Title: Direct healthcare costs associated with a multi-component COPD exacerbation prevention management intervention

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Acknowledgments

We would like to acknowledge The BRIDGES team for their advice on the design of the study protocol and support throughout project conduct. We would like to acknowledge the Applied Health Research Centre (AHRC) at the Li Ka Shing Institute of St. Michael's Hospital for data management and statistical analyses, specifically Judi Hall and Ashley Cohen. We would like to thank Deva Thiruchelvan and Yi Cheng ICES analysis staff.

The study was performed at Michael Garron Hospital in Toronto Canada and Southlake Regional Health Centre in New Market Canada. These research data were not previously presented.

As a prescribed entity under Ontario's privacy legislation, ICES is authorized to collect and use health care data for the purposes of health system analysis, evaluation, and decision support. Secure access to these data is governed by policies and procedures that are approved by the Information and Privacy Commissioner of Ontario. Parts of this material are based on data and/or information compiled and provided by CIHI. However, the analyses, conclusions, opinions, and statements expressed in the material are those of the author(s), and not necessarily those of CIHI.

Funding

This study was funded through the Bridges: Building Bridges to Integrate Care Program funded by the Ontario Ministry of Health and Long-Term Care. This study was supported by ICES, which is funded by an annual grant from the Ontario Ministry of Health (MOH) and the Ministry of Long-Term Care (MLTC). The analyses, conclusions, opinions, and statements expressed herein are solely those of the authors and do not reflect those of the funding or data sources; no endorsement is intended or should be inferred.

Disclosures

There are no conflicts of interest for any of the authors.

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Abstract (287 words)

Background: Healthcare costs attributed to COPD have been estimated at $4.7 trillion globally in the next 30 years. With the global burden of COPD rising, identification of interventions that might lead to healthcare cost savings is an imperative. Although many studies report the effect of COPD self-management interventions on patient outcomes and healthcare utilization, little data describes their effect on healthcare costs.

Methods: Using data linkage and established case costing methods with provincial Canadian health databases, we established public healthcare costs (acute and community) for the twelve months following randomization for the 462 participants enrolled in our randomised controlled trial of the Program of Integrated Care for Patients with Chronic Obstructive Pulmonary Disease and Multiple Comorbidities (PIC COPD+).

Results: Total median (IQR) in-hospital costs in the 12 months follow up for all (intervention and control) 462 trial participants were CAN$4,769 ($417 to $16,834) (equivalent to USD$3,566 ($312 to $12,588). Total costs incurred in the community were higher at $8,011 ($4,749 to $13,831) (equivalent to USD$5,990 ($4,749 to $10,342). Controlling for sex, income quintile, Johns Hopkins Aggregated Diagnosis Groups score, and living in an urban locality, we found lower community healthcare costs but no differences in acute care costs for participants receiving our multi-component COPD exacerbation prevention management intervention compared to usual care.

Conclusions: Controlling for important confounders we found lower public community healthcare costs but no difference in acute healthcare costs with our multi-component COPD exacerbation prevention management intervention compared to usual care. Community healthcare costs were

almost double those incurred compared to acute healthcare costs. Given this finding, although most COPD exacerbation management interventions generally focus on reducing the use of acute care, interventions that enable health care cost savings in the community require further exploration.

Keywords

Chronic Obstructive Pulmonary Disease; Self-Management; Health Care Costs; Data Linkage; health administrative databases.

Total wordcount: 1671

Background

As a chronic disease with rising prevalence and a long-term trajectory[1], chronic obstructive pulmonary disease (COPD) represents an escalating public health problem with significant economic implications to healthcare systems worldwide [2, 3]. COPD is a multi-factorial systemic disease comprising muscle wasting, cardiovascular disease, anxiety and depression, decreased fat free mass, metabolic syndrome, osteoporosis, and chronic infections [4]. In general COPD patients experience numerous comorbidities[5] which influence COPD prognosis and are affected by COPD exacerbations.

Previously, we reported on a randomised controlled trial evaluating the effectiveness of a multi-component case manager-led COPD exacerbation prevention/management intervention designed to reduce acute healthcare utilisation [6]. This multi-component, case manager-led intervention comprised a 40 minute standardized education session based on the Living Well with COPD Patient's Learning Tool[6], action plans for COPD and other comorbidity exacerbation management as well as case manager initiated telephone consultations (weekly for 12 weeks and monthly for subsequent 9 months. The control arm comprised usual care. In this trial, when we examined healthcare utilisation, we found reduced risk of emergency department (ED) visits and hospital admission *only* in those intervention participants requiring these acute healthcare services. There was no difference when considering all trial participants, with our data highly skewed due to many participants not requiring these services during the 12-months participants were enrolled in the trial. Although our trial was not powered for mortality, risk of death in the intervention group was nearly half that of control participants.

A subsequent randomised controlled trial that similarly combined action plans for both COPD and comorbidities [7] found no effect on COPD exacerbation frequency but fewer patients in the

intervention with ⩾1 respiratory-related hospitalisation. Lower probability of respiratory-related hospital admission was also reported in an earlier Cochrane review as well as improved health-related quality of life [8]. Despite these indications of benefit, little data describes the effect of COPD self-management interventions on subsequent healthcare utilization costs. This is an important gap in our understanding of programs that are essentially designed to divert costs away from expensive acute healthcare services through prevention of COPD exacerbation requiring hospitalization[9].

Therefore, we conducted an a priori planned data linkage to health administrative databases for the province of Ontario, Canada with the aim of determining the effect of our multi-component intervention compared to usual care on healthcare costs at 12 months after randomization. In Canada where we conducted the trial, costs of all medically necessary care are covered for all residents by universal public health insurance funded through general taxation.

Methods

We used unique encoded identifiers to link to the health administrative databases held at ICES (formerly the Institute for Clinical Evaluative Sciences), Ontario, Canada. These databases hold all data on all patient healthcare encounters funded by the public healthcare system in the province of Ontario. ICES is an independent, non-profit research institute whose legal status under Ontario's health information privacy law allows it to collect and analyze healthcare data for health system evaluation and improvement. We used the health administrative databases to identify: (1) hospitalizations, intensive care unit (ICU) admissions and in-hospital death from the Discharge Abstract Database; (2) emergency department (ED) presentations and same day surgery from the National Ambulatory Care Reporting System; (3) physician billings including procedures from the OHIP physician claims database; (4) prescription costs incurred in the community for individuals

eligible for the Ontario Drug Benefit program (5) inpatient rehabilitation from the National Rehabilitation Reporting System; (6) facility based continuing (residential) and long-term care services from the Continuing Care Reporting System and the Client Profile Database; (7) inpatient mental health stays from the Ontario Mental Health Reporting System; (8) home care services from the Home Care Database; and (9) death outside of hospital from the Registered Persons Database.

To establish costs, we first confirmed patterns of community and in-hospital healthcare utilization recorded in the ICES databases according to study allocation. We then calculated the costs of this healthcare utilization in Canadian dollars using established patient-level costing methodology [10]. We calculated total in-hospital and community (i.e., all public healthcare costs incurred while not a hospital in-patient) costs. In-hospital costs included those incurred through hospital admissions, ED visits, and same day surgeries. Community costs included those related to GP and specialist ambulatory clinic visits; long-term care; rehabilitation; home care; laboratory and non-physician billings; and out of hospital publicly funded prescription costs for those over 65 years of age on receiving benefits covered by the Ontario Drug Benefit program [11]. Although costs of the multi-component intervention were not specifically counted, most costs (e.g., clinic visits) were captured via these methods.

The use of data held at ICES was authorized under section 45 of Ontario's Personal Health Information Protection Act according to privacy regulations of ICES. Recruitment of participants to form the study cohort was approved by the Research Ethics Boards of the Michael Garron Hospital (Toronto, ON, Canada) (510-1205-Res-018, and Southlake Regional Health Centre (Southlake, ON, Canada) (#0033 1213). Written informed consent for data linkage was obtained from all trial participants.

We present healthcare costs as medians and interquartile ranges (IQR) due to skewed data distribution. We examined mortality after randomization using Kaplan-Meier curves. We performed unadjusted comparisons of costs according to study arm allocation using Mann-Whitney u tests. To examine variables within the ICES databases selected a priori as associated with healthcare costs, we created negative binomial regression models for community and in-hospital costs using the offset option to account for difference in follow-up. Analyses were conducted by an experienced ICES analyst using SAS EG version 7.15 (SAS Institute, Inc., Cary, NC). All analyses were two-tailed; P value of ≤ 0.05 considered significant.

Results

Of the 470 trial participants, ICES data linkage was possible for 462. We found no difference between intervention and control arm baseline characteristics (sex, age group, income quintile, Johns Hopkins ACG® Aggregated Diagnosis Groups (ADG) [12], geographic profile [13]) (Table 1). Johns Hopkins ADGs are a person-focused, diagnosis-based method of categorizing subjects' illnesses. Unadjusted comparison between groups using ICES data confirmed the numerically lower but non-statistically significance difference in ED visits at 12 months (mean (SD) 1.86 (2.57) versus 2.40 (3.45) visits, P=0.055) that we found for the main trial primary outcome using participant self-reported healthcare utilization data. ICES data confirmed no difference in the number of in-patient hospitalizations or days in hospital but confirmed the difference in mortality favoring the intervention arm (Figure 1).

Total median (IQR) in-hospital costs in the 12 months following randomization for all (intervention and control) 462 trial participants were CAN$4,769 ($417 to $16,834) (equivalent to US$3,566 ($312 to $12,588). Total costs incurred in the community were higher at $8,011 ($4,749 to $13,831)

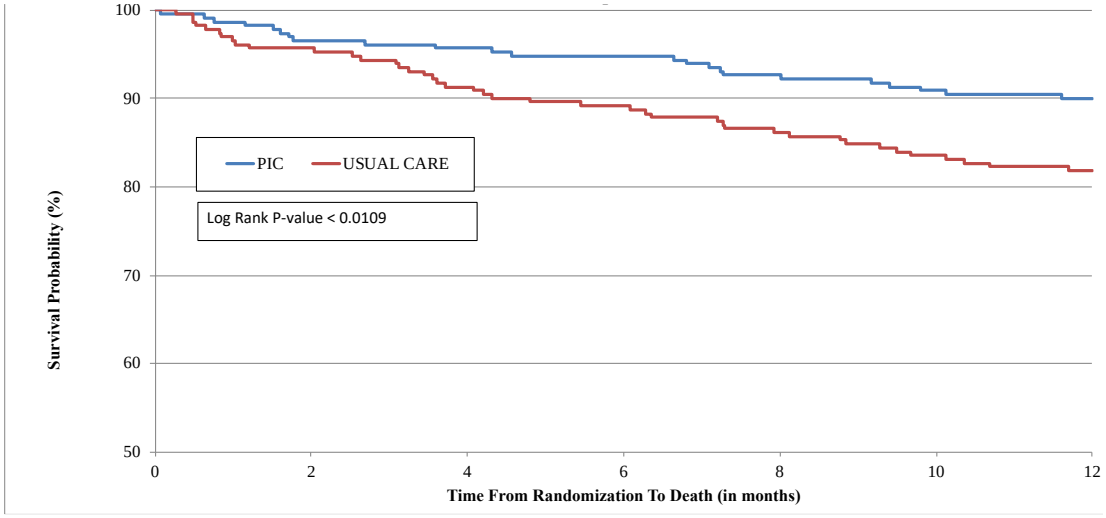

Figure 1: Kaplan-Meier curves of curvival by Program of Integrated Care and Usual Care for patients with COPD and multiple comorbidities

(equivalent to US$5,990 ($4,749 to $10,342). Unadjusted comparisons identified no difference in in-hospital or community publicly funded healthcare costs between participants receiving the multi-component COPD exacerbation prevention management intervention compared to participants in the control group (Table 2). Regression modelling indicated community health care costs were lower in those patients allocated to the intervention arm after controlling for sex, income quintile, total ADG score of 7 or more (indicative of greater co-morbidity), and living in an urban versus rural locality. There was no association with in-hospital costs by study arm allocation. Male sex and having a higher ADG score were associated with higher community and in-hospital costs (Table 3).

Discussion

This *a priori* planned evaluation using health administrative databases in the province of Ontario Canada suggests that our multi-component case manager-led COPD self-management program with action plans for COPD and comorbidity reduced public healthcare costs incurred through access to community services compared to participants randomised to usual care when adjusting for important covariates. Conversely, and contrary to our a priori hypothesis when designing the trial, we found no difference in in-hospital costs adjusting for the same covariates. Median community healthcare costs were almost double in-hospital costs indicating the burden patients with COPD and multi-morbidity place on community resources.

Our trial was not designed to assess cost effectiveness of our intervention and therefore these results need to be interpreted with caution. The COPD Patient Management European Trial (COMET) did demonstrate cost savings of EUR 37.50/patient/year for patients with severe or very severe COPD when considering unplanned all-cause hospitalization days, mortality, and quality-adjusted life expectancy [14]. This trial evaluated a very similar case manager-led multi-component self-

management program but also included home telemonitoring with an e-Health platform to aid in early exacerbation detection. As with our findings, the COMET trial also failed to demonstrate a difference in use of acute healthcare services but did demonstrate a reduction in mortality [15].

We identified a median overall direct annual healthcare cost of CAD $6,460 (US$4,830). This figure is substantially lower than a previous US study evaluating healthcare insurance claims in working age people with COPD (USD$11,984) [16]. Similar a 2023 study using data from 1,073 COPD patients within the Medical Expenditure Panel Survey reported an all-cause medical cost per patient per year of US$19,449 of which US$6145 was for prescription drugs [17]. This difference in direct costs likely reflects differences in healthcare costings in Canadian versus US healthcare systems. As well, medication costs were not included for approximately 25% of our cohort due to ineligibility for the Ontario Drug Benefit program and therefore not captured within ICES databases.

Despite no difference in acute healthcare costs, we did identify a reduction in community healthcare costs associated with our multi-component case manager-led COPD self-management program. Recently the global economic burden of COPD has been estimated at $4.33 trillion from 2020 to 2050, with the largest economic burden predicted for China ($1.36 trillion) and the US ($1.04 trillion) [18]. Given these substantial costs and that COPD prevalence continues to rise due to population aging, worsening air quality, and increasing total numbers of smokers worldwide [19], identification of exacerbation interventions that produce of healthcare cost-savings remains an imperative in COPD exacerbation management.

Strengths of our study include the use of extensively validated provincial healthcare databases that provide comprehensive data on both acute and community incurred healthcare costs. Another strength is the data linkage from a prospectively recruited cohort who had participated in a

randomized controlled trial of a self-management programme for patients with COPD and comorbidity. Our study has limitations. First, this study is subject to the limitations inherent to administrative database studies in terms of data availability and quality. However, reassuringly the patterns of healthcare utilization we identified using the databases reflected those we identified through participant self-report in real time throughout the trial. Second, our data do not reflect costs incurred by family members needing to provide care in the home to these participants including costs to them associated with lost income due to needing to provide care. They also do not consider private out-of-pocket, and third party insurance costs. Therefore overall costs may be underestimated. Finally, our data may not be generalisable to jurisdictions such as the US without publicly funded healthcare systems for acute and community healthcare provision. In such jurisdictions there will be greater reliance on private health insurance and different cost models. In countries with similar models of publicly funded healthcare services, cost savings we identified in community services are likely to be replicable.

Conclusion

In conclusion, we identified lower public community healthcare costs but no difference in acute care costs in the twelve months following randomization associated with our multi-component COPD exacerbation prevention management intervention compared to usual care. Community healthcare costs were almost double those incurred via accessing acute healthcare services. Given this finding, although most COPD exacerbation management interventions generally focus on reducing the use of acute care, interventions that enable health care cost savings in the community require further exploration.

Quick Look

Current Knowledge

Healthcare costs of COPD are excessive and the global burden of COPD continues to rise due population aging, worsening air quality, and increasing total numbers of smokers worldwide. Identification of interventions that reduce acute healthcare utilisation producing cost-savings is an imperative. Although many studies report the effect of COPD self-management interventions on patient outcomes and healthcare utilization, little data describes their effect on healthcare costs.

What this Paper Contributes to our Knowledge

Using established patient-level costing methodology we found lower public community healthcare costs but no difference in acute healthcare costs associated with our multi-component COPD exacerbation prevention management intervention compared to usual care when controlling for sex, income quintile, total ADG score of 7 or more, and living in an urban versus rural locality. Community healthcare costs were almost double those incurred via accessing acute healthcare services.

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Table 1: Demographic characteristics

Characteristic	PIC-COPD N = 231	Usual care N = 231
Female sex	116 (50.2%)	129 (55.8%)
Age category		
50-64	58 (25.1%)	69 (29.9%)
65-79	119 (51.5%)	103 (44.6%)
80+	54 (23.4%)	59 (25.5%)
Hopkin's ADG[a]		
1-7	91 (39.4%)	82 (35.5%)
>7	140 (60.6%)	149 (64.5%)
Income quintile		
1 (lowest)	46 (19.5%)	54 (22.9%)
2	54 (23.4%)	58 (25.1%)
3	45 (19.5%)	48 (20.8%)
4	51 (22.1%)	41 (17.7%)
5 (highest)	35 (15.2%)	30 (13.0%)
Urban living	228 (98.7%)	230 (99.6%)

a 1 year lookback for ADG score

Table 2 Unadjusted healthcare costs at 1 year

Healthcare cost	PIC-COPD	Usual care	Total	P-Value
Physician visits	$2,544	$2,722	$2,670	
	($1,462-$4,989)	($1,475-5$,500)	($1,468-$5,247)	0.745
Medications	$2,970	$2,746	$2,933	0.538
	($1,695-$4,360)	($1,432-$4,331)	($1,573-$4,353)	
Home care, long-term care and	$1,412	$1,617	$1,573	
outpatient costs	($623-$3,740)	($638-$4,486)	($637-$4,077)	0.356
Laboratory and non-physician	$144	$126	$135	
visits	($50-$275)	($19-$230)	($47-$249)	0.075
All community costs	$7,672	$8,339	$8,011	
(sum of above)	($4,940-$13,573)	($4,737-$14,154)	($4,749-$13,831)	0.621
All in-hospital costs	$4,642	$4,856	$4,769	
	($281-$15,355)	($564-$18,562)	($417-$16,834)	0.194
Total costs	$6,379	$7,205	$6,460	0.419
	($3,122-$16,545)	($3,169-$18,891)	($3,169-$17,709)	

All costs are median (IQR) and reported in CAD$.

Table 3: Adjusted Healthcare costs at 12 months following randomisation

Community costs				
Parameter	Rate ratio	95% CI	Wald chi^2	P value
Intercept	634.41	258.89 to 1554.80	199.08	<.0001
PIC COPD intervention arm	0.83	0.70 to 0.97	5.27	0.02
Males	1.21	1.03 to 1.43	5.45	0.02
Johns Hopkins ADG ⩾7	1.87	1.57 to 2.21	51.61	<.0001
Income quartile highest (reference)	1			
Income quartile next to highest	1.09	0.82 to 1.44	0.32	0.57
Income quartile middle	1.15	0.87 to 1.52	0.90	0.34
Income quartile next to lowest	0.91	0.69 to 1.19	0.52	0.47
Income quartile lowest	1.09	0.83 to 1.43	0.35	0.55
Income quartile missing	1.77	0.51 to 6.08	0.82	0.57
Living in urban location	1.27	0.53 to 3.03	0.28	0.59
In-hospital costs				
Parameter	Rate ratio	95% CI	Wald chi^2	P value
Intercept	792.11	71.18 to 8814.91	29.48	<.0001
PIC COPD intervention arm	0.73	0.46 to 1.14	1.96	0.16
Males	1.78	1.16 to 2.76	6.81	0.009
Johns Hopkins ADG ⩾7	2.15	1.34 to 3.43	10.15	0.001

Income quartile highest (reference)	1			
Income quartile next to highest	1.16	0.55 to 2.45	0.16	0.69
Income quartile middle	1.25	0.59 to 2.67	0.34	0.56
Income quartile next to lowest	0.82	0.40 to 1.69	0.28	0.60
Income quartile lowest	0.84	0.40 to 1.76	0.21	0.65
Income quartile missing	1.02	0.04 to 25.17	0	0.99
Living in urban location	1.30	0.13 to 13.03	0.05	0.82

Johns Hopkins ADG: Aggregated Diagnostic Groups