Comparison of laparoscopic and open splenectomy in children with hematologic disorders

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 laparoscopic splenectomy in children with primary hematologic disorders.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Children with non-malignant hematologic disorders undergoing elective splenectomy.

Setting
Children's tertiary care medical centre. The economic study was carried out in Dallas, USA.

Dates to which data relate
The effectiveness and resource data were collected between January 1993 and January 1996. 1995 prices were used.

Source of effectiveness data
The source of effectiveness data was a single retrospective study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculation was not used to determine the sample size. The sample selection was not randomized. 50 patients were non-randomly allocated to the laparoscopic or open group. There were 16 patients in the laparoscopic group (mean age 10.3 years) and 20 patients in the open group (mean age 9.7 years).28% of the cases were excluded from the study.

Study design
Retrospective cohort study. The study was carried out in a single centre. The duration of follow up was restricted to the duration of postoperative hospital stay.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The clinical outcome measures consisted of anesthesia and operative times, degree of blood loss, duration of postoperative analgesia, duration of hospital stay, percentage of patients who resumed a regular diet during the first 2 postoperative days, complication rate, and hematologic response. At analysis, the groups were not shown to be statistically comparable, although the authors reported that the patients' primary hematologic disorders were similar in each group, as were the indications for splenectomy. No adjustment for potential confounding variables was made.

**Effectiveness results**
The mean anesthesia and operative times in the laparoscopic group were 3.9 hours and 3.1 hours, respectively. The corresponding values for the open group were 2.3 hours and 1.6 hours. As a result, the open group had significantly shorter time than the laparoscopic group (P<0.001). The mean blood loss was estimated to be similar in both groups (74ml laparoscopic versus 78 ml open). The complication rate (31% in the laparoscopic and 40% in the open) and hematologic response were similar in both groups. The duration of postoperative analgesia and of the postoperative hospital stay were significantly longer in the open group. On average, the subjects in the open group needed 32 more hours of postoperative analgesia (99 versus 67 hours) and were discharged home 1.3 days later (4.9 versus 3.6 days) than those having a laparoscopic splenectomy (P<0.005 and <0.01, respectively). The percentage of patients who returned to regular diet in the first two postoperative days was significantly higher in the laparoscopic group (93% in laparoscopic versus 25% in open).

**Clinical conclusions**
The study showed that laparoscopic splenectomy is feasible and safe in children with non-malignant hematologic disorder.

**Measure of benefits used in the economic analysis**
The main measures of the benefits were anesthesia and operative times, duration of postoperative analgesia, duration of hospital stay, and percentage of patients who resumed a regular diet during the first 2 postoperative days.

**Direct costs**
Some quantities of resource use were analysed separately. The total cost of hospitalization were calculated for each patient based on the records provided by the finance office of the hospital. The main reported item in the costing was operating room charge. There was no requirement for discounting. The costs were adjusted to 1995 dollars and were calculated from the point of view of the payer. The costs of disease-specific operative preparation, diagnostic studies and surgeons' fee were excluded from the study as they were common to both alternatives.

**Currency**
US dollars ($)

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
The mean anesthesia and operative times in the laparoscopic group were 3.9 hours and 3.1 hours, respectively. The corresponding values for the open group were 2.3 hours and 1.6 hours. As a result, the open group had significantly shorter time than the laparoscopic group (P<0.001). The duration of postoperative analgesia and of the postoperative hospital stay were significantly longer in the open group. On average, the subjects in the open group needed 32 more hours of postoperative analgesia and were discharged home 1.3 days later than those having a laparoscopic splenectomy (P<0.005 and <0.01, respectively). The percentage of patients who returned to regular diet in the first two postoperative days was significantly higher in the laparoscopic group (93% in laparoscopic versus 25% in open). The duration of the
benefits were restricted to the duration of postoperative hospital stay.

Cost results
The average total cost of hospitalization was $13,410 for the laparoscopic group. The corresponding figure for the open group was $14,405. As a result the average total costs were not significantly different between the alternative groups (P>0.2). The duration of the costs was limited to the duration of postoperative hospital stay.

Synthesis of costs and benefits
Since the laparoscopic approach was considered to be the dominant strategy (with statistically similar costs but with better health outcome measures), the costs and benefits were not combined.

Authors' conclusions
Laparoscopic splenectomy is feasible and safe in children with hematologic disorders. Although it currently requires more operative time than the open approach, it is superior with regard to duration of postoperative analgesia, duration of hospital stay and recovery of bowel function.

CRD COMMENTARY - Selection of comparators
The selection of the comparator is clear.

Validity of estimate of measure of benefit
The estimates of the measures of benefits were not adjusted for confounding variables even though the study design used represents a potential source of bias. Because the sample size was relatively small, the power of the study may have been too low to detect a treatment effect (in particular with respect to hematologic response outcomes). As the authors mention, long-term follow up assessment may better detect the true nature of the advantages and disadvantages of laparoscopic versus open splenectomy.

Validity of estimate of costs
Some resource quantities were not reported separately from the costs.

Other issues
Insufficient explanation was given for the apparent discrepancies between the result of this study and other studies documented in the literature. No sensitivity analysis was performed.

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None stated.

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Other publications of related interest
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