The burden of illness in patients with moderate to severe chronic obstructive pulmonary disease in Canada

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MR Maleki-Yazdi, SM Kelly, SS Lam, M Marin, M Barbeau, V Walker. The burden of illness in patients with moderate to severe chronic obstructive pulmonary disease in Canada. *Can Respir J* 2012;19(5): 319-324.

INTRODUCTION: No recent Canadian studies with physician- and spirometry-confirmed diagnosis of chronic obstructive pulmonary disease (COPD) that assessed the burden of COPD have been published.

OBJECTIVE: To assess the costs associated with maintenance therapy and treatment for acute exacerbations of COPD (AECOPD) over a one-year period.

METHODS: Respiriologists, internists and family practitioners from across Canada enrolled patients with an established diagnosis of moderate to severe COPD (Global initiative for chronic Obstructive Lung Disease stages 2 and 3) confirmed by postbronchodilator spirometry. Patient information and health care resources related to COPD maintenance and physician-documented AECOPD over the previous year were obtained by chart review and patient survey.

RESULTS: A total of 285 patients (59.3% male; mean age 70.4 years; mean pack years smoked 45.6; mean duration of COPD 8.2 years; mean postbronchodilator forced expiratory volume in 1 s 58.0% predicted) were enrolled at 23 sites across Canada. The average annual COPD-related cost per patient was \$4,147. Across all 285 patients, maintenance costs were \$2,475 per patient, of which medications accounted for 71%. AECOPD treatment costs were \$1,673 per patient, of which hospitalizations accounted for 82%. Ninety-eight patients (34%) experienced a total of 157 AECOPD. Treatment of these AECOPD included medications and outpatient care, 19 emergency room visits and 40 hospitalizations (mean length of stay 8.9 days). The mean cost per AECOPD was \$3,036.

DISCUSSION: The current costs associated with moderate and severe COPD are considerable and will increase in the future. Appropriate use of medications and strategies to prevent hospitalizations for AECOPD may reduce COPD-related costs because these were the major cost drivers.

Key Words: Burden of illness; Chronic obstructive pulmonary disease; Cost of illness; Costs; Exacerbations; Health care resource use

Chronic obstructive pulmonary disease (COPD) is a respiratory disorder largely caused by smoking, and is characterized by progressive, partially reversible airway obstruction and lung hyperinflation, systemic manifestations, and increasing frequency and severity of acute exacerbations of COPD (AECOPD) (1,2).

AECOPD are primarily triggered by respiratory tract infections and are characterized by symptomatic, physiological and functional deteriorations leading to an increase in the use of maintenance medications and/or addition of medications (1). The impact of AECOPD includes the following: accelerated rate of decline in lung function (3); reduction in health-related quality of life (4); increased risk of hospitalization (5); significant increase in health care cost (6); and decreased survival (7). Therefore, prevention of AECOPD is a key component of COPD management.

Le fardeau de la maladie chez les patients ayant une maladie pulmonaire obstructive chronique modérée à grave au Canada

INTRODUCTION : Aucune étude canadienne récente n'a été publiée sur les patients atteints d'une maladie pulmonaire obstructive chronique (MPOC) dont le diagnostic est confirmé par le médecin et par spirométrie et qui évalue le fardeau de la MPOC.

OBJECTIF : Évaluer les coûts associés à la thérapie d'entretien et au traitement d'exacerbations aiguës de la MPOC (EAMPOC) sur une période d'un an.

MÉTHODOLOGIE : Des pneumologues, des internistes et des médecins de famille du Canada ont recruté des patients ayant un diagnostic établi de MPOC modérée à grave (initiative mondiale pour la maladie pulmonaire obstructive chronique de phases 2 et 3) confirmé par spirométrie après la prise de bronchodilatateurs. Ils ont obtenu l'information au sujet des patients, des ressources de santé liées au traitement d'entretien de la MPOC et des EAMPOC étayées par un médecin au cours de l'année précédente en analysant les dossiers et en distribuant un sondage aux patients.

RÉSULTATS : Au total, les chercheurs ont recruté 285 patients (59,3 % d'hommes; âge moyen de 70,4 ans; moyenne de paquets fumés par année : 45,6; durée moyenne de la MPOC : 8,2 ans; volume expiratoire maximal par seconde après la prise de bronchodilatateurs : 58,0 % de la valeur prévue) dans 23 établissements du Canada. Le coût annuel moyen lié à la MPOC par patient s'élevait à 4 147 \$. Chez les 285 patients, les coûts d'entretien s'élevaient à 2 475 \$ par patient, et les médicaments représentaient 71 % de ces coûts. Les coûts du traitement de l'EAMPOC correspondaient à 1 673 \$ par patient, et les hospitalisations représentaient 82 % de ces coûts. Quarante-huit patients (34 %) ont subi un total de 157 EAMPOC. Le traitement de ces EAMPOC incluait des médicaments et des soins ambulatoires, 19 consultations à l'urgence et 40 hospitalisations (hospitalisation moyenne de 8,9 jours). Le coût moyen par EAMPOC s'élevait à 3 036 \$.

EXPOSÉ : Les coûts actuels associés à une MPOC modérée ou grave sont considérables et augmenteront à l'avenir. L'utilisation convenable des médicaments et des stratégies pour prévenir les hospitalisations causées par des EAMPOC pourraient réduire les coûts liés à une MPOC parce que ce sont là des générateurs de coûts majeurs.

COPD is significantly underdiagnosed because spirometry is not routinely performed on all at-risk patients, particularly in early disease. For example, a 2007 Canadian study (8) showed that in a population at risk for the disease, 36% actually had a spirometric diagnosis of COPD. The prevalence and burden of COPD are projected to increase in the coming decades. A recent report by the Ontario Lung Association (9) highlighted a current prevalence of 5.9% and a projected increase to 6.9% of the Ontario population by 2041. A longitudinal study conducted in Ontario reported an overall lifetime risk of physician-diagnosed COPD at 80 years of age to be 27.6% (10).

There is considerable evidence that COPD management is not in accordance with current guidelines (2,11-13), possibly contributing to COPD-related costs. The costs of COPD are high and increase with the severity of the disease (14). Although COPD represents a major

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TABLE 1
Unit costs for outpatient resources, hospitalizations and time loss from work

Type of resource	Cost, \$CAD (2009)	Source
Health care professionals		
Family physician: 1st visit; 2nd and subsequent visits	68.75; 32.35	OSB-PS
Respirologist: 1st visit; 2nd visit; 3rd visit; 4th and subsequent visits	143.40; 68.75; 33.70; 20.00	OSB-PS
Internist: 1st visit; 2nd visit; 3rd visit; 4th and subsequent visits	143.40; 68.75; 33.70; 20.00	OSB-PS
Allergist	89.30	OSB-PS
Thoracic specialist	89.30	OSB-PS
Dietician	58.00	LHSC
Occupational therapist	69.00	LHSC
Physiotherapist	66.00	LHSC
Respiratory therapist	80.00	LHSC
Pulmonary medicine nurse practitioner	45.00	LHSC
Walk-in clinic	32.35	OSB-PS
Home care visit	52.30	CCHS
General practitioner home visit	41.75	OSB-PS
Smoking cessation counselling	48.85	OSB-PS
Procedures		
Spirometry	38.23	OSB-PS
Walk test	32.45	OSB-PS
Electrocardiogram	16.50	OSB-PS
Chest x-ray	33.75	OSB-PS
Pulmonary function test	149.42	OSB-PS
Bronchoscopy	131.48	OSB-PS and OSB-LF
Computed tomography scan	79.85	OSB-PS
Thorax scan	79.85	OSB-PS
Magnetic resonance imaging	77.20	OSB-PS
Echocardiogram	205.95	OSB-PS
Blood tests	8.27	OSB-LF
Blood gases	21.10	OSB-PS
Blood culture	15.51	OSB-LF
Sputum culture/Gram stain	11.37	OSB-LF
Cytology expectorant	6.72	OSB-LF
Ventilation-perfusion lung scan	79.85	OSB-PS
Rehabilitation		
Exercise training	132.00	LHSC
Smoking cessation counselling	48.85	OSB-PS
Patient teaching and self-management	48.85	OSB-PS
Swimming	184.95	South-Common indoor pool*
Devices†		
Wheelchair	169.50	SHHC
Walker	98.88	SHHC
Nebulizer machine	68.36	SHHC
Electric scooter	847.50	SHHC
Cane	3.55	SHHC
Continuous positive airway pressure machine	163.57	CPAP.com
Oxygen	798.00	Canadian Home Healthcare
Ambulance ride	500.00	Ministry of Health and Long-Term Care
Emergency room visits		
Hospital emergency	471.74‡	OCCI
Emergency department physician fee	65.10	OSB-PS
Hospitalizations		
Hospital daily cost	1,063.99‡	OCCI
Hospital physician: 1st day; subsequent days	143.40; 29.20	OSB-PS
Time loss from work (full day)	181.35	Statistics Canada

*Mississauga, Ontario; †Costs for devices were divided by the useful life years to obtain an annual cost; ‡Adjusted to 2009 cost. CCHS ComCare Health Services; LHSC London Health Sciences Centre, London, Ontario; OCCI Ontario Case Costing Initiative; OSB-LF The Ontario Schedule of Benefits for Laboratory Fees; OSB-PS The Ontario Schedule of Benefits for Physician Services; SHHC Shoppers Home Health Care, Canada

health issue in Canada, no recent Canadian studies with physician- and spirometry-confirmed diagnosis of COPD have been published that assess the complete cost of illness and its overall burden to the health care system.

A Canadian survey of COPD patients conducted in 2000/2001 reported an annual COPD-related cost of \$3,195 per patient (15). In addition, the prospective Resource Use Study in COPD (RUSIC), conducted in 2001/2002, reported costs to the health care system of \$641 and \$9,557 per patient for moderate and severe AECOPD, respectively (16).

The objective of the present study was to assess the direct and indirect costs associated with maintenance therapy and treatment for AECOPD in a real-world setting over a one-year period among patients with moderate to severe (Global initiative for chronic Obstructive Lung Disease [GOLD] 2 and 3) COPD using data from patient medical records and patient surveys.

METHODS

Study design and participants

The present study was a retrospective chart review including a patient survey. A sample size of 300 was selected based on the precision needed to estimate the primary end point of annual cost per patient. The patients completed a survey on the day they were enrolled. Data abstraction from the patient chart or electronic medical records was completed by the site staff for the year before the date the patient was surveyed.

Patients were enrolled between October 31, 2009 and January 31, 2010, from 23 general practitioner/family physician (GP/FP) and specialist (respirologist and internist) sites across Canada. The study protocol and patient informed consent received institutional review board approval. The sites assessed patients for eligibility as they presented to the physician's office for regularly scheduled visits, and were encouraged to enroll patients who were in GOLD stages 2 and 3.

Inclusion criteria were as follows: ≥50 years of age; smoking history ≥20 pack years; diagnosis of COPD at least one year before study (confirmed by postbronchodilator spirometry within the past year or after patient provided informed consent); postbronchodilator forced expiratory volume in 1 s (FEV₁)/forced vital capacity (FVC) <70% and moderate to severe COPD (postbronchodilator FEV₁ <80% and ≥30% of predicted). Patients were required to have documentation of receipt of care for COPD at the site over the past year.

Exclusion criteria were as follows: participation in any clinical trial within the past year; long-term oxygen therapy (>15 h/day) for chronic hypoxemia; history of concomitant pulmonary disease (eg, pulmonary fibrosis, active pulmonary tuberculosis, clinically significant bronchiectasis; history of asthma and/or onset of respiratory symptoms (eg, cough, wheeze, shortness of breath) before 40 years of age; and history of lung cancer.

Outcome measures

AECOPD were defined as sustained (>48 h) worsening of dyspnea, cough or sputum production leading to an increase in the use of maintenance medications and/or supplementation with additional medication (as defined in the Canadian Thoracic Society guidelines). The site investigator identified whether an AECOPD occurred from documentation of the exacerbation and any new medication and/or change in medication treatment that was contained in the patient's chart (1). The site provided the number and type of health care resources used for maintenance treatment of COPD (when patients were not experiencing an AECOPD as defined above). Resources related to an AECOPD were provided if one occurred. The patients provided information that was not expected to be in the chart (rehabilitation, medical devices, time missed from work and out-of-pocket expenses). Resources collected in the study were assigned costs from the province of Ontario and are reported in Canadian dollars (adjusted to 2009). The individual costs are listed in Table 1. For patients who were hospitalized, the study did not collect data regarding whether the patient

TABLE 2
Patient demographics and chronic obstructive pulmonary disease (COPD) characteristics

	Patients		
	All (n=285)	Male (n=169)	Female (n=116)
Age, years	70.4±9.4	70.4±9.5	70.4±9.2
FEV ₁ /FVC ratio*, %	56.4±13.6	56.3±13.7	56.6±13.6
FEV ₁ , % predicted	58±18.3	55.9±16.7	61.1±20.1
GOLD COPD severity†, n (%)			
GOLD 1	35 (12.3)	15 (8.9)	20 (17.2)
GOLD 2	145 (50.9)	87 (51.4)	58 (50.0)
GOLD 3	94 (33.0)	57 (33.7)	37 (31.9)
GOLD 4	11 (3.9)	10 (5.9)	1 (0.9)
COPD duration, years	8.2±7.4	8.7±7.9	7.5±6.6
Smoking status, n (%)			
Current smoker	105 (36.8)	57 (33.7)	48 (41.4)
Ex-smoker	178 (62.5)	110 (65.1)	68 (58.6)
Missing	2 (0.7)	2 (1.2)	0 (0)
Smoking, pack-years	45.6±20.7	47.2 ±22.0	43.2±18.5
Employment status‡, n (%)			
Retired	201 (70.5)	118 (69.8)	83 (71.6)
Full-time	37 (13.0)	29 (17.2)	8 (6.9)
Part-time	16 (5.6)	7 (4.1)	9 (7.8)
Homemaker	13 (4.6)	1 (0.6)	12 (10.3)
Other	21 (7.6)	16 (9.5)	5 (4.4)
Missing	6 (2.1)	4 (2.4)	2 (1.7)
Drug plan‡, n (%)			
Any health plan	265 (93.0)	157 (92.9)	108 (93.1)
Government health plan	196 (68.8)	105 (62.1)	91 (78.4)
Employer health plan	66 (23.2)	39 (23.1)	27 (23.3)
Private health plan	25 (8.8)	20 (11.8)	5 (4.3)
No health plan	20 (7.0)	12 (7.1)	8 (6.9)
Other§	8 (2.8)	5 (3.0)	3 (2.6)
Comorbidities‡, n (%)			
≥1 comorbidities	273 (95.8)	158 (93.5)	115 (99.1)
Cardiovascular	214 (75.1)	128 (75.7)	86 (74.1)
Musculoskeletal and connective tissue	130 (45.6)	63 (37.3)	67 (57.8)
Gastrointestinal	75 (26.3)	44 (26.0)	31 (26.7)
Endocrine/metabolic/nutrition disease	69 (24.2)	37 (21.9)	32 (27.6)
Psychiatric	62 (21.8)	36 (21.3)	26 (22.4)
Sleep disorders	41 (14.4)	27 (16.0)	14 (12.1)
Other¶	104 (37.0)	70 (41.6)	34 (29.4)

Data presented as mean ± SD unless otherwise indicated. *There were 36 patients with forced expiratory volume in 1 s (FEV₁)/forced vital capacity (FVC) ratios >70% on their most recent spirometry. However, all patients had a previously confirmed diagnosis of COPD by their physicians. †Global initiative for chronic Obstructive Lung Disease (GOLD) 1: Mild (FEV₁, % predicted ≥80%); GOLD 2: Moderate (50% ≤FEV₁, % predicted <80%); GOLD 3: Severe (30% ≤FEV₁, % predicted <50%); GOLD 4: Very severe (FEV₁, % predicted <30%); ‡Patients may report more than one response; §Other drug plans included the following: self (n=1), workers compensation (n=1), spouse (n=2), 50% done by self (n=1), percentage (n=1), missing (n=2); ¶Some of the other comorbidities that were reported by more than 5% of patients were cancer (excluding lung), kidney disease and neurological disorders. Each of the remaining comorbidities was reported by fewer than 5% of patients

was admitted to the ward or the intensive care unit. The discharge diagnosis and dates of admission and discharge were collected. This information was used to obtain a hospital cost from the Ontario Case Cost Initiative (OCCI) Costing Analysis Tool (17). The cost model provides fully allocated costs and includes the cost of days spent on the

Figure 1) Annual frequency of acute exacerbations of chronic obstructive pulmonary disease (AECOPD) per patient according to Global initiative for chronic Obstructive Lung Disease (GOLD) COPD severity

ward and days spent in the intensive care unit. The daily cost from the OCCI and the cost for physician was applied to the number of days for each hospitalization. The cost of emergency room visits were also obtained from the OCCI.

Data analysis

As part of the analysis, FEV₁ % predicted was recalculated for all patients using the equations provided by the European Community for Coal and Steel (18). The recalculated values were used to categorize patients according to COPD GOLD severity (GOLD 1 to 4). For this reason, patients may have been reassigned to GOLD stage 1 or 4, even though the inclusion criteria required them to be GOLD stage 2 or 3.

RESULTS

Forty-eight per cent of the patients were enrolled by GP/FPs and 52% were enrolled by specialists. Demographics and COPD severity are shown in Table 2 for all patients enrolled and also according to sex. The majority of patients were in GOLD stage 2 or 3, and 95.8% had one or more comorbidities.

Of the 98 patients (34%) who experienced at least one AECOPD in the previous year, 55 (19.3%) had one, 31 (10.9%) had two, nine (2%) had three, two (0.7%) had four and one (0.4%) had five, yielding a total of 157 AECOPD. Figure 1 provides the number of patients with one AECOPD and ≥2 AECOPD according to GOLD COPD severity. At GOLD 4, the percentage of patients with ≥2 AECOPD was three times higher than it was at other severity levels. However, the number of patients in GOLD 4 was small; therefore, these results should be interpreted with caution.

For maintenance treatment of COPD, 68.8% of patients were taking inhaled corticosteroids (ICS)/long-acting beta₂-agonist (LABA) combinations, 67.7% were taking long-acting anticholinergics (LAACs) and 65.6% were taking short-acting beta₂-agonists (SABAs) (Figure 2). In these categories, the most commonly used medications for maintenance treatment were tiotropium (67.7%), salbutamol (63.2%) and salmeterol/fluticasone (54.4%) (data not shown). When evaluated according to GOLD severity, the percentage of patients taking each medication was greater in the patients with more severe COPD (ie, GOLD 3 and 4). Medications to treat AECOPD included antibiotics (85.7% of the 98 patients with ≥1 AECOPD), systemic corticosteroids (57.1%), SABAs (25.5%), ICS/LABA combinations (11.2%) and others (15.3%).

Only 18.2% of patients participated in a rehabilitation program; the most common programs were exercise training (12.6%), patient teaching and self management (4.6%), and smoking cessation (2.8%). The health care professionals most frequently seen were GP/FP (56.8% of patients), respirologists (56.1%) and respiratory therapists (16.1%). Over the year, the mean number of GP/FP visits was 2.63 per patient (range 0 to 23 per patient) and the mean number of respirologist visits was 1.57 per patient (range 0 to 15 per patient). The most frequently performed procedures were spirometry (75.8%), chest x-ray (42.1%),

Figure 2) Use of medications for chronic obstructive pulmonary disease (COPD) maintenance treatment according to Global initiative for chronic Obstructive Lung Disease (GOLD) COPD severity. ICS Inhaled corticosteroids; LAACs Long-acting anticholinergics; LABA Long-acting beta₂-agonist combinations; SABA Short-acting beta₂-agonist; SAACs Short-acting anticholinergics; SCS Systemic corticosteroids. Other includes antibiotics, SCS, leukotriene receptor antagonists and theophylline (each used by less than 2% of all patients). Note: More than one medication class can be used per patient

Figure 3) Annual chronic obstructive pulmonary disease (COPD)-related costs (\$CAD 2009) per patient according to Global initiative for chronic Obstructive Lung Disease (GOLD) COPD severity. AECOPD Acute exacerbation of COPD

full pulmonary function testing (24.6%) and electrocardiogram (15.1%). The mean number of spirometry tests was 1.46 per patient (range 0 to 8 per patient); mean number of chest x-rays was 0.66 per patient (range 0 to 6 per patient); and mean number of full pulmonary function tests was 0.31 per patient (range 0 to 7 per patient). Spirometry performed to evaluate eligibility for the study was not included.

There were a total of 28 emergency room visits (19 for AECOPD according to the definition used in the present study) and 45 hospitalizations (40 for AECOPD). The mean length of hospital stay for an AECOPD was 8.9 days (range 2.0 to 25.0 days). Of all patients, 4.6% reported missing time from work due to COPD (mean one day per patient), and 1.8% said their caregivers missed time from work due to patients' COPD (mean 0.4 days per patient).

The mean ($\pm$ SD) annual total COPD-related cost per patient was \$4,147 $\pm$ 6,255. The total cost and the AECOPD- and maintenance-related costs increased with increased severity level (Figure 3).

The cost for treatment of AECOPD was \$1,673 per patient, which accounted for 40% of the total cost. Hospitalization cost (mean \$1,376 per patient) accounted for 82% of the mean total AECOPD cost (Table 3). The largest cost driver for maintenance was the cost of medications (\$1,744 per patient), which accounted for 71% of the mean total maintenance cost. The direct medical costs (\$3,895 per patient) accounted for 94% of the total costs, with only 6% attributable to time missed from work. The mean cost per AECOPD was \$3,036.

TABLE 3
Annual chronic obstructive pulmonary disease (COPD)-related costs (maintenance-related and acute exacerbation of COPD [AECOPD]-related) for all patients and cost per AECOPD

	Mean annual COPD-related cost per patient* All patients (n=285), \$		Mean cost per AECOPD† (n=157), \$	
	Total	Maintenance related	AECOPD related	AECOPD related
Medications	1,775	1,744	31	56
ER visits	53	17	36	65
Hospitalizations	1,497	121	1,376	2,498
Ambulance	25	2	23	41
Rehabilitation programs	22	22	0	0
Medical devices	27	27	0	0
Health care professionals	306	257	48	88
Procedures	145	129	16	28
Patient travel to health care professional	46	41	6	9
Direct costs	3,895	2,360	1,535	2,786
Patient's missed time from work	179	88	92	166
Caregiver's missed time from work	73	27	46	83
Indirect costs	252	115	137	249
Total	4,147	2,475	1,673	3,036

Costs presented in \$CAD (2009). *The mean annual COPD-related cost per patient is the mean cost across all 285 patients for total cost, separated out for maintenance-related and AECOPD-related costs, and further broken down according to type of resource. The AECOPD-related costs include costs for patients who had no AECOPD and whose AECOPD-related cost would be \$0; †The mean cost per AECOPD is the mean cost for the 157 AECOPD. This is calculated by dividing the AECOPD-related costs for all patients by 157 AECOPD. For example, the mean AECOPD-related cost per patient is \$1,673, and there were 285 patients. The total AECOPD-related cost is 285 patients $\times$ \$1,672.51 = \$476,665. There were 157 AECOPD; therefore, the average cost of an AECOPD is \$476,665/157 AECOPD = \$3,036 per AECOPD. ER Emergency room

DISCUSSION

One-third (34%) of patients in the present study experienced at least one AECOPD, and the cost for treatment of an AECOPD was \$1,673 per patient, which accounted for 40% of the total annual cost. The frequency of AECOPD and related costs increased in those in more advanced stages of the disease. Hospitalization cost (mean \$1,376 per patient) accounted for 82% of the mean total AECOPD cost.

In a previous Canadian study, Mittmann et al (16) reported an overall cost per moderate AECOPD of \$641, and \$9,557 per severe AECOPD. There were 609 participants and 790 AECOPD, of which 639 (81%) were moderate and 151 (19%) were severe. Hospitalization was required in 151 (19%) compared with 40 (25%) of the 157 AECOPD in our study. Mittmann et al (16) did not report an average cost per AECOPD; however, an average can be calculated using the following formula: (\$641 per moderate AECOPD $\times$ 639 moderate AECOPD + \$9,557 per severe AECOPD $\times$ 151 severe AECOPD)/790 total AECOPD = \$2,345. This cost is lower than the direct cost per AECOPD in our study (\$2,786), even after adjusting their costs to 2009 figures (\$2,486); however, the study designs were different.

The mean annual total cost per patient in our study (\$4,147) was higher than the \$3,196 reported in 2003 by Chapman et al (15) (\$1,997 in direct medical costs and \$1,198 for work lost), even after adjusting their costs to 2009 figures (\$3,583). However, their study was a telephone survey, whereas ours was based on chart review as well as patient survey and was less dependent on patient recall. In our study, COPD medications contributed to 71% of the annual cost of maintenance treatment, and this cost was approximately three times higher than that reported in the Chapman et al (15) study. This difference can be explained by the following: 92% of our study patients took maintenance medication compared with 62% of patients in the Chapman et al (15) survey; our patients had more severe COPD; and we evaluated a more comprehensive list of costs. The cost of work loss in the Chapman et al (15) survey (\$1,198) was almost five times higher than in our study (\$252). As expected, because 71% of our patients were retired (compared with 32% in the Chapman et al [15] survey), work loss costs were lower in our study.

It is of interest to evaluate medication use in the present study in light of treatment guidelines. We observed that only 25% of GOLD 1 and 29% of GOLD 2 patients experienced an AECOPD in the previous year, but 62.9% of GOLD 1 and 61.4% of GOLD 2 patients were on an inhaled ICS/LABA combination. This is not consistent with the Canadian guidelines, which recommend that regular therapy with ICS/LABA be used only in patients with GOLD 2 and higher with ≥ 1 AECOPD per year (1). Because the prevalence of mild and moderate COPD is greater than the prevalence of severe and very severe COPD, this approach may result in significant overspending of health care dollars. Use of LAACs and the ICS/LABA combination was consistent with treatment guidelines in the majority of GOLD 3 and GOLD 4 patients (LAACs: 79.8% and 81.8%, respectively; ICS/LABA combination: 78.0% and 100.00%, respectively).

Although 36.8% of patients were current smokers, fewer than 3% were participating in a smoking cessation program. The current guidelines emphasize that smoking cessation is the single most effective and cost-effective intervention to stop the progression of COPD (2). Therefore, more effective physician advice and readily available antismoking treatment may help to reduce cost and COPD-related complications.

The main strength of the study was that we evaluated patients with physician-diagnosed COPD confirmed with postbronchodilator spirometry, which allowed classification according to GOLD/Canadian Thoracic Society guidelines (1,2). In addition, resource use was collected primarily from patient charts and supplemented with patient surveys for data not expected to be in the charts. Finally, patients were enrolled from GP/FP and specialist sites across Canada, which makes the results generalizable if practice patterns are similar to those in the study. The exclusion/inclusion criteria were less restrictive than they would have been in an efficacy trial, thus increasing the generalizability of the results.

Limitations

Patients were included in the study based on the % predicted FEV₁ measured at the site. However, to standardize the spirometric data, measured values were expressed as a percentage of the European Community for Coal and Steel predicted values. Because of this, 35 patients (12%) were reclassified as GOLD 1 and 11 patients (4%) as GOLD 4. However, 84% fell within our predefined study population, and the cost and AECOPD results were not significantly different from those observed for patients in the immediately adjacent GOLD category (Figures 1 and 3).

Patients with long-term oxygen therapy (>15 h/day for chronic hypoxemia) were excluded from the study because they would be more likely to have very severe COPD (GOLD 4) and multiple comorbidities that would incur costs, making those attributable to COPD difficult to estimate. Only two patients were excluded from the study for this reason; however, the true cost of COPD may be greater than our findings.

Despite the inclusion criterion requiring patients to have a post-bronchodilator FEV₁/FVC ratio $<70\%$ on a test completed within the past year, there were 36 patients with FEV₁/FVC ratio $\geq 70\%$ on their most recent spirometry. Because these patients had confirmed physician-diagnosed COPD, and the results obtained when they were included ($n=285$) did not differ from the results obtained when they were excluded ($n=248$), the decision was made to include them in the analyses, consistent with a true intent-to-treat analysis.

CONCLUSION

The burden associated with moderate to severe COPD is currently considerable in terms of costs to the Canadian health care system. It is expected that the prevalence of COPD and its associated costs will continue to increase for the foreseeable future. Our results indicate that the two major cost contributors were medications and hospitalizations. Therefore, more appropriate use of medications to treat COPD, particularly in the early stages of the disease, and strategies to optimally detect, manage and prevent AECOPD at all levels of disease severity, may reduce COPD-related complications and the overall burden of the disease. Finally, because COPD is a heterogeneous disease, more research is required to understand the characteristics of each patient to provide the best individualised intervention.

AUTHOR CONTRIBUTIONS: M Reza Maleki-Yazdi, Suzanne M Kelly and Valery Walker contributed substantially to the concept, design and interpretation of data, drafted the manuscript and gave final approval. Sy S Lam and Martin Barbeau contributed to the concept and design, and revised the manuscript for important intellectual content and gave final approval. Mihaela Marin contributed substantially to the analysis and interpretation of data, drafted the manuscript and gave final approval. Twenty-three sites across Canada (respirologists, internists, and family practitioners) participated in this study. The authors thank the physicians responsible for the clinical care and assessment of the patients. The investigators consisted of: A Kelly and S Lam (Alberta); T Fera, D Hepburn, and P White (British Columbia); P Mehta and K Saunders (Manitoba); R Michael (Nova Scotia); PG Cox, A Dhar, T Fargher, I Ferreira, A Kaplan, WP Killorn, A Lam, R Luton, MR Maleki-Yazdi, M Miller, J Nemmi and R Shemilt (Ontario); M Labbe, B Pek, and L Theriault (Quebec). The authors also thank the following individuals at OptumInsight who were involved in the study at various stages: Heather Bennett, Megan Coombes, Jennifer Haig, Shelley Lee, Victoria Porter, Nicki Protopapas and Raina Rogoza. The authors also thank Heide Hass from Novartis, who was involved in the study.

FUNDING: The authors are grateful to Novartis (Canada) Inc for funding this study.

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