to treat renal failure and endovascular treatment of pulmonary embolism are included. Trial investigators extended the categorisation of re-interventions used by the EVAR-1 trial to obtain a consensus as to whether a re-intervention was for a life threatening condition (Table S1 [see Supplementary Material], with a full list of re-interventions).[1] Two observers categorised the re-interventions as arterial, laparotomy related, or other, with differences resolved by discussion. Separately, six patients or their spouses, from outside the trial, were asked to rank the main re-interventions: they were unanimous in reporting amputation of the leg as the most feared re-intervention, followed by graft infection.

The indications for re-intervention are tabulated both by randomised group and by treatment received. When two separate indications for re-intervention were corrected in the same operating or endovascular session these are listed separately but described in table footnotes. Multiple planned recurring procedures requiring time in the operating theatre (e.g., debridement, change of dressings) are excluded from the descriptive tables (e.g., there would be only a single listing for change of negative pressure wound therapy dressing, even if this occurred on several occasions).

CT scans were acquired in DICOM format from hospital archives, anonymised, and transferred to the core laboratory at St George's Vascular Institute for three dimensional reconstruction and analysis[10]; in total, 458 admission scans from patients with confirmed rupture were available.[11] Five morphological parameters (aortic diameter at 1 mm distal to the distal renal artery, aneurysm neck length from distal renal artery to sac, proximal neck angle α, maximum aneurysm diameter, and maximum common iliac diameter) were measured in a core laboratory and a sixth, neck conicality derived, as described previously.[11] From these parameters the endovascular repairs were categorised as either within liberal IFU or not (liberal IFU aneurysm neck length $\geq$ 10 mm, neck diameter $\leq$ 32 mm, and neck angle $< 60°$).[12] The 3 month follow up CT scans also were collected in the core laboratory and were used to confirm the diagnosis of any underlying conditions requiring re-intervention at this time. Individual patient data for baseline characteristics and follow-up to 1 year were also

Please cite this article in press as: Powell JT, et al., Re-interventions After Repair of Ruptured Abdominal Aortic Aneurysm: A Report From the IMPROVE Randomised Trial, European Journal of Vascular and Endovascular Surgery (2018), https://doi.org/10.1016/j.ejvs.2018.01.028