Clinical and Economic Outcomes Associated with Transitions of Tobacco Use Among a Cohort of Adult Male Smokers using U.S. Real-World Data

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Abstract

Background: Real-world data on the clinical and economic impact of switching from cigarettes to non-combustible tobacco products are lacking. This study describes select clinical outcomes and healthcare costs among adult males who continued to use combustible tobacco products (CS), switched to non-combustible smokeless products (ST), or quit tobacco (NT).

Methods: This retrospective cohort study identified male smokers from the Merative™ MarketScan® Commercial and Medicare Databases between 2011-2021. Index date was the earliest claim indicating a switch to smokeless tobacco for ST cohort, earliest claim indicating prior tobacco use for NT cohort, and randomly assigned for CS cohort. Patients had ≥12 months of continuous enrollment (CE) prior to and 36 months of CE following index. Matching weights were employed to balance characteristics at baseline and annual follow-up. Clinical outcomes and healthcare costs were described during the 3-year follow-up.

Results: Post-matching weights, approximately 1,349 patients were included in each cohort. Median age was 44, and 30% resided in a rural area. Chronic obstructive pulmonary disease (COPD) exacerbations decreased from year 1 to 3 among the ST (0.8% to 0.4%) and NT (3.3% to 3.1%) cohorts and increased among CS cohort (2.8% to 3.3%). The annual proportion of one or more claims for clinical outcomes of interest were relatively stable. Ischemic heart disease trended toward a decrease among the ST (6.4% to 5.7%) and NT (10.9% to 10.8%) cohorts and increase among the CS cohort (8.6% to 9.4%). Total healthcare cost decreased among the ST (-$5,329), and NT (-$6,825) cohorts, and were flat for the CS cohort (-$159) during follow-up.

Conclusions: Consistent with epidemiological evidence, our findings demonstrated male smokers who switched to ST or quit saw meaningful reductions in healthcare costs during follow-up while costs in continued smokers were unchanged, supporting the potential of healthcare claims data for assessing harm-reduction potential of non-combustible tobacco products.

Background

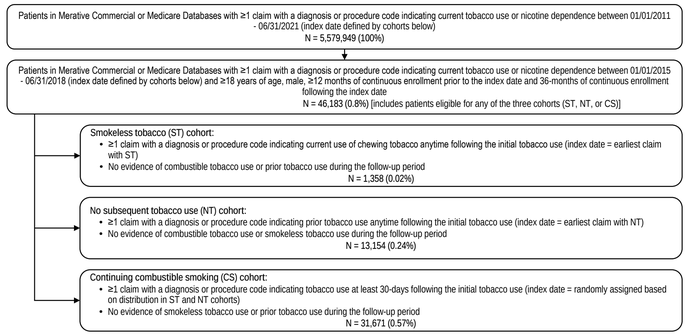
- Concerns about the detrimental effects of smoking combustible tobacco products (cigarettes being the most common) have motivated many people who smoke to attempt to quit, with current health problems being one of the most common factors in attempting to quit (Gallus, 2013; US HHS, 2020).
- Consistent with FDA's comprehensive plan announced in 2017 (Gottlieb, 2017) for adults who are not willing or unable to quit smoking, switching to non-combustible tobacco products, such as smokeless tobacco products, may offer a reduced-risk alternative (Nutt, 2014).
- There is limited previous research comparing the risk of adverse health outcomes between people who continue to smoke and people who stopped smoking and switched to non-combustible tobacco products using data from large-scale healthcare databases.
- The objective of this study was to describe and compare healthcare utilization and clinical outcomes among adult males who continue to use combustible tobacco products (CS), who switch to smokeless tobacco products (ST), and who have no subsequent tobacco use (NT).

Methods

Study Design and Data Source

- This retrospective cohort study identified males who used combustible tobacco products from the Merative™ MarketScan® Commercial and Medicare Databases between 2011-2021.

Patient Selection



Statistical Analysis

- Matching weights were implemented to balance selected demographic and clinical characteristics at baseline and annual follow-up across the three cohorts (Yoshida, 2017).
- Clinical outcomes, specifically chronic obstructive pulmonary disease (COPD) and ischemic heart disease (IHD) were identified through claims, and healthcare utilization and costs were described in the baseline and annual follow-up periods in the weighted cohorts.
- As an exploratory analysis, generalized linear models were used to estimate the association between exposure cohorts (reference was the CS cohort) and ≥ 1 COPD claim, ≥ 1 COPD exacerbation claim, and ≥ 1 IHD claim in the unweighted study population during both baseline and 36-month follow-up periods.

Results

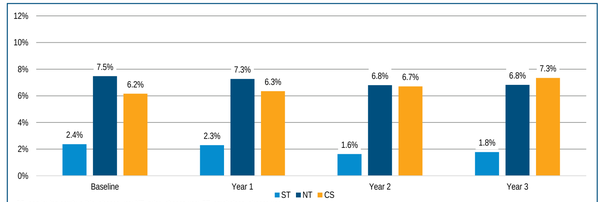
- After applying the matching weights, the ST, NT, and CS cohorts were balanced with regards to selected demographic and baseline clinical characteristics. The mean age across cohorts was 44 years and 30% resided in a rural area (Table 1).

Table 1. Baseline Demographic and Clinical Characteristics, Post Matching-Weights

	ST Cohort (N=1,349) Mean(SD)/%	NT Cohort (N=1,352) Mean(SD)/%	CS Cohort (N=1,348) Mean(SD)/%
Age (Mean, SD)	43.7(10.5)	43.5(12.1)	43.8(11.5)
Geographic region (%)			
Northeast	5.2%	5.2%	5.1%
North Central	33.4%	33.9%	33.1%
South	46.1%	45.5%	46.8%
West	15.1%	15.2%	14.8%
Unknown	0.2%	0.1%	0.1%
Urbanicity (%)			
Urban	69.4%	69.4%	69.7%
Rural	30.4%	30.4%	30.2%
Unknown	0.2%	0.1%	0.1%
Charlson Comorbidity Index (Mean, SD)	1.2	1.2	1.2
Clinical Characteristics (%)			
Alcohol use disorder	6.5%	6.6%	6.5%
Dyslipidemia	35.5%	36.6%	35.3%
Hypertension	46.6%	46.6%	46.7%
Obesity	23.3%	23.3%	23.5%
Osteoarthritis	11.7%	11.7%	11.9%

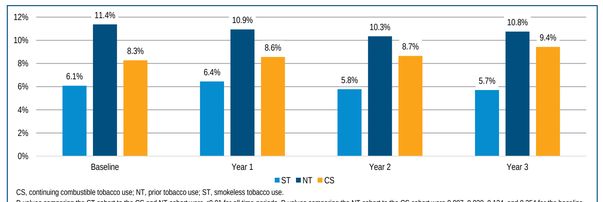
- After applying the matching weights, claims for COPD were highest among the NT cohort in the baseline period (7.5%), followed by the CS cohort (6.2%), and the ST cohort (2.4%). While the proportions of COPD claims were relatively stable over the follow-up period overall, COPD claims tended to decrease slightly in the ST and NT cohorts, whereas it tended to increase slightly in the CS cohort (Figure 2).
- After applying the matching weights, claims for IHD were highest among the NT cohort, followed by the CS and ST cohorts. In all cohorts, the annual proportion of IHD claims was relatively stable over the follow-up time. In the ST and NT cohorts, the annual proportion of IHD tended to decrease slightly from baseline through the follow-up periods, whereas the proportion tended to increase slightly in the CS cohort over follow-up periods (Figure 3).

Figure 2. Annual Proportion of Patients with COPD Claims



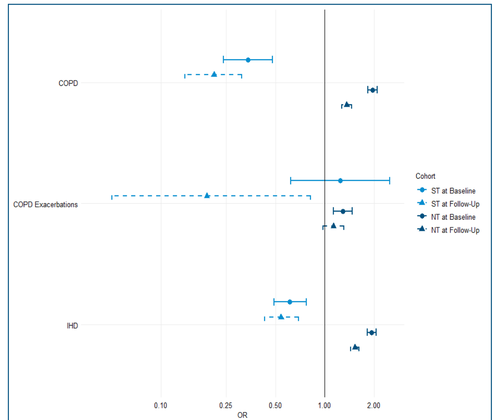
CS, continuing combustible tobacco use; NT, prior tobacco use; ST, smokeless tobacco use.
P-values comparing the ST cohort to the CS and NT cohort were <0.001 for all time periods. P-values comparing the NT cohort to the CS cohort were >0.05.

Figure 3. Annual Proportion of Patients with IHD Claims



CS, continuing combustible tobacco use; NT, prior tobacco use; ST, smokeless tobacco use.
P-values comparing the ST cohort to the CS and NT cohort were <0.01 for all time periods. P-values comparing the NT cohort to the CS cohort were 0.007, 0.038, 0.134, and 0.254 for the baseline, year 1, year 2, and year 3 time periods, respectively.

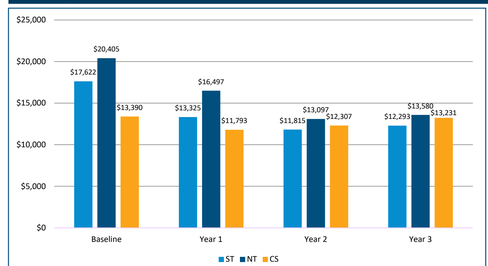
Figure 4. Unadjusted Odds Ratios for COPD, COPD Exacerbations, and IHD at Baseline and 36-month Follow-up.



The unweighted sample size by cohort: [CS (n=31,671), NT (n=13,154), ST (n=1,350)]. The reference category for all models was the CS cohort. The COPD exacerbation model was limited to patients who had COPD in the baseline period [CS (n=2,140), NT (n=1,632), ST (n=32)].
CS, continuing combustible tobacco use; COPD, chronic obstructive pulmonary disease; IHD, ischemic heart disease; NT, prior tobacco use; ST, smokeless tobacco use.

- Compared to CS patients, the unadjusted odds of COPD and IHD were lower at both baseline [OR (95%): 0.34 (0.24-0.48) and 0.61 (0.49-0.77), respectively] and 3-year follow-up [OR (95%): 0.21 (0.14-0.31) and 0.54 (0.43-0.69), respectively] for ST patients. (Figure 4).
- Compared to CS patients, the unadjusted odds of COPD and IHD were higher at both baseline [OR (95%): 1.96 (1.83-2.09) and 1.93 (1.82-2.06), respectively] and 3-year follow-up [OR (95%): 1.36 (1.27-1.46) and 1.53 (1.44-1.62), respectively] for NT patients. (Figure 4).
- Compared to total average healthcare costs at baseline, average costs were lower at year 3 among the ST (-$5,329), and NT (-$6,825) cohorts, and nearly unchanged for CS cohort (-$159) (Figure 5).

Figure 5. Total average healthcare costs in the baseline and annual follow-up periods



CS, continuing combustible tobacco use; NT, prior tobacco use; ST, smokeless tobacco use.
Total healthcare costs were significantly different between the NT and CS cohorts (p-value<0.001; and the ST and CS cohorts (p-value=0.004) in the baseline period. Total healthcare costs were significantly different between the NT and CS cohorts (p-value=0.001; and the ST and NT cohorts (p-value=0.027) in year 1 of follow-up. There were no statistically significant difference in years 2 or 3.

Limitations

- This study is subject to limitations common to all retrospective administrative claims studies, such as potential misclassification of tobacco use status, covariates, and study outcomes.
- Observable smoking behavior was limited to the duration of a patient's follow-up period and was reliant upon diligent coding by the healthcare provider. Therefore, differences in cumulative exposure to combustible tobacco (e.g., pack-years) could not be calculated and accounted for in weighted models.
- Due to limited ICD-9 data on smokeless tobacco use, the study was limited to patients who had an index year of 2015 or later.
- Compared to patients with persistent combustible tobacco use, the odds of clinical outcomes were lower for patients switching to smokeless tobacco use and higher for patients that quit all tobacco products both before and after the smoking behavior change. This highlights the complexity in identifying smoking behavior changes and creating comparable cohorts among long-term smokers using claims data and warrants additional methodologic approaches to fairly compare these cohorts.

Conclusion

- Consistent with epidemiological evidence, our findings demonstrated adult males with a history of combustible tobacco use who either switched to smokeless tobacco products or had no evidence of any subsequent tobacco use saw reductions in direct healthcare costs compared to those who continued combustible tobacco use. These results support the feasibility of utilizing healthcare claims data for assessing the harm-reduction potential of non-combustible tobacco products.
- There is a significant gap in the ability to identify the use of non-combustible tobacco products, other than smokeless chewing tobacco, in healthcare claims data. It would be valuable for future studies to be able to investigate the harm-reduction potential of more frequently used non-combustible tobacco products, such as e-cigarettes.

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