Characteristics of New Users of Aclidinium Bromide in the United Kingdom

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CONFLICT OF INTEREST

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BACKGROUND

- Aclidinium bromide, a long-acting antagonist of lung M3 receptors (LAMA), was approved in Europe in 2012 as maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).
- As part of the pharmacovigilance plan, a drug utilization study in the United Kingdom (UK), Denmark, and Germany is ongoing.
- The protocol was registered in the EU PAS Register (ID number: ENCEPP/SDPP/6559).
- We present the results of the baseline phase of the study conducted in the UK using the Clinical Practice Research Datalink (CPRD).

OBJECTIVE

- To describe the characteristics of new users of aclidinium bromide and other selected COPD medications with regard to age, sex, comorbidities, comedications, and COPD severity.

METHODS

- An observational cohort study was conducted of new users of aclidinium bromide and other COPD medications in the CPRD, between 2012 and 2015.
- Other COPD medications included in the study were as follows:
  - Tiotropium
  - Other LAMA: glycopyrronium bromide, umeclidinium
  - LAMA/long-acting beta-2 agonists (LABA): glycopyrronium/indacaterol, umeclidinium/vilanterol
  - LABA: formoterol, salmeterol, indacaterol
  - LABA/inhaled corticosteroid (ICS): formoterol/budesonide, formoterol/beclomethasone, formoterol/mometasone, formoterol/fluticasone, salmeterol/fluticasone propionate, vilanterol/fluticasone
- Patients were characterized according to age, sex, COPD diagnosis and severity, medical history, and comedications at the date of the first prescription of the study medications, defined as the index date.
- Patients with COPD were identified through Read codes in CPRD and ICD-10 hospital discharge codes in Hospital Episode Statistics.
  - ICD-10 codes were: J40 to J42 Chronic bronchitis, J43 Emphysema, and J44 Other COPD.
  - Severity of COPD was classified as mild, moderate, severe, and very severe, according to an adapted validated algorithm (Table 1).[1]
- Medical history was defined by Read codes in CPRD and ICD-10 hospital discharged diagnoses in HES recorded at any time before the index date.
- Use of medications was defined by Gemscript codes in CPRD recorded in the 12 months before the index date.
- The annual age- and sex-standardized prevalence of use of each study medication was estimated using the 2013 adult European Union population.
- Descriptive statistics were performed to characterize new users of the study medications.

Table 1. Assessment of COPD Severity

Severity of COPD	Definition
Mild	Up to 2 prescriptions in the last year for a bronchodilator of the same drug class with > 6 months between them
Moderate	Regular bronchodilator treatment, defined as ≤ 2 prescriptions or refills of the same drug class with a maximum interval of 6 months in the last year
Severe	Occurrence of ≤ 1 of the following events in the prior year: • Hospitalization for COPD • Third course of antibiotics for respiratory tract infections • Second course of systemic corticosteroids for the treatment of COPD exacerbation
Very severe	Use of oxygen therapy or scheduled for lung transplant

DISCUSSION AND CONCLUSIONS

- This drug utilization study characterized 3,604 new users of aclidinium bromide and 146,410 new users of other COPD medications in the CPRD (UK), in the first 34 months after launch of aclidinium bromide (September 2012-June 2015).
- New users of aclidinium bromide and new users of other LAMA medications were older, had a higher percentage of men, and had more frequent diagnoses of COPD than new users of LABA and LABA/ICS.
- Among new users diagnosed with COPD, we found the following:
  - The frequency of comorbidity was homogeneous across the study medications, and there were no marked differences between new users of LAMA and new users of LABA or LABA/ICS.
  - Hypertension, depressive disorders, diabetes, obesity, urinary tract infection, and ischemic heart disease were the most frequent comorbid conditions.
  - New users of aclidinium bromide were prior users of respiratory medications more frequently and had severe COPD more frequently than new users of other study medications.

REFERENCE

1. Verhamme KM, Afonso AS, van Noord C, Haag MD, Koudstaal PJ, Brusselle GG, et al. Tiotropium Handihaler and the risk of cardio- or cerebrovascular events and mortality in patients with COPD. Pulm Pharmacol Ther. 2012 Feb;25(1):19-26.

CONTACT INFORMATION

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RESULTS

- The study included 3,604 new users of aclidinium bromide, 30,720 new users of tiotropium, 3,288 new users of Other LAMA, 399 new users of LAMA/LABA, 14,175 new users of LABA, and 97,828 new users of LABA/ICS.
- For 2014, the prevalence per 100,000 population (men/women) was 63.7/52.3 for aclidinium bromide, 1,150.7/1,088.7 for tiotropium, 54.1/48.2 for Other LAMA, 2.6/1.8 for LAMA/LABA, 294.9/366.6 for LABA, and 3,091.1/3,761.9 for LABA/ICS.

Figure 1. Age-Specific Prevalence of Use of Aclidinium Bromide and Other Study Medications in 2014, per 100,000 Population

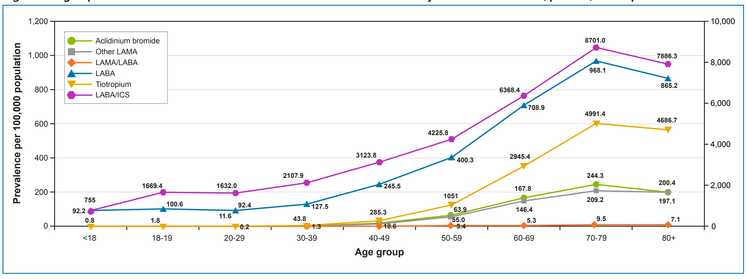

Figure 2. Age Distribution of New Users of Aclidinium Bromide and Other Study Medications

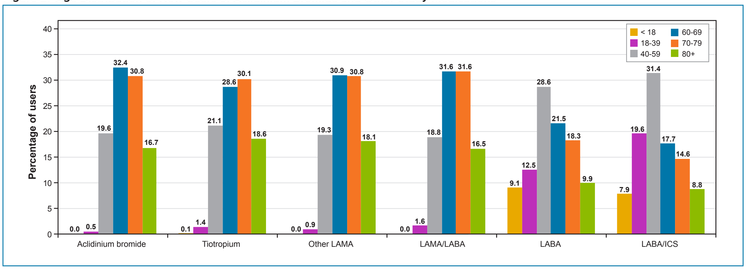

Figure 3. Distribution of New Users of Aclidinium Bromide and Other Study Medications, by COPD and Asthma Diagnoses—Adults Aged 18 Years or Older

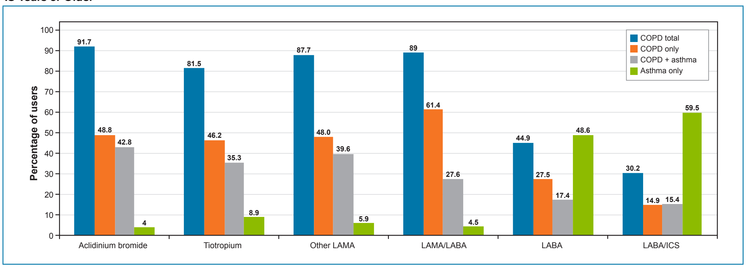

Figure 4. Distribution of COPD Severity Among New Users of Aclidinium Bromide and Other Study Medications Aged 40 Years or Older With COPD, by Study Medication

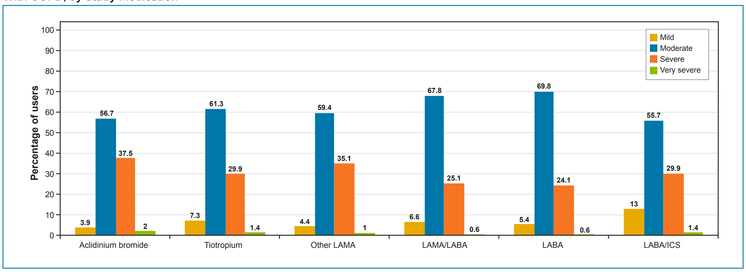

Table 2. Medical History at Baseline Among Adult New Users Aged 40 Years or Older With COPD, by Study Medication; UK, CPRD

Condition	Study Medication, %					
	Aclidinium Bromide (N = 3,295)	Tiotropium (N = 24,872)	Other LAMA (N = 2,863)	LAMA/LABA (N = 351)	LABA (N = 5,726)	LABA/ICS (N = 26,793)
Hypertension	52.9	52.6	53.5	43.6	51.2	52.8
Depressive disorders	41.0	39.4	37.2	39.9	38.3	40.4
Diabetes	39.5	36.4	32.6	39.0	35.2	37.5
Obesity	31.7	31.7	31.4	33.6	33.0	33.5
Urinary tract infection	27.8	28.4	27.6	29.1	27.9	30.3
Ischemic heart disease	22.5	24.0	20.4	19.1	21.7	24.5
Renal failure	21.8	20.7	18.8	17.7	18.6	21.4
Osteoporosis	16.7	15.2	15.3	14.5	13.6	15.4
Pneumonia	14.9	15.9	15.8	17.4	12.7	16.3
Angina	14.8	15.8	13.3	11.4	13.7	16.3
Arrhythmias	14.5	16.2	13.6	16.2	13.4	16.6
Cerebrovascular diseases	13.3	15.4	14.6	12.8	13.0	16.0
Malignant neoplasms	11.5	13.6	12.4	12.8	12.7	13.5
Prostatic hyperplasia	11.3	11.1	10.6	10.8	10.0	10.9
Acute myocardial infarction	8.3	8.8	7.5	8.3	7.7	8.8
Heart failure	8.2	10.0	7.0	6.6	7.3	10.4
Glaucoma	4.5	6.0	5.5	3.4	6.4	6.1
Heart conduction disorders	3.3	4.0	3.1	3.1	3.3	4.2
Pulmonary embolism	3.2	3.3	2.9	2.8	2.7	3.4
Bladder neck obstruction	0.8	0.8	0.6	0.6	0.5	0.8

Table 3. Prescription of the Medications Within 12 Months Before the Index Date Among New Users Aged 40 Years or Older With COPD, by Study Medication; UK, CPRD

Prior Study Medication in 12 Months Before the Index Date	Study Medication, %					
	Aclidinium Bromide (N = 3,295)	Tiotropium (N = 24,872)	Other LAMA (N = 2,863)	LAMA/LABA (N = 351)	LABA (N = 5,726)	LABA/ICS (N = 26,793)
Study medication						
Aclidinium bromide	NA	1.0	3.0	6.3	2.0	1.5
Tiotropium	49.5	NA	40.4	43.0	44.1	47.8
Other LAMA	2.8	0.6	NA	8.5	3.1	1.3
LAMA/LABA	0.1	< 0.1	0.5	NA	0.0	< 0.1
LABA	6.6	5.7	10.7	18.2	NA	9.6
LABA/ICS	68.6	55.5	58.3	34.2	22.7	NA
Other respiratory medications						
SAMA	9.4	9.9	9.2	2.0	7.9	7.4
SABA	91.0	86.1	90.1	88.0	88.0	86.5
ICS	10.0	13.3	12.7	10.0	27.5	21.5
Oral glucocorticoids	53.6	44.9	51.8	39.9	39.8	46.1
Xanthines	6.3	3.7	4.6	2.0	2.3	3.5
LTRA and omalizumab	4.2	3.6	3.0	2.6	2.2	3.4
Mucolytics	17.7	11.2	15.3	15.4	8.8	10.7
Antihistamines for systemic use	15.0	13.7	13.3	14.2	12.9	14.4
Cough and cold preparations	7.6	8.3	7.1	5.7	7.4	8.7
Oxygen therapy	2.0	1.4	1.0	0.6	0.6	1.4
Other medications						
Antibiotics	79.3	75.5	78.0	68.7	71.7	75.9
Vaccines	9.1	11.7	6.5	6.8	11.0	11.9
Cardiovascular medications	69.0	69.1	68.7	68.1	66.4	68.5
Insulins	3.2	3.4	2.7	2.8	3.1	3.6
Blood glucose–lowering drugs	11.1	11.1	10.1	6.6	10.4	11.7

LTRA = leukotriene receptor antagonists; NA = not applicable; SABA = short-acting β2 agonists; SAMA = short-acting muscarinic antagonists.