DEBATE:

# What Does the Current Evidence on EVAR for Ruptured AAA Tell Us?

## EVAR Versus Open Repair for Ruptured Abdominal Aortic Aneurysms

Randomized trials have provided new evidence about outcomes in all patients with ruptured aneurysms, not just those anatomically suitable for EVAR.

**BY ROBERT J. HINCHLIFFE, MD, FRCS, AND JANET T. POWELL, MD, PHD, FRCPATH**

Public health measures, principally smoking cessation and aneurysm screening, have contributed to making ruptured abdominal aortic aneurysms a less common vascular emergency than in the late 20th century.[1] Vascular surgical services have also undergone change during this time period, with the emergence of fewer and larger centers and the prominent role now played by endovascular surgery. Observational studies, systematic reviews, and administrative databases have all indicated that endovascular repair of a ruptured abdominal aortic aneurysm is associated with much lower operative mortality (~25%) compared to open repair (~45%). If true, this would be marvelous, and to provide equity of patient care nationally, all older persons should live within reach of a vascular center that provides 24/7 endovascular care.

However, health care providers require better evidence before investing in organizational change. Currently, only the minority of patients with ruptures

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## Randomized Trials Show EVAR Is the Best Option for Ruptured AAAs

The conclusion that IMPROVE, AJAX, and ECAR demonstrate that EVAR confers no survival benefit over open repair is misleading.

**BY FRANK J. VEITH, MD, AND CARON B. ROCKMAN, MD**

Despite favorable single-center reports and other data showing that endovascular aneurysm repair (EVAR) is superior to open repair for the treatment of ruptured abdominal aortic aneurysms (rAAAs),[1] the issue of which form of repair is best remains controversial. Many claim that the data showing superior outcomes for EVAR are flawed by patient selection.[2,3] Thus, some investigators believe that a case can be made for carrying out randomized comparisons of the two treatment paradigms to produce level 1 evidence that will settle the issue.

Recently, three such well-intended randomized controlled trials (RCTs) have published or presented some of their results. These are the AJAX trial from Amsterdam,[4] the ECAR trial from France,[5] and the IMPROVE trial from the United Kingdom.[6] All three trials concluded that 30-day mortality outcomes after treatment for rAAA are no better with EVAR than with open repair. The objective of this article is to show that this conclusion may be unjustified and to

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are treated with endovascular repair and at a wide variety of hospitals.[2-4] Most observational data do not report how many patients were turned down for repair nor do they report results on contained versus frank rupture, patient sex, comorbidities, hemodynamic stability, or aortic anatomy. For these reasons, the data may end up comparing better-risk patients who are treated with endovascular aneurysm repair (EVAR) and worse-risk patients who are treated with open repair. This amounts to an "apples-to-oranges" comparison—a problem that cannot be resolved by propensity matching. Randomized trials are required to resolve such issues and provide objective analysis of which treatment strategy, endovascular or open repair, is best for patients and for providers.

## THE AJAX AND ECAR TRIALS

Endovascular repair is not yet applicable for all patients in all centers, and the use of off-the-shelf devices remains restricted by morphology at the aneurysm neck, iliac, and access arteries. Perhaps we should have taken more notice of findings from earlier work and the EVAR 2 trial, which showed that long aneurysm necks protect against rupture.[5,6] Ruptured aneurysms might be the most difficult to manage with endovascular repair. Such issues have to be considered when designing randomized trials. Two small trials, AJAX in the Amsterdam area and ECAR in France, decided to randomize only those patients who were eligible for both open repair and EVAR: patients had to be considered to have a reasonable chance of withstanding open repair and have aortic anatomy suitable for standard EVAR. Both trials were small, and both showed no difference in 30-day mortality between patients who were randomized to EVAR or open repair.[7,8] However, the 30-day mortality for all patients was low, 24% to 25% in AJAX and 19% to 22% in ECAR, which was much lower than anticipated. However, neither trial randomized more than one-third of the ruptures reported to the trial centers.

The AJAX trial also raised another important consideration: the accuracy of the rupture diagnosis by CT scan. Three of the patients who were randomized to open repair were identified as having intact aneurysms, and another underlying cause of admission was identified only at laparotomy. Given that the patients were randomized, it also seems likely that a few patients treated with EVAR also did not have a rupture. None of the observational series or administrative data address this important issue; hence, the emergency diagnosis of rupture is not 100% accurate.

## THE IMPROVE TRIAL

By far, the largest randomized trial to date has been IMPROVE. It had a pragmatic approach and randomized patients with an in-hospital clinical diagnosis of ruptured aneurysm, made by a senior clinician, before a CT scan was performed. This trial had national coverage within England and also included one Welsh, one Canadian, and two Scottish centers. It randomized two-thirds of the eligible patients. This trial again showed no difference in mortality between the two randomized groups: endovascular strategy (EVAR if possible and open repair if not) versus open repair.[9]

Because it was a pragmatic trial, a small proportion of patients breached the randomization protocol to provide learning opportunities about both clinical care and the delivery of service. Most of the patients who underwent EVAR when randomized to open repair did so because the anesthesiologist determined that general anesthesia was too risky, and any repair had to be performed using local anesthesia. Similarly, some patients who were anatomically suitable for EVAR actually underwent open repair, primarily because they were rapidly deteriorating, and it was faster to start an open repair procedure than to start endovascular repair; this was a recurring theme in all three trials. The trial also showed that some patients deteriorated too rapidly to even reach the operating theater. All of this is real life. On the other hand, the data analysis used the diagnosis of rupture made in a core laboratory, where CT scans were read by experts. There were cases where the local site had diagnosed an acute symptomatic aneurysm and missed the rupture and other cases where the local site had noted rupture but the patient needed to be reclassified as having an acute symp-

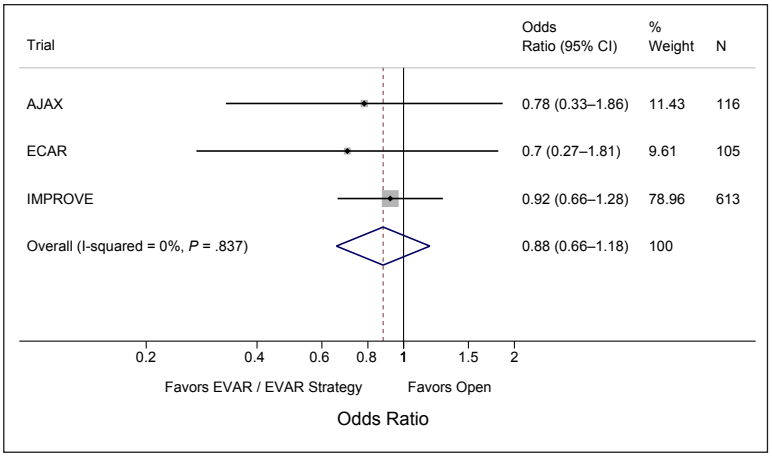


**Figure 1. Thirty-day mortality by randomized group: individual patient meta-analysis from three trials.**

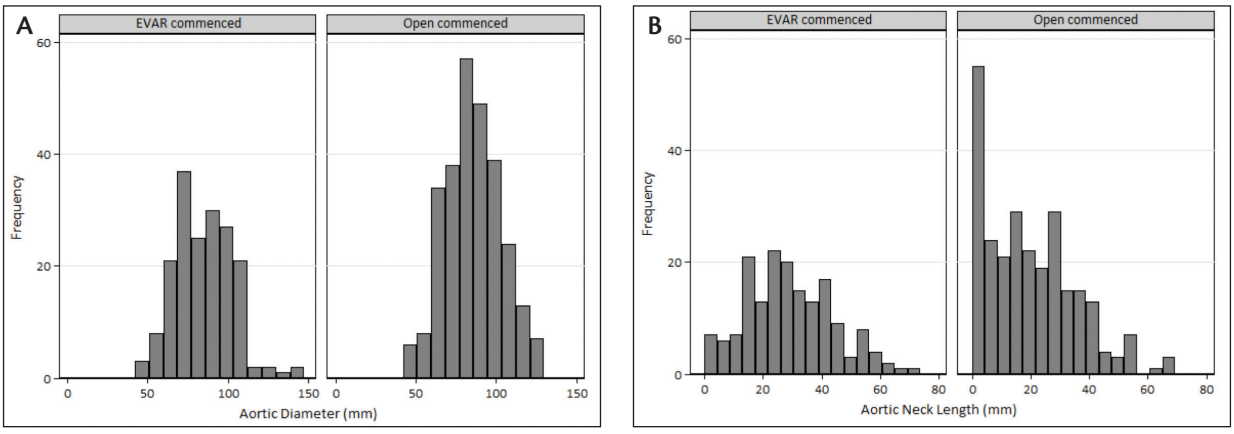


**Figure 2. Maximum aortic diameter (A) and aneurysm neck length (B) by treatment received. All those with aortic diameters < 5.5 cm had ruptures in the iliac portion of an aortoiliac aneurysm.**

tomatic aneurysm. Therefore, the IMPROVE trial only classified patients as having a rupture when blood was seen outside the aneurysm sac on CT scan or if there was a retroperitoneal hematoma in association with an aortoiliac aneurysm at laparotomy.

Not all patients arrive at hospitals that can provide either endovascular or any vascular emergency service. At the beginning of the IMPROVE trial, it became clear that there was a wide variety of practice with respect to patient referral to a vascular center and speed of secondary transfer. There is a suspicion that only the most stable patients were offered secondary transfer, as the 30-day mortality rates of trial patients with primary and secondary presentations were very similar.[10] Through a Delphi consensus approach, we formulated guidelines for patient transfer, which have been accepted by radiologists, vascular surgeons, and emergency medicine physicians in the United Kingdom.[11] The audit target is to have the patient in an emergency ambulance in transit to an alerted vascular center within 30 minutes of the patient's arrival at the transferring hospital. We hope that these guidelines will result in a greater proportion of our patients being offered aneurysm repair, particularly EVAR.

The operative mortality rate in the IMPROVE trial was much higher than for either AJAX or ECAR (35% in the endovascular strategy group and 37% for the open repair group). This is largely because the IMPROVE trial included a wider spectrum of patients, not just those known to be morphologically suitable for EVAR, as well as high-risk patients who did not reach the operating theater/endovascular suite alive. The three trials have collaborated to merge their results in an independent patient meta-analysis. The results are very homogeneous (Figure 1), with an odds ratio of 0.88 (95% confidence interval, 0.66–1.18), showing no clear benefit for EVAR/endovascular strategy.

Within the IMPROVE trial, the 30-day mortality of patients who underwent EVAR was similar to the mortality reported from the AJAX and ECAR trials (22%–25%) versus those who underwent open repair (37%–38%), but patients are no longer within their randomized groups, and this comparison is an apples-to-oranges comparison. However, it prompted investigation into whether the reasons for this difference might be rooted in morphological differences.[12] Although the maximum aneurysm diameters were very similar for those who underwent EVAR and open repair (Figure 2A), the distribution of aneurysm neck lengths was very different (Figure 2B). Almost all of the patients with short aneurysm necks underwent open repair, and EVAR was reserved for patients with long-necked aneurysms. Many of the patients who underwent open repair had juxtarenal aneurysms with neck lengths < 10 mm, which is outside the instructions for use of all fully licensed infrarenal endografts. It has previously been observed that such patients have a very high mortality rate after open repair.[13] Even more interestingly, for patients with long aneurysm necks (≥ 15 mm), the operative mortality rate was similar for EVAR and open repair. This enables us to interpret both the much higher 30-day mortality rates for IMPROVE versus AJAX and ECAR, as well as the unexpected results from AJAX and ECAR. Patients with long aneurysm necks do well regardless of which type of repair they undergo. It also advises us that standard EVAR using off-the-shelf infrarenal endografts that are currently available will never be able to deal with more than about 70% of all ruptures on a national basis.

Data in a randomized trial are prospectively collected and monitored for accuracy by trial monitors, and in large trials, a number of subgroup or additional analyses are possible. IMPROVE included > 20% women, and it seems as though, in this subgroup, there is a real benefit of EVAR in reducing 30-day mortality. We could also investigate issues raised by the patients who

breached trial protocol, including the effects of blood pressure and type of anesthesia used.[10] For patients who undergo EVAR, there is a noticeable benefit in conducting the procedure under local anesthesia, with a three- to fourfold reduction in operative mortality versus general anesthesia. Concerns have also been raised about too much "hypotensive hemostasis," because for those in whom systolic pressure dropped below 70 mm Hg, the 30-day mortality was 50%.

## CONCLUSION

In summary, randomized trials have produced excellent new evidence about the management of ruptured abdominal aortic aneurysms that is not available from observational data. Endovascular repair will certainly have a place, particularly for women, many of whom are currently denied any repair.[14] Open repair has shown excellent results too, particularly in patients who are anatomically suitable for EVAR. Future efforts need to be focused on improving the diagnosis of rupture and better management of juxtarenal aneurysms. The favorable results for EVAR conducted under local anesthesia might require further evidence to encourage anesthesiologists to consider this practice. ■

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attempt to make the case that EVAR is in fact the better treatment for rAAAs, if it can be performed.

## RECENT RCT DATA

The AJAX and ECAR trials, which randomized relatively small numbers and proportions of the total rAAA patients screened (116/520 and 107/372, respectively), excluded many patients from randomization for a variety of reasons. Both AJAX and ECAR also excluded hypotensive or unstable rAAA patients who were not offered EVAR and were subsequently treated by open repair or underwent no reparative treatment. Unfortunately, these high-risk patients are precisely the ones who might have better outcomes if they were treated by EVAR. Therefore, these exclusions may have prevented these trials from showing survival and other advantages that EVAR might have had in the overall population of patients with rAAAs. In addition, more optimal utilization of preoperative fluid restriction (hypotensive hemostasis),[1] supra-aortic balloon control,[7] and adjunctive open abdomen treatment of abdominal compartment syndrome[8] might have even further improved the EVAR outcomes in AJAX and ECAR.

IMPROVE was a larger RCT, which was conducted in 29 high-volume centers in the United Kingdom and at one Canadian center. It was carefully planned,[9] and much useful information was collected.[10,11] Its most important findings were presented in the report of its 30-day outcomes.[6] Although 652 possible rAAA patients were excluded from IMPROVE for various reasons, the trialists did randomize 613 additional patients with a diagnosis of rAAA to either an endovascular strategy group (316 patients) or an open repair group (297 patients). Patients were randomized before CT scans were performed. As a result, 33 of the 316 patients in the endovascular strategy group ultimately proved to have another diagnosis, and eight had a symptomatic but unruptured AAA. In the open repair group, 22 of the patients ultimately proved to have another diagnosis, and 14 had a symptomatic but unruptured AAA.

Nevertheless, in IMPROVE, the overall 30-day mortality rate in the endovascular strategy group was 35%; in the open repair group, it was 37% ($P$ = .67). Clearly, there was no significant difference between the 30-day mortality rates in these two groups based upon these percentages. The primary conclusion of the main IMPROVE trial article was, "A strategy of endovascular repair was not associated with significant reduction in 30-day mortality."[6] This resulted in a headline appearing in *Vascular News,* which read, "No Difference Between Endovascular & Open Repair for Ruptured Aneurysms."[12]

## DISCUSSION

To understand why these conclusions may be misleading, one must closely examine the detailed data from the IMPROVE trial.[6] Of the 316 patients who were initially randomized to the endovascular strategy group, only 154 (about half) were actually treated by EVAR, and 112 ultimately underwent open repair, largely because of anatomic unsuitability for EVAR based on their CT scans. An additional 17 patients in this group received no treatment at all. The 30-day mortality rate for the patients who were actually treated by EVAR in this group was 25.3% (38 of 150); for those treated by open repair in this group (initially randomized to EVAR), it was 38.4% (43 of 112) (25.3% vs 38.4%; $P$ = .06). For those who did not receive any AAA reparative treatment in this group, the 30-day mortality rate was 94.1% (16 of 17).

Of the 297 patients who were randomized to the open repair group, 36 actually underwent EVAR, 220 underwent open repair, and 19 received no treatment. The 30-day mortality rate in this group who were initially randomized to open repair but actually underwent EVAR was 22.2% (8 of 36), 36.8% (81 of 220) for those who underwent open repair (22.2% vs 36.8%; $P$ = .09), and 100% (19 of 19) for those who received no reparative treatment at all. Overall, in the two randomized groups taken together, the 30-day mortality rate for rAAA patients who were actually treated by EVAR was 24.7% (46 of 186), and for those who were actually treated by open repair, it was 38.1% (128 of 336) (24.7% vs 38.1%; $P$ < .002).

## CONCLUSION

The IMPROVE trial was worthwhile, has provided useful information regarding the treatment of ruptured AAAs, and will undoubtedly provide more in the future.[10,11] However, in our opinion, the main conclusion of IMPROVE's key article on 30-day outcomes is not supported by its data.[6] This conclusion that "a strategy of endovascular repair was not associated with a significant reduction in 30-day mortality" is misleading because more than half (162 of 316) of the patients who were randomized to the endovascular strategy group did not actually undergo treatment by EVAR. This invalidates any intention-to-treat analysis and prevents the trial from providing useful level 1 evidence regarding 30-day mortality for the two rAAA treatments. Although it may not constitute true level 1 evidence, we believe a better conclusion justified by IMPROVE's data would be: In patients with rAAA who can be treated by EVAR, 30-day survival is superior to that of patients treated via open repair. The superiority of EVAR, when it can be performed, for the treatment of rAAA is further supported by the decreased proportion of rAAA patients who receive no corrective treatment when EVAR is utilized compared to when open treatment is being used.[13]

Finally, in our opinion, there is no need for additional RCTs of EVAR versus open repair in the rAAA setting. ■

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# REBUTTALS

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Health care systems in the United States, Britain, France, and the Netherlands are all different, and care must be taken with the interpretation of data from unfamiliar systems. The IMPROVE trial did randomize 55 patients whose discharge diagnosis was not an rAAA. Ultrasonography to detect an AAA is a core competency for British Emergency Medicine trainees, which is used to avoid delaying the diagnosis of a ruptured aneurysm in elderly patients who have collapsed and/or are in shock and have abdominal or back pain. So, of these 55 patients, 45 had a bystander AAA (mean diameter, 6.8 cm), and one had a thoracoabdominal aneurysm. Only nine patients did not have an aortic aneurysm. Surely, this "overdiagnosis" is far better than the 42% rate of missed diagnoses reported in a recent systematic review.[1] The patients whom Dr. Veith described as receiving no treatment rapidly deteriorated and died before an operation could be started.

Finally, Dr. Veith uses a per-protocol analysis based on the IMPROVE data to justify his viewpoint that emergency EVAR for ruptures saves lives. However, the two groups he selects are no longer comparable, and there will be many confounders, which have not been considered. Important among these confounders is aortic morphology. Those with short aneurysm necks, who are unsuitable for EVAR, have a very high operative mortality rate with open repair, whereas those with long aneurysm necks have a low mortality rate with open repair, as confirmed in the AJAX and ECAR trials.[2]

In both the United States and Europe, the majority of ruptures remain treated with open repair. Some centers do not provide emergency EVAR or do not provide it every day. The findings of the IMPROVE trial suggest that emergency EVAR should be more widely available (even though this may not save a significant number of lives), and this is a key point on which Dr. Veith and the IMPROVE trial investigators would surely agree.

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We do not need a rebuttal in this debate. The detailed data from all the trials, as we have presented them, speak for themselves. Any reasonable person would have to agree with our conclusion on this topic that "EVAR is a better treatment than open repair for rAAAs, if EVAR can be performed." We acknowledge that the ability to perform EVAR may vary from locale to locale and from institution to institution. However, if our conclusion is accepted, it will promote wider use of EVAR and the adjuncts that will facilitate it.[1,2] This in turn will result in improved patient survival with rAAAs, which should be the goal of all who treat this challenging entity. ■

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