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Use of Non-randomised Evidence Alongside Randomised Trials in a Systematic Review of Endovascular Aneurysm Repair: Strengths and Limitations

Chambers Duncan, Fayter Debra, Paton Fiona, Woolacott Nerys Eur J Vasc Endovasc Surg 2010;39:26-34.

Objective: To assess whether limitations of randomised controlled trials (RCTs) of endovascular aneurysm repair (EVAR) can be addressed by evidence from non-randomised studies.

Design: Analysis of data from a systematic review.

Methods: We conducted a review of EVAR versus open repair or non-surgical management of abdominal aortic aneurysms. In addition to RCTs, we included pre-specified registries of EVAR and open repair.

Results: The six included RCTs randomised patients in 2003 and earlier. Of the three registries included, one contributed data on a large (>8000) sample of patients treated with newer generation EVAR devices and followed up for up to 8 years. However, treatment dates of these patients overlapped with those of the RCTs. The other registries were of limited usefulness. A large (>45,000) controlled observational study published while the review was in progress broadly supported the findings of RCTs comparing EVAR with open surgery. A comparison of outcomes across all studies did not support the hypothesis that the findings of the RCTs are no longer representative of clinical practice.

Conclusions: Both randomised and non-randomised sources of evidence have strengths and weaknesses for assessing the effectiveness of EVAR. Further research should explore the optimum use of registry data, including patient-level analyses.

Intra-aneurysm Sac Pressure in Patients with Unchanged AAA Diameter after EVAR

Dias N.V., Ivancev K., Kölbel T., Resch T., Malina M., Sonesson B. Eur J Vasc Endovasc Surg 2010;39:35-41.

Objective: To study intra-aneurysm sac pressure and subsequent abdominal aortic aneurysm (AAA) diameter changes in patients without endoleaks that remain unchanged in AAA diameter more than 1 year after endovascular aneurysm repair (EVAR).

Methods: A total of 23 patients underwent direct intra-aneurysm sac pressure (DISP) measurements 16 months (IQR: 14–35 months) after EVAR. Tip-pressure sensors were used through translumbar AAA puncture. Mean pressure index (MPI) was calculated as the percentage of mean intra-aneurysm pressure relative to the simultaneous mean intra-aortic pressure. Aneurysm expansion or shrinkage was assumed whenever the diameter change was ≥ 5 mm. Values are presented as median and interquartile range.

Results: In 18 patients, no fluid was obtained upon AAA puncture (group A). In five patients, fluid was obtained (group B). In group A, follow-up continued for 29 months (IQR: 15–35 months) after DISP; five AAAs shrank, 10 remained unchanged and three expanded (MPIs of 26% (IQR: 18–42%), 28% (IQR: 20–48%) and 63% (IQR: 47–83%) and intra-sac pulse pressures of 3 mmHg (IQR: 0–5 mmHg), 4 mmHg (IQR: 2–8 mm Hg) and 12 mmHg (IQR: 6–20 mmHg), respectively, for the three subgroups). MPI and intra-sac pulse pressures were higher in AAAs that subsequently expanded ($P = 0.073$ and 0.017, respectively). MPI and pulse pressure correlated with total diameter change ($r = 0.49$, $P = 0.039$ and $r = 0.39$, $P = 0.109$, respectively). Pulse pressure had a greater influence than MPI on diameter change ($R^2 = 0.346$, $P = 0.041$, beta standardised coefficient of 0.121 for MPI and 0.502 for pulse pressure). Similar results with stronger, and significant correlation to pulse pressure were obtained when relative diameter changes were used ($r = 0.55$, $P = 0.017$). In group B, MPI and AAA pulse pressure were 32% (IQR: 18–37%) and 1 mmHg (IQR: 0–6 mmHg), respectively. After 36 months (IQR: 21–38 months), one AAA shrank, three continued unchanged while one expanded.

Conclusions: AAAs without endoleak and unchanged diameter more than 1 year after EVAR will often continue unchanged. Expansion can eventually occur in the absence of intra-sac fluid accumulation and is associated with higher and more pulsatile intra-sac pressure. However, in patients with intra-sac fluid, expansion can occur with low intra-sac pressures.

Re-interventions, Readmissions and Discharge Destination: Modern Metrics for the Assessment of the Quality of Care

Holt P.J.E., Poloniecki J.D., Hofman D., Hinchliffe R.J., Loftus I.M., Thompson M.M. Eur J Vasc Endovasc Surg 2010;39:49-54.

Aim: To determine whether administrative data can be used to determine metrics to inform the quality agenda. To determine the relationship between these metrics and the method of abdominal aortic aneurysm (AAA) repair undertaken.

Methods: The Hospital Episode Statistics (HES) data were taken for a 5-year period (01.04.2003–31.03.2008). Cases of elective AAA repair were identified. Outcomes were determined in terms of mortality, discharge destination, re-intervention rates and emergency readmission rates. The results were interpreted in light of whether AAA repair was open or endovascular and whether patients were octogenarians or younger patients.

Results: There were 18,060 elective AAA repairs with a mean in-hospital mortality rate of 5.9%. Of these 14,141 were open repairs with a mean mortality of 6.5% and 3919 EVAR (22%) with a mean mortality of 3.8%. EVAR patients were less likely to be discharged to ongoing care ($p < 0.001$) but were associated with a higher rate of re-intervention ($p = 0.001$) than open repairs. No differences were seen in one-year readmission rates.

Octogenarians were more likely to undergo EVAR ($p = 0.001$), to be readmitted within 30-days ($p = 0.009$), to require further interventions on their index admission ($p < 0.001$) and less likely to be discharged home ($p < 0.001$) than younger patients.

Conclusion: Administrative data can be used to identify metrics other than mortality and length of stay. These metrics might be used to inform service provision. In particular for AAA repair, differences in these outcomes were identified between open repair and EVAR and between octogenarians and younger patients.

Patient Preference for Surgical Method of Abdominal Aortic Aneurysm Repair: Postal Survey

Reise J.A., Sheldon H., Earnshaw J., Naylor A.R., Dick F., Powell J.T., Greenhalgh R.M. Eur J Vasc Endovasc Surg 2010;39:55-61.

Objectives: To determine whether men with small abdominal aortic aneurysm have a preference between either endovascular or open aneurysm repair for future treatment.

Design: Prospective study of self-declared treatment preference following receipt of a validated patient information pack.

Participants: Men aged 65–84 years ($n = 237$) with asymptomatic aneurysm (4.0–5.4 cm) detected by population-based screening.

Methods: An unbiased, validated patient information pack and questionnaire were developed to conduct a postal survey.

Results: One hundred sixty seven participants (70%) returned a completed questionnaire; 24 (10%) did not respond at all. Initially, only 38 (23%) declared a treatment preference. After reading the information pack, 130 participants (80%) declared a treatment preference: 30 preferred open repair (18%), 77 endovascular repair (46%), 23 were happy with either option (14%) and only 34 remained without any preference (20%). Nearly all (92%) thought that the information pack had prepared them well for future discussions with clinicians and with no single feature identified as influencing the preference-making process, 66 respondents (40%) still opted to "take the advice of the doctor".

Conclusion: The patient information pack facilitated the development of treatment preferences with endovascular repair being preferred to open repair. Nevertheless for patient-centred care, vascular centres must continue to safely provide both open and endovascular repair.

Asymptomatic Low Ankle-Brachial Index in Vascular Surgery Patients: A Predictor of Perioperative Myocardial Damage

Flu W.-J., van Kuijk J.-P., Voûte M.T., Kuiper R., Verhagen H.J.M., Bax J.J., Poldermans D. Eur J Vasc Endovasc Surg 2010;39:62-9.

Objectives: This study evaluated the prognostic value of asymptomatic low ankle-brachial index (ABI) to predict perioperative myocardial damage, incremental to conventional cardiac risk factors imbedded in cardiac risk indices (Revised Cardiac index and Adapted Lee index).

Materials and methods: Preoperative ABI measurements were performed in 627 consecutive vascular surgery patients (carotid artery or abdominal aortic aneurysm repair). An ABI < 0.90 was considered abnor-