Amplatzer Vascular Plug to occlude the internal iliac arteries in patients undergoing aortoiliac aneurysm repair

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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
The study examined the use of the Amplatzer Vascular Plug (AVP) to occlude the internal iliac artery (IIA) in patients undergoing aortoiliac and/or common iliac aneurysm endograft repair. The diameter of the AVP was chosen to be approximately 30 to 50% greater than that of the blood vessel. This device was compared with the use of traditional coils.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients requiring the treatment of aortoiliac and/or isolated iliac aneurysms. The inclusion criteria for repair were rapid growth, size greater than 5 cm at the largest diameter for abdominal aortic aneurysms, and size greater than 3 cm for isolated iliac artery aneurysms.

Setting
The setting was a hospital. The economic study was carried out at the Pinnacle Health Hospitals, Harrisburg (PA), USA.

Dates to which data relate
The effectiveness, resource use and cost data were collected between July 2003 and December 2004. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. It was unclear whether the costing was conducted prospectively or retrospectively.

Study sample
No power calculations to determine the sample size were reported. The sample size appears to have included all patients who presented to the authors' surgical department for the treatment of aortoiliac or isolated iliac aneurysms during the study period. From July 2003 to July 2004, 10 patients underwent a pre-procedural occlusion of IIA with coils, while
between August and December 2004, 5 patients underwent occlusions of IIA with AVPs. Of the 10 patients with coils, 9 patients were male; all of the 5 patients with AVPs were male. The mean age (+/- standard deviation) was 71 (+/- 10) years in the coil group and 78 (+/- 6 years) in the AVP group.

**Study design**
This was a cohort study that was undertaken in a single institution. It was unclear whether the study was conducted prospectively or retrospectively. The mean duration of follow-up was 3.5 months (Range: 1 to 9) for the coil group and 2.4 months (Range: 1 to 7) for the AVP group, (p=0.508). No loss to follow-up was reported. No blinded assessment was reported.

**Analysis of effectiveness**
All of the patients included in the study were accounted for in the analysis. The primary health outcomes used were duration of the procedure and complication rates. At analysis, the groups were shown to be comparable in terms of their age and primary aneurismal issues.

**Effectiveness results**
The mean duration of the procedure was 11 days (Range: 7 to 30) for the coil group and 19 days (Range: 0 to 78) for the AVP group.

The numbers (rate) of detected complications in the coil and AVP groups, respectively, were:

3 (30%) and 2 (40%) for buttock claudication, (p=1.000);  
0 (0%) and 1 (20%) for endoleak, (p=0.333);  
0 (0%) and 1 (20%) for groin haematoma, (p=0.333);  
3 (30%) and 0 (0%) for 2nd coiling requirement, (p=0.505); and  
2 (20%) and 0 (0%) for device dislodging, (p=0.524).

**Clinical conclusions**
The AVP allowed reliable occlusion of the IIA in patients undergoing endograft repair for aortoiliac aneurysms. The use of AVP with a precise placement at the origin of the artery avoided significant complications.

**Measure of benefits used in the economic analysis**
No summary benefit measure was derived and only separate clinical outcomes were reported. As such, a cost-consequences analysis was performed.

**Direct costs**
The quantity/cost boundary adopted appears to have been that of the hospital. Only the costs of the coils and AVPs were included in the economic analysis. The quantities and the costs were reported separately. The estimation of the quantities and costs was based on actual data. Discounting was not conducted. The price year was not reported.

**Statistical analysis of costs**
The costs and resource use were treated stochastically. The number of devices used per IIA and costs were compared using the independent samples t-test, with significance set at the 0.05 level.
Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average total cost per IIA was $3,500 for coils and $375 for the AVP.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The Amplatzer Vascular Plug (AVP) was a cost-effective alternative to occlude the internal iliac artery (IIA) in patients undergoing endograft repairs of aortoiliac aneurysms.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear since the use of coils represented traditional practice. You should verify whether this health technology is relevant to your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a cohort study, which was appropriate for the study design. The patient groups were shown to have been comparable in terms of their age and primary aneurismal issues. However, since no power calculations were reported and the study sample was very small, the study might have lacked sufficient power to detect all differences in baseline characteristics or clinical outcomes between the two groups. In addition, blinding of the outcome assessment was not reported. These factors may introduce potential bias. Nevertheless, several strengths of the analysis should be pointed out. First, the inclusion criteria used in the study were reported. Second, appropriate statistical analyses were undertaken to test for statistically significant differences between the two study groups. Finally, all of the patients included in the study were accounted for in the analysis.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study. This approach is more informative and appropriate for the interventions considered.

Validity of estimate of costs
The perspective adopted in the economic analysis was not reported, but it appears to have been that of the hospital. Only the costs of coils and the AVPs were included; other relevant costs were not taken into consideration. The authors acknowledged that taking the operating time and labour costs into account would have increased the savings with AVPs. Therefore, such omissions were unlikely to have affected the authors’ conclusions. The costs and the quantities were
reported separately for some resource use categories, which will enhance the generalisability to other settings. Statistical analyses were used to test for significant differences in costs and resource use. Discounting was not performed, which was appropriate given the short period of analysis. The price year was not reported and this will limit future inflation exercises.

**Other issues**
The authors did not compare their findings with those from other studies. The issue of the generalisability of the authors’ results to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. No further limitations of the study were reported in the Discussion section.

**Implications of the study**
The results of this study support the use of AVP to occlude the IIA in patients undergoing aortoiliac and/or common iliac aneurysm endograft repair.

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**Other publications of related interest**


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