CRD summary
The review concluded that P-EVAR appeared safe and effective in selected patients. Local access-related complications were low. Further work was needed to identify the most suitable candidates for P-EVAR. Limitations in the included studies and reported review processes and pooling of studies mean that the authors' conclusions should be treated with caution.

Authors' objectives
To evaluate the evidence to support the use of percutaneous endovascular aortic aneurysm repair (P-EVAR) over standard aortic stent-graft delivery through open arterial exposure in the groin.

Searching
MEDLINE and EMBASE were searched for articles published in English from January 1991 to July 2009; search terms were reported.

Study selection
Prospective and retrospective studies and those with a control group (standard open groin exposure) were eligible for inclusion in the review. Primary outcome was success rate or percutaneous closure (defined as closure of the common femoral artery without the need of open surgical dissection). Secondary outcomes included: operative duration, hospital stay, time to ambulation, blood loss, cost and late loco-regional complications (defined as any event that led to delayed healing, additional intervention or follow-up). Case reports were excluded.

The one included RCT compared P-EVAR with standard open femoral access. Individuals with thoracic aortic pathology were included in eight studies. Exclusion criteria varied across studies; the most common exclusion criteria were heavy femoral artery calcification, scarred groins and patients with femoral artery aneurysms. Most studies used Prostar XL; two studies used ProGlide. Sheath size ranged from 14F to greater than 20F.

The authors did not state how many reviewers performed the study selection.

Assessment of study quality
The authors did not state that they formally assessed the internal validity of the included studies. Aspects of methodological quality were discussed in the text.

Data extraction
Two reviewers independently extracted means for calculation of success of percutaneous closure and complication rates (percentages). Data that enabled calculation of relative risks were extracted.

Methods of synthesis
Data was pooled after significant heterogeneity was excluded. Pooled estimates were reported as weighted means and relative risks (RR) along with 95% confidence intervals (CI); the authors did not describe the methods used. Success rates and complication rates were analysed using Fisher's exact test (p<0.05 was considered significant). Between-study heterogeneity was assessed using the $\chi^2$ test.

The authors considered a number of factors that might have influenced the outcomes (patient and device selection, sheath size, scarred groins, obesity, access-related complication rate, hospital stay, operative time, blood loss, time to ambulation and cost).

Results of the review
Twenty-two studies were included in the review (n=1,270 patients, range seven to 292): one randomised controlled trial
(RCT), 10 prospective non-randomised studies and 11 retrospective non-randomised studies. One retrospective study (n=183) was excluded from the pooled analyses due to the possibility of an overlap in population with another study.

Overall success rate of percutaneous closure was 92% (95% CI 90.1 to 93.9) with a range of 65% to 100%. Success rate for totally percutaneous closure (where percutaneous closure was attempted and successful without open dissection in either groin) was 79% (95% CI 74.9 to 83.1; 13 studies).

A significantly better success rate with ProGlide (93.7%, 95% CI 91.5 to 95.9; three studies) was found compared with Prostar (90%, 95% CI 88.4 to 91.6; 19 studies). No significant difference was found in success rate between studies that considered all comers and those that excluded patients with femoral artery calcification and groin scarring. Three studies reported a significant difference in success rate with increasing sheath size. Failure was attributed to patients with scarred groins in one study; another study found no association between success rate and previous catheterisation. One prospective study found a significant association with failure and obesity and another demonstrated no correlation of failure to obesity.

Wound complication rates ranged from 2% to 26% and the overall access-related complication rate was 4.4% (95% CI 3.5 to 5.3). P-EVAR was associated with fewer access-related complications compared with patients who underwent standard open groin arterial exposure (RR 0.47, 95% CI 0.28 to 0.78; seven studies); the authors reported that no significant statistical heterogeneity was found. Three studies (one RCT and two retrospective studies) found an increase in access-related complication rate in P-EVAR with sheath size. One retrospective study demonstrated a significant association of complications with large sheath size and obesity.

Mean hospital stay was 2.07 days (seven studies). Hospital stay was shorter in patients who underwent P-EVAR compared with EVAR (weighted mean 2.7 versus 3.5 days; three studies), although only one prospective study found a statistically significant difference.

P-EVAR was associated with significantly less operative time than open groin exposure (weighted mean 106 versus 145 minutes); operative time was reported to be significantly shorter in five of the eight studies.

The RCT found no significant between group differences (P-EVAR, open EVAR and failed P-EVAR) in blood loss. Two prospective studies reported similar blood loss between P-EVAR and open EVAR, but greater blood loss with failed P-EVAR. One other prospective study found significantly less blood loss with P-EVAR compared with open EVAR.

One RCT and one prospective study found ambulation time was shorter with P-EVAR compared with open EVAR. One retrospective study reported ambulation in 81% of patients four to six hours following P-EVAR.

Cost information

The RCT found that P-EVAR average procedure cost €99 more than open EVAR. One non-randomised prospective study reported less cost associated with P-EVAR, but this was not statistically significant. One retrospective study found an overall increase in procedural cost for P-EVAR despite shorter operative time due to cost of closure devices (US $295 per device). No study investigated effect of reduced hospital stay on overall cost.

Authors’ conclusions

P-EVAR appeared safe and effective in selected patients and local access-related complications were low. Further work is needed to identify the most suitable candidates for P-EVAR.

CRD commentary

The review question was supported by clear inclusion criteria in terms of study design and outcomes, but not with regard to participants and intervention. Only two electronic databases were searched. The search was restricted by language and no attempt was made to locate unpublished studies, which raised the possibility of publication bias. Appropriate steps were taken to minimise the likelihood of reviewer error and bias in data extraction; whether similar methods were used during study selection was unclear. Methodological quality of the included studies was not formally assessed, which made it difficult to assess the reliability of these results. Limited study data was presented and there was some discrepancy in the text as to how many studies contributed to some of the results reported. It was unclear how
studies were pooled. As a consequence of these considerations, the authors' conclusions should be treated with caution.

Implications of the review for practice and research

Practice: The authors stated that adoption of adjuncts such as intraoperative ultrasound guided puncture to reduce P-EVAR access rate complications should be routine practice, particularly in the initial learning curve where failure and complications were reported more often.

Research: The authors stated that an RCT that included data on overall cost effectiveness as well as outcome data was required to help define the role of P-EVAR in the management of abdominal aortic aneurysms.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.