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**A prospective randomized comparison of laparoscopic appendectomy with open appendectomy: clinical and economic analyses**

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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 use of laparoscopic appendectomy (LA) as a minimal access procedure in general surgical practice.

**Type of intervention**

Treatment.

**Economic study type**

Cost-effectiveness analysis.

**Study population**

The study population comprised all patients presenting to an emergency general surgical practice with a pre-operative diagnosis of acute appendicitis.

**Setting**

The setting was a hospital. The economic study was carried out in Rochester, MN, USA.

**Dates to which data relate**

The effectiveness and resource data were collected between 18 July 1992 and 9 August 1995. The price year was 1995.

**Source of effectiveness data**

The effectiveness data were derived from a single 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 calculations were carried out before beginning the study. The results of the power analysis suggested that a sample of 200 randomised patients would yield 80% power to detect a significant mean decrease of at least 1.3 days of hospitalisation between the two interventions, at the traditional level of statistical significance.

Beginning in July 1992 Emergency Department patients with a diagnosis of acute appendicitis were selected and randomised for the sample. Following the indication of the preliminary study, 200 patients were included in the study. Two randomised patients did not meet entry criteria and were eliminated from the study before the operation. A total of 198 patients were evaluable: 105 were randomised to OA and 93 to LA. LA was converted to OA in 15 patients (16%).

### Study design

The study was a randomised controlled trial carried out in a single centre. Randomisation was performed according to a random numbers table in blocks of 4 patients, and stratified by surgeon. Patients were then assigned using sealed sequenced envelopes. Follow-up lasted for one year after discharge. Patients were contacted by telephone at the end of post-operative weeks 1, 2 and 3, and at the end of post-operative months 1, 3 and 12. Patients who were lost to telephone follow-up were sent a questionnaire, one year post-operatively. Complete follow-up was obtained for 195 patients (98.5%): 100% in the OA group and 96.8% in the LA group.

### Analysis of effectiveness

The analysis of the clinical study was based on intention to treat. However, a "pure" analysis was also conducted, excluding those patients who were initially randomised to LA but who ended up having OA. The primary health outcomes assessed were:

the duration of the operation;

the number of days of tolerance of general diet;

the number of patients not requiring parenteral analgesia, and the duration of treatment for those that did;

the number of patients not requiring oral analgesia, and the duration of treatment for those that did;

the number of wound infections;

the total duration of hospital stay;

the duration of post-operative hospital stay; and

the number of days to return to full activity.

Quantitative health outcomes were compared using the Wilcoxon rank sum test. Qualitative variables were compared using a chi-squared or Fisher exact test. The groups were shown to be comparable in terms of patient demographics and clinical characteristics.

### Effectiveness results

The median duration of the operation was significantly greater for LA compared with OA: 107 minutes versus 91 minutes, ( $p < 0.001$ ).

Twenty patients (22%) in the LA versus 3 patients (3%) in the OA did not require parenteral analgesia; this difference was statistically significant, ( $p < 0.0001$ ).

The number of days of parenteral analgesia required were significantly fewer for the LA group than for the OA group, ( $p < 0.001$ ).

The proportion of patients who did not use oral analgesics was significantly greater in the LA group: 22% compared with 9% in the OA group, ( $p = 0.01$ ). However, the difference in the number of days for those patients that did require oral analgesia was not statistically significant.

The median time to full activity was lower for LA than for OA: 14 versus 21 days, ( $p < 0.02$ ).

There were no significant differences between the two groups in terms of the number of days of tolerance of general diet, the number of wound infections, and the total duration of hospital stay.

The duration of post-operative hospital stay was significantly less for the LA group, ( $p < 0.01$ ).

Sub-group analyses, based on the type of appendicitis, were also performed; results were less reliable because no power calculation was performed. Overall, the sub-group analyses confirmed the main findings of the previous groups.

### **Clinical conclusions**

The effectiveness analysis indicated that the LA strategy was slightly more effective than the OA intervention with respect to a few clinical outcomes.

### **Measure of benefits used in the economic analysis**

Since no summary measure of health benefit was used in the economic analysis, a cost-consequences analysis was performed.

### **Direct costs**

A specialised database, the Olmsted County Healthcare Expenditure and Utilization Database (OCHEUD), was used to obtain standardised inflation-adjusted estimates of the cost of each service or procedure in 1995 constant dollars. The quantities and costs were not reported separately. The costs and quantities were estimated on the basis of data derived from hospital records. The direct costs included billed charges and direct hospital costs, such as physician services, room and board, supplies, operating room expenses and in-patient medication. The quantity/cost boundary was that of the hospital. The price year was 1995.

### **Statistical analysis of costs**

The robustness of standard t-tests was examined using bootstrapped estimates of the difference in mean costs.

### **Indirect Costs**

Indirect costs were associated with lost productivity during the hospitalisation and subsequent recuperative period. They occurred within a two-year period and were not discounted. The estimation was based on gender- and age-specific average hourly wage rates from the Bureau of Labor Statistics Current Population Survey in 1996.

### **Currency**

US dollars (\$).

### **Sensitivity analysis**

No sensitivity analysis was carried out.

### **Estimated benefits used in the economic analysis**

See the effectiveness results reported above.

### **Cost results**

In the intention to treat analysis the mean total costs were \$11,577 for LA and \$13,965 for OA. The mean difference was \$2,388, (p=0.09).

The direct costs were slightly greater for LA than for OA, \$5,357 and \$4,945 respectively, but the difference was not statistically significant, (p=0.29).

The indirect costs were significantly lower in the LA group, compared with the OA group: \$6,220 versus \$9,020, (p=0.01).

In the "pure" analysis, the mean total costs were \$9,135 and \$13,965 for LA and OA, respectively. The mean difference was \$4,631, ( $p=0.00$ ).

The direct costs were slightly lower for LA than for OA, \$4,741 versus \$4,945, but the difference was not statistically significant, ( $p=0.49$ ).

Indirect costs were significantly lower in the LA group, compared with the OA group: \$4,395 and \$9,020, respectively.

### **Synthesis of costs and benefits**

Not applicable.

### **Authors' conclusions**

The authors concluded that the effectiveness measures indicated a small advantage of LA compared with OA. Moreover, if the indirect costs were included in the analysis, LA could be relatively less expensive than OA in the treatment of acute appendicitis.

### **CRD COMMENTARY - Selection of comparators**

The choice of the comparator was based on the selection of the current practice strategy, namely OA. You should consider whether this is a widely used technology in your own setting.

### **Validity of estimate of measure of effectiveness**

Appropriate statistical analyses were carried out to increase the internal validity of the findings. Several measures of effectiveness were used, although some were mainly aimed at calculating costs, such as the duration of hospital stay and duration of operation, rather than to reflect the treatment efficacy.

### **Validity of estimate of costs**

All categories of cost relevant to the perspective adopted were included in the analysis. Non-parametric bootstrapping techniques were conducted to guarantee the robustness of the significance tests in the presence of skewed data, and a multiple linear regression was performed to control for confounding factors. The authors pointed out that the adoption of a particular perspective can affect the result of the study: if the payer perspective had been adopted ( i.e. indirect costs were excluded) the OA strategy would have been preferred because the key advantage of LA was the shorter recuperation period.

### **Other issues**

The issue of generalisability was not addressed explicitly, but the authors made several comparisons with the findings of other published studies.

The results appeared robust because of the pre-study power analysis.

### **Implications of the study**

Even if the adoption of LA resulted in questionable advantages with regards to effectiveness, this approach was relatively less expensive than the OA strategy. The economic significance of LA cannot, therefore, be ignored.

### **Source of funding**

None stated.

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