Is pediatric laparoscopic splenectomy safe and cost-effective?

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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 health technology studied was laparoscopic splenectomy (LS), which was performed on patients in the paediatric age group. LS was performed in the lateral decubitus position using 4 trocars (three 5-mm and one 10-mm) as described by Smith et al. (see 'Other Publications of Related Interest' below).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children requiring splenectomy. Any patient referred to the laparoscopic surgeon unless the spleen was believed to be too large to manipulate into the sac for removal (splenic tip at the level of the iliac crest in a 4-year-old), was included in the study.

Setting
The setting was tertiary care in a children's hospital. The economic study was carried out in the USA.

Dates to which data relate
The dates for effectiveness evidence were 1 July 1994 to 30 June 1996. Dates for resources used were 1 July 1994 to 30 June 1996. No adjustment to a common price year was made.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same sample of patients as used in the effectiveness study.

Study sample
No power calculations were reported in determining the size of the patient sample. All patients treated in the hospital during the time period were included in the study, namely 20 children needing splenectomy. 6 patients had idiopathic thrombocytopenic purpura, 11 had hereditary spherocytosis, 2 had beta-thalassemia and 1 had myelodysplasia. There were 10 patients in each treatment group, mean age in the LS group was 10.3 years (range: 4 - 17) and mean age in the OS group was 8.3 years (range: 4 - 17). The average weight in the LS group was 38.5kg and in the OS group 35.2kg. Four patients in each group underwent concomitant cholecystectomy.
Study design
This was a retrospective chart review based on a non-randomised clinical study. The referring physician decided the type of surgery to be performed. All the surgery was carried out at the same children's hospital. It is not clear how long the follow-up was, although, in the LS group, there was a clearly stated follow-up of 6-12 months. There was no loss to follow-up, the authors implying that the surgery was successful for all 20 children.

Analysis of effectiveness
The analysis was based on treatment completers only. During the operation blood loss and operating time were measured. The following health outcomes were recorded post operatively: haematocrit count; length of time before a liquid diet; length of time before discharge. In terms of baseline comparability between the two groups, there were a number of differences: among the 11 patients with hereditary spherocytosis, there were 7 in the LS group and 4 in the OS group; the patients with idiopathic thrombocytopenic purpura were split equally between the two groups, three in each treatment group; the patients with myelodysplasia and beta-thalassemia were all in the OS group; the average age of the LS group was 10.3 years and in the OS group it was 8.3 years; the average weight in the LS group was 38.5kg and 35.2kg in the OS group.

Effectiveness results
The effectiveness results were as follows:

Blood loss in the LS group averaged 99ml and 34ml in the OS group, (p<0.17).

Operating time for the LS group was 211 (range: 145 - 365) minutes and 90 (range: 77 - 105) minutes for the OS group, (p<0.01).

The authors stated that their most recent operative times (since the study was completed) for LS were 120-140 minutes, and therefore the operative times recorded in the study were out of date.

One patient in each group had a postoperative haematocrit decrease of more than 3 points.

Patients in the LS group began to take a liquid diet at a mean of 1.4 days post-operatively, the figure for the OS group was 2.0 days.

The time to hospital discharge was 64 hours (range: 43 - 92) for the LS group and 79 hours (range: 68 - 121) for the OS group, (p<0.3).

The authors report that those parents who had themselves experienced splenectomy all thought that LS was superior to OS, however it is not clear how many fell into this category.

Clinical conclusions
LS is as safe as OS. For suitable patients LS is superior to OS because patients can be discharged earlier from hospital and can resume all their activities by one week after surgery. Patients in the OS group were not allowed to resume normal activities until 2-6 weeks, the advice depending on the surgeon. Therefore LS patients have less time in pain, discomfort or being forced to rest.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis. A cost-consequences analysis was therefore performed. The health benefits associated with the effectiveness results are reported above.

Direct costs
The costs were taken from the hospital charges that were received by the patients. Discounting was not relevant due to
the short period of analysis (less than one year). Quantities and costs were not analysed separately. The following costs were recorded: operating room costs; hospital costs, patient charges for hospital equipment. The surgical fee was the same for both kinds of surgery and, appropriately, was not included in the analysis. No price reflation was carried out and as such no price year was provided. There was no difference reported between average and marginal costs. Operative time was significantly longer in the LS group compared with the OS group (211 minutes versus 90 minutes for splenectomy). The authors stated that their most recent operative times (since the study was completed) for LS were 120-140 minutes, and therefore the operative times recorded in the study are out of date. They also stated that experience since the study has reduced operative time, which will therefore result in reduced costs.

Statistical analysis of costs
Cost data were treated stochastically and were analysed using student's t-test. The level of significance was 0.05 with standard deviation (sd) also being reported.

Indirect Costs
No measurement of indirect costs was made, but it is clear that the authors were aware of the greater indirect costs of OS as it takes much longer for the patients to resume their normal lives. The authors were similarly aware of the indirect costs to the family of having a child at home and of the cost to the child in having to sacrifice time to convalescence, but they did not translate this into monetary terms due to methodological difficulties. Their measurement of the time taken to hospital discharge and normal life (the latter was deduced rather than actually measured) could be taken as a proxy for indirect costs.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
Only costs incurred in hospital were calculated. Total hospital charges (+/- sd) for the LS group were $13,033 +/- 2,976 and for the OS group, $7,106 +/- 1,923, (p<0.001). These were reported as average patient charges.

Synthesis of costs and benefits
The estimated costs and benefits were not combined. Costs and benefits were described according to a cost-consequences approach. LS was more expensive in terms of hospital costs but it was more effective as it had fewer negative side effects until recovery.

Authors' conclusions
The authors concluded that the costs of LS are greater than the costs of OS. However, the children who underwent LS could return home and resume normal activity quicker than those who underwent OS, and the authors therefore argue that the greater costs are justified. They point out that the cost of LS should decline in the future as surgeons become more skilled and able to perform the operation in less time. They also point out that the hospital charges system inflated the patient charge for LS as compared with the hospital cost of OS.
CRD COMMENTARY - Selection of comparators
The comparison of OS with LS for children was valid as, before the advent of laparoscopy, OS was standard practise.

Validity of estimate of measure of effectiveness
The results of the part of the study that aimed to show that both types of surgery were equally safe and able to achieve the desired goal were not given in detail. The authors focussed on the differences in the clinical consequences of the two kinds of surgery as a way of comparing effectiveness. The source of the effectiveness data (retrospective case control) is susceptible to a number of biases and confounding variables which tend to limit the validity of the results. The sample was the whole study population at this hospital during the time period. The authors stated that the patients were similarly matched in age, weight and disease process. Splenic size was the same in both groups but the disease pattern in the two groups was not identical. The authors did not justify their choice of the size of the trial, namely 20 patients. The authors state that 3 surgeons were used for OS and one was used for LS. It would have been interesting to have known how much variation there was between the results of the 3 surgeons performing OS as there is the potential for confounding in terms of explaining the results.

Validity of estimate of measure of benefit
The estimate of benefit derived directly from the effectiveness evidence. The validity of the benefit measures was therefore reflected in the above commentary on the validity of effectiveness.

Validity of estimate of costs
The authors used patient charges as a proxy for costs, but using actual hospital costs would have enhanced the validity of the results and their generalisability to other settings. The authors state that patient charges have an element of arbitrariness about them and it is clear that this factor has served to increase the relative costs of LS compared to OS. Therefore a more representative measure of costs would make LS more attractive. The authors did not discuss the possibility that prices may have changed during the time period and therefore there should have been an adjustment to a common price year. The authors did not include the cost for the child of being forced to rest; similarly they did not include the indirect costs for the families of having a child in hospital and then caring for the child when unable to go to school, although they did mention that these costs exist. Rectifying this omission would further increase the relative advantages of LS.

The only quantitative data included were operating time for splenectomy and splenectomy with cholecystectomy. A price for operating time was not included. The only price information given was that of the average cost of the minimum disposable equipment used in LS. Again these features of the cost analysis limit generalisability to other settings.

Other issues
The authors refer to other publications which assessed the safety of laparoscopic splenectomy for children and concluded that the procedure was safe. They state that the results of their study agreed with those in other publications. The authors acknowledged that the higher costs for LS in their hospital, which they describe, depend on the cost of disposable equipment and longer operating times. They also noted that these costs may vary between hospitals, but do not have any data to show this variation. They acknowledge that their results cannot be generalised to other hospitals in the USA, and as such they cannot be generalised to other countries. The authors stated that increased skill over time has already reduced the operating time and therefore the cost of LS. They expect this trend to continue.

Implications of the study
The authors have established that their paediatric patients made a faster recovery from splenectomy when this was carried out by LS as compared to OS, and their study did not show any increased risk to patient health. The authors do not give any data assessing the operation from the patients’ perspective. They regard it as sufficient to show that normal activity was resumed earlier with LS. A more thorough analysis of patient well-being at discharge and at follow-up would have been helpful. The authors’ data on costs is incomplete, and a more thorough analysis of costs would
probably reduce the relative costs of LS as compared with OS and thus lend further support to the authors’ conclusions in favour of LS.

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None stated.

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**Other publications of related interest**


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