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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-

mal. Patients with ABI > 1.40 or (a history of) intermittent claudication were excluded. Serial troponin-T measurements were performed routinely before and after surgery. The main study endpoint was perioperative myocardial damage, the composite of myocardial ischaemia and infarction. Multivariate regression analyses, adjusted for conventional risk factors, evaluated the relation between asymptomatic low ABI and perioperative myocardial damage.

Results: In total, 148 (23%) patients had asymptomatic low ABI (mean 0.73, standard deviation ± 0.13). Perioperative myocardial damage was recorded in 107 (18%) patients. Multivariate regression analyses demonstrated that asymptomatic low ABI was associated with an increased risk of perioperative myocardial damage (odds ratio (OR): 2.4, 95% CI: 1.4–4.2)

Conclusions: This study demonstrated that asymptomatic low ABI has a prognostic value to predict perioperative myocardial damage in vascular surgery patients, incremental to risk factors imbedded in conventional cardiac risk indices.

A Systematic Review of Implementation of Established Recommended Secondary Prevention Measures in Patients with PAOD

Flu H.C., Tamsma J.T., Lindeman J.H.N., Hamming J.F., Lardenoye J.H.P. Eur J Vasc Endovasc Surg 2010;39:70-86.

Objective: Since patients with peripheral arterial occlusive disease (PAOD) are at high-risk for cardiovascular morbidity and mortality, preventive measures aimed to reduce cardiovascular adverse events are advocated in the current guidelines. We conducted a systematic review to assess the implementation of secondary prevention (SP) measures in PAOD patients.

Methods: PubMed, Cochrane Library, EMBASE and Web of Science databases were searched to perform a systematic review of the literature from 1999 till June 2008 on SP for PAOD patients. Assessment of study quality was done following the Cochrane Library review system. The record outcomes were antiplatelet agents, heart rate lowering agents, blood pressure lowering agents, lipid lowering agents, glucose lowering agents, smoking cessation and walking exercise.

Results: From a total of 2137 identified studies, 83 observational studies met the inclusion criteria, of which 24 were included in the systematic review comprising 34 157 patients. These patients suffered from coronary artery disease (n = 3516, 41%), myocardial infraction (n = 2647, 38%), angina pectoris (n = 1790, 31%), congestive heart failure (n = 2052, 14%), diabetes mellitus (n = 10 690, 31%),hypertension (n = 20 823, 73%) and hyperlipidaemia (n = 15 067, 64%). Contrary to what the guidelines prescribe, antiplatelet agents, heart rate lowering agents, blood pressure lowering agents and lipid lowering agents were prescribed in 63%, 34%, 46% and 45% of the patients, respectively. Glucose lowering agents were prescribed in 81% and smoking cessation in 39% of the patients.

Conclusion: The majority of patients suffering from PAOD do not receive the entire approach of SP measures as suggested by the current guidelines. To our knowledge, the cause of this undertreatment is multifactorial: patient, physician or health-care-related.

Endovenous Laser Ablation (980 nm) of the Small Saphenous Vein in a Series of 147 Limbs with a 3-Year Follow-up

Desmyttère J., Grard C., Stalnikiewicz G., Wassmer B., Mordon S. Eur J Vasc Endovasc Surg 2010;39:99-103.

Aim: This study aims to demonstrate the treatment outcomes of endovenous laser ablation (EVLA) of incompetent small saphenous veins (SSVs) with a 980-nm diode laser.

Materials and methods: Between 1 June 2003 and 30 June 2006, 128 patients (147 limbs) with varicose veins and reflux in the SSV on duplex ultrasound (US) examination were treated with a 980-nm diode laser under US guidance. EVLA was performed using pulsed mode with a power of 10 W. The pulse duration (1.5–3 s) was chosen to deliver a linear endovenous energy density (LEED) depending on the SSV diameter measured 1.5 cm below the sapheno-popliteal junction (SPJ) with the patient standing. For SSV diameters between 2 and 4.5 mm, the LEED applied was 50 J cm^{-1}. The LEED was 70 J cm^{-1} for 4.5–7 mm, 90 J cm^{-1} for 7–10 mm. Patients were evaluated at 1-week, 1-month, 1-year, 2-year and 3-year follow-up.

Results: The initial technical success rate was 100% in 147 patients. The SSV remained closed in 114 of 117 limbs (97%) after 1 year, all of 61 limbs after 2 years and all of 30 limbs after 3 years. For the three SSVs where re-canalisation was observed, the diameter was greater than 9 mm. Major complications have not been detected and, in particular, there was no deep venous thrombosis (DVT). Ecchymoses were seen in 60% with a median duration of 2 weeks. Temporary paraesthesia (mostly hypoaesthesia) was observed in 40% of treated legs with a median duration of 2 weeks. The maximum duration did not exceed 4 weeks. No skin discolouration, superficial burn, thrombophlebitis or palpable induration was observed.

Conclusion: EVLA of the incompetent SSV with a 980-nm diode laser appears to be an extremely safe technique. After successful treatment, there is a very low rate of re-canalisation of the SSV. Obliteration of the SSV was confirmed at 1-, 2- and 3-year follow-up; this study suggests that this procedure will provide a lasting result.

Radiofrequency Ablation vs Conventional Surgery for Varicose Veins – a Comparison of Treatment Costs in a Randomised Trial

Subramonia S., Lees T. Eur J Vasc Endovasc Surg 2010;39:104-11.

Objective: To compare the costs involved (from procedure to recovery) following radiofrequency ablation and conventional surgery for lower limb varicose veins in a selected population.

Design: Prospective randomised controlled trial.

Methods Patients with symptomatic great saphenous varicose veins suitable for radiofrequency ablation were randomised to either RF ablation or surgery (sapheno-femoral ligation and stripping). The hospital, general practice and patient costs incurred until full recovery and the indirect cost to society, due to sickness leave after surgery, were calculated to indicate mean cost per patient under each category.

Results: Ninety three patients were randomised. Eighty eight patients (47 – RF ablation, 41 – surgery) underwent the allocated intervention. Ablation took longer to perform than surgery (mean 76.8 vs 47.0 min, $p < .001$). Ablation was more expensive (mean hospital cost per patient £1275.90 vs £559.13) but enabled patients to return to work 1 week earlier than after surgery (mean 12.2 vs 19.8 days, $p = 0.006$). Based on the Annual Survey of Hours and Earnings (Office of National Statistics, UK) for full time employees, the cost per working hour gained after ablation was £6.94 (95% CI 6.26, 7.62).

Conclusion: The increased cost of radiofrequency ablation is partly offset by a quicker return to work in the employed group (ISRCTN29015169http://www.controlled-trials.com).