

## An Endovascular Strategy for Suspected Ruptured Abdominal Aortic Aneurysm Brings Earlier Home Discharge but Not Early Survival or Cost Benefits

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Many patients with suspected ruptured abdominal aortic aneurysm (AAA) are likely to present at a hospital which may not be able to offer either emergency repair or emergency repair by both endovascular and open emergency repair. Within the past year, two small trials of haemodynamically stable patients with aortic anatomy suitable for conventional endovascular aneurysm repair (EVAR) have shown that, in specialist centres, operative mortality is similar after either open or endovascular repair (20–25%).<sup>1,2</sup> However, in practice the aortic anatomy is unknown at the time of early clinical suspicion of ruptured AAA and shock may develop rapidly, so where should these patients be treated? This was the question underpinning the IMPROVE trial. Is the operative mortality lower with an endovascular strategy versus open repair, and consequently should the patient be directed to a hospital offering a 24/7 endovascular service?

The IMPROVE trial randomized 613 patients with a clinical diagnosis of ruptured AAA to either an endovascular strategy, with an urgent computed tomography (CT) scan followed by EVAR or open repair for adverse aortic anatomy, or to an open repair strategy, where CT scan was optional. This was a pragmatic, “real-world” trial, with a high proportion of known hospital presentations of ruptured aneurysm being randomized. The last patient was randomized in July 2013 and the primary outcome from this trial (30-day mortality) has been presented recently.<sup>3</sup> Overall there was no difference in 30-day mortality, 35% in the endovascular strategy group versus 37% in the open repair group. These results included those patients who died before surgery (6%), patients with suitable anatomy for EVAR who crossed over to open repair because either facilities or personnel for EVAR were not immediately available or the patient deteriorated rapidly and it was quicker to start open repair (5%), those randomized to open repair but crossed over to EVAR because of their frailty or clinical decision concerning their suitability for general anaesthesia (6%), as well as those with symptomatic aneurysms (4%) or other final diagnoses (9%). In the AJAX trial, the mean time to arrival in an operating suite for endovascular repair was over 70 minutes, almost 30 minutes longer than the time

taken to reach the operating theatre for open repair.<sup>1</sup> In the IMPROVE trial, the time for patients with rupture to reach the operating suite was much shorter, 37 and 47 minutes for the open and endovascular groups respectively. Nevertheless, the longer time needed for patients to reach endovascular repair could provide a potential disadvantage. Following this initial delay, patients surviving repair left theatre alive at similar times after randomization in each group, since the median length of the procedure was 180 minutes for the endovascular strategy and 199 minutes for the open repair group.

For the patients with aneurysms in the endovascular strategy group, 64% were considered to be anatomically suitable for conventional EVAR and, among those treated with EVAR, the operative mortality was 25%, very similar to the results for EVAR in the AJAX and ECAR trials. In contrast, the operative mortality following open repair in this group was 38% compared with the 37% operative mortality in the open repair group. The results for open repair appear worse than those reported from the AJAX and ECAR trials, but IMPROVE included patients in shock and those with adverse aortic anatomy.

The IMPROVE trial also reported 30-day costs, which showed that the endovascular group had greatly reduced stay in intensive care, which offset the extra cost of endovascular devices. On balance, costs after 30 days were non-significantly lower in the endovascular strategy group.

With a trial of this size, limited subgroup analysis was possible. Surprisingly, for the 133 women survival was better with an endovascular strategy, odds ratio 0.44 (95% CI 0.22–0.91). Hardman index was a good prognostic indicator for both endovascular and open repairs and additional analysis of the ruptured aneurysm cohort showed the direct linear relationship between lowest systolic blood pressure and operative mortality (51% for those with pressures < 70 mmHg), which questions the thresholds recommended for hypotensive haemostasis.<sup>4</sup> Patients transferred from hospitals not offering emergency repair had similar risk profiles and outcomes as patients presenting directly to the trial hospitals.<sup>4</sup> Patients who received endovascular repair under local anaesthesia had a lower mortality (13%) than those who underwent the procedure under general anaesthesia (34%), which translated to a fourfold benefit for local anaesthesia after adjustment for prespecified confounders, odds ratio 0.25 (95% CI 0.10–0.70). Patients in the endovascular strategy group were discharged from hospital faster and a much greater number

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(94%) were discharged directly to home rather than step-down care (vs. just 77% in the open repair group). This latter outcome, number of patients being discharged to home, was the primary outcome measure favoured by patients and their families when they were consulted about the trial design. Neither this outcome nor in-hospital mortality emerged as the favoured primary outcome after the proposal for the trial emerged from peer review. Nevertheless, based on the IMPROVE results to date both patients and their families are likely to favour endovascular repair when this is feasible.

So the IMPROVE trial has again shown that for patients with good aortic anatomy and relative haemodynamic stability, the operative mortality for EVAR is only 25%, but this only represents about 60% of the cohort presenting for emergency aneurysm repair. In those who need open repair (either for anatomical reasons or extreme urgency), mortality is much higher (38%). Given the observations that survival with discharge directly to home is higher and costs non-significantly lower in the endovascular group, it may be that patients with ruptured abdominal aortic aneurysms should be treated in centres that can offer both endovascular and open aortic surgery at all times. However, it remains crucial to identify both which patients benefit from endovascular repair and whether the endovascular strategy is cost-effective after longer patient follow up before final decisions are made about altering the provision of hospital services for ruptured AAA.

#### DISCLAIMER

The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the National Institutes of Health Research, the National Health Service or the Department of Health.

#### CONFLICT OF INTEREST

None.

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Other contributors to the IMPROVE trial have been listed previously.<sup>3</sup>

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