The personal financial burden of chronic rhinosinusitis: A Canadian perspective

Jonathan Yip, M.D., Allan D. Vescan, M.D., F.R.C.S.C., Ian J. Witterick, MD, F.R.C.S.C., and Eric Monteiro, M.D., F.R.C.S.C.

ABSTRACT

Background: Previous studies describe the financial burden of chronic rhinosinusitis (CRS) from the perspective of third-party payers, but, to our knowledge, none analyze the costs borne by patients (i.e., out-of-pocket expenses [OOPE]). Furthermore, this burden has not been previously investigated in the context of a publicly funded health care system.

Objective: The purpose of this study was to characterize the financial impact of CRS on patients, specifically by evaluating its associated OOPEs and the perceived financial burden. The secondary aim was to determine the factors predictive of OOPEs and perceived burden.

Methods: Patients with CRS at a tertiary care sinus center completed a self-administered questionnaire that assessed their socioeconomic characteristics, disease-specific quality of life (22-item Sino-Nasal Outcome Test [SNOT-22]), workdays missed due to CRS, perceived financial burden, and direct medical and nonmedical OOPEs over a 12-month period. Total OOPEs were calculated from the sum of direct medical and nonmedical OOPEs. Regression analyses determined factors predictive of OOPEs and the perceived burden.

Results: A total of 84 patients completed the questionnaires. After accounting for health insurance coverage and the median direct medical, direct nonmedical, and total OOPEs per patient over a 12-month period were Canadian dollars (CAD) \$336.00 (2011) [U.S. \$339.85], CAD \$129.87 [U.S. \$131.86], and CAD \$607.10 [U.S. \$614.06], respectively. CRS resulted in an average of 20.6 workdays missed over a 12-month period. Factors predictive of a higher financial burden included younger age, a greater number of previous sinus surgeries, <80% health insurance coverage, residing out of town, and higher SNOT-22 scores.

Conclusion: Total OOPEs incurred from the treatment of CRS may amount to CAD \$607.10 [U.S. \$614.06] per patient per year, within the context of a single-payer health care system. Managing clinicians should be aware of patient groups with a greater perceived financial burden and consider counseling them on strategies to offset expenses, including obtaining travel grants, using telemedicine for follow-up assessments, providing drug samples, and streamlining diagnostic testing with medical visits.

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Rhinosinusitis is one of the leading causes of employee absenteeism and short-term disability, and accounts for a total of 11.5 million workdays missed.^{1,2} As a result, the range of overall chronic rhinosinusitis (CRS) related health care costs has been quoted to be U.S. \$3.9 billion to U.S. 12.5 billion per year.^{3–7} At the patient level, CRS has been shown to impose detrimental effects on quality of life.^{8–11} The individual financial burden attributable to CRS has been described by assessing its direct medical costs, which are expenses for medical resources, including expenditures for physician visits, diagnostic tests, surgery, hospital services, and prescription medications. When excluding the cost of surgery, annual direct medical costs of CRS treatment were estimated to be U.S. \$2700 (2014) per patient, with prescription drug expenditure representing approximately U.S. \$1315 (2014).⁶

These figures, however, primarily reflect costs from the perspective of third-party payers and not the actual costs borne by patients. Moreover, there currently is no study, to our knowledge, that has evaluated the financial burden of CRS in Canada. Despite a publicly funded health care system, the economic burden of CRS may still impact the treatment decisions of Canadians. Fernandes *et al.*¹² previously showed that differences in socioeconomic status impacted the decision of Canadian patients with CRS to undergo sinus surgery due to uncertainty regarding their ability to pay for postoperative medications and to take time off work. The primary purpose of our study was to characterize the financial

burden of CRS in a publicly funded health care system, specifically by measuring their out-of-pocket expenses (OOPE) and perceived personal financial burden. As secondary objectives, the study sought to understand factors that may influence this burden.

METHODS

Subjects and Recruitment

Adult patients who fulfilled the diagnostic criteria for CRS according to the Canadian Clinical Practice Guidelines¹³ and who presented to our tertiary rhinology clinic for follow-up were eligible for study inclusion. Patients with a concomitant diagnosis of cystic fibrosis, primary ciliary dyskinesia, autoimmune disease, or immune deficiency were excluded. All eligible participants were approached between January 2011 and June 2012 for study participation. A convenience sample of patients who completed the questionnaire was included in the study. The demographic, clinical, surgical, and follow-up data were collected through chart review. The research ethics board at Mount Sinai Hospital approved the study design.

Questionnaire

A 23-item questionnaire (Supplemental Appendix 1) was developed through a literature review and expert input. Before implantation, a pilot study was conducted among six patients to test the instrument for face validity and readability. The results obtained from the pilot study were not included in the final analysis. The questionnaire captured employment status, annual household income, health insurance coverage, expenses related to CRS, and the 22-item Sino-Nasal Outcome Test (SNOT-22) score.¹⁴ OOPEs were defined as the total dollar amounts paid by patients and reflected costs incurred after deducting health insurance coverage. Monetary values are presented in 2011 Canadian dollars (CAD). OOPEs were classified as direct medical or nonmedical expenses.

For direct medical OOPEs, the participants were instructed to recall the amount of OOPEs incurred from 10 different medical therapies for

From the Division of Rhinology, Department of Otolaryngology—Head and Neck Surgery, University of Toronto, Toronto, Ontario, Canada

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Address correspondence to Eric Monteiro, M.D., Division of Rhinology, Department of Otolaryngology—Head and Neck Surgery, University of Toronto, Mount Sinai Hospital, 600 University Avenue, Room 401, Toronto, ON, Canada M5G 1X5

E-mail address: emonteiro@mtsinai.on.ca

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CRS over the previous 12 months. With respect to direct nonmedical costs, travel expenses related to CRS treatment were estimated based on the mode of transportation used to access outpatient care from an otolaryngologist, family physician, and/or allergist. Car users' marginal costs were calculated from their reported driving distance multiplied by the Canadian Automobile Association estimate of operating costs per kilometer driven; because operating costs varied with mileage and engine size, we used an average figure of CAD \$0.569/km [U.S. \$0.597/km].¹⁵ Car users were also asked to provide an estimate of parking costs accrued.

Indirect costs, which represented income loss due to CRS, were not calculated because it has been recommended by the World Health Organization to exclude these costs in cost-effective analyses (CEA).¹⁶ Alternatively, workdays lost over the previous 12 months by the patient and his or her caregiver(s) due to CRS were used as a surrogate measure. The participants were asked to specify how many workdays were missed due to symptoms, postoperative recovery, and outpatient medical visits related to CRS. Also, the patients were asked to rate the personal financial burden imposed by CRS. The perceived burden question was phrased, "Overall, how much of a burden are out-of-pocket expenses/costs for sinusitis treatment and care?"

Data Analysis

Data extracted from the questionnaires were analyzed by using SPSS Statistics for Macintosh 22.0 (SPSS, Chicago, IL). The total annual OOE for each patient was calculated as the sum of direct medical and nonmedical OOE's over 12 months. Univariate analyses were used to test the possible associations between key variables and total OOE's. These variables included age, gender, employment status, annual household income, prescription drug coverage, location of residence, SNOT-22 scores, and the total number of sinus surgeries. Cutoffs of 80% prescription drug coverage and CAD \$80,000 [U.S. \$80,917.12] annual household income were used to divide the cohort because they represented the median values. Continuous values for the aforementioned variables were not used because they were reported as interval data. Due to the non-normal distribution of OOE's, medians were reported and nonparametric statistical tests were used.

Associations were tested by using the Spearman rank correlation coefficient for continuous variables, Mann-Whitney tests for dichotomous data, and Kruskal-Wallis tests for variables with three or more groups. Stepwise multivariate regression analysis was performed on all variables that were significant at $p \leq 0.05$ on univariate analyses. Due to the skewness of the cost data, total OOE's were log-transformed (base 10). The results of the multivariate regression are presented in β values with 95% confidence intervals (CI), associated p values, and R^2 . Variables that were significant in the multivariate model at $p \leq 0.05$ were considered predictive of total OOE's. Similarly, univariate analyses were conducted to determine factors associated with the perceived personal financial burden. Multivariate ordinal regression was performed on all variables that were significant at $p \leq 0.05$ on univariate analyses. The results of the model are presented as odds ratio (OR) estimates with 95% CI and associated p values. Variables that were significant in the multivariate model were considered predictive of the perceived burden. Goodness of fit of the ordinal regression model was assessed by using the Pearson goodness of fit statistic.

RESULTS

Cohort Characteristics

A total of 356 patients were eligible for inclusion, and 89 questionnaires (25.0%) were returned. However, five questionnaires were incomplete and discarded, which gave a final cohort of 84 patients (23.6%). Demographic, socioeconomic, and clinical characteristics of the study population are summarized in Table 1. The majority of the patients were employed (72.6%) and had annual household

Table 1 Demographic, socioeconomic, and clinical information (N = 84)

Characteristic	
Age, mean (range), y	51.7 (19–79)
Gender, no. (%)	
Men	44 (52.4)
Women	40 (47.6)
Marital status, no. (%)	
Single	9 (10.7)
Separated, divorced, widowed	5 (6.0)
Married	69 (82.1)
Living with partner	1 (1.2)
Employment status, no. (%)	
Full- or part-time	45 (53.6)
Self-employed	16 (19.0)
Unemployed	9 (10.7)
Retired	11 (13.1)
Disability (i.e., Ontario Disability Support Program)	3 (3.6)
Annual Household Income, no. (%)	
<CAD \$40,000 [U.S. \$40,458.56]	9 (10.8)
CAD \$40,000 [U.S. \$40,458.56] to CAD \$79,999 [U.S. \$80,916.11]	18 (21.5)
≥CAD \$80,000 [U.S. \$80,917.12]	54 (64.3)
Missing	3 (3.6)
Level of education, no. (%)	
High school diploma or less	16 (19.0)
Some college or university	15 (17.9)
College or university degree	33 (39.3)
Postgraduate degree	20 (23.8)
Prescription drug coverage, no. (%)	
Private insurance	61 (72.6)
Public prescription drug plan	9 (10.7)
Both private and public	7 (8.3)
No coverage	7 (8.3)
Residing out of town	28 (33.3)
Mean SNOT-22 score, no. (range)	52.3 (0–103)
Diagnosis, no. (%)	
Chronic rhinosinusitis without nasal polyps	41 (48.8)
Chronic rhinosinusitis with nasal polyps	40 (47.6)
Fungal rhinosinusitis	3 (3.6)
No. sinus surgeries, mean ± SD	2.7 ± 2.1

CAD = Canadian dollars; SNOT-22 = 22-item Sino-Nasal Outcome Test; SD = standard deviation.

incomes exceeding CAD \$80,000 [U.S. \$80,917.12] (64.3%). With respect to diagnoses, 41 patients (48.8%) had CRS without nasal polyposis, 40 (47.6%) had CRS with nasal polyposis, and 3 (3.6%) had fungal rhinosinusitis. In addition, almost all the patients (90.5%) had undergone at least one sinus surgery, with a mean number of 2.7 surgeries. In terms of health insurance coverage, 77 study participants (91.7%) had public or private plans. Within this group, 67 patients had insurance plans that covered ≥80% of the cost of prescriptions. These plans, however, did not provide reimbursement for over-the-counter medications, special equipment, and/or complementary and alternative medicines.

OOE's

The direct medical, nonmedical, and total OOE's incurred from CRS management over a 12-month period are outlined in Table 2. The median (interquartile range [IQR]) total direct medical OOE incurred over a 12-month period was CAD \$336.00 [U.S. \$339.85] (IQR, CAD \$487.77 [U.S. \$493.36]) per patient. The direct nonmedical OOE's presented in Table 2 represent costs incurred after accounting

Table 2 OOPes from the past 12 months by category (N = 84)

Cost Category	Patient, no. (%)	Median OOPes in Past 12 Months, median (interquartile range), CAD \$
Direct medical OOPes*		
Intranasal corticosteroids	66 (78.6)	\$22.00 (\$76.47)
Oral corticosteroids	37 (44.0)	\$0.00 (\$12.25)
Other nasal steroid mixtures	36 (42.6)	\$17.00 (\$60.38)
Antibiotics	55 (65.5)	\$30.00 (\$85.00)
Antihistamine	39 (46.4)	\$70.00 (\$135.00)
Saline solution nasal rinses	66 (78.6)	\$77.50 (\$74.25)
Antifungals	3 (3.6)	\$180.00 (\$2910.00)
Decongestants	33 (39.3)	\$50.00 (\$87.50)
Special equipment	46 (54.8)	\$100.00 (\$150.00)
Other therapies	22 (26.2)	\$184.55 (\$500.00)
Total direct medical OOPes	79 (94.0)	\$336.00 (\$487.77)
Direct nonmedical OOPes		
Car	65 (77.4)	\$162.73 (\$529.17)
Parking	52 (61.9)	\$60.00 (\$76.75)
Taxi	5 (6.0)	\$38.00 (\$458.00)
Public transit	30 (35.7)	\$15.00 (\$20.50)
Airplane	3 (3.6)	\$600.00#
Walk	2 (2.3)	
Total direct nonmedical OOPes§	84 (100.0)	\$129.87 (\$495.72)
Total OOPes (direct medical and nonmedical)	84 (100.0)	\$607.10 (\$930.16)

OPE = Out-of-pocket expense; CAD = Canadian dollar.

*Direct medical OOPes reflect costs incurred after deducting prescription drug coverage.

#Interquartile range could not be calculated.

§Direct nonmedical OOPes reflect costs after deducting government travel grants.

To convert 2011 CAD to US, multiply CAD value by 1.011464.

for government travel grants. Although one-third of the cohort reported that they resided out of town relative to the hospital, only three patients (3.6%) received travel grants for an average $\pm$ standard deviation amount of CAD \$1144.83 [U.S. \$1157.95] $\pm$ CAD \$379.78 [U.S. \$384.13]. Automobile operating costs were the most commonly reported direct nonmedical OOPes (77.4%). Overall, the patients in-

curred a median total OPE of CAD \$607.10 (IQR, CAD \$930.16 [U.S. \$940.82]) over a 12-month period.

Associations of demographic, socioeconomic, and clinical factors with total OOPes are shown in Table 3. On univariate analysis, higher total OOPes were significantly associated with younger age, residing out of town, CRS without nasal polypsis, <80% prescription drug

Table 3 Univariate analyses and stepwise multivariate linear regression model predicting total OOPes from the past 12 months

Variable	p Value	Unadjusted β Coefficient (95% CI)	R ² *
Univariate analysis#			
Age	0.016		
Gender	0.700		
Employment status	0.148		
Level of education	0.149		
<\$80,000 annual household income	0.802		
Residing out of town	<0.001		
Diagnosis	0.008		
Total no. sinus surgeries	0.022		
SNOT-22 score	0.005		
<80% Prescription drug coverage	0.035		
Stepwise multivariate analysis§			
Residing out of town	<0.001	0.470 (0.239–0.701)	0.264
<80% Prescription drug coverage	0.040	0.283 (0.014–0.553)	
Total no. sinus surgeries	0.048	0.052 (0.001–0.103)	

OPE = Out-of-pocket expense; CI = confidence interval; SNOT-22 = 22-item Sino-Nasal Outcome Test.

*For the final multivariate linear regression model.

#Due to the heterogeneity of nonparametric statistical tests, only p values are shown.

§Factors excluded from the model: age, diagnosis (i.e., chronic rhinosinusitis subtype), and SNOT-22.

coverage, a higher number of previous sinus surgeries, and higher SNOT-22 scores ($p < 0.05$). Stepwise multivariate linear regression showed that residing out of town ($\beta = 0.470$ [95% CI, 0.239–0.701]; $p = <0.001$), having $<80\%$ prescription drug coverage ($\beta = 0.283$ [95% CI, 0.014–0.553]; $p = 0.040$), and higher number of previous sinus surgeries ($\beta = 0.052$ [95% CI, 0.001–0.103]; $p = <0.048$) independently predicted higher total OOPes over a 12-month period. The final model accounted for approximately one-fourth of the total variance in total OOPes ($R^2 = 0.264$).

Indirect Costs

The mean number of workdays missed by patients and their caregivers due to symptoms and various aspects of treatment for CRS are presented in Table 4. Among the 61 employed patients, 56 reported an average of 20.6 workdays (range, 0.1–160.0 workdays) missed due to CRS. More than one-fourth of the employed cohort felt “somewhat worried” or “worried” that treatment for CRS was threatening their job security. Moreover, many caregivers ($n = 39$) also lost time from work; they averaged 4.0 workdays (range, 0.1–3.0 workdays) missed.

Perceived Financial Burden

Seventeen participants (20.2%) perceived their financial burden to be “significant” or “unmanageable,” as demonstrated in Fig. 1. Due to the small number of subjects who reported an “unmanageable” burden, they were grouped together with the “significant” burden group in subsequent statistical analyses. Age, number of sinus surgeries, SNOT-22 score, and amount of prescription drug coverage were significantly associated with the patient-reported financial burden on univariate analyses (Table 5). The ordinal regression model demonstrated that younger age (OR 0.957 [95% CI, 0.924–0.990]; $p = 0.011$), higher number of previous sinus surgeries (OR 1.293 [95% CI, 1.031–1.623]; $p = 0.026$), higher SNOT-22 scores (OR 1.029 [95% CI, 1.011–1.048]; $p = 0.002$), and $<80\%$ prescription drug coverage (OR 2.936 [95% CI, 1.016–8.482]; $p = 0.047$) independently predicted greater perceived financial burden. The model fit was considered adequate ($\chi^2 = 226.338$; d.f. = 242; $p = 0.757$) and accounted for 37.2% of the total variance in the perceived financial burden.

DISCUSSION

CEAs have the ability to serve as a policy-making tool by promoting value-based decision-making. Thus far, CEAs in CRS have focused on the societal burden of CRS interventions, to maximize the generalizability of findings.¹⁷ However, characterization of costs associated with CRS treatment from the individual patient perspective has been limited because previous studies primarily captured expenses from the viewpoint of third-party payers.¹⁷ In our opinion,

OOPe is an important metric to consider in CEAs because it is representative of individual burden by reflecting expenses entirely borne by patients. OOPes in turn can directly influence health care decisions. The latter point has been supported by a Canadian study, which found that the uncertainty of paying for postoperative medications might hinder patients with CRS from proceeding with sinus surgery.¹² Anecdotally, the patients in a subset of our study cohort stated that they coped with their OOPes by discontinuing medical therapies for CRS. Further studies, however, will first need to ascertain whether patient OOPes influence treatment compliance before the value of OOPes in future CEAs of CRS interventions can be established.

In our study, the median total OOPes incurred over a 12-month period was CAD \$607.10 [U.S. \$614.06] (2011) per patient, but there was a wide variance (IQR, CAD \$930.16 [U.S. \$940.82]). In comparison, within the same publically funded health care system, the average annual OOPes have been reported to be CAD \$1,824.97 [U.S. \$1845.89] to CAD \$2066.72 [U.S. \$2090.41] (2011) in diabetes,¹⁸ U.S. \$1416.12 (2002) in chronic kidney failure,¹⁹ and average $\pm$ standard deviation CAD \$1595.41 [U.S. \$1613.70] $\pm$ CAD \$1446.97 [U.S. \$1463.56] (2011) in early breast cancer.²⁰ The wide IQR that we observed may be due to the variation in disease severity and comorbidities within our cohort, which unfortunately were not captured in our data set, and could have impacted health care utilization. Benninger and Holy previously showed that comorbidities influenced direct medical costs because patients with no respiratory comorbidities accrued lower annual costs than those with aspirin-exacerbated respiratory disease (U.S. \$296.4 versus \$2189.0).²¹ Another explanation for the variability may be the heterogeneity in the treatment course among the cohort because our study was not sensitive to the timing of surgery relative to data collection, which is known to impact expenses.^{7,22–24}

As a surrogate measure of indirect costs, we quantified the average number of workdays missed by patients and their caregivers within the past 12 months, which we found to be 20.6 and 4.0 days, respectively. In comparison, Bhattacharyya²⁵ reported a mean of 4.8 days of missed work per 12-month period when using a similar questionnaire-based approach. Rudmik *et al.*²⁶ demonstrated that the mean workdays lost due to absenteeism among patients with refractory CRS was 24.6 days per year, based on extrapolation of the number of workdays lost over a 3-month period. Our findings more closely matched those of the latter study likely because most of our cohort had refractory CRS due to the nature of our tertiary care practice. However, a methodologic limitation was that we did not use validated, objective metrics to characterize productivity loss. Furthermore, another limitation was the recall duration. Most studies on productivity loss recommend a maximum recall duration of 3 months, and the accuracy of recall of workdays missed decreases to 51% at 12 months.^{27,28} When accepting a margin of error of 3 days, the accuracy at 12 months increases to 78%.²⁸ Therefore, our results should be interpreted with caution.

Some other limitations of our study deserve mention. Our response rate of 25.0% was low for economic evaluations and represented a selection bias. Furthermore, the mean annual household income was higher than the national annual income and, therefore, affected the overall generalizability of our results. Another limitation is the use of a nonvalidated questionnaire and the reliance on patient-reported expenses, which may have been subject to recall bias. The literature is mixed with respect to the reliability of self-reported drug expenses.²⁹ However, it is likely that the OOPes reported are underestimated because patients tend to underreport their health care utilization.^{30,31} Also, we did not collect objective measures of disease and could not precisely establish whether disease severity impacted OOPes. To address the aforementioned issues, a prospective observational study that uses validated metrics should be carried out to enhance the strength of the results.

When applying the results of our study, clinicians should identify factors predictive of a higher perceived financial burden among their patients with CRS and suggest avenues to address potential barriers to

Table 4 Workdays lost by employed patients and caregivers due to various aspects of treatment for rhinosinusitis

Variable	No. (%)	Workdays Lost in the Past 12 Months, mean (range)
Employed patients		
Absence due to symptoms	35 (41.7)	12.9 (2.0–100.0)
Surgery and postoperative recovery	36 (42.9)	14.2 (3.0–123.0)
Medical appointments	54 (64.3)	3.3 (0.1–20.0)
Emergency department visits	6 (7.1)	2.4 (0.1–5.0)
Total workdays lost	56 (66.7)	20.6 (0.1–160.0)
Employed caregivers		
Total workdays lost	39 (46.4)	4.0 (0.1–3.0)

Figure 1. Patients' self-reported perceived financial burden from treatment for chronic rhinosinusitis.

Table 5 Univariate analyses and ordinal regression analysis predicting perceived financial burden

Variable	p Value	Odds Ratio (95% CI)	Pseudo R ² *
Univariate analysis#			
Age	0.021		
Gender	0.294		
Employment status	0.054		
Level of education	0.143		
<\$80,000 annual household income	0.060		
Residing out of town	0.099		
Diagnosis	0.088		
Total no. sinus surgeries	0.014		
SNOT-22 score	0.003		
<80% prescription drug coverage	0.013		
Ordinal regression analysis			
Age	0.011	0.957 (0.924–0.990)	0.372
Total no. sinus surgeries	0.026	1.293 (1.031–1.623)	
SNOT-22 score	0.002	1.029 (1.011–1.048)	
<80% Prescription drug coverage	0.047	2.936 (1.016–8.482)	

CI = Confidence interval; SNOT-22 = 22-item Sino-Nasal Outcome Test.

*The Nagelkerke statistic was used for the model.

#Due to the heterogeneity of nonparametric statistical tests, only p values are shown.

care. For example, providing drug samples or recommending only evidence-based, cost-effective treatments may minimize direct medical expenses. In appropriately selected patients with CRS, there may be a role for early surgical intervention to alter the progression and development

of disease, and to decrease health utility.^{21,32} Furthermore, assisting patients to obtain government travel grants, using telemedicine for follow-up assessments, and streamlining diagnostic testing with outpatient visits may help reduce nondirect medical and indirect costs.

CONCLUSION

Results from this study demonstrated that total OOPes may amount to CAD \$607.10 (2011) [U.S. \$614.96] per patient per year in the context of a publically funded health care system. Factors predictive of a greater perceived financial burden may include younger age, a higher number of previous sinus surgeries, <80% health insurance coverage, and worse disease-specific quality of life. Clinicians should identify these factors and assist patients in identifying appropriate coping strategies to facilitate access to care.

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