Systematic review of endoscopic sinus surgery for nasal polyps

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CRD summary
This well-conducted review concluded that endoscopic sinus surgery may offer some advantages in effectiveness over comparator techniques in the removal of nasal polyps. However, the authors also highlighted the enormous variation in the results of the included studies and their severe methodological limitations.

Authors' objectives
The authors aimed to systematically review the clinical effectiveness of functional endoscopic sinus surgery (FESS) for the removal of nasal polyps.

Searching
The following electronic databases were searched: the Cochrane Library (Issue 2, 2002), MEDLINE (1966 to April 2002), PubMed (February to May 2002), EMBASE (1980 to March 2002), Science Citation Index (1981 to May 2002), Web of Science Proceedings (1981 to May 2002), BIOSIS Previews (1985 to May 2002), CINAHL (1982 to February 2002), DARE (May 2002), HTA (May 2002), the National Research Register (Issue 1, 2002), HMIC databases (May 2002), the British Library Catalogue (March 2002), Current Controlled Trials (May 2002), Clinical Trials.gov (May 2002) and Proceedings (FirstSearch) databases (1993 to May 2002). The SERNIP and Medical Devices Agency web pages were also examined. The searches were limited to English language publications only. The search terms were listed in the report with full details of the search strategy available on request.

Additional searches involved checking the references of full papers retrieved, together with the examination of industry submissions provided to the National Institute of Clinical Excellence.

Study selection
Study designs of evaluations included in the review
Comparative studies and case series were eligible for inclusion. Case series were required to examine more than 50 patients with nasal polyps. The following study types were excluded: narrative reviews, editorials, single case studies or reports, expert opinion papers and preclinical or biological studies. Reviews published over 5 years ago were also excluded. The included studies reported follow-up ranging from 6 to 42 months.

Specific interventions included in the review
Studies examining functional endoscopic sinus surgery (FESS) in the excision of nasal polyps were eligible for inclusion. Comparative studies were required to compare FESS with conventional procedures. Studies assessing only the pathology or histology of polyps were excluded. The included studies examined the effectiveness of the procedure carried out both under general and local anaesthetic. Where reported, post-operative management involved the use of either topical or systemic steroids.

Participants included in the review
Studies adequately describing the patient population in terms of surgical indications and numbers of patients with polyps were eligible for inclusion. Studies detailing animal models were excluded. The majority of the included studies examined patients with a variety of disease including polyps; a selection focused only on patients with polyps. Both adults and children were examined in the primary studies. The majority of the studies were conducted in the USA or Europe.

Outcomes assessed in the review
Studies reporting patient-relevant outcomes were eligible for inclusion. Those only reporting on the histological appearance of polyps, mean blood loss, or duration of surgery were excluded. The data were required to be presented in such a way that the results of nasal polyp excisions could be isolated from procedures for other conditions.
Symptomatic improvement was chosen as the primary outcome measure of the review; revision rates, recurrence or residual disease, and complications were also reported in detail.

How were decisions on the relevance of primary studies made?
Two reviewers screened potentially relevant studies independently. Where necessary, disagreements were resolved by consensus. Decisions were made prior to data extraction and detailed examination of the study results.

Assessment of study quality
The internal validity (reflected in the study's sample size and potential for selection, performance, detection or attrition bias) and external validity (defined in terms of generalisability, patient characteristics, usual care setting, standard treatment regime, standard treatment outcomes, and length of follow-up) of comparative studies were assessed using structured forms. Similarly, the internal validity and external validity of case series were assessed, with reference to sample size, and potential for selection, performance and attrition bias, as well as generalisability, patient characteristics, usual care setting, standard surgical regime, standard treatment outcomes, and length of follow-up. The quality of the included studies was assessed by one reviewer and checked by a second reviewer.

Data extraction
The data were extracted by one reviewer and checked for accuracy by a second reviewer. Any disagreements were resolved by consensus. In addition to extracting the reported study results, the reviewers calculated results on an intention-to-treat basis using original data where available.

Methods of synthesis
How were the studies combined?
The results of the included studies were synthesised in narrative form. The results were also presented in forest plots, but were not combined.

How were differences between studies investigated?
Differences between the studies were highlighted in the ordering of the results according to primacy of outcome measure, rigour of study design and the proportion of patients with polyps.

Results of the review
Thirty-three studies (n=11,147) were included in this review: 3 randomised controlled trials (RCTs; n=240), 3 controlled clinical trials (CCTs; n=2,699) and 27 case series reports (n=8,208).

Symptomatic improvement (5 RCTs/CCTs).
Three trials reported greater symptomatic improvement for FESS techniques, with the improvement ranging from 78 to 85% compared with 43 to 72% for comparative techniques. Two of these studies displayed statistically significant differences. A further trial reported no difference between the techniques (82%). Another trial reported that radical nasalisation showed greater improvement than conventional ethmoidectomy (41% versus 8%); the differences were statistically significant.

Symptomatic improvement (case series).
For participants with nasal polyps, symptomatic improvement ranged from 37 to 99% (n=10). In the mixed patient group (with and without nasal polyps), overall symptomatic improvement ranged from 40 to 98% (n=17).

Recurrence of polyps or disease (2 RCTs/CCTs).
In the one trial that reported disease recurrence, the rates were not significantly different between FESS and Caldwell-Luc techniques (8% versus 14%). A different trial reported no significant differences in polyp recurrence between endoscopic ethmoidectomy and polypectomy (28% versus 35%).
Recurrence of polyps or disease (case series).

Amongst patients with polyps, recurrence ranged from 8 to 66% (n=13). Amongst those with mixed disease, recurrence ranged from 4 to 33% (n=6).

Residual disease.

RCTs/CCTs: no comparative study reported on this outcome.

Case series: residual disease ranged from 12 to 75% of sides that were operated on (n=4).

Revision surgery.

In the RCTs/CCTs, neither of the two trials reporting revision surgery as an outcome detected statistically significant differences in rates between the groups. In the case series, revision ranged from 6 to 42% amongst patients with polyps (n=4), and from 3 to 9% amongst those with mixed disease (n=9).

Complications (3 RCTs/CCTs).

One trial comparing FESS with Caldwell-Luc reported no major complications in either group. Another trial reported a rate of total complications of 1.4% for FESS techniques compared with 0.8% for conventional procedures. A trial comparing functional ethmoidectomy with radical nasalisation reported total complications of 7.7% for the latter technique, but none for the former.

Complications (case series).

The total complications ranged from 0.3 to 22.4% (n=23).

Validity.

The authors highlighted the low generalisability of results to the UK setting, the non-independent assessment of outcomes, and the variable follow-up of all the included studies, all of which threaten external validity.

In addition, the internal validity of the included RCTs was reduced by limited study power (n=2), inadequate randomisation (n=3), baseline differences between the groups (n=2), variation in the intervention of interest (n=3) and loss to follow-up (n=3). Similarly, the CCTs were subject to non-random allocation (n=3), baseline differences between the groups (n=3), variation in the intervention of interest (n=3) and loss to follow-up (n=2). Finally, the authors pointed out the main threats to the internal validity of the case series studies: the lack of a control group, susceptibility to selection bias, variation in the intervention applied and loss to follow-up (n=15).

Cost information

Existing economic evaluations of FESS for the excision of nasal polyps were separately identified and described. The cost of the procedure was estimated to range from £237 (day case) to £968 (elective). Further details were reported.

Authors’ conclusions

FESS may offer some advantages in effectiveness over comparator techniques, but there was enormous variation in the range of results reported and there were severe methodological limitations.

CRD commentary

The research question and the inclusion criteria were clearly reported. The searches were extensive, but the limitation to English language studies might have introduced an element of bias. The validity of the included studies was assessed, and the results were presented according to rigour of study design. Details of the studies were clearly presented, and the narrative synthesis of the results appears appropriate given the heterogeneity of the included studies. It is clear that the authors took steps to minimise bias in the conduct of their review. The conclusions of this review appear to be very
reliable. This research was commissioned and funded by the NHS R&D Health Technology Assessment Programme.

**Implications of the review for practice and research**

Practice: The authors stated that the evidence-base is insufficiently robust to clearly guide policy-makers regarding the diffusion of FESS and its place in the management of chronic rhinosinusitis or polyposis.

Research: The authors highlighted a need for high-quality, local, long-term comparative evidence in the area of FESS.

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