EPIDEMIOLOGY AND 12-MONTH ANTIBIOTIC USE IN THE OUTPATIENT SETTING AMONG ADULT PATIENTS WITH COMPLICATED URINARY TRACT INFECTIONS: A RETROSPECTIVE DATABASE ANALYSIS

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Study Summary

Background

cUTIs are one of the most common bacterial infections and represent substantial burden to the healthcare system. We examined the epidemiology and treatment patterns associated with cUTI in a large U.S. database containing longitudinal IP and OP patient-level data.

Methods

We conducted a retrospective cohort study of adult patients in IBM® MarketScan® Commercial or Medicare Supplemental Databases with at least 1 IP or non-diagnostic OP claim with a diagnosis for cUTI between 01/01/2017- 06/30-2019. Demographics and clinical characteristics were quantified.

Results

95,332 patients met study criteria. Most (86%) were commercially insured, mean (SD) age was 48 (17) and 70% were female. Mean baseline Charlson Comorbidity Index was 0.77. During the 30 days post-index, 22% were treated as IP and 78% were strictly treated as OP. In the 12-month follow-up period among index IP, 81% required ≥ 2 antibiotics, 40% required ≥ 4 antibiotics, and 42% received an IV antibiotic in the outpatient setting. For both IP and OP, fluoroquinolones were the most common oral antibiotic class (59%), followed by cephalosporins (40%), trimethoprim-sulfamethoxazole (31%), penicillins (30%), and nitrofurantoin (26%). Cephalosporins were the most common IV antibiotic class (39%).

Conclusion

Regardless of index treatment setting, approximately 40% of all cUTI patients required ≥4 antibiotic therapies and almost half received an IV antibiotic in the outpatient setting during the 12-month follow-up period.

Background

- Complicated urinary tract infections (cUTIs) are one of the most common bacterial infections in both the community and healthcare setting.¹
- Oral antibiotics have long been a mainstay of treatment for cUTIs, but use
 has been compromised by resistance to commonly used oral antibiotics.^{1,2}
- In the U.S., the percentages of E. coli in cUTIs, identified as resistant to
 extended-spectrum cephalosporins, fluoroquinolones,
 trimethoprim/sulfamethoxazole or classified as multi-drug resistant
 (MDR), have dramatically increased in recent years.^{3,4}
- Data from a recent U.S. national database study indicated that there are over 2.8 million cases of cUTI per year, resulting in annual 30-day total costs in excess of \$6 billion.⁵
- Despite the incidence and recurrent nature of cUTIs, limited data are available in the U.S. on the healthcare burden associated with cUTIs in the year following the initial diagnosis.

Objective

 To examine the epidemiology and treatment patterns associated with cUTIs over a 12-month follow-up period in a large U.S. database containing longitudinal inpatient (IP) and outpatient (OP) patient-level claims data.

Methods

Study Design and Data Source

Retrospective observational cohort study of adult patients with cUTIs in the IBM[®]
MarketScan[®] Commercial Claims and Encounters and Medicare Supplemental
Databases between January 1, 2017 and June 30, 2019

Study Criteria (Figure 1)

- ≥18 years of age on the index cUTI date
- ≥6 months of continuous enrollment (CE) with medical and pharmacy benefits prior to the index cUTI date
- ≥12 months of CE following the index cUTI date or evidence of inpatient death
- No evidence of a prior cUTI during the 6-month baseline period

Cohorts

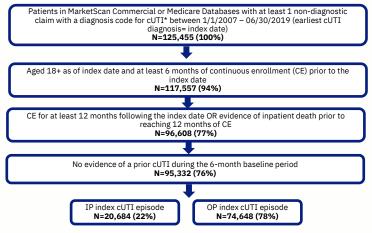
- Patients were classified as having an inpatient (IP) cUTI episode if they were hospitalized within 30 days following the initial cUTI diagnosis.
- Patients were classified as an outpatient (OP) cUTI if index cUTI episode occurred in outpatient setting and they were not hospitalized within 30 days of index cUTI diagnosis.

Outcomes

- · Number of antibiotics received in the OP setting in the 12-month follow-up period
- Recurrence, defined as either 3+ unique cUTI episodes in a 12-month period or 2+ unique cUTI episodes in a 6-month period, at least 30 days apart
- Readmissions, assessed within 30 days of discharge among cUTI patients with an inpatient admission



Figure 1. Patient Selection



^{*}For patients whose cUTI diagnosis occurred in OP setting, evidence of antibiotic receipt within +/-3 days of index or evidence of a subsequent IP admission for a cUTI within 3 days following index was required.

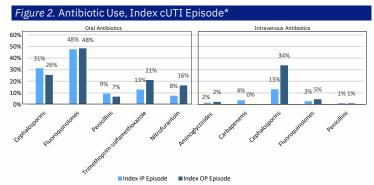
Results

Table 1. Baseline Demographic and Clinical Characteristics*

	Thuex IF COTT Episode	N=74,648
	N=20,684	
Age, mean years (SD)	54 (18)	47 (17)
Sex, N (%)		
Male	7,841 (38%)	20,324 (27%)
Female	12,843 (62%)	54,306 (73%)
Heath plan type ^a , N (%)		
Comprehensive	1,846 (9%)	4,161 (6%)
EPO/PPO	10,393 (50%)	37,801 (51%)
HMO	2,774 (13%)	10,269 (14%)
POS/POS with capitation	1,531 (7%)	5,828 (8%)
CDHP/HDHP	3,638 (18%)	15,192 (20%)
Geographic region, N (%)		
Northeast	3,702 (18%)	10,748 (14%)
North Central	5,151 (25%)	15,923 (21%)
South	9,407 (46%)	36,175 (49%)
West	2,370 (11%)	11,652 (16%)
Payer, N (%)		
Commercial	16,073 (78%)	66,296 (89%)
Medicare supplemental	4,611 (22%)	8,352 (11%)
Top Provider Type, N (%)		
Acute care hospital	10,664 (52%)	32,227 (43.2)
Urology	7,195 (35%)	12,866 (17%)
Radiology	1,032 (5%)	1,938 (3%)
Family Practice	451 (2%)	10,385 (14%)
Charlson Comorbidity Index, mean (SD)	1.3 (2.1)	0.6 (1.4)
Select Clinical Conditions & Procedures, N (9	%)	
Urinary stones	1,868 (9%)	5,987 (8%)
Chronic kidney disease	1,866 (9%)	2,339 (3%)
Cancer	1,969 (10%)	3,747 (5%)
Renal failure	1,172 (6%)	1,029 (1%)
Cystoscopy	1,464 (7%)	4,582 (6%)
Urodynamics	1,102 (5%)	4,713 (6%)
Sepsis	860 (4%)	758(1%)

*All reported demographic and clinical characteristics were significantly different between cohorts at p<0.05

"CDHP/HDHP, consumer-directed health plan/high-deductible health plan; EPO/PPO, exclusive /preferred provider organizations; HMO, health maintenance organization; POS, point of service; (other/categories not shown, <2.5% of patients); SD, standard deviation



*The index cUTI episode spanned from 3 days prior to the index date (to account for antibiotic use) through 30 days following the index date.

Figure 3. Number of Any Antibiotics Received and IV Antibiotics Received in Outpatient Setting in 12-Month Follow-Up Period

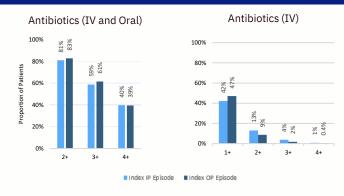
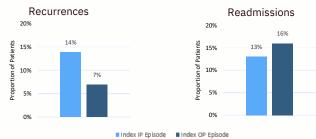


Figure 4. Proportion of Patients with Recurrences and Readmissions in 12-Month Follow-Up Period



Conclusions

- cUTI is a complicated clinical condition treated across multiple settings of care and healthcare practitioners.
- This study shows significant antibiotic use among both index IP and OP cUTI patients over a 12-month follow-up period.
- Regardless of index treatment setting, approximately 40% of all cUTI patients required ≥4 antibiotic therapy and almost half with receive an IV antibiotic in the outpatient setting in the 12-months post index date.
- As hospital reimbursement and antimicrobial stewardship programs are increasingly tied to quality and efficiency of care, these findings highlight the need for new treatment approaches and antibiotics that reduce highlighting the persistent or recurring nature of many cUTIs.

References

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Disclosure

TPL is an employee of the Albany College of Pharmacy and Health Sciences. MR is an employee of Spero Therapeutics. JM and MAB are employees of IBM Watson Health. This study was funded by Spero Therapeutics.