Exacerbation Rates and Healthcare Resource Utilization in Asthma Patients Initiating Tiotropium Respimat

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BACKGROUND

- Tiotropium bromide inhalation spray, 1.25 µg, delivered through the Respimat® slow moving-mist inhaler (TIO-RMT) is a bronchodilator indicated for the long-term maintenance treatment of asthma in patients 6 years of age and older[1]
- Clinical studies have shown that tiotropium is effective and safe in both adults and children/adolescents[2]
- The 2015-2019 GINA strategy reports recommend tiotropium as an add-on treatment option for patients on ICS/LABA therapy with a history of exacerbations[3]

STUDY OBJECTIVE

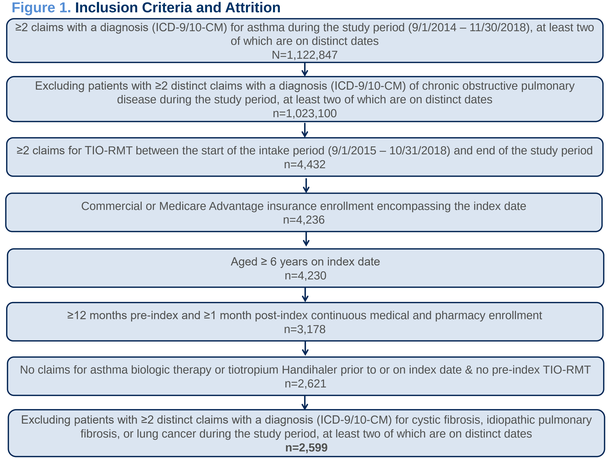
- To characterize a real-world cohort of asthma patients initiating TIO-RMT and compare the pre- vs. post-initiation differences in asthma exacerbation rates, and asthma-related and all-cause healthcare resource utilization (HRU)

METHODS

Design and patient selection

- This retrospective, observational, claims-based cohort study used integrated administrative medical and pharmacy claims and laboratory test result data from the HealthCore Integrated Research Database (HIRD®) to characterize asthma patients initiating TIO-RMT
- Index date was defined as the date of a patient's first claim for TIO-RMT during the intake period
- Patients meeting the study criteria (see Fig. 1) were also stratified by age on index date and each age stratum was described separately:
  - Adults (>18 years)
  - Adolescents (12 – 17 years)
  - Pediatrics (6 – 11 years)

Figure 1. Inclusion Criteria and Attrition



Key Outcomes

- Asthma-related HRU: A medical claim with a diagnosis code for asthma at any position (ICD-9-CM: 493.xx; ICD-10-CM: J45.20 - J45.998)
- Asthma exacerbations: (1) Inpatient asthma exacerbation: an inpatient stay with asthma as the primary diagnosis (2) ER asthma exacerbation: an ER visit (not leading to hospitalization) with asthma as the primary diagnosis (3) Ambulatory asthma exacerbation: outpatient encounter with asthma diagnosis in any position of a medical claim and receipt of oral corticosteroids within 7 days following the outpatient encounter.

Analyses

- Unadjusted statistical tests (t-test for continuous variables; chi-square for categorical variables) were performed to compare pre-index and post-index outcomes
- Continuous post-index outcomes, such as HRU and costs, were annualized on a standardized per-patient per-year basis for the comparison

RESULTS

Table 1. Baseline Patient Characteristics

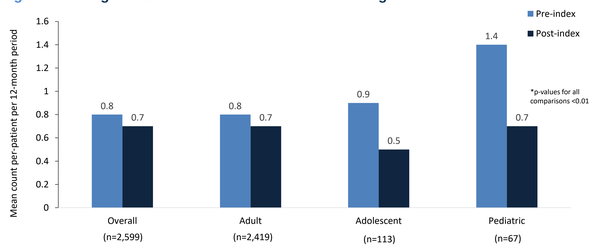
Characteristic, n (%)*	Overall (n=2,599)	Adults (n=2,419)	Adolescents (n=113)	Pediatrics (n=67)
Demographics				
Age at index (years), mean (SD)	48.2 (15.7)	50.9 (12.7)	14.4 (1.8)	8.9 (1.7)
Male	1,757 (67.6%)	1,661 (68.7%)	67 (59.3%)	29 (43.3%)
U.S. region				
Northeast	334 (13.1%)	307 (13%)	13 (11.7%)	14 (21.2%)
Midwest	457 (17.9%)	420 (17.7%)	20 (18%)	17 (25.8%)
South	1,015 (39.9%)	950 (40.1%)	43 (38.7%)	22 (33.3%)
West	741 (29.1%)	693 (29.2%)	35 (31.5%)	13 (19.7%)
Index prescriber specialty				
Pulmonology	834 (32.1%)	798 (33%)	16 (14.2%)	20 (29.9%)
Allergist / immunology	893 (34.4%)	795 (32.9%)	64 (56.6%)	34 (50.7%)
Primary care / internal medicine / pediatrician	297 (11.4%)	283 (11.7%)	12 (10.6%)	2 (3%)
Other index prescriber specialties	543 (20.9%)	514 (21.2%)	21 (18.6%)	8 (11.9%)
Unknown / missing	32 (1.2%)	29 (1.2%)	0 (0.0%)	3 (4.5%)
Baseline clinical characteristics				
Quan-Charlson comorbidity score, mean (SD)	1.4 (1.1)	1.4 (1.1)	1 (0.1)	1 (0.3)
GINA staging				
Mild (step 1 and 2)	777 (29.9%)	747 (30.9%)	25 (22.1%)	5 (7.5%)
Moderate (step 3)	446 (17.2%)	415 (17.2%)	23 (20.4%)	8 (11.9%)
Severe (step 4 and 5)	1376 (52.9%)	1257 (52%)	65 (57.5%)	54 (80.6%)
Relevant comorbid conditions				
Allergic rhinitis	1,600 (61.6%)	1,457 (60.2%)	86 (76.1%)	57 (85.1%)
Acute sinusitis	810 (31.2%)	754 (31.2%)	33 (29.2%)	23 (34.3%)
Chronic sinusitis	533 (20.5%)	502 (20.8%)	20 (17.7%)	11 (16.4%)
Gastroesophageal reflux disease	909 (35%)	882 (36.5%)	13 (11.5%)	14 (20.9%)
Shortness of breath / dyspnea	916 (35.2%)	875 (36.2%)	28 (24.8%)	13 (19.4%)
Baseline asthma medication use				
Number of medication classes used, mean (SD)	3.4 (1.4)	3.4 (1.4)	3.7 (1.4)	4.3 (1.4)
Any ICS	2,163 (83.2%)	2,002 (82.8%)	99 (87.6%)	62 (92.5%)
Low dose (per GINA guidelines)	336 (12.9%)	293 (12.1%)	30 (26.5%)	13 (19.4%)
Medium dose (per GINA guidelines)	1,295 (49.8%)	1,197 (49.5%)	63 (55.8%)	35 (52.2%)
High dose (per GINA guidelines)	706 (27.2%)	637 (26.3%)	32 (28.3%)	37 (55.2%)
LABA-ICS (FDC)	1,932 (74.3%)	1,800 (74.4%)	82 (72.6%)	50 (74.6%)
Any inhaled SABA	2,145 (82.5%)	1,980 (81.9%)	99 (87.6%)	66 (98.5%)
Any inhaled SAMA	598 (23%)	537 (22.2%)	30 (26.5%)	31 (46.3%)
Oral corticosteroids	1,813 (69.8%)	1,682 (69.5%)	78 (69%)	53 (79.1%)

*All measures reported as n(%) unless specified
SD: standard deviation, GINA: Global Initiative for Asthma, ICS: inhaled corticosteroid, FDC: fixed-dose combination, LABA: long-acting beta agonist, SABA: short-acting beta agonist, SAMA: short-acting muscarinic antagonist, ICU: intensive care unit, ER: emergency room

Table 2. Follow-up time after index date by subgroup

	Overall	Adults	Adolescents	Pediatrics
Length of follow-up (days), mean (SD)	448 (291.7)	450.3 (292.4)	452.1 (290.7)	355.7 (257.2)

Figure 2. Change in asthma exacerbations after initiating TIO-RMT*



- For the overall cohort, mean exacerbation counts were significantly fewer post-index for each exacerbation type (inpatient, ER, ambulatory) (p<0.005)

Table 3. Asthma-related HRU

Utilization Type, Per-Patient-Per-Year, mean (SD)	Pre-index	Post-index	p-value
Inpatient visits			
Overall	0.1 (0.4)	0.2 (1.4)	**<.0001**
Adult	0.1 (0.4)	0.2 (1.4)	**<.0001**
Adolescent	0.1 (0.4)	0.1 (0.4)	0.9418
Pediatric	0.2 (0.6)	0.2 (1.2)	0.4787
Length of inpatient stay (days) for all patients			
Overall	0.4 (1.6)	0.3 (1.8)	**0.0278**
Adult	0.4 (1.6)	0.3 (1.8)	**0.0277**
Adolescent	0.4 (1.5)	0.3 (1.5)	0.6719
Pediatric	0.3 (1.1)	0.4 (1.6)	0.6962
Length of inpatient stay (days) for patients with ICU visits			
Overall	6.1 (4.4)	4.3 (4.7)	**0.0274**
Adult	6.2 (4.5)	4.3 (4.8)	**0.0297**
Adolescent	3.7 (0.5)	2.2 (1.3)	0.0543
Pediatric	4.9 (1.2)	7.6 (6.4)	0.3635
Pharmacy claims			
Overall	29.7 (19.6)	16.8 (10)	**<.0001**
Adult	30.6 (19.9)	17 (10)	**<.0001**
Adolescent	17.5 (10.8)	14.5 (9.5)	**<.0001**
Pediatric	18.2 (8.6)	15.8 (10.7)	**0.0484**

- There were no statistically significant differences in asthma-related ER visits pre vs. post-initiation of TIO-RMT

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Figure 3. Asthma-related outpatient encounters and physician office visits

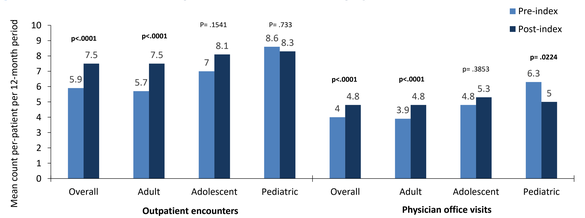

Table 4. All-cause HRU

Utilization Type, Per-Patient-Per-Year, mean (SD)	Pre-index	Post-index	p-value
Outpatient encounters			
Overall	34.7 (30.7)	39 (34.6)	**<.0001**
Adult	35 (31)	39.6 (34.8)	**<.0001**
Adolescent	30.5 (25.2)	32.3 (30.8)	0.4623
Pediatric	29.5 (23.6)	29.7 (29.8)	0.9500
Physician office visits			
Overall	13 (9.3)	13.9 (10.9)	**<.0001**
Adult	13.1 (9.5)	14.1 (11)	**<.0001**
Adolescent	11.4 (7)	11.4 (8.6)	0.9606
Pediatric	11.7 (6.8)	10.9 (8.2)	0.3269
Emergency room (ER) visits			
Overall	0.5 (1.2)	0.5 (1.3)	**0.0106**
Adult	0.5 (1.2)	0.5 (1.3)	**0.013**
Adolescent	0.4 (0.9)	0.5 (1.4)	0.7411
Pediatric	0.7 (1.4)	0.5 (0.9)	0.1396
Pharmacy claims			
Overall	29.7 (19.6)	36.5 (21.7)	**<.0001**
Adult	30.6 (19.9)	37.5 (21.8)	**<.0001**
Adolescent	17.5 (10.8)	23.1 (13.9)	**<.0001**
Pediatric	18.2 (8.6)	22 (14.5)	**0.0055**

- There were no significant differences in mean all-cause inpatient visits, length of inpatient stay (LOS), and LOS for patients with ICU visits

LIMITATIONS

- Important patient clinical characteristics were not available in claims data, such as forced expiratory capacity, peak expiratory flow, quality of life, smoking history, and severity of symptoms
- Pre and post-index comparisons were unadjusted

CONCLUSION

- A reduction in mean asthma-related exacerbations, pharmacy claims, and length of inpatient stay was observed post-initiation of Tio-RMT in this real-world cohort
- Further corroboration of these results and additional exploration of add-on Tio-RMT outcomes against alternate treatment approaches is needed

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