

Endovascular and open repair did not differ for mortality rates at 2 years in abdominal aortic aneurysm

Blankensteijn JD, de Jong SE, Prinssen M, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med.* 2005;352:2398-405.

Clinical impact ratings: Hospitalists ★★★★★☆ Critical Care ★★★★★☆☆

QUESTION

In patients with abdominal aortic aneurysm, how does elective endovascular repair compare with conventional open repair?

METHODS

Design: Randomized controlled trial (Dutch Randomized Endovascular Aneurysm Management [DREAM] Trial).

Allocation: Concealed.*

Blinding: Blinded (outcome assessors and {data safety and monitoring committee}†).*

Follow-up period: 2 years.

Setting: Surgery clinics at 26 centers in the Netherlands and 4 centers in Belgium.

Patients: 351 patients (mean age 70 y, 92% men) with abdominal aortic aneurysm ≥ 5 cm in diameter who were suitable candidates for both endovascular and open repair.

Intervention: Endovascular repair {after having done at least 5 procedures}‡ (n = 173) or conventional open repair {at the discretion of the operating surgeon}‡ (n = 178).

Outcomes: All-cause mortality, cardiovascular-related mortality, aneurysm-related noncardiovascular mortality, and survival free of moderate or severe complications.

Patient follow-up: 95% (intention-to-treat analysis).

MAIN RESULTS

Endovascular and open repair did not differ for rates of all-cause mortality, cardiovascular-related mortality, or aneurysm-related noncardiovascular mortality (Table), or for the rate of survival free of moderate or severe complications.

CONCLUSION

In patients with abdominal aortic aneurysm, elective endovascular repair and conventional open repair did not differ for rates of all-cause

mortality, cardiovascular-related mortality, or aneurysm-related noncardiovascular mortality at 2 years.

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*See Glossary.

†Information provided by author.

‡Prinssen M, Verhoeven EL, Buth J, et al. *N Engl J Med.* 2004;351:1607-18.

Endovascular vs open repair in abdominal aortic aneurysm at 2 years[§]

Outcomes	Endovascular repair	Open repair	RRI (95% CI)	NNH
All-cause mortality	12%	10%	14% (-37 to 107)	Not significant
Cardiovascular-related mortality	4.0%	2.8%	44% (-51 to 323)	Not significant
			RRR (CI)	NNT
Aneurysm-related noncardiovascular mortality	1.2%	4.5%	74% (-5 to 94)	Not significant

[§]Abbreviations defined in Glossary; RRI, RRR, NNH, NNT, and CI calculated from data in article.

COMMENTARY

Current randomized trials of endovascular aneurysm repair (EVAR) have left many questions unanswered because of sample size, selection of surgeons, appropriateness of outcomes, and analysis.

The DREAM trial had a sample size of 351 patients and only 45% power to detect a patient-important absolute risk difference of 3% in perioperative mortality. In addition, DREAM is a trial with a low event rate in which 19 patients were lost to follow-up (5%), and 4 patients with undetermined deaths may have had an effect on the overall results.

Surgeons were allowed to participate if they had done ≥ 5 EVARs. Cumulative sum failure analysis shows that at a minimum, 60 EVARs, or 20 with an individual device, are necessary before optimal rates of clinical success can be achieved (1). Does the reintervention rate in the first 9 months for the EVAR group reflect avoidable technical problems? Would greater experience with EVAR of the participating surgeons affect outcome? An expertise-based, randomized, controlled trial (2) would probably have avoided differential expertise bias, minimized the influence of unblinding, and minimized crossovers.

Such utility outcomes as quality-adjusted life-years (QALYs), which aggregate the length of survival with aspects of quality of life associated

with the outcome, could have provided useful information regarding the comparison of the 2 interventions. QALYs, together with attitudes toward risk and length of life, could help patients choose between EVAR and open repair.

Although initial trials seemed encouraging for EVAR, all of them—including this one—have substantial design and sample size limitations. These results provide the impetus for a large expertise-based trial to determine the true short- and long-term effects of EVAR compared with open repair. Surgeons and patients will remain uncertain about the appropriateness of these 2 interventions until such research is done.

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References

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