Total percutaneous access for endovascular aortic aneurysm repair ("Preclose" technique)


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study examined the clinical and economic impact of percutaneous access using the Preclose technique with the Proglide device, versus open surgical femoral exposure for endovascular aneurysm repair. The percutaneous access was safe and feasible, especially for smaller sheath sizes. The reduction in operating room costs was, however, offset by the cost of the device. The authors' conclusions should be considered with a degree of caution, given the limitations of the study.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to examine the clinical and economic impact of wholly percutaneous access using the Preclose technique with the Proglide device, compared with open surgical femoral exposure, for endovascular aneurysm repair (EVAR) and thoracic EVAR (TEVAR).

Interventions
The Preclose technique with the Proglide device was compared with conventional open surgery. The Preclose technique was the deployment of two Proglide devices, before inserting the sheath, with the sutures left outside the body for closure after the procedure.

Location/setting
USA/hospital.

Methods
Analytical approach:
This economic evaluation was based on a single study. The time horizon of the analysis was restricted to the length of hospital stay or to 30 days post-operatively. The authors did not explicitly state the perspective of their study.

Effectiveness data:
The clinical data were derived from the retrospective review of medical records of patients who underwent EVAR and TEVAR at a single tertiary care centre. Two contemporary cohorts of 183 consecutive patients (114 EVAR and 69 TEVAR) in the Preclose group and 154 consecutive patients (108 EVAR and 46 TEVAR) in the open group were compared. The decision on which method of femoral access to use depended on anatomical factors and surgeon preference. There were no statistically significant differences between the two groups in their baseline clinical characteristics. The patients were followed-up for up to 30 days post-operatively. The key clinical endpoint was the success rate (see the definition in 'Measure of Benefit') at 30 days.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The health outcomes were not combined and no summary benefit measure was used. The primary clinical endpoint was the success rate. For the Preclose group, this was defined as the closure of the arteriotomy without the need for additional surgical or endovascular procedures, stemming from haemorrhage, infections, or ischaemic complications, related to the access site. For the open procedure, success was defined as a primary suture repair of the arteriotomy.
without the need for additional local reconstruction such as endarterectomy, patch angioplasty, or interposition grafting.

Cost data:
The economic analysis considered the cost of the device and the operating room (OR) stay. These costs were derived from the authors’ institution. The resource use data came from the sample of patients included in the effectiveness study. All costs were in US dollars ($) and the price year was not reported.

Analysis of uncertainty:
The issue of uncertainty was not addressed.

Results
The overall success rate was 94.3% with Preclose and 93.8% with open surgery (p=0.86). In the Preclose group, smaller sheaths were more successful than larger sheaths (99% for 12F to 16F compared with 91.4% for 18F to 24F, p<0.01).

The number of complications was 16 in both groups. The all-cause mortality was 2.2% with Preclose and 1.3% (p=0.69) with open surgery, but access-related mortality was 0% in both groups.

Procedure times were shorter in the Preclose group resulting in statistically significantly lower OR costs for Preclose patients. However, when including the cost of the device, total costs were $7,881 with Preclose and $7,351 with open surgery for EVAR; and $5,679 with Preclose and $6,556 with open surgery for TEVAR. It was not stated whether these differences were statistically significant.

Authors’ conclusions
The authors concluded that percutaneous access for EVAR was safe and feasible using the Preclose technique with the Proglide device, especially for smaller sheath sizes. Savings from the reduction in operating room costs were offset by the cost of the closure device.

CRD commentary
Interventions:
The selection of the comparators was appropriate and the two procedures were extensively described.

Effectiveness/benefits:
The source study was limited mainly due to its retrospective analysis of an administrative database. Furthermore, the allocation of patients to study groups was based on surgeons’ preferences, which may have affected the validity of the comparison. The groups appear to have been comparable at baseline, but the potential impact of confounding factors was not investigated. No formal justification for the sample size was given. Moreover, the study was based on several subgroup analyses, which reduced the power of the study to detect statistically significant differences between the two procedures. These issues should be considered when assessing the validity of the analysis.

Costs:
The perspective was not explicitly stated, but appears to have been that of the authors’ institution, given the types of costs included and the data source. In general, the cost analysis was not extensively described. It was unclear whether the costs represented charges for the hospital or the true costs of the services. The price year was not reported, which limits the possibility of carrying out reflation exercises in other time periods. Standard tests were used to determine the statistical significance of the cost differences.

Analysis and results:
The findings were clearly presented and discussed. A synthesis of the costs and benefits was not performed. The issue of uncertainty was not investigated. These issues tend to limit the validity of the study.

Concluding remarks:
There were a few limitations to this study, and the authors’ conclusions should therefore be considered with a degree of caution.
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