Open versus laparoscopic splenectomy for idiopathic thrombocytopenic purpura: clinical and economic analysis


**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 laparoscopic splenectomy (LS) for idiopathic thrombocytopenic purpura (ITP) requiring surgical intervention.

**Type of intervention**
Treatment.

**Economic study type**
Cost-effectiveness analysis.

**Study population**
The study population comprised patients with ITP who had been treated with LS or OS. Patients with other medical conditions as the primary indication for surgical intervention (e.g. those with lymphoproliferative disorders and haematologic diseases) were excluded.

**Setting**
The setting was secondary and tertiary care. The economic study was carried out in Rochester (MN), USA.

**Dates to which data relate**
The effectiveness and resource use data were collected from January 1995 to December 2000. The price year was 2000.

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

**Link between effectiveness and cost data**
The resource use data were taken from the same patient sample as that used in the effectiveness study, although one patient who was included in the clinical analysis was later excluded from the economic analysis because of the presence of co-morbid conditions that confounded the estimated costs.

**Study sample**
The authors did not report any power calculations. The study sample was selected by examining all medical records of patients who underwent LS or OS for ITP at a single institution between January 1995 and December 2000 (in total, 118 patients). To be included in the effectiveness analysis, the patients had to have been followed up for a minimum of 1 year. The final sample size was 86 patients, of which 42 had undergone LS and 44 had undergone OS. Thirty-two patients were excluded from the initial sample. In 31 of these another non-ITP medical condition was the primary
indication for surgical intervention. The remaining patient was excluded because his co-morbid conditions and additional procedures were deemed severe enough to confound the assessment of splenectomy-related health outcomes. No patients were reported to have refused to participate in the study. The authors did not report any evidence that the study sample was representative of the study population.

**Study design**
This was a retrospective cohort study that was conducted in a single centre. The patients were followed up for a minimum of 1 year (range: 1 - 6). No blinding of the outcome assessment appears to have been undertaken.

**Analysis of effectiveness**
All of the patients included in the study were accounted for in the analysis. Therefore, an intention to treat analysis was performed. A secondary analysis was also performed, based on treatment completers only, which excluded those patients who experienced converted procedures. The primary health outcomes in the analysis were:

- the duration of the operation and anaesthesia,
- the intraoperative transfusion rates,
- the postoperative complication rates,
- the days of parenteral analgesia,
- the number of days before resuming a normal diet, and
- postoperative length of stay.

The median and mean values (and corresponding standard deviations, SDs) were reported for most of the effectiveness outcomes. The mean difference in outcomes between LS and OS patients was also reported.

The study showed no significant differences between the treatment groups in terms of age, gender, or relevant prognostic factors (i.e. ASA physical status classification, associated co-morbidities, presenting symptoms, admission haemoglobin and platelet counts). However, the numbers compared in each group were relatively small, and so the failure to find significant differences between the study groups may have been a consequence of the small sample sizes. The authors noted that higher percentages of men and of patients with renal disease (approaching significance) were observed in the OS group. The effectiveness data were analysed in a multivariate model to adjust for observable differences between patients in terms of demographics, severity and co-morbidities. According to these variables, the effectiveness results were presented both adjusted and unadjusted.

**Effectiveness results**
Nine (21.4%) of the 42 LS procedures were converted to OS.

The LS intervention was found to take significantly longer than OS. The mean operative and anaesthesia times were, respectively, 167.07 (SD=13.52) minutes and 200.83 (SD=12.74) minutes for LS and 119.21 (SD=11.00) minutes and 150.66 (SD=16.06) minutes for OS. The corresponding mean differences were 47.87 minutes (95% confidence interval, CI: 42.59 - 53.14; p=0.000) for mean operative time and 50.17 minutes (95% CI: 43.94 - 56.41; p=0.000) for anaesthesia time.

On average, patients undergoing LS had significantly fewer postoperative days of parenteral analgesia (1.18 fewer than OS, 95% CI: -1.49 - -0.87; p=0.000) and days to tolerance of general diet (1.69 fewer than OS, 95% CI: -2.00 - -1.38; p=0.000).

Patients undergoing LS were also discharged 2.03 days earlier than patients undergoing OS (95% CI: -2.84 - -1.23; p=0.000).
There were no significant differences between the groups in terms of the other primary clinical end points.

When patients who were converted from LS to OS were excluded from the analysis, the effectiveness differences already found were more pronounced, although postoperative complications were more common in the LS group (0.73 versus 0.61 for the OS group; p=0.019).

Clinical conclusions
LS showed an advantage over OS in terms of reduced recovery time and the patients' ability to tolerate a general diet sooner.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used in the economic analysis. In effect, a cost-consequences analysis was performed instead.

Direct costs
The direct costs included appear to have been those of the health service, and comprised direct hospital costs and direct physician costs. With the exception of length of stay, the resource quantities were not reported separately from the costs. The cost data were taken from an administrative database (the Mayo Clinic Healthcare Expenditure and Utilisation Database), which provided standardised, inflation-adjusted costs, reported for the year 2000. This database allows the conversion of charge data into economic cost data by using cost-to-charge ratios. The authors reported both total billed charges and total direct costs of care. Although discounting does not appear to have been carried out, it would not have been relevant since the costs were estimated as those incurred by the patients from the date of surgery to hospital discharge (which was less than 2 years). The authors excluded costs that were deemed unrelated to the study procedures. The costs reported were the median and mean costs per patient.

Statistical analysis of costs
The mean and median costs were reported, along with their SD. The costs were analysed using a generalised linear model, adjusting for prognostic and demographic factors. This is an appropriate method for analysing cost data, which are typically skewed.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were reported.

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

Cost results
For patients undergoing LS, the mean cost per patient was $6,431 for hospital costs, $1,700 for physician costs, $14,399 for direct charges and $8,134 for direct costs. The corresponding costs for OS were $6,533 (hospital costs), $1,681 (physician costs, $11,431 (direct charges) and $8,200 (direct costs).
The direct charges were significantly higher in the LS group (mean difference $2,968, 95% CI: 191, 5,745; p=0.037). However, when patients who were converted from LS to OS were excluded, this significant difference in the total direct charges between LS and OS costs per patient was no longer reflected.

Although the study found no other significant differences in terms of cost, it is unlikely that it had sufficient power to detect any such differences.

Synthesis of costs and benefits
Not relevant since a cost-consequences analysis was undertaken.

Authors' conclusions
Laparoscopic splenectomy (LS) compared favourably with open splenectomy (OS) in terms of effectiveness and costs.

CRD COMMENTARY - Selection of comparators
The comparator was justified as having been the most common practice in the authors' setting. You should decide whether OS is a widely used procedure in your own setting.

Validity of estimate of measure of effectiveness
The retrospective cohort design meant that the study was open to selection bias, as the authors stated. The multivariate analysis adjusted for observed covariates, but there is the potential that unobserved confounders might have introduced bias into the results, given the non-randomised method of treatment allocation. Although the study design should mean that the study sample could be representative of the study population in the study location, the fact that patients were recruited from a single centre means that, in fact, this is unlikely. The patient groups were shown to be comparable at analysis, but the number of patients with each characteristic was small, thus the study might have been underpowered with respect to detecting any difference in prognostic or demographic factors. The authors acknowledged that the technique for LS entails a steep learning curve, which the surgeons at the institution studied may not have yet fully climbed.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study. The reader is therefore referred to the commentary in the 'Validity of estimate of measure of effectiveness' section (above).

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted appear to have been included in the analysis, as the costing was based on a database that assessed the total direct costs and billed charges in practice. The authors stated that they tried to capture disease-specific costs. However, it was often difficult to determine whether the costs were disease-related. The inclusion of the indirect costs or costs to the patient outside of hospital may have been advisable, to rule out the possibility that costs were transferred from the hospital to the patient by the early discharge. As the authors stated, if the indirect costs had been included, it is likely that LS would have shown economic advantages in terms of lower productivity losses.

With the exception of length of stay, the quantities were not reported separately from the costs. The database consulted used a technique to convert charge data to represent the economic cost of the items used. Discounting was not used, but it was not required since a period of less than 2 years was considered for the cost estimation. The price year was reported. Statistical analyses of the costs were performed to reduce uncertainty surrounding the cost results. However, given the small sample size, the statistical comparisons might have lacked sufficient power to detect significant differences in costs across the study groups.
Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have reported their results selectively. Their conclusions did not extend beyond the scope of the analysis.

Implications of the study
The authors recommended that LS be combined with preoperative imaging, or more careful scrutiny, to overcome the problem of accessory spleens being missed with a laparoscopic approach.

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