

Effectiveness of extensive sinus surgery with post-operative medical management for chronic rhinosinusitis

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Abstract

Objective: To prospectively assess treatment outcomes of chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery and post-operative medical treatment over a prolonged follow-up period.

Methods: Patients undergoing functional endoscopic sinus surgery in the tertiary referral practice of a single surgeon were studied prospectively. Symptoms were scored by patients pre-operatively and over a minimum follow-up period of 12 months.

Results: The study comprised 200 non-consecutive patients. The median pre-operative symptom score was 16 (out of a maximum of 25) (95 per cent confidence interval = 15 to 17). Symptom scores reduced to a median of 7 (95 per cent confidence interval = 6 to 8) after 12 months of follow up ($p < 0.0001$). The median symptom score improved for all symptoms and across all patient subgroups.

Conclusion: Extensive functional endoscopic sinus surgery offers significant and durable symptom improvement in patients with chronic rhinosinusitis refractory to medical treatment. This improvement extends to all patient subgroups. Prolonged medical therapy is recommended after functional endoscopic sinus surgery.

Key words: Adult; Chronic Disease; Follow-Up Studies; Humans; Nasal Polyps; Prospective Studies; Sinusitis; Treatment Outcome

Introduction

Since its introduction more than 30 years ago,¹ functional endoscopic sinus surgery (FESS) has become the preferred surgical approach in patients with chronic rhinosinusitis resistant to medical therapy.² Given the high prevalence of chronic rhinosinusitis³ and the limited efficacy of medical therapy in more severe cases,⁴ FESS is now one of the most commonly performed elective surgical procedures in the Western world.⁵ Successful outcomes have been reported in approximately 80 per cent of FESS cases.^{6,7} Functional endoscopic sinus surgery failures are generally revised after a prolonged post-operative follow-up period, during which more medical therapy is typically prescribed.⁷

The indication for FESS for the treatment of chronic rhinosinusitis remains poorly defined, and there is little consensus about the extent of sinus dissection that is required. Factors such as the heterogeneity of the condition,⁸ the surgical treatments performed,⁶ the outcomes measured⁹ and the dearth of randomised trials¹⁰ make interpretation of the current literature difficult. The rapid evolution in surgical techniques¹¹ may

mean that results achieved in older patient series, such as those showing no improvement in olfaction,¹² are no longer relevant.^{13,14} Post-operative medical care is also evolving, with an increasing recognition of the importance of aspirin desensitisation in aspirin-exacerbated respiratory disease patients¹⁵ and prolonged administration of topical therapies in all.¹⁶ Accordingly, there is a requirement for more contemporary series to define the efficacy of surgical management in chronic rhinosinusitis patient subgroups.¹⁷

The most clinically relevant measure of chronic rhinosinusitis severity is the patients' assessment of symptoms. The five major symptoms are nasal obstruction, anterior and posterior rhinorrhoea, discomfort, and hyposmia.² The persistence of symptoms after medical therapy remains the principal indication for surgical treatment.¹⁸ Our clinical approach has been to use a simple patient-reported scoring system based on the severity of each symptom over the previous fortnight, with each symptom graded out of 5, giving a maximum potential score of 25. This represents a minor modification from the recently validated Adelaide Disease Severity Score.¹⁹ A similar

symptom-based approach was used in a large meta-analysis, which concluded that nasal obstruction improved the most with FESS, and hyposmia and headache improved the least.²⁰

Some series have shown that improvements in morbidity afforded by FESS are durable beyond six months,^{7,21} but the number of series with prolonged follow up is relatively small.

Various prognostic indicators of post-operative outcome have been identified. In a large multi-institutional study, the most highly predictive factor of poor outcome was previous FESS.²² Despite this, clear improvements in symptoms in revision FESS cases are achievable.²³ The presence of co-morbid asthma and aspirin-exacerbated respiratory disease have also each been associated with worse outcomes from surgery.^{24,25} The prognostic significance of nasal polyposis is less certain.^{22,25}

This study describes the efficacy of a uniformly extensive FESS procedure followed by long-term medical management in a heterogeneous group of chronic rhinosinusitis patients.

Materials and methods

The study received approval from the University of Auckland Human Participants Ethics Committee.

Non-consecutive patients for whom bilateral middle meatal antrostomies, sphenoethmoidectomies and frontal recess dissections ('comprehensive FESS') were performed for the treatment of chronic rhinosinusitis in the practice of a single surgeon (RGD) (in a tertiary rhinology practice), between August 2008 and March 2011, were studied prospectively. All patients fulfilled the European position paper on rhinosinusitis and nasal polyps (2007) diagnostic criteria for chronic rhinosinusitis.²⁶ Medical therapy, in the form of oral and topical corticosteroids, oral antibiotics, and saline lavage, had failed in these patients.¹⁸

All patients were asked pre-operatively about aspirin sensitivity and an aspirin challenge test was performed when the history was unclear. All patients in whom aspirin-exacerbated respiratory disease was identified were referred for aspirin desensitisation, which was begun approximately two weeks post-operatively in conjunction with a short course of montelukast.

In accordance with evidence-based guidelines,¹⁶ ongoing topical treatments in the form of nasal saline lavage and twice daily intranasal steroid spray were recommended to all patients in the post-operative period. All patients received a one to two week course of post-operative antibiotics and patients with nasal polyposis also received a course of oral corticosteroids of similar duration.

Patients with disease localised to the maxillary antra and/or anterior ethmoid sinuses for whom more limited surgery was indicated were excluded from this study. Such patients without pansinusitis may represent a different clinical phenotype.²⁷ Patients were also excluded if they had co-existent primary

TABLE I
SYMPTOM SCORE QUESTIONNAIRE

| Please rate the severity of your sinusitis symptoms out of 5 in the last 2 weeks, where 0 = no symptoms & 5 = worst possible symptoms | Score |
|---|-------|
| Blocked nose | |
| Runny nose | |
| Post-nasal drip | |
| Facial pressure, pain or discomfort | |
| Loss of sense of smell | |

mucociliary anomalies such as cystic fibrosis or primary ciliary dyskinesia.

The age, sex, ethnicity, presence or absence of nasal polyps in the middle meatus, pre-operative Lund–Mackay score,²⁸ and symptom scores (Table I) were recorded, as well as history of asthma, aspirin-exacerbated respiratory disease and previous FESS.

Post-operatively, patients completed symptom score sheets at each clinical review. Patients discharged from follow up before 12 months were contacted by telephone to collect symptom scores at or beyond 12 months.

The primary outcome measure for analysis was the total symptom score after more than 12 months of follow up. Where appropriate, the total reduction in symptom score, from the pre-operative score to the score at more than 12 months post-operation, was calculated.

Absolute numbers and proportions (percentages) were used for describing categorical variables. Continuous variables such as age and symptom scores were checked for normality. Age and Lund–Mackay score were described using medians and interquartile ranges. Medians and 95 per cent confidence intervals (CIs) (distribution-free) were generally calculated for symptom scores, and the signed-rank test was used to assess reductions in symptom scores. Boxplots were graphed for the total symptom score across all follow-up periods and for the reductions in individual symptom scores. General linear models and multiple regression models were used for identifying factors related to the total symptom score after more than 12 months of follow up. SAS (version 9.3) software was employed to carry out the statistical analysis (SAS Institute, Cary, North Carolina, USA).

Results

A total of 200 patients, for whom follow-up data beyond the 12th post-operative month were available, were included in this study. The demographic and clinical details are documented in Table II. Fifty-seven cases (28.5 per cent) represented revision surgery, and 18 of the 101 nasal polyposis cases had aspirin-exacerbated respiratory disease (17.8 per cent). Age was not normally distributed. Median age was 46 years (interquartile range, 19).

TABLE II
PATIENT DEMOGRAPHIC AND CLINICAL DETAILS

| Parameter | Values |
|---|----------------|
| Age (median (IQR); years) | 46 (19) |
| Sex ratio (males : females) | 104:96 |
| Lund–Mackay score (median (IQR)) | 14 (5) |
| Presence of nasal polyps (<i>n</i> (%)) | 101/200 (50.5) |
| Revision surgery (<i>n</i> (%)) | 57/200 (28.5) |
| Asthma (<i>n</i> (%)) | 73/200 (36.5) |
| AERD (<i>n</i> (%)) | 18/101 (17.8) |
| Simultaneous septoplasty (<i>n</i> (%)) | 62/200 (31) |
| Simultaneous inferior turbinate reduction (<i>n</i> (%)) | 46/200 (23) |

IQR = interquartile range; AERD = aspirin-exacerbated respiratory disease

The median pre-operative symptom score was 16 (interquartile range, 7.5; 95 per cent CI = 15 to 17). There was a statistically significant reduction in the total symptom score after more than 12 months of follow up (Figure 1).

The total reduction in symptom score over the follow-up period was considered with patients grouped on the basis of: the presence or absence of nasal polyps, aspirin-exacerbated respiratory disease, asthma and previous surgery. All the symptom score reductions were statistically significant ($p < 0.001$; signed-rank test for paired data). These data are presented in Table III.

Lund–Mackay score, sex and previous surgery were statistically related to the pre-operative total symptom score in the multiple linear regression model (Table IV). The model had an R-square of 0.1599, indicating reasonable fit of data, and the statistical model was significant too (analysis of variance, $p = 0.0037$). One point of the Lund–Mackay score was associated with a 0.27 (95 per cent CI = 0.06 to 0.48) increase in the pre-operative total symptom score, whereas

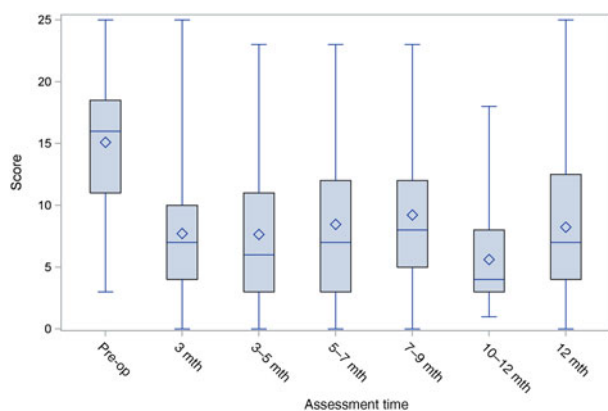


FIG. 1

Total symptom scores across all follow-up periods. The number of patients available for analysis at each point in follow up was: 153 at 3 months, 97 at 3–5 months, 74 at 5–7 months, 33 at 7–9 months, 13 at 10–12 months, and 200 at 12 months or later.

Pre-op = pre-operative; mth = months

males and patients who had undergone previous surgery were associated with a 2.32 (95 per cent CI = -3.84 to -0.80) and 1.80 (95 per cent CI = -3.51 to -0.09) decrease in pre-operative total symptom score respectively. However, no factors were associated with the post-operative reduction in total symptom score (the associated statistical models are not included).

When the reduction in individual symptom scores was considered over the study period, there was a non-significant trend towards greater improvements in nasal obstruction and anterior rhinorrhoea, and lesser improvements in facial pain and hyposmia. These data are presented in Figure 2.

Of the 200 patients, 5 had problems with bleeding that required some escalation of care. Of these, one patient required transfusion and one returned to the operating theatre. A breach of the lamina papyracea was identified in three patients, but there were no major orbital or skull base complications.

Discussion

With increasing pressure on healthcare spending, it is important that the long-term efficacy of FESS is determined.¹⁷ Given the difficulties in performing blinded, randomised trials in surgical research, well-designed case series studying FESS outcomes are of increasing importance.¹⁰ This level of evidence of 4 study adds further weight to the body of evidence indicating that contemporary FESS provides durable symptomatic improvement in chronic rhinosinusitis.

A study of FESS outcomes in which post-operative aspirin desensitisation was not utilised reported a 50 per cent recurrence of symptomatic nasal polyposis at six months post-FESS.²⁵ These data, combined with anecdotal experience, may have discouraged clinicians from managing aspirin-exacerbated respiratory disease surgically. However, this study clearly shows marked symptom improvement when FESS is combined with an appropriate aspirin desensitisation regimen in these patients. Significant improvements were also noted in revision cases, another group that have in the past been considered less attractive surgical candidates.²²

A strength of this study is the consistency of the approach followed, in the form of extensive surgery and simultaneous medical management. There is, however, no consensus regarding the extent of surgery in FESS procedures. As was the case for all patients in this series, we perform frontal dissection when there is mucosal thickening in the frontal recess or opacification of the sinus; this has proved to be a safe and effective strategy. The decision to proceed was based on computed tomography (CT) findings, and not on the presence of symptoms that are thought to indicate frontal sinus problems such as headaches or pressure symptoms. Many patients with extensive frontal disease on CT scanning do not complain of these symptoms. There are no data from randomised

TABLE III
SYMPTOM SCORES BY PATIENT AND DISEASE GROUPINGS, PRE- AND POST-OPERATION, AND SYMPTOM SCORE REDUCTIONS

| Grouping | Pre-operative symptom score Median (95% CI) | >12 month symptom score Median (95% CI) | Symptom score reduction | | |
|---|--|--|-------------------------|-----|----------|
| | | | Median (95% CI) | IQR | <i>p</i> |
| CRS with nasal polyps (<i>n</i> = 101) | 16 (15 to 17) | 7 (5 to 8) | -7 (-9 to -5) | 7 | <0.0001 |
| CRS without nasal polyps (<i>n</i> = 99) | 15 (15 to 17) | 7 (6 to 9) | -7 (-9 to -5) | 9 | <0.0001 |
| CRS with nasal polyps & AERD (<i>n</i> = 18) | 17.5 (13 to 20) | 7.5 (3 to 12) | -9 (-15 to -4) | 11 | 0.0002 |
| CRS with nasal polyps without AERD (<i>n</i> = 83) | 15 (14 to 16) | 7 (5 to 8) | -7 (-9 to -5) | 6 | <0.0001 |
| Asthma (<i>n</i> = 73) | 17 (15 to 18) | 7 (6 to 9) | -8 (-10 to -7) | 10 | <0.0001 |
| No asthma (<i>n</i> = 127) | 15 (14 to 16) | 7 (6 to 8) | -7 (-8 to -5) | 7 | <0.0001 |
| Revision surgery (<i>n</i> = 57) | 15 (12 to 17) | 8 (7 to 10) | -7 (-8 to -3) | 7 | <0.0001 |
| Primary surgery (<i>n</i> = 143) | 16 (15 to 17) | 7 (6 to 8) | -8 (-9 to -6) | 8 | <0.0001 |
| Total symptom score (<i>n</i> = 200) | 16 (15 to 17) | 7 (6 to 8) | -7 (-8 to -6) | 8 | <0.0001 |

CI = confidence interval; IQR = interquartile range; CRS = chronic rhinosinusitis; AERD = aspirin-exacerbated respiratory disease

TABLE IV
FACTORS ASSOCIATED WITH TOTAL SYMPTOM SCORE PRE-SURGERY*

| Factors | Reference group | Parameter estimate | Standard error | <i>t</i> | <i>p</i> | 95% CI |
|-------------------|-----------------|--------------------|----------------|----------|----------|----------------|
| Lund-Mackay score | - | 0.27 | 0.11 | 2.55 | 0.012 | 0.06 to 0.48 |
| Polyps | No | -1.42 | 0.86 | -1.65 | 0.101 | -3.12 to 0.28 |
| Asthma | No | 1.12 | 0.80 | 1.39 | 0.167 | -0.47 to 2.71 |
| Previous surgery | No | -1.80 | 0.86 | -2.08 | 0.039 | -3.51 to -0.09 |
| Age (years) | - | -0.02 | 0.03 | -0.72 | 0.476 | -0.07 to 0.03 |
| Sex | Female | -2.32 | 0.77 | -3.01 | 0.003 | -3.84 to -0.80 |
| Maori | European/other | 2.66 | 1.64 | 1.62 | 0.108 | -0.59 to 5.91 |
| Pacific | European/other | 1.42 | 1.72 | 0.82 | 0.411 | -1.98 to 4.82 |
| Asian | European/other | 0.82 | 1.48 | 0.56 | 0.578 | -2.10 to 3.75 |

*Analysed using a multiple linear regression model. CI = confidence interval

studies in which one side of the sinuses are fully dissected and the outcome achieved compared to a more limited dissection on the contralateral side. This experimental model would assume no crossover effect. Until a definitive randomised study is performed, advocates of conservative and radical approaches will continue to argue their case.

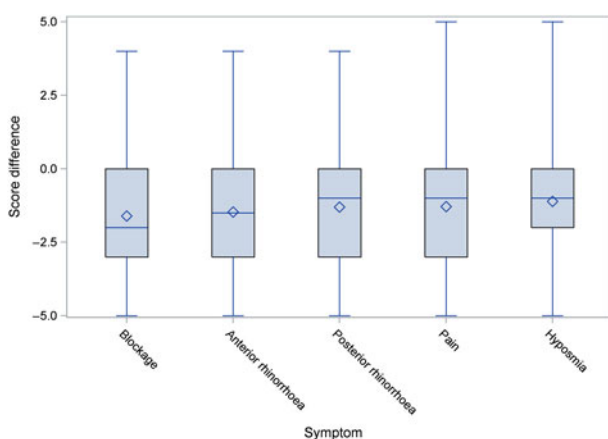


FIG. 2

Reduction in individual symptom scores.

One likely reason for the favourable outcome in the majority of our patients is our recommendation that topical medical treatment be continued indefinitely in patients following extensive sinus surgery. It is recognised that sinus penetration of topical medications is greatly improved by FESS.²⁹ The efficacy of saline lavage has been clearly demonstrated in the post-operative period.³⁰ A recently performed meta-analysis suggests that intranasal corticosteroids are even more effective in the post-operative period than in patients who have not undergone FESS.³¹

The extent of radiologically evident disease has been reported to have limited correlation to pre-operative symptom severity.^{9,32} In this study, however, there was a correlation between Lund-Mackay scores and pre-operative symptom scores, with prior surgery also being predictive of higher symptom scores. Other studies have found the greatest FESS-related improvements in nasal obstruction and anterior rhinorrhoea, and lesser improvements in pain and hyposmia.^{20,33} There was a non-significant trend towards the same finding in this study; however, the study may not have been sufficiently powered to identify such an effect. Such observations are of clear utility in the pre-operative counselling of patients.

- **This study investigated extensive functional endoscopic sinus surgery (FESS) with post-operative medical management for chronic rhinosinusitis**
- **This approach led to significant and durable improvement in all major symptoms**
- **Treatment efficacy extended to all subgroups studied, including revision surgery patients**
- **Aspirin desensitisation afforded similar improvements in aspirin-exacerbated respiratory disease patients as in other subgroups**
- **Improvements were greater in nasal obstruction and anterior rhinorrhoea, and lesser in facial pain and hyposmia**
- **The relative role of more limited FESS versus comprehensive FESS in chronic rhinosinusitis remains unclear**

There are other limitations to this study and ways in which it could be extended. This is an audit of treatment outcomes rather than surgical complications, although the safety of FESS has been well studied.³⁴ We utilised a symptom scoring system that was modified slightly from the recently validated Adelaide Disease Severity Score.¹⁹ Although patient symptoms are central to treatment planning,³⁵ there are some limitations to the use of raw symptom data in studying chronic rhinosinusitis, such as the phenomenon of response shift.³⁶ This study is not multi-centred and is limited to the practice of a single surgeon, although this allowed consistency in the management provided to the patients studied.

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