Role of somatostatin analogues in the management of enterocutaneous fistulae

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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 long-acting somatostatin analogues added to standard care for the treatment of patients with enterocutaneous fistulae. The somatostatin analogue used was Sandostatin 300 microg/day, administered subcutaneously in three divided doses.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients older than 12 years old with enterocutaneous fistulae. Patients were included in the study if spontaneous closure of the fistula was deemed possible. Cases of distal obstruction, disrupted gut, malignancy, etc., for which spontaneous closure was not possible, were excluded from the analysis. Patients with peritonitis requiring surgery were also excluded.

Setting
The setting of the study was secondary care. The study was conducted in Bahawalpur, Pakistan.

Dates to which data relate
The effectiveness and resource use data were collected between 1999 and 2002. The price year was not reported.

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

Link between effectiveness and cost data
The costing was carried out, probably prospectively, on the same patient sample as that used in the analysis of clinical effectiveness.

Study sample
No power calculations were performed. Thirty-three patients were included in the analysis, of which 17 were treated by conventional methods (standard care) and 16 received a somatostatin analogue plus standard care. The sample comprised 55% males and 45% females. The mean age was 39 years (age range: 14 - 68) for the males and 34 years (age range: 19 - 56) for the females. The method used to select the sample was not described. No evidence was provided that the initial study sample was appropriate for the clinical study question.
Study design
It was stated that the study was a randomised controlled trial (RCT) that was conducted in four surgical units of one hospital in Pakistan. The method of randomisation and further details on the study design were not provided. The patients were treated and followed until the complete closure of a fistula or death. No loss to follow-up was reported. No blinding of the outcome assessment was reported.

Analysis of effectiveness
It was not stated whether the analysis of the clinical study was conducted on an intention to treat basis. The clinical outcomes examined were time to the fistula closure, total length of hospital stay, and mortality. A fistula was considered closed when its secretions ceased and remained nil for 3 months. It was stated that the groups were similar at baseline in their age, gender, anatomical location and cause of enterocutaneous fistulae. No further adjustments for potential confounders were performed.

Effectiveness results
The average time to fistula closure was 17.7 days in the standard care group and 14 days in the somatostatin group, (t-test 1.18; p>0.05).

The mean length of hospital stay was 19 days in the standard care group and 15 days in the somatostatin group, (t-test 1.27; p>0.05).

Mortality was 2 out of 17 (12%) in the standard care group and 3 out of 16 (19%) in the somatostatin group, (chisquared test 0.311; p>0.05).

None of the differences in clinical outcomes between the groups were statistically significant.

Clinical conclusions
The use of a somatostatin analogue showed some beneficial effects in terms of time to fistula closure and length of hospital stay when added to standard care, but these effects were statistically insignificant.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used. The study was, therefore, a cost-consequences analysis.

Direct costs
The direct costs comprised medical treatment costs only. The costs were not analysed in their cost components. It was reported that all patients were treated in a general ward and that any bed charges and charges of nurses or doctors' visits were excluded from the analysis. The quantities and the costs were not provided separately. The costs were estimated using actual data derived from the RCT, while resource use was collected between 1999 and 2002. The unit costs were probably based on the hospital's prices. Discounting was not undertaken, but this was not necessary as the costs were incurred during less than one year. The price year was not reported.

Statistical analysis of costs
The costs were treated stochastically and the mean costs were provided. A statistical analysis of the costs was performed using Student's t-test.

Indirect Costs
The indirect costs were not included in the analysis.
Currency
Pakistani rupees (Rs).

Sensitivity analysis
No sensitivity analysis was conducted.

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

Cost results
The average treatment cost per patient was Rs31,500 in the standard care group and Rs43,600 in the somatostatin group.

The difference in costs between the groups was statistically significant, \((p<0.05)\).

Knock-on costs were probably not dealt with in the costing, although no details of the cost elements included were provided.

Synthesis of costs and benefits
Not applicable as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Somatostatin analogues were shown to result in statistically insignificant clinical benefits when added to standard care. However, their use significantly increased the cost of treatment. Thus, the role of somatostatin in the closure of enterocutaneous fistulae was not established.

CRD COMMENTARY - Selection of comparators
The comparator of the analysis was defined as standard care at the authors' setting. You should decide whether the comparator reflects routine care in your own setting.

Validity of estimate of measure of effectiveness
It was stated that the analysis was based on an RCT, which is the 'gold' standard for evaluating effectiveness. However, no further details on the design of the study were provided. In particular, the absence of power calculations when determining the sample size, and the lack of reported blinding of the outcome assessment or method of randomisation, presented potential limitations to the reliability of the findings. Consequently, the study might have had insufficient power to detect differences in outcomes between the two groups. All these factors could introduce bias into the results. The study sample was likely to be representative of the patient population. The patient groups were reported to be comparable at baseline. No statistical analyses were undertaken to account for potential biases and confounding factors.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences analysis.

Validity of estimate of costs
The analysis included medical treatment costs only. The costs were not analysed in their cost components, so it is not known what they consisted of. The costs and the quantities were not reported separately. These facts substantially
hinder the reproducibility of the results. It was reported that bed charges and nurses or doctors’ charges were excluded from the estimation of the costs, which might have affected the results. The resource use quantities were taken from a single study, while the unit costs were probably based on the hospital's prices, although it was not clearly stated in the paper. A statistical analysis of the costs was performed. Discounting was not undertaken, but it was unnecessary since the costs were incurred during less than one year. The price year was not reported and this limits the generalisability of the results.

Other issues
The authors compared their findings on clinical effectiveness with those of other studies. The issue of generalisability to other settings was not addressed. The results of the study were adequately reported. The study considered depressed patients with enterocutaneous fistulae and this was reflected in the authors' conclusions. The authors' conclusions reflected the scope of the analysis. The authors did not report any further limitations of their study.

Implications of the study
From the results of the analysis, it can be inferred that the use of somatostatin analogues added to standard care for the treatment of enterocutaneous fistulae may have some beneficial effects, but at an increased cost. Larger trials are required to explore the clinical and cost-effectiveness of somatostatin analogues in the treatment of patients with enterocutaneous fistulae.

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