Early operative intervention versus conventional treatment in epistaxis: randomized prospective trial

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 intranasal endoscopic sphenopalatine artery ligation (ESAL) for the treatment of recurrent epistaxis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were referred for epistaxis control to the otolaryngology service at the authors' setting (University of Alberta). Patients suffering from bleeding disorders, systemic anticoagulation, Rendu-Osler-Weber syndrome, or nasal malignancy were excluded from the study. Also excluded were those who had a recent history of nasal surgery and those who could no be operated on for medical reasons.

Setting
The setting was secondary care, the otolaryngology-head and neck surgery ward at the University of Alberta. The economic study was carried out in the USA.

Dates to which data relate
The dates to which the effectiveness and resource data related were not reported. 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 prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The sample size was not determined in the planning phase. In addition, power calculations were not carried out retrospectively. Initially, patients who were referred to the otolaryngology service for epistaxis were treated with Merocel nasal dressings bilaterally (Xomed Surgical Products, Jacksonville). Those patients who failed Merocel packings were enrolled in the study. Overall, 19 patients were enrolled in the study. The ratio of males to females was 7:3 in the conventional group and 4:5 in the ESAL group. The average age of the patients was 66.2 years (range: 48 - 89) in the conventional group and 57.3 years (range: 41 - 77) in the ESAL group. No patients were reported to have
refused to participate and no patients were excluded from the initial sample.

**Study design**
The analysis was based on a single-centre prospective randomised trial. The patients were randomised to either the conventional nasal packing group or the ESAL group, but the method of randomisation was not described. The patients were followed up by telephone questionnaire, 3 to 14 months after discharge. Overall, 6 patients (32%) were lost to follow-up, three (33%) from each of the two groups. The reasons for withdrawals were not reported.

**Analysis of effectiveness**
It was not reported whether the analysis was conducted on an intention to treat basis. The primary outcomes used were:

- observed treatment failure (defined as re-bleeding anteriorly or posteriorly, requiring additional treatment),
- the length of hospitalisation, and
- the patients' satisfaction with therapy (assessed by telephone questionnaire after patient discharge).

It was reported that the patient groups were comparable in terms of the demographic characteristics. Further characteristics of the patients who were lost to follow-up were not discussed. No adjustments for confounding factors were carried out.

**Effectiveness results**
Observed treatment failure reached 50% in the conventional nasal packing group but only 11% in the ESAL group. The difference was not statistically significant, (p=0.141).

The average length of hospitalisation was 4.7 days in the conventional nasal packing group versus 1.6 days in the surgical group. This difference was statistically significant, (p=0.001).

The authors reported that all patients in the surgical group were very satisfied with their therapy, while all patients in the conventional group described their experience as painful and unpleasant.

**Clinical conclusions**
The authors reported that "ESAL is an excellent, well-tolerated method of treating recurrent epistaxis".

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

**Direct costs**
The health service costs included in the analysis were for the procedure, hospitalisation and doctors' fees (including radiologists, surgeons and anaesthetists). The costs and the quantities were not reported separately. The quantities were most probably derived from the single study, while the source of the costs was not reported. Since the costs were incurred during less than 2 years, discounting was not relevant. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically (no statistical analysis was conducted).

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

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

**Cost results**
The average total costs per patient were reported. The average cost per patient was $12,213 in the conventional nasal packing group and $5,133.25 in the ESAL group.

**Synthesis of costs and benefits**
Not relevant.

**Authors’ conclusions**
Compared with conventional packing, intranasal endoscopic sphenopalatine artery ligation (ESAL) resulted in a significant cost-reduction and shortening of hospitalisation.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparators was explicitly justified. You should decide if they represent widely used health technologies in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective randomised trial, which was appropriate given the study question. The study sample was representative of the study population, and the patient groups were comparable in terms of their demographic characteristics. The method of randomisation was not discussed, neither were the characteristics of the patients lost to follow-up (apart from their gender and age). No reasons for withdrawals were provided, making it difficult to judge the internal validity of the study. Power calculations were not reported, and the sample size seems to have been relatively small. Thus, it was not possible to ascertain whether the results were due to the intervention or to chance.

**Validity of estimate of measure of benefit**
No summary measure of benefit was derived. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The perspective adopted was not reported, consequently, it was not possible to determine whether all the relevant costs had been included. For instance, it was not evident whether the overhead costs were included in the analysis. Since the indirect costs were not included in the economic analysis, we can rule out a societal perspective. The costs and the quantities were not reported separately and only the average total costs were reported. The quantities of resources used were most probably derived from the single study but no statistical analysis on resource use was undertaken, thus
limiting the reliability of the conclusions. The source of the prices was not reported, and no sensitivity analysis was carried out to test the robustness of the estimates used. Discounting was not relevant because of the short time horizon. However, the price year was not reported, thus impeding any future reflation exercises. Finally, it was unclear whether charges were used to proxy prices.

Other issues
The authors did not compare their findings with other published results. However, this may have been due to a lack of published literature in this specific area. The issue of generalisability was not addressed. The authors presented their results selectively. For example, the method for assessing the patients' satisfaction with treatment was not described, and no numerical results of the assessment were given. The study enrolled patients with recurrent epistaxis and this was reflected in the authors’ conclusions. The authors did not report any limitations to their study.

Implications of the study
The authors did not make any explicit recommendations for changes in policy or practice, or the need for further research.

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