Prospective, randomized evaluation of midline fascial closure in gastric bariatric operations

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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
Midline fascial closure in gastric bariatric operations.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing gastric restrictive operations for morbid obesity.

Setting
Robert Wood Johnson University Hospital, New Brunswick, New Jersey, USA.

Dates to which data relate
The years were not clearly stated, but effectiveness data were collected during a 6-year period.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
Costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
229 patients were randomised to have closure of the midline fascia using either double stranded #1 PDS suture placed in a continuous fashion and #1 Ethibond suture placed using interrupted figure-eight technique. Randomisation was carried out in the operating room according to the last digit of the patient's hospital identification number. Patients with an even number had closure with Ethibond (n=109) and patients with an odd digit (n=120) had closure with PDS. Mean post-operative follow-up for all patients was 29.4 months.

Study design
Randomised controlled trial. Only mean post-operative follow up was mentioned: this was 29.4 months for all patients.
Analysis of effectiveness
Based on treatment completers only. The main health outcomes used in the review were: number of cases of fascial dehiscence, number of wound infections and number of late incisional hernias. There was no difference in age, sex distribution, preoperative weight, or type of operation between the two groups.

Effectiveness results
Two of the 109 patients who had closure with Ethibond suffered an acute dehiscence of the midline fascia. There were no cases of fascial dehiscence in the PDS group. There were no wound infections in either group. There were 20 late incisional hernias (18%) in the Ethibond group and 11 late hernias (10%) in the PDS group (P <=0.04).

Clinical conclusions
Although a variety of obesity related comorbidities including eight type II diabetics were present in the study sample, no single comorbidity or any combination of medical problems were associated with development of incisional hernia.

Measure of benefits used in the economic analysis
The main health outcomes used in the review were: number of cases of fascial dehiscence, number of wound infections and number of late incisional hernias.

Direct costs
Resources and costs were not reported separately. Direct health service costs were considered such as: the cost of suture material and the time required to completely close the linea alba. Price date was not stated.

Statistical analysis of costs
Unpaired Student's t test was used for the statistical analysis of closure time.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Two of the 109 patients who had closure with Ethibond suffered an acute dehiscence of the midline fascia. There were no cases of fascial dehiscence in the PDS group. There were no wound infections in either group. There were 20 late incisional hernias (18%) in the Ethibond group and 11 late hernias (10%) in the PDS group (P<=0.04).

Cost results
The mean closure time was 13.3 minutes in the Ethibond group vs. 9.1 minutes in the PDS group (p<0.0001). Although the cost per suture pack for #1 PDS was $4.63 vs. $1.76 per pack of #1 Ethibond, the mean cost of sutures per patient was $4.81 for PDS vs $11.09 for Ethibond, due to the lower number of sutures.

Synthesis of costs and benefits
#1 PDS placed in a continuous fashion was the dominant strategy.
Authors' conclusions

#1 PDS placed in a continuous fashion provided a more secure and cost-effective closure for the midline fascia in morbidly obese patients than #1 Ethibond placed using an interrupted figure-eight technique.

CRD COMMENTARY - Selection of comparators

There was a valid reason for the choice of the comparators, as both techniques were widely used in the authors' setting.

Validity of estimate of measure of effectiveness

The authors acknowledged that the study was somewhat flawed because two independent variables, the type of suture and the method of closure, were compared in only two groups of patients. Hence, it is not clear which of these two variables were responsible for the significant differences in wound healing parameters observed between the two groups in the study.

Validity of estimate of costs

Resource quantities were not reported separately from prices. All important cost items were considered.

Other issues

The issue of generalisability to other settings/countries was not addressed, but appropriate comparisons were made with other relevant studies.

Source of funding

None stated.

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