Pyloromyotomy: a comparison of laparoscopic, circumumbilical, and right upper quadrant operative techniques


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
Three surgical procedures for hypertrophic pyloric stenosis (HPS) in infants were examined. More specifically, Ramstedt pyloromyotomy through a right upper quadrant (RUQ) transverse incision, laparoscopic surgery (LAP) and a circumumbilical approach (UMB). Details of the operative techniques were reported.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing a pyloromyotomy.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered from January 1997 and June 2003. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that included in the effectiveness study.

Study sample
Limited information on the method used to select the sample was given. Overall, 290 patients were included in the study. There were 51 patients (71% boys) in the LAP group, 190 (84% boys) in the RUQ group, and 49 (65% boys) in the UMB group. The age of the infants was 4.9 (+/- 2) weeks in the LAP group, 5.0 (+/- 3) weeks in the RUQ group, and 5.2 (+/- 3) weeks in the UMB group. It was not stated whether some patients were excluded for any reason from the initial study sample.
Study design
This was a retrospective cohort study that was carried out at a single centre, the Department of Surgery, Children’s Hospital and Regional Medical Center and University of Washington School of Medicine, Seattle, Washington. All interventions were performed by residents under the supervision of attending staff. The length of follow-up was not reported. No patients were lost to the follow-up assessment.

Analysis of effectiveness
All of the patients included in the initial study sample were accounted for in the analysis of effectiveness. The outcome measures used in the effectiveness study were:

the operating room time,
the operation time,
the postoperative length of stay,
the time to ad libitum feedings,
postoperative emesis,
the conversion rate, and
the complication rate (including mucosal perforation, wound infection, wound dehiscence, incisional hernia, and persistent emesis).

The cosmetic result was also shown.

At baseline, the study groups were generally comparable in their demographics and other clinical characteristics, except for a higher proportion of girls in the UMB group.

Effectiveness results
The operating room time was 71 (+/- 13) minutes in the LAP group, 74 (+/- 14) minutes in the RUQ group, and 83 (+/- 15) minutes in the UMB group, (p<0.0001 for all comparisons).

The operation time was 25 (+/- 9) minutes in the LAP group, 32 (+/- 9) minutes in the RUQ group, and 42 (+/- 11) minutes in the UMB group, (p<0.001 for LAP versus both UMB and RUQ, and for RUQ versus UMB).

No statistically significant differences in the other outcome measures were observed.

The rate of conversion from LAP to RUQ was 4%.

Mucosal perforation occurred in 3 patients in each of the RUQ and UMB groups, but in none of the LAP group.

Incisions associated with both LAP and UMB yielded excellent cosmetic results in comparison with the RUQ approach.

Clinical conclusions
The effectiveness analysis showed that the three interventions were quite comparable, but operation times were considerably shorter for LAP than for RUQ and UMB.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.
Direct costs
The perspective used in the analysis of the costs was not explicitly stated, although it might have been that of the hospital. The analysis considered the costs associated with surgery, anaesthesia and the recovery room. However, a breakdown of items was not provided. The unit costs were not presented separately from the quantities of resources used. Resource use was estimated from data gathered retrospectively from the sample of infants included in the effectiveness study. Hospital charges were used to derive the costs. Discounting was not relevant since the costs were incurred during a short timeframe. The price year was not reported.

Statistical analysis of costs
Statistical analyses were carried out to test the statistical significance of differences in the costs.

Indirect Costs
The indirect costs were not included in the economic evaluation.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not carried out.

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

Cost results
Surgery charges were $1,299 (+/- 331) for LAP, $1,238 (+/- 411) for RUQ and $1,574 (+/- 433) for UMB, (p<0.0001 for all comparisons).

Anaesthesia costs were $586 (+/- 137) for LAP, $578 (+/- 167) for RUQ and $731 (+/- 190) for UMB, (p<0.0001 for all comparisons).

Differences in recovery room costs did not reach statistical significance.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was performed.

Authors’ conclusions
The use of laparoscopic surgery (LAP) for the treatment of hypertrophic pyloric stenosis (HPS) in infants was associated with shorter operation times in comparison with Ramstedt pyloromyotomy through a right upper quadrant (RUQ) transverse incision and a circumumbilical approach (UMB), with low costs and no complications. Thus, laparoscopic pyloromyotomy proved to be a safe and effective approach to the treatment of HPS.

CRD COMMENTARY - Selection of comparators
The authors justified the choice of the comparators, which were appropriate and reflected treatment options for infants with HPS. You should decide whether they are valid comparators in your own setting.
Validity of estimate of measure of effectiveness
The effectiveness evidence came from a cohort study. The retrospective nature of the study and the lack of random allocation of patients to the study groups represent two limitations of the analysis. In fact, the method used to allocate the patients was not reported. Consequently, the potential impact of selection bias and confounding factors cannot be ruled out. The study groups were comparable at baseline, except for the proportion of female participants. The evidence came from a single centre, which might limit the representativeness of the patient sample. No formal justification for the size of the sample was provided, and power calculations were not reported. Details of the follow-up were presented clearly. Further, the authors noted that only one surgeon supervised all LAP procedures, while the other techniques were performed by several different surgeons. These issues tend to limit the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective adopted in the study was not stated, although it might have been that of the hospital. The analysis of the costs was restricted to the direct medical costs incurred while the patients were hospitalised. A detailed breakdown of the cost items was not provided since the costs were presented as macro-categories. Hospital charges were used to derive the costs, but charges might not have been the most appropriate proxies for actual costs. The price year was not reported, which limits the possibility of performing reflation exercises in other time periods. Standard statistical analyses were carried out to compare the costs estimated in each group. However, the cost estimates were specific to the study setting and the issue of variability in the data was not addressed in the sensitivity analysis.

Other issues
The authors stated that some of their findings, such as complication rates, were comparable with those reported in other studies. However, the issue of the generalisability of the study results to other settings was not explicitly addressed, and sensitivity analyses were not carried out. This limits the external validity of the study. The analysis referred to infants with HPS and this was reflected in the authors' conclusions. The authors noted some limitations of their study, such as the small sample size and the retrospective design, which have been highlighted already.

Implications of the study
The study results suggested that the LAP approach may result in shorter operation times. In addition, it has the potential to reduce both operative and hospital costs in comparison with other surgical procedures for HPS in infants.

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Other publications of related interest


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