Systematic review of the endoscopic modified Lothrop procedures for the treatment of chronic frontal sinusitis

Authors' objectives
To compare the safety and efficacy of the endoscopic-modified Lothrop procedure (EMLP) against the current benchmark treatment of osteoplastic flap procedure (OPF) with or without fat obliteration.

Searching
MEDLINE from 1981, EMBASE from 1974, Current Contents from 1993, and the Cochrane Library from 1966 were all searched up to early 2001. The search terms were reported in the paper. Foreign language papers were identified from their abstracts, but were not translated unless they appeared to add different or more extensive results. Unpublished studies were excluded.

Study selection
Study designs of evaluations included in the review
The eligible studies included randomised and non-randomised controlled trials, case series and case reports. It was stated that 'other designs were included if considered relevant and if valid reasons were given in the protocol'.

Specific interventions included in the review
EMLP, either wholly intranasally or in combination with an external approach, must have been compared with OPF with or without fat obliteration. Studies where OPF was performed using filling material other than autogeneous fat or using a superiorly-based flap were excluded. Studies where non-sinus surgery was performed at the same time were also excluded.

Participants included in the review
Patients diagnosed with chronic frontal sinusitis were eligible, as were those who had undergone prior sinus surgery. Patients with cystic fibrosis, inverted nasal papiloma or malignant tumours were excluded.

Outcomes assessed in the review
The studies had to report at least one of the following: peri-operative and post-operative mortality or morbidity; peri-operative and post-operative factors such as operative time, blood product usage, operative failure rate, rate of recurrent or persistent disease; evaluation of success by nasofrontal communication patency, health of the mucous membranes, ventilation of the sinus and any sinus opacity; and convalescence indicators such as convalescence period, wound healing time and hospital stay.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The included papers were assessed against a hierarchy of evidence that used study design to rank the evidence. The authors do not report any method for assessing other elements of validity. The authors discussed specific methodological shortcomings. The authors do not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data
Methods of synthesis
How were the studies combined?
The studies were combined using a narrative approach.

How were differences between studies investigated?
Differences between the studies were not systematically investigated.

Results of the review
Nine studies (total n=151) were included in the review. There were two comparative studies (n=63), one prospective and one retrospective, and seven case series (n=88), two of which were prospective.

There were very little comparative data on post-operative safety. One comparative study (n=36) reported a higher incidence of intra-operative cerebrospinal fluid leak following EMLP than with OPF, and a lower incidence of decreased forehead sensation (0% for EMLP and 14% for OPF). In addition, 5% of the OPF patients lost their fat graft due to infection. The second comparative study (n=27) reported transient visual disturbance in one EMLP patient as the only adverse EMLP outcome, but OPF adverse outcomes were not available. Two case series reported nonfatal intra-operative cerebrospinal fluid leakage (10 to 11%) in EMLP patients. The reported post-operative morbidity across six EMLP case-series was one case of iatrogenic septal perforation.

There were also very little comparative data on efficacy. One study reported shorter hospital stays for EMLP, compared with OPF, and EMLP was performed as an out-patient procedure in 65% of the patients. Subjective symptom improvement was reported for 70% of the EMLP patients in one study, with a 95% nasofrontal patency rate under post-operative endoscopic examination, but these outcomes were not reported for the study’s OPF patients. A second study reported 100% subjective symptom resolution for OPF patients, without measuring their nasofrontal patency, compared to 87% of the EMLP patients having normal sinus ventilation after two and a half years. Two EMLP patients required revision surgery in this study, compared with no OPF patients. The nasofrontal patency reported in case series for EMLP patients ranged from 57 to 100%.

There were little safety data on OPF, and the authors caution that the data are only indicative. The reported complications were limited to scalp haematoma, embossment, and morbidity associated with the fat donor site. Resolution of frontal sinus disease was achieved in 95 to 100% of patients in three studies. Disease recurrence ranged from 5 to 8%. Frontal headache was the most common adverse effect (23%).

The limited data on quality of life outcomes indicated an improvement in 74% of the patients after EMLP, and a decrease in symptoms for 86 to 90%. One study reported the quality of life for OPF patients; 65% were satisfied with OPF.

Authors' conclusions
While EMLP may ultimately prove to be as safe and efficacious as OPF, long-term follow-up data to confirm its durability are currently lacking. The safety and efficacy of EMLP for chronic frontal sinusitis cannot be determined due to an incomplete and poor-quality evidence-base. More research is required.

EMLP was associated with out-patient or short in-patient stays, compared with three days for OPF. The limited data suggested that EMLP caused fewer post-operative adverse outcomes, but had a much higher incidence of intra-operative cerebrospinal fluid leak. Symptom resolution may be lower with EMLP and disease recurrence higher. Common complications of OPF were absent with EMLP.

CRD commentary
The review question and the inclusion criteria were clear, except in relation to foreign language papers. The search for published studies was adequate, but excluded 'grey' literature; some data may therefore have been missed. Details of the
individual studies were reported in full. The review procedures for selecting and abstracting studies were not described, so it is impossible to assess whether they were sufficient to guard against error or bias. Whilst there was no systematic validity assessment of the included studies, the authors discussed their methodological shortcomings and threats to validity. The synthesis method was appropriate and the conclusions were justified from the data presented.

Implications of the review for practice and research
Practice: The authors state that EMLP should only be performed by a properly trained EMLP-accredited otolaryngological surgeon.

Research: The authors state that a well-conducted multicentre prospective study that uses objective measures of success, and has a follow-up of at least five years, is required.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.