Endovascular, transperitoneal, and retroperitoneal abdominal aortic aneurysm repair: results and costs

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.

Health technology
Endovascular (EV) repair of infrarenal abdominal aortic aneurysms (AAAs). Imaging modalities were used to determine precise aneurysm and aortic measurements in all patients who underwent EV repair. A transfemoral approach, either unilateral or bilateral, depending on the graft configuration (tube versus bifurcated versus aortoiliac with femorofemoral bypass graft) was employed to conduct the EV procedure. The grafts were manufactured by EndoVascular Technologies (Menlo Park, California) and consisted of a Dacorn material with attachment systems proximally and distally.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients who were candidates for endovascular repair of infrarenal AAAs. Patients requiring additional procedures at the time of aneurysm repair or those who did not fulfil physiologic inclusion criteria for endovascular repair (Food and Drug Administration protocol, American Anaesthesia Association class I to IV, life expectancy longer than 2 years), or those who met the exclusion criteria (ruptured aneurysm, active infection, weight of more than 350 pounds, transplant patients, bleeding diathesis, or aneurysm etiology other than atherosclerosis) were excluded from the analysis.

Setting
Hospital. The economic study was carried out in Los Angeles, USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients treated between February 1993 and August 1997. The price year was not explicitly specified.

Source of effectiveness data
The evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same study sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 125 patients with AAAs who underwent either open or EV repairs: 61 in the EV group, 24 in the RP group, and 40 in the TA group. The age distribution of patients was not reported. The distribution of patients in the EV group in terms of type of endovascular procedure was as follows: 30 had tube endografts, 24 bifurcated endovascular grafts, and 7 underwent aortouniiliac and femorofemoral reconstruction.

**Study design**
This was a retrospective cohort study, carried out in a single centre. The duration of the follow-up was 30 days after the operation or until hospital discharge. Loss to follow-up was not reported.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was intention to treat. The clinical outcomes were operative factors (total operating time, total blood loss, and any intraoperative complications requiring a change in operative plan), postoperative morbidity occurring within the first 30 days or before hospital discharge (pneumonia, postoperative bleeding, myocardial infarction, renal failure, graft thrombosis, respiratory failure, and wound complications), and mortality (defined as death occurring within 30 days of the procedure or during the same hospital admission). The patient groups were comparable in terms of preoperative risk factors except for hyperlipidemia, which was significantly higher in the RP group. The most frequent anatomic reasons for excluding patients from the EV group were the absence of a proximal neck, presence of significant iliac aneurysmal disease, and occlusive disease.

**Effectiveness results**
The EV group had a mean (SD) operating time of 283 (92) minutes versus 296 (115) for the RP group and 298 (122) for the TA groups, (NS). The operating time was significantly longer for the subgroup of EV patients who underwent aortouniiliac and femorofemoral repair (372 mins.) compared with those who had the EV tube or bifurcated repairs. The mean blood loss for the three study groups was 300 mL (range: 100 - 1300 mL) for the EV group, 700 mL (range: 200 - 3000 mL) for the RP group, and 786 mL (range: 150 - 3000 mL) for the TA group. The difference between the TA and RP groups was not significant while the EV group had a significantly lower estimated blood loss, (p<0.05). Six cases of perigraft leaks which were persistent at 30 days (9.6%) were observed in the EV group. The EV group also had six cases (9.6%) of conversions to surgical repair. The percentage of cases of respiratory failure was 0% in the EV group versus 4.2% in the RP group and 12.5% in the TA group (statistically significantly higher in the TA group, p<0.05). The percentage of cases of respiratory failure was 0% in the EV group, 12.5% in the RP group, and 2.5% in the TA group (TA versus RP versus EV, p<0.05). The corresponding values for incidence of arrhythmias were 0% for the EV group, 12.5% for the RP group, and 10% for the TA group, (TA and RP versus EV, p<0.05). The three groups were similar in terms of all other postoperative (30-day) morbidity. The EV group had a 30-day mortality rate of 0% versus 4.2% for the RP group and 2.5% for the TA group, (p>0.3).

**Clinical conclusions**
The mortality rate in these series was not significantly different across the TA, PR, and EV approaches. EV AAA repair significantly shortens hospital stay and ICU use and has a lower morbidity rate.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

**Direct costs**
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs in terms of operating time and hospital stay. Cost components were reported separately. The cost analysis covered the costs of the procedures (including operating room, supplies, pharmacy, radiology, respiratory service, and clinical laboratories) and hospital stay, including complications. The perspective adopted in the cost analysis was not explicitly...
specified. The costs associated with the EV device were included in supplies. A conversion factor was used to normalise cost figures in order to maintain institutional confidentiality. Actual costs were used as opposed to charges or reimbursement. The source of cost data was the confidential computerised system used in a hospital to track cost items. Cost analysis was performed based on the intention to treat principle. The date of the price data was not explicitly specified. The cost analysis did not cover the costs of preoperative evaluations either because of lack of availability of the relevant data or to avoid bias against the EV approach. It was reasoned that the minimum necessary studies for EV repair remains to be established.

**Statistical analysis of costs**
Statistical analysis was performed on cost components and total costs. However, the types of statistical tests performed were not reported.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($) normalised in the cost analysis to monetary units (1,000 units equalled the cost per patient of the cheapest intervention).

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total (SD) normalised cost associated with the EV approach was 1000 (480.1) versus 1176.3 (466.3) for the RP group and 1469 (689.8) for the TA group, (EV versus TA, p<0.0003; EV versus RP, p>0.1; RP versus TA, p<0.05). The operating room costs were similar across the three study groups. In the subgroup of the EV patients who underwent aortouniiliac/femorofemoral repairs, the cost factor was significantly higher (1604) than the corresponding value for the entire group.

**Synthesis of costs and benefits**
Costs and benefits were not combined. The EV and RP approaches were statistically equivalent in effectiveness and (total) cost outcomes except for the incidence of wound complications and arrhythmias.

**Authors' conclusions**
The authors concluded that transabdominal repair is associated with a higher incidence of respiratory failure and overall cost when compared with the RP or EV approaches. EV AAA repair significantly shortens hospital stay and ICU use and has a lower morbidity rate. Cost savings in the length of stay for the EV group are significantly reduced by the increased cost of supplies and radiology, which accounts for the similar cost between EV repair and RP repair. Considering the increased resource use during follow-up for patients undergoing EV aneurysm repair, the difference in cost between the TA approach and the EV approach may be insignificant.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator (use of TA or RP). Both alternatives were the conventional
methods in the context in question. You, as a database user, should consider whether these are widely used health
technologies in your own setting.

**Validity of estimate of measure of effectiveness**

As the authors acknowledged, the internal validity of the effectiveness results can not be reasonably guaranteed given
the retrospective nature of the study design and the relatively small sample size. The study groups were found to be
comparable in terms of preoperative risk factors, except for hyperlipidemia, which was significantly higher in the RP
group. The surgical group and the EV group were different in terms of anatomic features. It is not clear whether the
study sample was representative of the study population given the fact that the study patients were also participants in a
strictly monitored, Food and Drug Administration-approved protocol.

**Validity of estimate of measure of benefit**

The authors did not derive a measure of health benefit. The economic analysis was therefore a cost-consequences
design.

**Validity of estimate of costs**

Some quantities (operating room and hospital stay) were reported separately from the costs. Adequate details of the
methods of cost estimation were given. The exclusion of the costs of preoperation evaluations may have adversely
affected the internal validity of the cost results. Statistical analysis was performed on some components of the resource
use data and cost data. The price year was not specified. The potential impacts of the EV approach on indirect costs
(lost productivity) were not investigated.

**Other issues**

In view of the retrospective nature of the study design and its small sample size and lack of sensitivity analysis, some
degree of caution may need to be exercised in the interpretation of the study results, as acknowledged by the authors.
The issue of generalisability to other settings or countries was not addressed. Some comparisons were made with other
studies. The study sample consisted of patients who were participants in a strictly monitored Food and Drug
Administration-approved protocol, and this seems to be reflected in the authors' comments. The age distribution of the
study patients was not reported. Costs and benefits could be synthesised by performing cost-effectiveness analysis,
which would involve selecting a single benefit measure. The authors conjectured that differences in surgical skills may
have introduced bias into the results since the TA approach was distributed among the institution's surgeons while the
RP approach was performed mostly by one surgeon. However, it was reported that no differences were noted in the
results of the TA group by the study team, suggesting comparability in surgical skill. It was acknowledged that the EV
group in this study represented the experience with one particular device (EndoVascular Technologies, Menlo Park,
Calif), which may or may not be comparable with other devices under investigations.

**Implications of the study**

The eventual long-term outcome and cost of care of patients in the EV group awaits further analysis, which was in
progress at the time of the study. EV AAA repair is unlikely to save money for the health care system and its use is
likely to be driven by patient and physician preference, because of a significant decrease in morbidity rate and length of
hospital stay.

**Source of funding**

None stated.

**Bibliographic details**

Quinones-Baldrich W J, Garner C, Caswell D, Ahn S S, Gelabert H A, Machleder H I, Moore W S. Endovascular,