Comparison of 2 preferred methods used for frontal sinus obliteration

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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 different techniques for frontal sinus obliteration were assessed. One was frontal sinus obliteration with abdominal fat. The other was frontal sinus obliteration using a hydroxyapatite cement (HAC) (Mimix; Walter Lorenz Surgical) composed of a powder (tetracalcium phosphate and alpha-tricalcium phosphate) and citric acid.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with isolated frontal sinus fractures, without any other upper face or midface fractures. The inclusion criteria specified:

- patients with isolated frontal sinus fractures (i.e. without any other upper face or midface fractures);
- the presence of a bony fracture involving the anterior and/or posterior table of the frontal sinus, including the nasofrontal duct (NFD), necessitating obliteration; and
- medical stability to undergo the proposed surgical procedure.

Patients with isolated anterior table fractures without NFD involvement or displaced posterior table fractures requiring cranialisation were excluded from the study.

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

Dates to which data relate
The effectiveness and resource use data were measured between February 1998 and December 2003. 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 effectiveness and cost data were derived from the same study sample. The costing was carried out retrospectively.
Study sample
The authors did not report the use of power calculations. From the 22 patients with frontal sinus fractures who were available for the analysis, 12 patients (age range: 15 - 69 years; 10 males) met the inclusion criteria. These patients were divided into two groups according to the technique used to obliterate the frontal sinus. Group A contained 6 patients who underwent frontal sinus obliteration with abdominal fat, while group B contained 6 patients who underwent frontal sinus obliteration using Mimix (i.e. HAC).

Study design
This was a retrospective cohort study that was conducted in a single centre between February 1998 and December 2003. The mean follow-up was 3 months for group A and 2 months for group B. No blinding of the assessment was reported.

Analysis of effectiveness
The primary health outcomes assessed in the effectiveness analysis were the operating time and complication rate. The authors did not state whether the two groups were comparable at baseline in terms of their demographic and clinical characteristics. No adjustment for confounding factors appears to have been conducted.

Effectiveness results
The mean operating time was 144 minutes (range: 86 - 175) in group A and 130 minutes (range: 96 - 203) in group B. The difference was not statistically significant, (p=0.5236).

No complications were reported in either group during the follow-up period.

Clinical conclusions
The authors concluded that there was no statistical difference in operating time and complication rates between the two interventions.

Measure of benefits used in the economic analysis
The effectiveness analysis indicated an equal efficacy between interventions and, therefore, only the costs were considered in the economic analysis. No summary measure of health benefits was derived.

Direct costs
Discounting was not carried out as the costs were incurred during less than one year. Only the total operating room cost was included in the analysis. This cost combined the cost of operating room utilisation and the cost of materials. The unit costs and the quantities were reported separately for operating room utilisation. The source of the unit costs was not reported, but it was likely to have been derived from the authors' setting. The resource use data were derived from patient operative and nursing records. The price year was not reported.

Statistical analysis of costs
The costs were expressed as mean values and were analysed using the t-test.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analysis was reported.

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

Cost results
The mean total operating room cost was $8,683.33 (range: 6,272.20 - 9,863.40) for group A and $10,622 (range: 8,634 - 12,874) for group B. This cost-difference was found to be statistically significant, (p=0.0420).

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Frontal sinus obliteration using autogenous abdominal fat appears to have been more cost-effective in comparison with the use of hydroxyapatite cement (HAC). The slight difference in total operating time was not statistically significant, and this factor alone should not be a deterrent from performing this surgical procedure.

CRD COMMENTARY - Selection of comparators
The authors explicitly justified the choice of the comparator. Frontal sinus obliteration using autogenous abdominal fat reflected the method currently used by many surgeons in USA. You should judge whether this comparator is relevant in your own setting, or whether other comparators could have been relevant as well.

Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort study. The nature of the study meant that the authors were unable to control or attempt to minimise systematic differences between the patient groups. It is not possible for the reader to assess whether there may have been confounding factors that influenced the results as summary statistics were not presented for the patients in each group; although with this study design it is difficult to rule out. The lack of power calculations and the small sample size meant that it was unclear whether the study sample was sufficiently large to prove the statistically significant difference in health outcomes. In addition, the small follow-up period in each group and the difference of follow-up between groups may impact on the statistically significant difference in health outcomes. The study sample appears to be representative of the study population.

Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of the interventions. Therefore, the economic analysis only included the costs.

Validity of estimate of costs
Although the perspective adopted was unclear, it appears that the categories of costs relevant to a hospital perspective have been included. The authors focused on differences in costs between the two strategies, but only limited details on the cost analysis were reported. The costing could have been reported more thoroughly by breaking down the cost and resource use elements in order for the reader to assess the key cost-drivers. For example, it was unclear whether the professional's fees and overhead costs were evaluated. It would also appear that the costs associated with the nursing time after discharge from the operating room were not included in the analysis. This omission might have affected the cost results, as well as the authors' conclusions.

The unit costs and the quantities were reported separately for operating room utilisation, and this will enable the
extrapolation of this analysis to other settings. The resource use data and unit costs were taken from the authors’ setting, but the lack of any sensitivity analyses on both parameters potentially limits the interpretation of the findings. The failure to report the price year also limits any future reflation exercise. Discounting was appropriately not carried out since all the costs were incurred during less than one year.

Other issues
The authors compared their clinical results with those from other studies and found different results, such as postoperative wound infections after performing frontal sinus obliteration using abdominal fat. They did not compare the economic results with other studies, reporting instead that this was the first analysis of the cost-difference between abdominal fat and HAC approaches for frontal sinus obliteration. The issue of generalisability to other settings was not addressed. The conclusions reported were an accurate reflection of the scope of the analysis and of the results presented. Several limitations, which centred on the small sample size and the lack of proper long-term follow-up, were presented.

Implications of the study
The authors made no recommendations for policy or practice following their study. They suggested that further investigation of frontal sinus obliteration with autogenous and alloplastic material, as well as longer follow-up periods, are needed to elucidate more information on this matter. They also suggested that as newer bioengineering technology emerges, one would expect that the overall cost of HAC would decrease, possibly altering their data in any future comparison studies.

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