

## INTRODUCTION

- COPD has an onerous economic burden on patients and the healthcare system.
    - In 2010, the total economic burden of COPD in the US was estimated at \$42.6 billion in direct healthcare expenditures, of which \$11.3 billion were for hospital care.<sup>1</sup>
    - Each year COPD accounts for an average of 1.7 million emergency room (ER) visits, and 692,000 inpatient stays in the US.<sup>2,3</sup>
  - The 2018 Global Initiative for Chronic Obstructive Lung Disease (GOLD)<sup>4</sup> recommendations identify dual therapy with long-acting muscarinic antagonists (LAMAs) plus long-acting beta2 agonists (LABAs) for patients who have persistent symptoms and/or exacerbations on LAMA or LABA monotherapy (2018 GOLD guidelines were current during study design).
    - Escalation to triple therapy (TT; LAMA+LABA+inhaled corticosteroids [ICS]) is recommended in cases of further exacerbations and only after assessing the risks/benefits (e.g., pneumonia and other adverse effects linked to ICS use).
  - However, evidence reveals that TT is over-prescribed across all disease severities and inconsistent with GOLD recommendations, potentially impacting resource utilization.<sup>5,6</sup>
- Objective:** Compare COPD-related, non-COPD pneumonia-related, and all-cause health care resource utilization (HCRU) among initiators of tiotropium+olodaterol (TIO+OLO) – a fixed-dose dual bronchodilator approved in the United States (US) – vs. TT in an on-treatment study design.

## METHODS AND MATERIALS

- This is a retrospective observational study using the Optum Research Database.
- Study inclusion criteria were:
- Initiation of COPD treatment (LAMA monotherapy, ICS+LABA, LAMA+LABA (TIO+OLO is a subset), TT in free or fixed-dose combinations) with ≥30 days of treatment between 01/01/2014 and 03/31/2018 (Identification period)
    - The date of treatment initiation was set as index date
  - ≥2 diagnoses for COPD on separate dates of service, in any position on the medical claim, during the study period (01/01/2013 to 05/31/2018)
  - ≥40 years of age as of the index date, full demographic information
  - Continuous medical/pharmacy coverage for 12-months pre-index (baseline) and for ≥30 days post-index (follow-up)
  - Medicare Advantage Part D (MAPD) insurance coverage
  - No asthma, cystic fibrosis, or lung cancer (identified with ≥2 diagnoses) during the study period

- Analysis:**
- This post-hoc analysis examined TIO+OLO and TT initiators who were propensity score matched 1:1 to adjust for observed baseline differences.
    - Matching was conducted on baseline demographics, prescriber specialty, exacerbation history, comorbidities including pneumonia, COPD medication use, medical resource use and cost quartiles.
  - Patients were followed while on treatment until the earliest occurrence of index regimen discontinuation (≥60 day gap) or switch, coverage disenrollment, or end of study period.
  - COPD (or pneumonia)-related HCRU was defined as medical claims with a diagnosis of COPD (or pneumonia/acute bronchitis/bronchiolitis) in any position on the claim.
    - The claim's corresponding health plan paid costs were considered for estimating the cost burden.
  - Annualized population rates were calculated by cohort as (sum of events or cost/sum of observation on-treatment days)\*365.

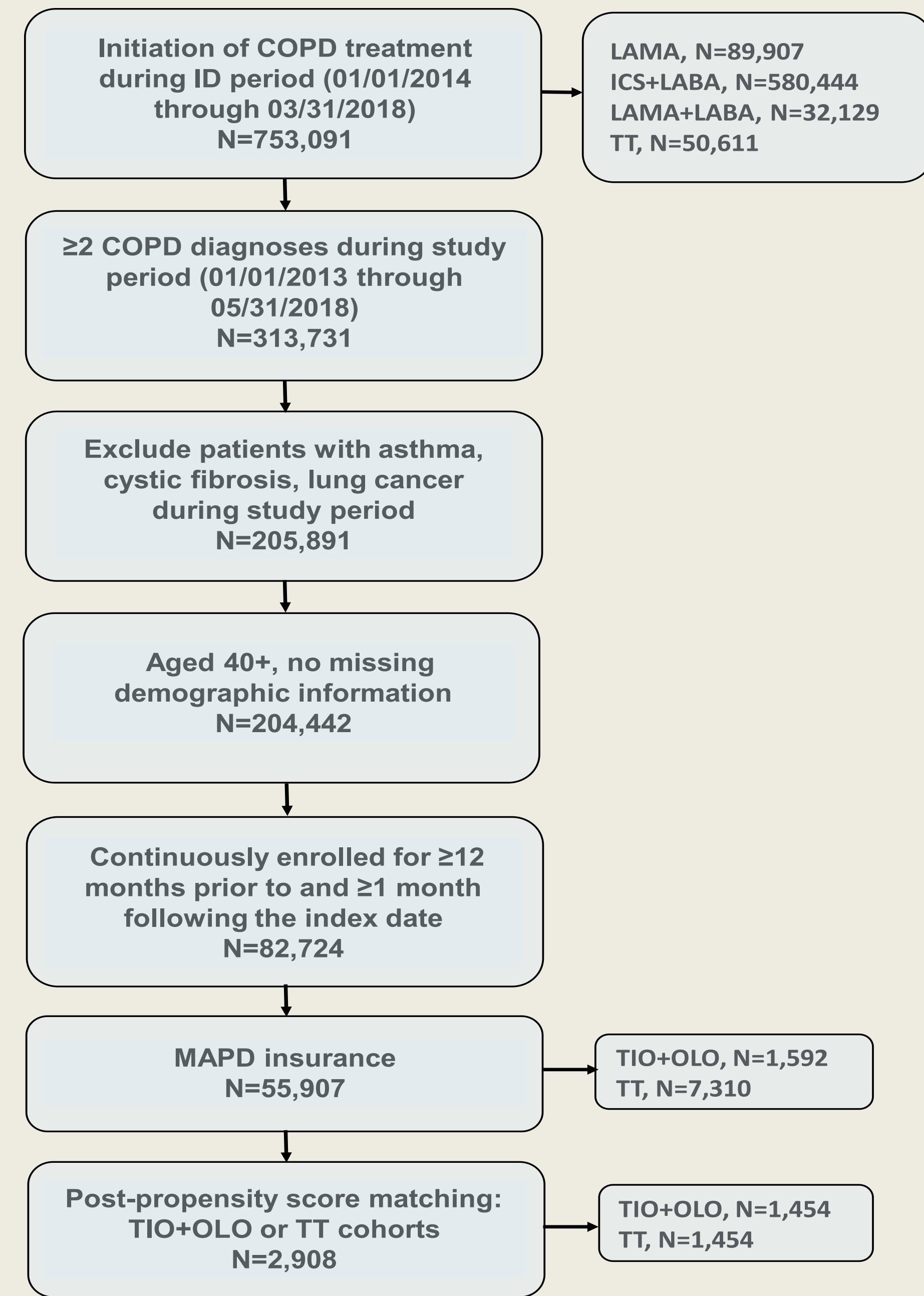
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## RESULTS

Post-propensity-score matching, a total of 2,908 patients identified (1,454 in each cohort). (see Figure 1)

Figure 1. Attrition diagram



**Patient characteristics**

- Post-match, cohorts were well balanced on baseline characteristics (standardized difference was ≤10%). (see Table 1)

Table 1. Post-match select patient characteristics by cohort

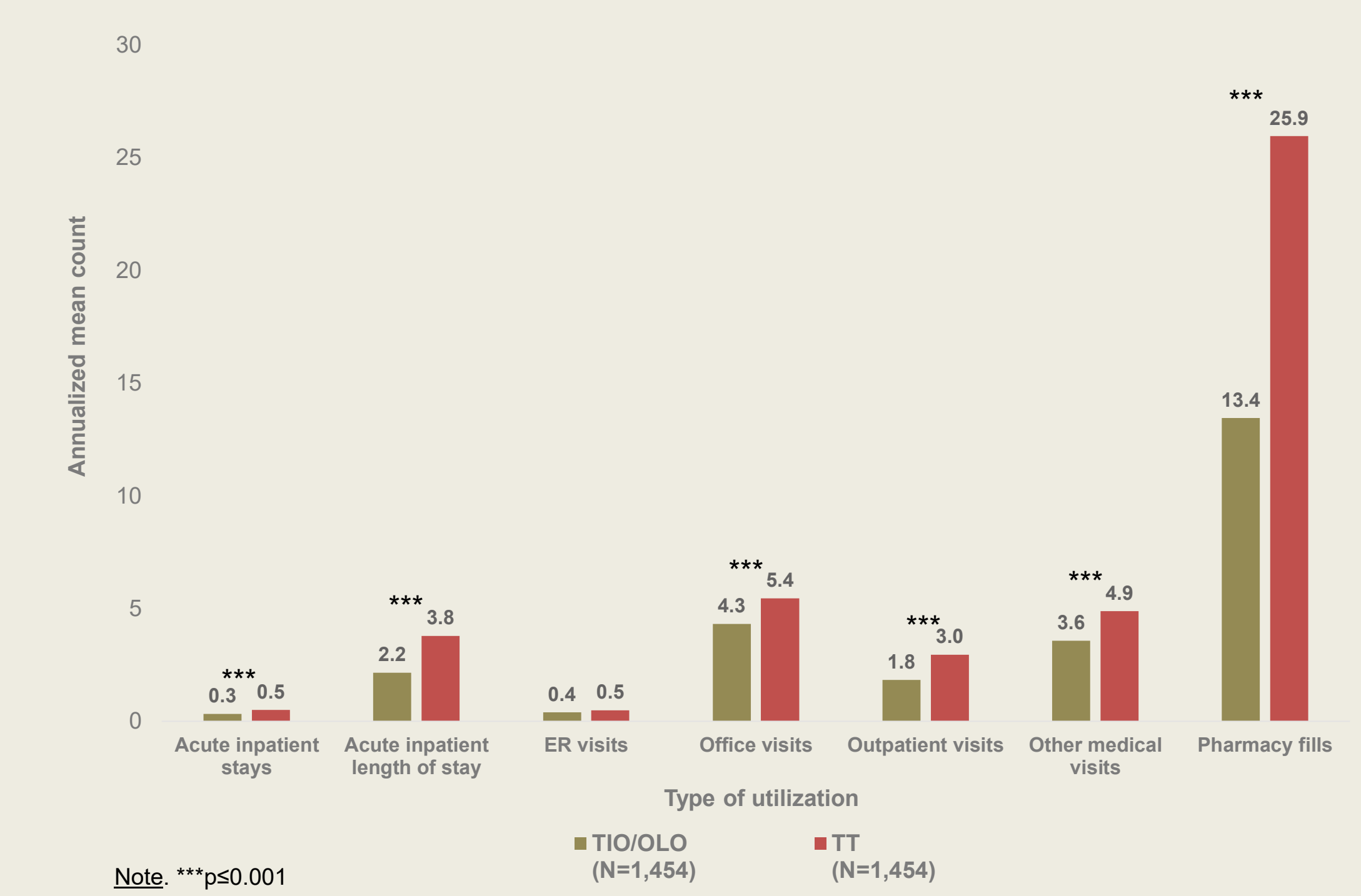
Post-Match Baseline Characteristics	TIO+OLO (N=1,454)		TT (N=1,454)		Post-match Standardized difference (%)
	Mean	SD	mean	SD	
Age	72.18	8.68	72.20	8.43	-0.20
Count of any exacerbations	0.66	1.04	0.74	1.09	-7.89
	N	%	n	%	
Male	763	52.48	772	53.09	-1.24
Baseline Charlson comorbidity score (continuous)	2.32	1.82	2.28	1.82	2.31
Baseline Charlson comorbidity score (categorical)					
0	92	6.33	124	8.53	-8.40
1	592	40.72	589	40.51	0.42
2	194	13.34	160	11.00	7.16
3	270	18.57	269	18.50	0.18
4	130	8.94	132	9.08	-0.48
5+	176	12.10	180	12.38	-0.84
Pneumonia or acute bronchitis/bronchiolitis	452	31.09	422	29.02	4.50
Naive to long-acting bronchodilators	1,330	91.47	1,320	90.78	2.42

**Health care resource utilization**

The TIO+OLO cohort had significantly lower annualized COPD-related acute inpatient stays (0.3 vs. 0.5, p<0.001; mean length of stay (LOS); 2.2 vs. 3.8 days, p=0.001), office visits (4.3 vs. 5.4, p<0.001), outpatient visits (1.8 vs. 3.0, p<0.001) and other medical services (3.6 vs. 4.9, p<0.001) than the TT cohort while on treatment.

Annualized mean counts of COPD-related medication fills were 13.4 in the TIO+OLO cohort and 25.9 in the TT cohort (p<0.001) (see Figure 2).

Figure 2. COPD-related annualized mean counts by cohort



Non-COPD pneumonia-related resource use was lower in the TIO+OLO cohort for acute inpatient stays (0.09 vs. 0.15), ER visits (0.07 vs. 0.11), office visits (0.12 vs. 0.23) and other medical visits (0.07 vs. 0.25; all p<0.05) (see Figure 3).

All-cause resource use was also lower in the TIO+OLO cohort for acute inpatient stays (0.4 vs. 0.6, p<0.001; mean LOS: 2.8 vs. 4.6 days, p<0.01), office visits (17.9 vs. 19.9, p<0.01), outpatient visits (9.0 vs. 11.3, p<0.001) and other medical visits (9.5 vs. 13.1, p<0.001) (see Figure 4).

TIO+OLO patients had a significantly lower mean count of all-cause pharmacy fills than TT patients (60.0 vs. 84.7, p<0.001; data not shown)

Figure 3. Non-COPD pneumonia-related annualized mean counts by cohort

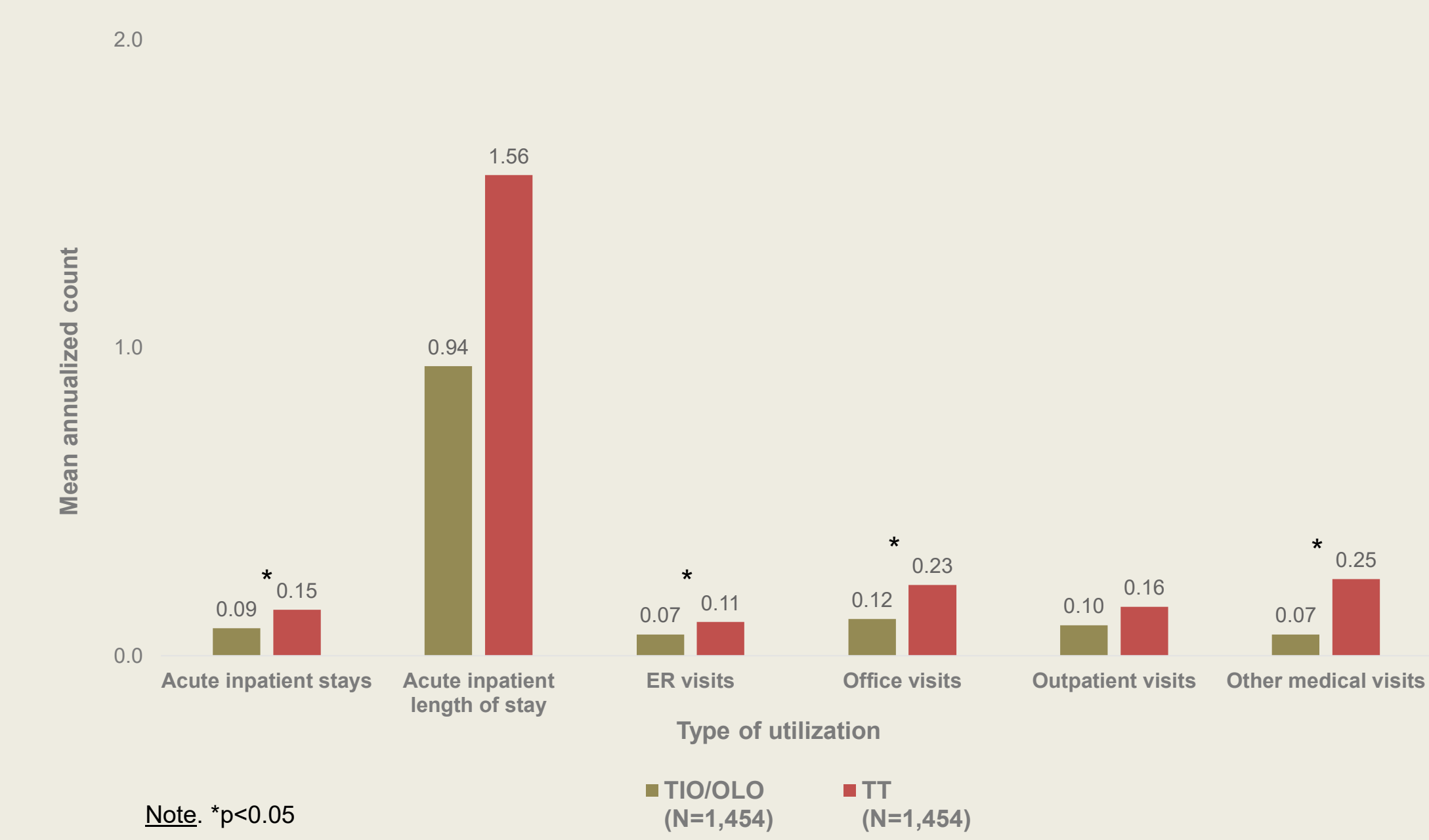
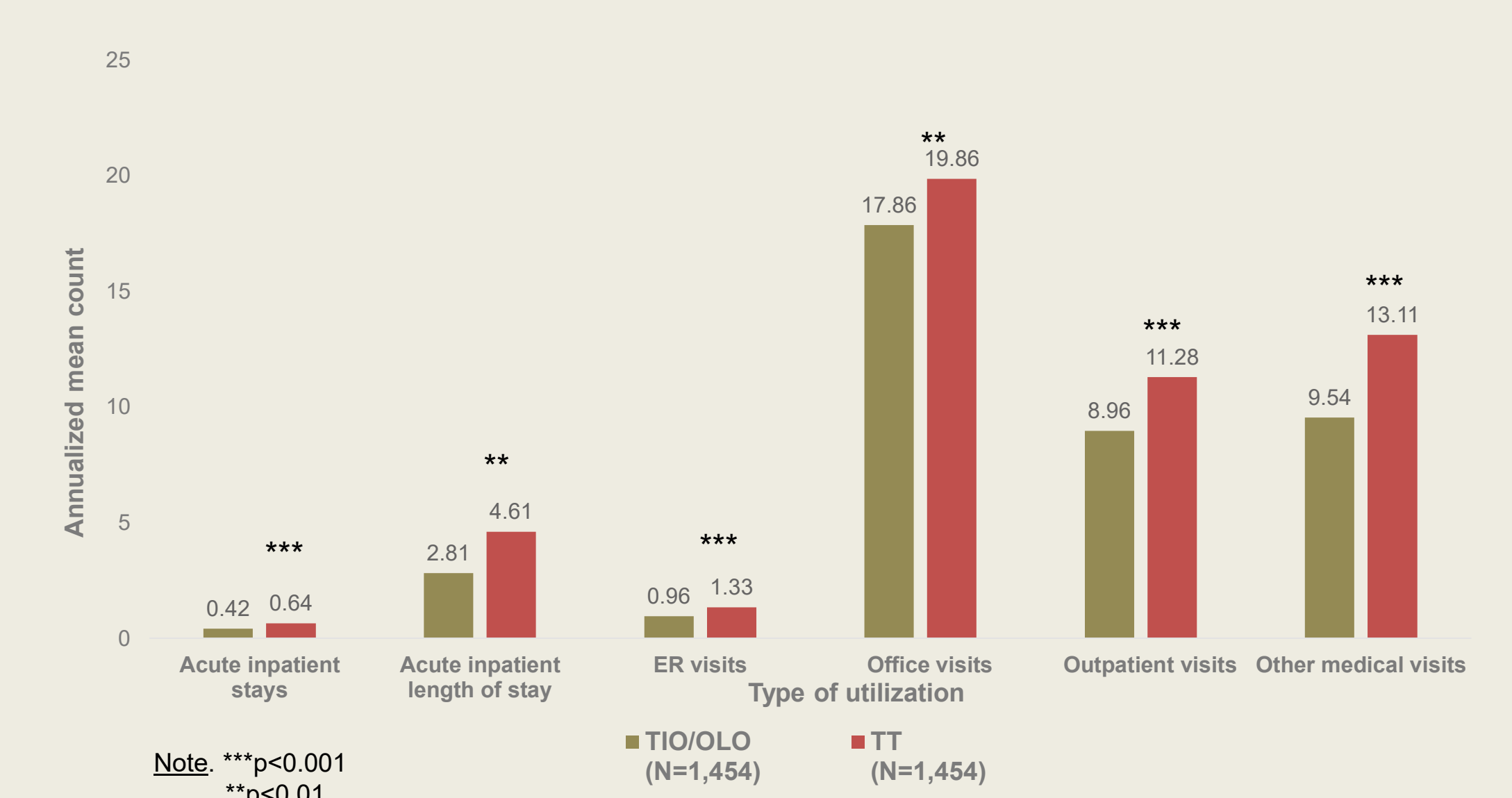


Figure 4. All-cause annualized mean counts by cohort

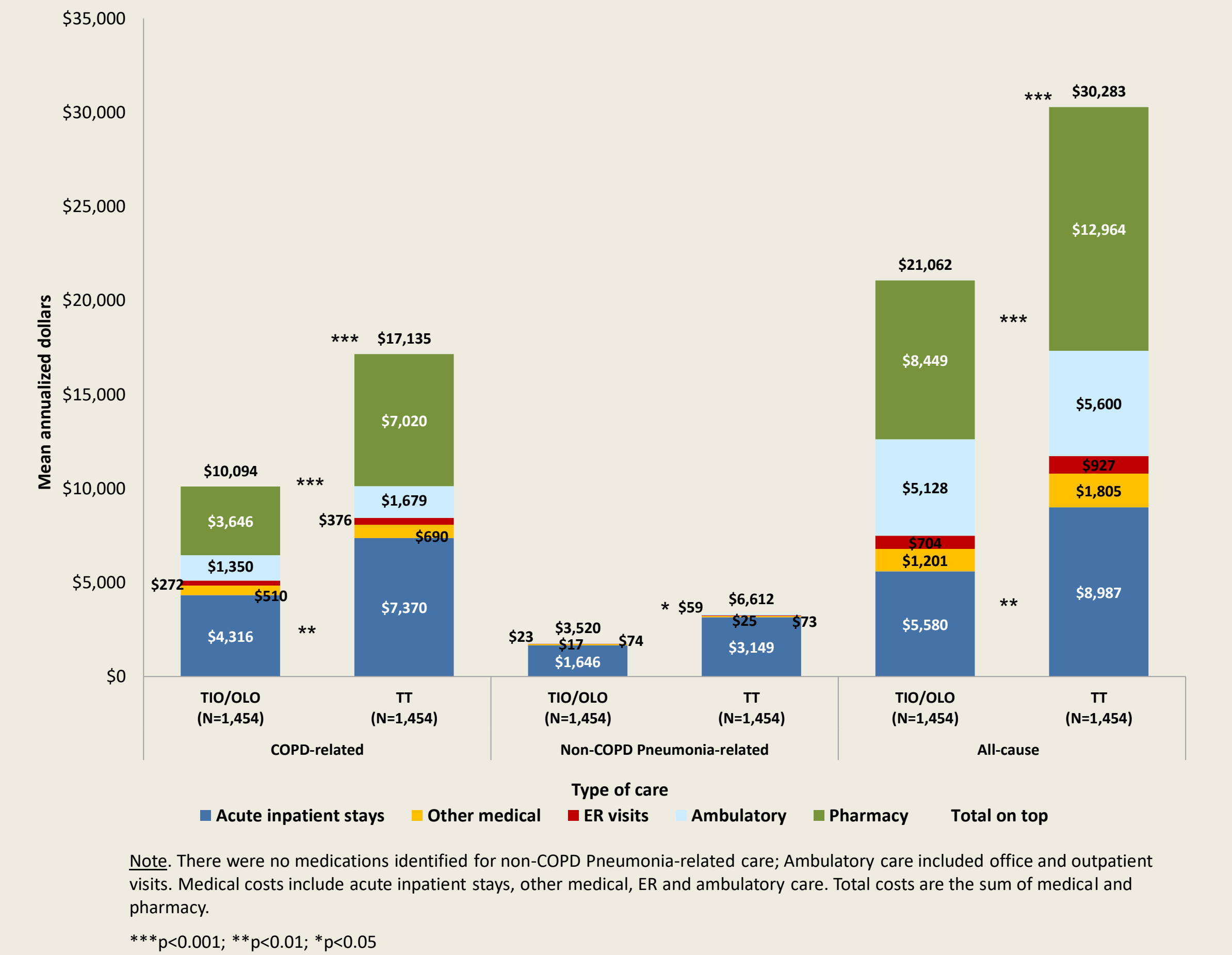


**Cost**

The TIO+OLO cohort had significantly lower annualized mean costs than the TT cohort, including (see Figure 5):

- COPD-related medical costs (\$6,449 vs. \$10,115; p=0.002; data not shown), acute inpatient stays (\$4,316 vs. \$7,370; p=0.006) and pharmacy costs (\$3,646 vs. \$7,020; p<0.001). Total mean COPD-related costs were therefore lower (\$10,094 vs. \$17,135; p<0.001).
- Non-COPD pneumonia-related ambulatory costs (\$23 vs. \$59; p=0.037), office visits (\$10 vs. \$17; p=0.021; data not shown). Mean medical costs did not differ significantly.
- All-cause mean medical costs (\$12,613 vs. \$17,319; p=0.001; data not shown), acute inpatient stays (\$5,580 vs. \$8,987; p=0.006) and pharmacy costs (\$8,449 vs. \$12,964; p<0.001). Total mean all-cause costs for TIO+OLO were also lower (\$21,062 vs. \$30,283; p<0.001).

Figure 5. Annualized health care costs by care category and cohort



## LIMITATIONS

- The presence of a diagnosis code on a medical claim is not positive proof of disease, but may have been incorrectly coded or included as rule-out criteria. However, we required ≥2 diagnosis codes for COPD plus ≥1 claim for a long-acting bronchodilator-containing regimen, to strengthen the patient selection process.
- While pharmacy claims demonstrate that a prescription was filled, whether patients took the medication as prescribed is unknown.
- No single TT inhaler was available for the entire study period (unlike TIO+OLO). Use of multiple inhalers may be less convenient and more expensive for patients, and could potentially impact outcomes despite the on-treatment study design.
- Results of this study are based on a population of MAPD enrollees and may not be generalizable to patients with COPD who have other forms of insurance or are uninsured.

## CONCLUSIONS

- COPD patients initiating TIO+OLO utilized significantly lower COPD-related, non-COPD pneumonia-related, and all-cause healthcare resources, across categories, relative to TT.
- Patients treated with TIO+OLO also had lower mean annualized costs for medical (driven by acute inpatient stays) and pharmacy settings in both COPD-related and all-cause care categories.
- These findings challenge the value of prescribing TT for all COPD patients by providing important real-world insight on the economic impact of potentially inappropriate TT prescribing.

## REFERENCES

- Prevention of COPD Available from: <http://www.goldcopd.org>, Accessed January 29, 2013
- Dalal AA, Shah M, D'Souza AO, Rane P. Costs of COPD exacerbations in the emergency department and inpatient setting. *Respir Med.* 2011;105(3):454-60.
- Ford ES. Hospital discharges, readmissions, and ED visits for COPD or bronchiectasis among US adults: findings from the nationwide inpatient sample 2001-2012 and Nationwide Emergency Department Sample 2006-2011. *Chest.* 2015;147(4):989-98.
- Global Initiative for Chronic Obstructive Lung Disease, Inc. Pocket guide to COPD diagnosis, management, and prevention: A guide for healthcare professionals, 2018. Accessed at [www.goldcopd.org](http://www.goldcopd.org).
- Safka KA, Wald J, Wang H, McIvor L, McIvor A. GOLD stage and treatment in COPD: a 500 patient point prevalence study. *Chronic Obstr. Pulm. Dis.* 4(1), 45-55 (2016).
- Simeone JC, Luthra R, Kaila S, et al. Initiation of triple therapy maintenance treatment among patients with COPD in the US. *Int. J. Chron. Obstruct. Pulmon. Dis.* 12, 73-83 (2017).