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Main Article

Outcome of endoscopic sinus surgery for chronic rhinosinusitis patients: a Canadian experience

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Abstract

Objectives: To determine the effect on patients' quality of life of functional endoscopic sinus surgery performed for chronic rhinosinusitis within a tertiary care centre in Montreal, Canada.

Methods: A prospective cohort study was undertaken. Subjects were consecutive patients with a diagnosis of chronic rhinosinusitis who had failed medical treatment and were undergoing functional endoscopic sinus surgery. Questionnaires assessing general health outcomes (i.e. the second version of the Short Form 12 questionnaire) and disease-specific outcomes (i.e. the Chronic Sinusitis Survey) were completed pre-operatively and a minimum of three months post-operatively.

Results: A total of 152 patients were enrolled over a seven-month period, of whom 120 completed the post-operative surveys. The most common co-morbidity was asthma (40 per cent). Of the 120 patients with completed questionnaires, 72 per cent reported clinical improvement, 12 per cent reported deterioration and 15 per cent remained unchanged. The average improvement in Chronic Sinusitis Survey score was 17 per cent.

Conclusion: Patients with chronic rhinosinusitis achieved a significant improvement in disease-specific quality of life after functional endoscopic sinus surgery. There was no significant improvement in general health related quality of life, as measured using the Short Form 12 questionnaire.

Key words: Chronic Rhinosinusitis; Endoscopic Sinus Surgery; Quality of Life

Introduction

Chronic rhinosinusitis is a clinical syndrome characterised by mucosal inflammation of the nose and paranasal sinuses.[1] It is one of the most common chronic illnesses in North America, with an incidence of approximately 13 per cent in the US. The disease's economic impact has been estimated at $5.8 billion annually in the US, considering both direct and indirect costs.[2] Chronic rhinosinusitis has a negative impact on patients' health-related quality of life (QoL); such patients score substantially lower on QoL measures compared with the normal population. These patients' scores are also lower than those of patients with diabetes and congestive heart failure.[3]

The exact aetiology and mechanism of chronic rhinosinusitis remain elusive. Although maximal medical therapy has not been defined or widely agreed upon, the efficacy of functional endoscopic sinus surgery (FESS) is well established.

Quality of life outcome measures have been widely used to evaluate disease impact and intervention efficacy. Such measures evaluate two components: general health and disease-specific health.[4–7]

The current study evaluated the outcome of FESS within chronic rhinosinusitis patients.

Materials and methods

Study design

A prospective, non-randomised, longitudinal study was conducted in a tertiary care rhinology centre (the Royal Victoria Hospital, McGill University Health Center, Montreal, Quebec, Canada). All patients were treated by the senior author (MS).

Patient selection

Subjects comprised consecutive patients diagnosed with chronic rhinosinusitis according to the criteria of the Sinus Allergy and Health Partnership Task Force 2003.[1] These patients had all failed maximal medical therapy, and FESS was indicated for management of their chronic rhinosinusitis. In our centre, maximal medical therapy consisted of oral prednisone for 14 to 21 days, oral wide spectrum antibiotics for 14 days, and topical corticosteroid therapy

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twice daily for a minimum of two months. Patients were re-evaluated at a follow-up visit two to three months following completion of medical therapy. Patients with no subjective symptomatic improvement, or worsening symptoms, in the absence of any objective improvement on endoscopic evaluation, were deemed to have failed medical therapy, and a surgical option (FESS) was thus offered.

We excluded from the study patients with a history of previous nasal or sinus surgery, sinonasal tumours, ciliary immotility syndromes, autoimmune disorders, granulomatous diseases, or cystic fibrosis.

Outcome measures

A general health QoL survey and a disease-specific QoL survey were used as clinical outcome tools.

General health outcomes were evaluated using the second standard version of the Short Form 12™ questionnaire (QualityMetric, Lincoln, Rhode Island, USA; derived from the widely used Short Form 36 QoL outcome measure tool).[8] This tool assesses the same eight domains of general health status evaluated in the Short Form 36 questionnaire (Table I).

Disease-specific QoL outcomes were assessed using the Chronic Sinusitis Survey.[9] This is a six-item, duration-based questionnaire which specifically targets nasal and sinus symptoms. It is divided into two sections: the first contains three symptom-based questions, while the second contains three medication-based questions.

Patients completed both questionnaires during a pre-operative visit, and then again post-operatively after a minimum follow-up period of three months. The Short Form 12 questionnaire was scored using an online scoring system (QualityMetric) and standardised to normative population data. The Chronic Sinusitis Survey was scored by converting the data to a percentage scale between 0 and 100.[9,10]

All patients underwent pre-operative computed tomography (CT) scanning of the sinuses, and were staged using the Harvard CT staging system (Table II).[11] Endoscopic findings were recorded, together with the extent of FESS performed and the sinuses dissected. The presence of other co-morbidity and/or a smoking habit was also noted.

TABLE I

EIGHT SUBSCALES AND PHYSICAL AND MENTAL COMPONENT SUMMARIES OF SHORT FORM 12 (VERSION TWO)™ GENERAL HEALTH SURVEY[8]

Subscale	Definition
PF	Physical functioning
RP	Role, physical
BP	Bodily pain
GH	General health
VT	Vitality
SF	Social functioning
RE	Role, emotional
MH	Mental health
PCS	Physical component summary
MCS	Mental component summary

Statistical analysis

The mean score changes for both the Short Form 12 questionnaire and the Chronic Sinusitis Survey were compared using confidence intervals with 95 per cent confidence levels. Subgroup analysis was performed using a linear regression model (SAS version 9.1; SAS Institute Inc., Cary, North Carolina, USA).

Results

Demographics

We enrolled a total of 152 patients undergoing FESS between May 2005 and December 2005. Of these, 120 patients completed the post-operative surveys and were included in the study. These patients comprised 62 men (52 per cent) and 58 women (48 per cent), with a mean age ± standard deviation of 47.3 ± 15 years (range, 18 to 86 years).

The most common co-morbid condition was asthma, present in 40 per cent of patients, followed by environmental allergy (33 per cent). Samter's triad (asthma, aspirin sensitivity and nasal polyps) was present in 6 per cent of patients. Other co-morbid conditions were found in 23 per cent of patients, including hypertension (13 per cent), smoking (9 per cent) and depression (1 per cent) (Table III).

The distribution of CT staging was as follows: no patients were stage 0; 13 per cent were stage I; 21 per cent were stage II; 42 per cent were stage III; and 24 per cent were stage IV.

Endoscopic examination revealed nasal polyps in 49 per cent of patients.

The following surgical procedures were performed: maxillary antrostomy with ethmoidectomy (93 per cent of patients), sphenoidotomy (42 per cent), frontal sinusotomy (38 per cent) and septoplasty (42 per cent). The mean follow-up period was seven months (range, three to 21 months).

Chronic sinusitis survey

A statistically significant improvement was seen in Chronic Sinusitis Survey scores, comparing pre- and post-operative results (Table IV and Figure 1). The mean score change was 6.84 points for medication usage, 27.11 points for symptoms and 17 points for total scores. We used an improvement of 8 points or more as a cut-off threshold to indicate clinical improvement, as originally described by Gliklich

TABLE II

HARVARD COMPUTED TOMOGRAPHY STAGING SYSTEM FOR CHRONIC RHINOSINUSITIS

Stage	CT findings
0	Normal (<2 mm mucosal thickening on any sinus wall)
I	All unilateral disease or anatomical abnormality
II	Bilateral disease limited to ethmoid or maxillary sinuses
III	Bilateral disease with involvement of ≥1 sphenoid or frontal sinus
IV	Pansinus disease

CT = computed tomography

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TABLE III

PATIENT CO-MORBIDITY

Co-morbidity	Patients	
	n	%
Asthma	48	40
Allergy	39	33
Samter's triad*	8	6
Smoking	11	9
Hypertension	16	13
Depression	1	1

*Asthma, aspirin sensitivity and nasal polyps.

and Metson.[9] An 8-point change in the Chronic Sinusitis Survey score required a four out of eight week (or 50 per cent) change in symptom duration or medication usage. Using this 8-point cut-off, there was a statistically significant change in patients' symptom scores and total Chronic Sinusitis Survey scores (confidence intervals (CIs), 20.11–34.12 and 11.67–22.29, respectively). There was also a positive improvement in medication usage scores (CI, 1.12–12.57); however, this difference was not statistically significant as the 95 per cent lower confidence level fell below 8 points.

The Chronic Sinusitis Survey mean score improvement showed consistent statistical significance across all patient subgroups (being 14.53 for asthma patients, 23.07 for allergy patients and 19.21 for patients without co-morbidity).

The Chronic Sinusitis Survey results indicated that 72 per cent of chronic rhinosinusitis patients who underwent FESS improved, 12 per cent worsened and 15 per cent remained unchanged, three to 21 months (mean, seven months) following FESS.

Short Form 12 questionnaire

Comparison of the pre- and post-operative Short Form 12 questionnaire subscales, as well as the Short Form 12 questionnaire physical and mental component summaries, demonstrated no statistically significant improvement in any of the subscales (Table IV and Figure 2), nor any statistically significant differences between the patient subgroups.

A statistically significant improvement was defined as a difference of 6.6 points for the physical component summary and 7.5 points for the mental component summary, at a 95 per cent confidence level. However, none of the estimated means of difference between the pre- and post-operative Short Form 12 questionnaire scores reached the cut-off point to attain statistical significance.

The Short Form 12 questionnaire data were also evaluated for patients with asthma ($n = 48$), allergy ($n = 38$) and no co-morbidity ($n = 31$). None of

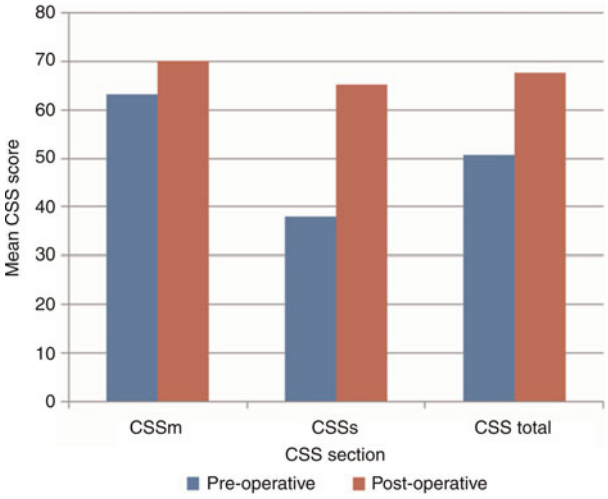

FIG. 1

Patients' pre- and post-operative mean scores for the Chronic Sinusitis Survey (CSS). Statistically significant changes were observed, comparing pre- and post-operative scores, for the CSS symptom questions (CSSs) and the CSS total scores. CSSm = CSS medication questions

TABLE IV

RESULTS FOR CHRONIC SINUSITIS SURVEY AND SHORT FORM 12 QUESTIONNAIRE*

Tool	Score (mean ± SD)		Change (mean ± SD)	95% CL for mean	
	Pre-op	Post-op		Lower	Upper
CSS					
– CSSm	63.13 ± 24.15	69.98 ± 24.36	6.84 ± 31.38	1.12	12.57
– CSSs	37.99 ± 29.40	65.11 ± 30.81	27.11 ± 38.43	20.11	34.12
– CSS total	50.56 ± 21.60	67.54 ± 23.41	16.98 ± 29.11	11.67	22.29
SF-12					
– PF	50.64 ± 8.85	49.67 ± 9.20	−0.79 ± 9.31	−2.52	0.93
– RP	49.47 ± 9.70	48.43 ± 10.25	−1.04 ± 9.80	−2.86	1.03
– BP	48.84 ± 10.93	49.51 ± 10.60	0.98 ± 10.49	−0.96	2.93
– GH	51.02 ± 9.23	50.11 ± 9.45	−0.55 ± 8.34	−2.09	0.97
– VT	51.01 ± 9.79	51.24 ± 9.42	0.44 ± 10.90	−1.58	2.46
– SF	48.95 ± 10.10	49.20 ± 9.58	0.53 ± 10.21	−1.36	2.42
– RE	49.12 ± 10.35	48.94 ± 9.35	−0.13 ± 11.12	−1.93	2.19
– MH	49.82 ± 9.59	50.90 ± 9.55	1.36 ± 9.21	−0.34	3.06
– PCS	50.14 ± 8.84	49.25 ± 9.89	−0.72 ± 8.60	−2.33	0.87
– MCS	49.48 ± 9.41	50.31 ± 9.22	1.16 ± 9.24	−0.54	2.88

*$n = 120$ patients. SD = standard deviation; CL = confidence level; pre-op = pre-operative; post-op = post-operative; CSS = Chronic Sinusitis Survey; CSSm = CSS medication questions; CSSs = CSS symptom questions; SF-12 = Short Form 12 questionnaire; PF = physical functioning; RP = role, physical; BP = bodily pain; GH = general health; VT = vitality; SF = social functioning; RE = role, emotional; MH = mental health; PCS = physical component summary; MCS = mental component summary

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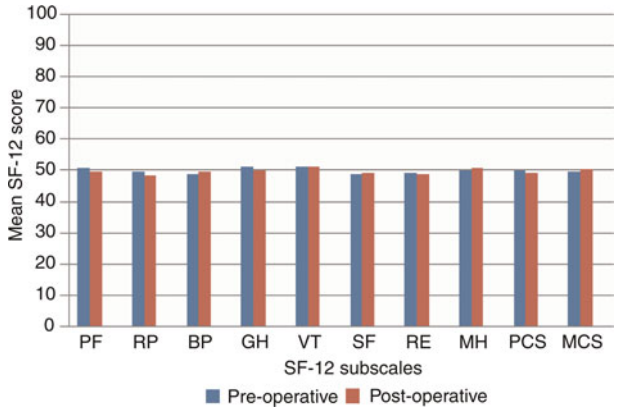

FIG. 2

Patients' pre-operative and post-operative mean scores of the Short Form 12 questionnaire (SF-12). No statistically significant changes were observed for any of the subscales or the physical and mental component summaries. PF = physical functioning; RP = role, physical; BP = bodily pain; GH = general health; VT = vitality; SF = social functioning; RE = role, emotional; MH = mental health; PCS = physical component summary; MCS = mental component summary

these subgroups showed a statistically significant difference between the pre- and post-operative Short Form 12 questionnaire subscales scores.

A linear regression model was tested, using age, sex, nasal polyps, CT stage, asthma, allergy or non-co-morbidity as independent variables. However, we could identify no independent predictors for total Chronic Sinusitis Survey outcome improvement.

Discussion

Functional endoscopic sinus surgery is widely considered to be the standard of care for the treatment of medically refractory chronic rhinosinusitis. An estimated 50 per cent of patients with chronic rhinosinusitis will ultimately require FESS in the treatment of their disease.[12] Clinical outcomes for FESS have been studied extensively using different outcome tools. Theses tools have included general health QoL instruments such as the Short Form 36 and Short Form 12 questionnaires, as well as symptom-based, disease-specific outcome questionnaires such as the Chronic Sinusitis Survey, Sinonasal Outcome Test 20, Rhinosinusitis Disability Index and Rhinosinusitis Symptoms Inventory.[13]

In the current study, we used the Chronic Sinusitis Survey because it is duration-based and covers medication usage and symptoms. This survey has demonstrated its statistical reliability and validity.[10] In addition, it is very sensitive to clinical changes over time. Previous studies have shown no significant difference in Chronic Sinusitis Survey post-operative scores at three, six and 12 months post-operatively.[14]

General health status and the impact of other co-morbidity were assessed using the second standard version of the Short Form 12 questionnaire, a validated QoL survey. The Short Form 12 questionnaire is a short, multipurpose questionnaire containing only 12 questions. It is derived from the widely used Short Form 36 health survey and evaluates the same eight domains, being developed as a much shorter, yet still valid, alternative to the longer questionnaire. The introduction of normative value based scoring, whereby a linear transformation of the scores is used to achieve a mean of 50 and a standard deviation of 10 in a normal general US population, makes comparisons across the scales much more meaningful and simplifies their interpretation in relation to population norms.[8]

Most prior studies evaluating FESS outcomes have demonstrated a statistically and clinically significant improvement in chronic rhinosinusitis patients' sinonasal symptoms and QoL following FESS.[4–7,10,15–17] The statistically significant improvement in Chronic Sinusitis Survey scores noted in the current study is comparable to previously reported figures.[10,17,18] Although 40 per cent of chronic rhinosinusitis patients had asthma, subgroup analysis did not show any significant differences in improvement, comparing patients with asthma, other co-morbidity and no co-morbidity. The presence of asthma was not a negative or positive predictor for the total Chronic Sinusitis Survey outcome. These findings in the asthma subgroup differ from those of previous studies using the Chronic Sinusitis Survey.[9,10]

- **Functional endoscopic sinus surgery (FESS) for chronic rhinosinusitis has been shown to improve patient symptoms, quality of life and intranasal endoscopic appearance; reported data support the use of FESS in chronic rhinosinusitis refractory to medical therapy**
- **This study investigated the outcome of FESS in chronic rhinosinusitis patients; findings were consistent with previously reported results**
- **A statistically significant improvement in sinonasal symptoms was observed when a disease-specific outcome measure was used (the Chronic Sinusitis Survey); however, no significant improvement was observed when using a general health outcome measure (the Short Form 12 questionnaire)**

The results of the Short Form 12 QoL questionnaire did not show a statistically significant improvement or deterioration for any of the subscales or the physical and mental component summaries. The Short Form 12 questionnaire was selected for this study because it was shorter and therefore less laborious for patients to complete. In addition, previous studies have shown reliability and consistency of scores compared to the Short Form 36 questionnaire.[19,20] However, the Short Form 12 questionnaire's brevity and ease of use come at the expense of precision, compared with the Short Form 36 questionnaire. A larger sample size is necessary for the former questionnaire to achieve the same degree of statistical significance as the latter. Furthermore, as the Short Form 36 questionnaire sample size decreases, the precision of the result declines.[8] In the current study, the sample size ($n = 120$) was not large enough for the results of the Short Form 12

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questionnaire to reach statistical significance. Previous, similar studies using the Short Form 36 questionnaire with a similar sample size showed a modest but statistically significant improvement.[10] It is quite conceivable that detection of a modest improvement was not possible in the current study due to the loss in precision resulting from use of the Short Form 12 rather than the Short Form 36 questionnaire.

Chronic rhinosinusitis and asthma affected 40 per cent of the study patients; these patients had been referred by a tertiary asthma centre specialising in the treatment of refractory asthma, and frequently suffered from severe, steroid-dependent asthma which was difficult to treat. One wonders whether the refractory nature of these patients' lower airways disease affected their general health, contributing to the lack of improvement in general QoL indicated by the Short Form 12 questionnaire results.

Conclusion

Following FESS in chronic rhinosinusitis patients, a clinically and statistically significant improvement in disease-specific QoL was reported by 72 per cent of patients, with an average improvement of 17 points, when assessed by the Chronic Sinusitis Survey. However, there was no detectable improvement in general health related QoL as assessed by the Short Form 12 questionnaire.

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