Endoscopic stapling technique for the treatment of Zenker diverticulum vs standard open-neck technique: a direct comparison and charge analysis

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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
Two methods for the treatment of Zenker diverticulum (ZD) were compared. The two methods were endoscopic stapling of the common party wall between the diverticulum sac and the oesophagus, and the standard open-neck technique involving diverticulectomy and cricopharyngeus myotomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients treated for ZD at the Mt. Sinai Medical Center, New York (NY), USA. No inclusion or exclusion criteria were reported.

Setting
The setting was secondary care. The economic study was carried out in New York, USA.

Dates to which data relate
The dates to which the effectiveness, resources and prices related were not reported.

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

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study.

Study sample
The sample size was not determined in the planning phase of the study, nor were power calculations carried out retrospectively. The method used to select the sample was not reported. The authors did not justify the choice of patient sample. The sample size was very small, thus it is difficult to generalise the findings with confidence. Eight patients underwent endoscopic stapling and eight patients underwent the standard open approach with verticulectomy. There was no report of patients refusing to participate or being excluded.
Study design
The study was a randomised controlled trial that was conducted in a single centre. The authors not provide any details of the method of randomisation. The duration of follow-up was not reported explicitly, but it appears to have been until the patient was discharged from hospital. There appears to have been no loss to follow-up in either of the two groups.

Analysis of effectiveness
All the patients included in the study were accounted for in the analysis. The primary health outcomes were operative time, hospital days and days to oral intake. From the details provided, the two patient groups appear to have been broadly similar at analysis. Five men and three women underwent the endoscopic technique. Their mean age was 76.6 years (range: 67 - 86). Four men and four women underwent the open (diverticulectomy) technique. Their mean age was 72.2 (range: 59 - 91). There do not appear to have been any confounding variables. It was unclear whether the analysis was conducted on an intention to treat basis or on treatment completers only.

Effectiveness results
The operative time was 25.5 (+/- 15.78) minutes for the endoscopic stapling technique and 87.6 (+/- 35.10) minutes for the open technique. The difference between the two groups was statistically significant, (p<0.001).

Hospital stay was 1.3 (+/- 0.59) days for the endoscopic group and 5.2 (+/- 1.03) days for the open procedure group. The difference between the two groups was statistically significant, (p<0.001).

The time to oral intake was 0.8 (+/- 0.26) days for the endoscopic group and 5.1 (+/- 1.25) days for the open procedure group. The difference between the two groups was statistically significant, (p<0.001).

Clinical conclusions
In this study, patients undergoing the endoscopic procedure experienced a shorter operative time, a reduced length of hospital stay and a shorter time before oral intake than patients undergoing the open procedure.

Measure of benefits used in the economic analysis
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Direct costs
The resource quantities and the costs were not reported separately. Hospital costs were included in the analysis. These were operative charges and inpatient stay charges. The authors explained that operative costs fees were based primarily on the length of surgery, with time being divided into 30-minute blocks. The surgeons’ fees were included as part of the analysis and were the same for both procedures. The use of an EndoGIA stapler was included in the operative cost of the endoscopic procedure. The sources of the cost data were not clear, although the authors did refer in the paper to charges. No model was used to extrapolate to a longer timeframe or another setting. It was unclear how the charges or costs were estimated, but they appear to have been derived from actual data. Discounting was not relevant. The study reported the costs attributable to individual patients and the average cost for each of the two groups studied. The dates to which the price data referred were not given.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
No indirect costs were reported.
Currency
US dollars ($). No conversions were undertaken.

Sensitivity analysis
No sensitivity analysis was reported.

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

Cost results
The operative costs were approximately $5,178 for the endoscopic procedure and $5,113 for the open procedure.

The cost of hospitalisation was $3,589 (+/- 1,711) for the endoscopic group and $11,439 (+/- 2,372) for the open procedure. There was a statistically significant difference between the hospital costs for the two groups, (p<0.001).

There was no statistical analysis of the costs or confidence intervals.

The costs of adverse effects or knock-on costs were not relevant.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
Compared with the standard open technique, the endoscopic stapling technique resulted in statistically significantly shorter operative time, hospital stay and time to resume oral feeding. The charges for the operating procedures were found to be roughly equivalent for both techniques, but the total hospital charges for patients treated with the endoscopic approach were significantly less than those for patients treated with the open technique.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified on the basis of safety and efficacy results reported in the literature. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. The patient groups appear to have been comparable at analysis. The analysis of the results appears to have been carried out credibly.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs
It appears that all the categories of cost relevant to the perspective adopted have been included in the analysis, and that relevant costs were included. The costs and the quantities were not reported separately. A statistical analysis of the prices was not performed. The price date was omitted. Discounting and currency conversion were not relevant. It would appear that charges were used to proxy costs.
Other issues
The authors did not explicitly compare their findings with those from other studies. They also did not address the issue of generalisability to other settings. The authors do not appear to have presented their results selectively. The authors’ conclusions did not acknowledge the small sample size studied. The authors recognised that not all patients with a diagnosis of ZD are candidates for an endoscopic stapling approach. One limitation of the study was reported. Namely, days of lost earnings to the patients were not included in the analysis. The authors commented that patients who are employed would favour the minimally invasive procedure.

Implications of the study
The authors felt that an analysis that accounts for the enhanced revenue that could be generated by re-scheduling the operating room, taking the shorter endoscopic procedure into consideration, would further favour the endoscopic approach.

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