Minimal incision abdominal aortic aneurysm repair

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
Performing minimal incision (MINI) repair for patients undergoing elective repair of an infrarenal abdominal aortic aneurysm (AAA) repair. The procedure consisted of a standard endoaneurysmorrhaphy performed through an 8- to 10-cm minilaparotomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing elective replacement of infrarenal AAA. Selection criteria for MINI repair included: elective repair; infrarenal aneurysm; no iliac disease requiring a bifurcated graft placement; and the ability to tolerate general anaesthesia. Selection criteria for LAP AAA repair had an extra element in that patients had to have no contraindication to laparoscopy.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients enrolled between June 1997 and July 1998 for the MINI and OPEN techniques and between January 1995 and December 1996 for the LAP approach. The price year was not given.

Source of effectiveness data
The evidence for the final clinical outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was retrospectively undertaken on the same patient 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 11 patients in the MINI group (mean (SD) age of 72.4 (6.3) years), 17 patients in the LAP group (mean (SD) age of 70.8 (4.9) years), and 37 patients in the OPEN group (mean (SD) age of 73 (6.8) years).
Study design
This was a non-randomised study with both concurrent and historical controls, carried out on a single site. The duration of the follow-up appears to have been for 30 days after operations. Loss to follow-up (excluded patients from the statistical analysis) was 0 in the MINI group, 2 in the LAP group (conversion to OPEN), and 5 patients in the OPEN group (incomplete chart data).

Analysis of effectiveness
The principle used in the analysis of effectiveness was treatment completers only. The health outcomes were operative time, blood loss, length of hospital stay, local complications, 30-day mortality, gastrointestinal function, need for postoperative fluid resuscitation, and duration of nasogastric tube decompression. The three study groups were comparable in terms of age, sex, risk factors, and aortic dimensions.

Effectiveness results
The mean operative time (SD) was significantly less in the MINI group (129.7 (29.5) minutes) than in either the LAP group (244.8 (50.6) minutes, p<0.1) or the OPEN group (209.9 (102.5) minutes, p<0.05). Intraoperative blood loss was 522.7 (287.5) mL in the MINI group compared to 1,214.7 (744.5) mL in the LAP group (p=NS), and 1,795.8 (1590) mL in the OPEN group, (p<0.05). No significant differences in intraoperative fluid management were observed. Length of stay was 5.18 (MINI), 18.7 (LAP), and 17.4 days (OPEN), (p<0.05). Local complications occurred in 18.2% (MINI), 23.5% (LAP), and 29.7% (OPEN) of patients, (NS). No statistically significant 30-day mortality was noted among the three groups. Patients undergoing minilaparotomy demonstrated decreased compromise of gastrointestinal function, with a decreased need for postoperative fluid resuscitation (6,799.7 mL, 7,781.8 mL, and 11,061.1 mL, p<0.05) and shortened nasogastric tube decompression (1.6 days, 1.5 days, and 4.1 days, p<0.05).

Clinical conclusions
The MINI technique is a safe, effective and durable procedure that should reflect the durability of the Creech technique. Correspondingly, it avoids the morbidities of the conventional repair’s long abdominal incision and shares the benefits of the LAP AAA repair with its minilaparotomy. MINI repair is an approach that leads to significant improvement in recovery.

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. Some quantities were reported separately from the costs and cost items were reported separately. The cost analysis covered the costs of the different surgical modalities which included the costs for operating room, intensive care, and floor care, but excluded professional fees. The perspective adopted in the cost analysis was not explicitly specified. Charges were used instead of true costs. The source of charge data was the corporate finance department of the study hospital. The price year was not given.

Statistical analysis of costs
Statistical analysis was performed to compare the groups in terms of costs (the type of analysis was not specified).

Indirect Costs
Not included.

Currency
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

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

**Cost results**
The mean (SD) total hospital charges were $22,692 (5,246) in the MINI group, $59,922 (107,532) in the LAP group and $62,324 (70,618) in the OPEN groups, (p<0.05).

**Synthesis of costs and benefits**
Costs and benefits were not combined.

**Authors' conclusions**
MINI repair is a technically feasible technique that combines the benefits of minimally invasive surgery with those of conventional open repair with few, if any disadvantages. It was also associated with substantial reduction in hospital charges.

**CRD COMMENTARY - Selection of comparators**
An implicit justification was given for the choice of the comparators: the LAP approach is a minimally invasive technique, and the open approach was considered the conventional method in the context in question. The MINI technique was an attempt to combine these two techniques and, as such, it seems appropriate that it should be compared with the parent techniques. 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**
The internal validity of the effectiveness results cannot be guaranteed given the non-randomised nature of the study design, the lack of power calculations, the relatively small sample size, and the fact that the analysis was based on treatment completers only. The three study groups were comparable in terms of age, sex, risk factors, and aortic dimensions. The patient sample appears to have been representative of the study population, and was chosen to establish comparative groups. It was deemed that the MINI approach was associated with a low learning curve, but no objective assessment of this feature of the new technique appears to have been made in the study.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

**Validity of estimate of costs**
Some quantities were reported separately from the costs and adequate details of the methods of cost estimation were given. The use of charge data instead of true costs may have adversely affected the internal and external validity of the cost results. The price year and perspective adopted in the cost analysis were not reported. The effects of different procedures on indirect costs were not addressed. Cost results may not be generalisable to other settings or countries. Some statistical analyses were conducted on resource use and charge data.
Other issues
In view of the non-randomized nature of the study design, the relatively small sample size, and the lack of sensitivity analysis, the study results may need to be interpreted with some degree of caution. The issue of generalisability to other settings or countries was not addressed although some comparisons were made with other studies. The study sample was limited to patients undergoing elective replacement of infrarenal AAA to achieve comparable groups, and this limitation was acknowledged in the authors' comments.

Implications of the study
The facility of the procedure, combined with the potential cost benefits, encourage further study for consideration of this technique as a viable alternative for the management of AAAs.

Source of funding
None stated.

Bibliographic details

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MeSH
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