Single-layer continuous versus two-layer interrupted intestinal anastomosis: a prospective randomized trial

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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
Single-layer continuous, versus two-layer interrupted, intestinal anastomosis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Adult patients requiring intestinal anastomosis at Denver Health Medical Centre.

Setting
Hospital. The economic study was set in the USA.

Dates to which data relate
Effectiveness, resource use, and cost data were collected between September 1996 and September 1999. The price year was not reported.

Source of effectiveness data
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 analysis.

Study sample
59 patients were randomised to single-layer anastomosis and 66 to two-layer anastomosis. 65 single-layer continuous, and 67 two-layer interrupted anastomoses were performed. Patients requiring anastomosis to the rectum or third or fourth portion of the duodenum, and patients requiring gastrointestinal anastomosis were excluded. Patients were also excluded if the surgeon did not believe that either technique could be used because of technical concerns such as edema and scarring. To detect a significant difference in leakage rates based on the data, a power analysis indicated that 1,500 patients would be required.

Study design
A prospective randomised controlled trial was carried out at a single centre. Randomisation was performed using random permuted blocks of 10. Opaque sealed envelopes indicating the technique to be used were placed in the operating rooms. Patients were followed up until discharge. There appears to have been no loss to follow-up.

**Analysis of effectiveness**
The analysis of the clinical study was based on intention to treat. The primary health outcomes included leaks, abscesses, time, and length of stay. At analysis, groups were shown to be comparable in terms of age, gender, diagnosis, and location of the anastomosis.

**Effectiveness results**
3.1% of the one-layer group had leaks compared to 1.5% in the two-layer group, (p=0.62). 3.1% of the one-layer group had abscesses compared to 3.0% in the two-layer group, (p=0.0). The time needed to perform the anastomosis was 20.8 minutes in the one-layer group and 30.7 minutes in the two-layer group, (p=0.000). The length of stay was 7.9 days in the one-layer group and 9.9 days in the two-layer group, (p=0.084). It was also reported that 4 patients died, but no deaths were related to the anastomosis.

**Clinical conclusions**
A single-layer anastomosis can be constructed in significantly less time, and with a similar rate of complications, compared with the two-layer technique.

**Measure of benefits used in the economic analysis**
The authors only reported individual health outcomes and, therefore, the analysis was of cost-consequences design.

**Direct costs**
Direct costs were not discounted due to the short time horizon of the study (less than 1 year). Quantities and costs were reported separately. Direct costs related to the actual hospital costs for performing intestinal anastomoses. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Costs and quantities were collected from hospital records. The price year was not reported.

**Statistical analysis of costs**
Continuous data were analysed using the Student t-test.

**Indirect Costs**
Indirect costs were not included.

**Currency**
US dollars ($).

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

**Estimated benefits used in the economic analysis**
Not applicable. For the effectiveness results see above.
Cost results
The total costs per anastomosis were $4.51 in the one-layer group and $35.38 in the two-layer group.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
A single-layer anastomosis can be constructed in significantly less time and with a similar rate of complications compared with the two-layer technique. It also costs less than any other method and can be incorporated into a surgical training programme without a significant increase in complications.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used namely traditional treatment. You, as a user of the database, should decide if this health technology is relevant to your own setting.

Validity of estimate of measure of benefit
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population and patient groups were shown to be comparable at analysis. As acknowledged by the authors, the study sample was too small to detect differences in leakage rates. However, reference was made to other published studies with similar results. The analysis of effectiveness was handled credibly. The authors did not derive a summary measure of health benefit and the analysis used a cost-consequences design.

Validity of estimate of costs
The advantages of the cost analysis were: all relevant direct cost categories were included, statistical analysis was conducted on costs, and quantities and costs were reported separately. However, the price year was not reported, no sensitivity analyses were reported on quantities or costs, and it was unclear whether charges had been used to proxy costs.

Other issues
The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors did not present their results selectively. The study considered adult patients requiring intestinal anastomosis and this was reflected in the authors' conclusions. The authors stated that the study design did not include the time required to prepare the bowel for anastomosis, which is considerably less for the one-layer technique. Moreover, most of the anastomoses were performed by residents, who were often unfamiliar with the technique or were performing their first intestinal anastomosis.

Implications of the study
The findings of this study suggest that single-layer continuous anastomosis is superior to the two-layer interrupted technique and can be incorporated into a surgical training programme without a significant increase in complications. The findings should, however, be interpreted with care, given that the study was not powered to detect one of the important complications (leakage) in anastomoses. Further research is needed to estimate the true leakage rates of the two types of anastomosis.

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