Persistence With Overactive Bladder Pharmacotherapy in a Medicaid Population

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Abstract

Statement of Problem and Rationale: The management of chronic conditions, such as overactive bladder (OAB), is often limited by lack of patient adherence to medication. This article compares persistence rates among Medicaid patients who were prescribed 1 of 3 drugs for treatment of OAB: 2 long-acting agents with once-daily dosing, tolterodine tartrate extended-release capsules (tolterodine ER) and oxybutynin chloride extended release (oxybutynin ER), and oxybutynin immediate release (oxybutynin IR), requiring 3 tablets daily.

Methodology: The study population was comprised of continuously enrolled Medicaid managed care patients filling prescriptions for tolterodine ER, oxybutynin ER, or oxybutynin IR between January 1, 2000, and December 31, 2003. Patients taking any OAB drug in the first 6 months of their observed period of enrollment were excluded to capture new users only. Using survival analyses adjusted for age, sex, and race, the rates of persistence by drug were analyzed. Possession time, the degree to which patients keep medication available even though they may not be taking it daily as prescribed, was also measured.

Results: Of 1637 patients (75% women, 45% African American, 26% younger than 18 years of age), 182 were started on tolterodine ER, 215 on oxybutynin ER, and 1240 on oxybutynin IR. Only 32% of those taking oxybutynin IR and 44% of those taking either long-acting agent remained adherent past 30 days. Of those remaining after 30 days, the risk of nonadherence was higher for oxybutynin ER than for tolterodine ER (hazard ratio = 1.47; 95% confidence interval, 1.01-2.14).

Conclusion: Persistence rates are better for patients taking drugs with once-daily dosing, but there is a need for a better understanding of nonpersistent patients.

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Overactive bladder (OAB) has been described as a "syndrome of symptoms," and defined by the International Continence Society as urgency, with or without urge incontinence, usually with frequency and nocturia.[1] OAB affects nearly 33 million people in the United States,[2] making it more prevalent than asthma (15 million), osteoporosis (10 million), diabetes mellitus (7 million), or Alzheimer's disease (4 million).[3] The estimated total economic cost of OAB was $12.02 billion in 2000, with $9.17 billion and $2.85 billion incurred in the community and institutions, respectively.[4] This estimate is relatively conservative, because it did not include the costs of care for dry institutional residents with OAB.[4]

Medications used to treat OAB have anticholinergic properties. These agents block muscarinic effects inhibiting involuntary bladder contractions. Extended-release formulations of antimuscarinic agents offer the convenience of once-a-day dosing. Studies comparing extended- and immediate-release formulations of oxybutynin and tolterodine have reported a better therapeutic window with extended-release formulations and better side effect profiles.[5] With good compliance and adherence to these medications, patients' quality of life can be improved and health services utilization costs can be reduced.[6]

Because of the chronic nature of OAB, it is essential that medication be taken as prescribed. Persistence has been shown to be one of the critical predictors of outcomes in chronic conditions.[7] Despite improvements in recent years in the tolerability and efficacy of OAB medications, many patients do not comply with the instructions.[8-10] With long-term treatment, persistence is even more difficult for these patients.

Medication persistence rates in patients with OAB have been found to be low regardless of setting.[8,9,11,12] For example, Yu and

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colleagues[10] investigated 1-year persistence patterns for OAB/urinary incontinence (UI) medication treatment in the California Medicaid program. They enrolled adult patients diagnosed with OAB/UI who had received at least 1 OAB/UI medication from July 1999 to April 2001. Persistence patterns of patients were measured as time to discontinuation; adherence was measured as medication possession ratio (MPR), which compares the cumulative days of drug supply with the elapsed time since the date of the first prescription of the drug being measured. They found that of 6518 eligible patients, 5751 patients (88.2%) discontinue within the following year, and only 14.6% patients have an MPR $\geq$ 0.80. Significant predictors of higher persistence include Caucasian, 75 years of age or older, past medication use, and initiating the extended-release form of the drug.[10]

OAB is of special significance to state Medicaid plans because of its higher severity in women,[2] the high population of women in Medicaid, and higher per capita expenditures for adults with Medicaid.[13] Poor compliance can be attributed to a variety of factors, including low level of education, cultural and social support factors, and side effects.[14-16] These factors, such as low education level, may be more prevalent among underserved populations, such as Medicaid beneficiaries. It would be likely that a higher prevalence of OAB and lower persistence rates exist simultaneously in the Medicaid population.

To date, there is a paucity of literature on medication adherence patterns among Medicaid-eligible patients with OAB. The objective of this study was to compare persistence and adherence patterns among Medicaid managed care patients prescribed 1 of 3 drugs for treatment of OAB: tolterodine tartrate extended-release capsules (tolterodine ER), oxybutynin chloride extended release (oxybutynin ER), and oxybutynin immediate release (oxybutynin IR).

Methods

Sample. The total population consisted of more than 400 000 Medicaid recipients from a mid-Atlantic state who were not in institutions or eligible for Medicare. Recipients had to be enrolled in 1 of 8, prepaid, state-contracted managed care organizations (MCOs). Enrollees include both those who qualified because of low income or by having high medical expenses relative to their income. All prescription claims were retrieved for the Medicaid MCO enrollees receiving at least 1 prescription between January 2000 and December 2003 for tolterodine ER, oxybutynin ER, or oxybutynin IR. For each patient, the longest period of continuous enrollment was identified. Successive enrollment periods that were less than 45 days apart were combined into a single continuous enrollment period. The sample was limited to new users by excluding those who had used tolterodine ER or oxybutynin (ER or IR) in the first 6 months of the selected enrollment period, or had any use in a prior enrollment period. Statistical significance is determined at the $\alpha = .05$ level.

Medication-taking Status. OAB medication-taking status was categorized into switching, discontinuation, or persistence. The index date of a study drug (index drug) was captured for each patient. If that patient filled a prescription for a different OAB drug within 15 days of when their preceding prescription was scheduled to run out, the patient was classified as a "switch." If a patient did not fill *any* OAB prescription within the same time period, this patient was classified as "discontinued." If a patient did not switch or discontinue after the first prescription, they were considered persistent, and each subsequent prescription for the same drug was confirmed until a switch or discontinuation was identified or until the patient had no claims in the enrollment period. As a sensitivity analysis, results were computed with refill windows varying from 15 days to 30 days. If a patient had switched drugs, the dispensing date of the new drug was recorded as the switch date; if a patient had discontinued, the original dispensing date plus the day's supply were used to calculate the discontinuation date.

Medication Possession Time. Although it is recommended that patients take their medication on a daily basis, many patients

with OAB do not follow this practice. For example, they may take the drug only when they are going to leave their house. Thus, also tracked was the length of time patients maintained possession of the drug. That is, the time patients kept a certain minimum level of medication on hand through refills was measured, although they may not have been persistent with the prescribed regimen.

Possession time was measured as the time patients maintained an MPR of at least 30%. The MPR typically compares the cumulative days of drug supply with the elapsed time. Here, the possession time was defined to be the period during which the patient maintained a given possession ratio. The patient may have continued to refill the prescription, but not often enough to be compliant with therapy every day. The calculation used was:

MPR_n = Cumulative possession ratio at nth prescription
= Cumulative days supply of first n prescriptions/[Date of nth prescription + days supply of nth prescription – Date of first prescription]

Where each prescription prior to n has maintained an MPR of >.3 (ie, MPR_{n-1} >.3 for all n)

Because the denominator did not include surplus days, the surplus days after the nth prescription were not counted in the numerator either. The MPR_n was an estimation of medication persistence during the period between the date of first prescription and the date of nth prescription.

Analysis. Patient demographic characteristics were examined by drug group. Percent by age category, sex, and race were calculated. A product-limit life table analysis was used to construct survival curves of patient persistence and possession time by index drug. Patients still persistent at the end of their enrollment period were censored at that point. To determine whether differences in persistence and possession time by drug are statistically significant after adjusting for age, sex, and race, a time-dependent, Cox proportional hazard model was used. The time-dependent model allows different hazard ratios (HRs) in different time periods, and it can be used to account for differences in behavior between patients who drop after the first prescription and those who refill at least once. Persistence was computed using the 15-day refill buffer. A model was also tested in which the maximum follow-up allowed was 360 days, in case extreme observations had a disproportionate effect on results. Finally, models were also run in which a variable was added (individually) to indicate whether a patient had a qualified diagnosis for OAB or a contraindication in the 6 months before initiating medication. The codes used for these diagnoses and contraindications are listed in the **Appendix.**

Results

Sample. The search of prescription records of more than 400 000 enrollees in Medicaid MCOs for tolterodine ER, oxybutynin IR, or oxybutynin ER filled between January 1, 2000, and December 31, 2003, yielded 20 667 prescriptions of 3054 unique patients. After exclusions, the sample by index drug included 1240 oxybutynin IR patients, 215 oxybutynin ER patients, and 182 tolterodine ER patients (**Table 1**). Another 48 patients had started on nonstudy OAB drugs. Of these 1637 patients, 75% were women, 26% were younger than 18 years old, and 45% were African American. The most significant difference between the index drug cohorts was that 30% of the oxybutynin IR users were younger than 18 years of age; only 3% of the tolterodine ER users and 17% of the oxybutynin ER users were younger than 18 years of age. The efficacy of tolterodine ER has not been demonstrated in pediatric populations.

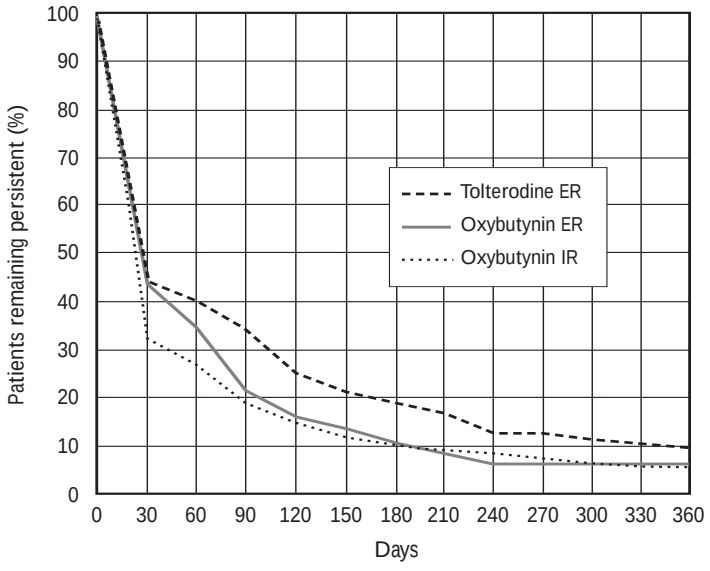
Persistence. The unadjusted survival curves of patient persistence by index drug are shown in **Figure 1.** Only 32% of those starting on oxybutynin IR and 44% of those starting on either tolterodine ER or oxybutynin ER remained persistent after 30 days (P <.001). That is, they did not refill their initial prescription. The 1-year persistence rates were 9%, 6%, and 5% for tolterodine ER, oxybutynin ER, and oxybutynin IR, respec-

Table 1. Baseline Characteristics of Study Cohort by Index Drug

		Index drug		
		Tolterodine ER (%) (n = 182)	**Oxybutynin ER (%) (n = 215)**	**Oxybutynin IR (%) (n = 1240)**
Age, yrs	< 18*	3	17	30
	18-29	13	11	7
	30-39	17	13	12
	40-49	31	24	21
	50-59	28	25	19
	60-64	8	10	11
Race	Caucasian	51	57	48
	African American	44	37	46
	Other/unknown	5	6	6
Women		82	79	73

*Efficacy has not been demonstrated for tolterodine in pediatric populations.
ER indicates extended release; IR, immediate release.

Figure 1. Persistent Time by Drug*



*Unadjusted for covariates.
ER indicates extended release; IR, immediate release.

tively (P = .086). Results are only slightly better if the more generous refill buffer of 30 days is allowed. By this criterion, 30-day persistence rates are 49%, 48%, and 39% for tolterodine ER, oxybutynin ER, and oxybutynin IR, respectively (P = .004). The corresponding 1-year rates are 12%, 5%, and 8% (P = .038).

To determine whether differences in persistence by drug are statistically significant after adjusting for age, sex, and race, a time-dependent Cox model was constructed that allowed different HRs before and after the critical 30-day mark. Using the Cox model without controlling for covariates, and only the time variable, results showed that oxybutynin IR had a significantly higher rate of discontinuation than tolterodine ER within the first 30 days (HR = 1.25; 95% confidence interval [CI], 1.01-1.53). After this initially poorer start, oxybutynin IR users discontinue at statistically the same rate as tolterodine ER users. This corresponds to the unadjusted survival curve.

In a Cox model adjusting for age (<18 years, 18-40 years, >40 years), sex, and race (Caucasian, African American, other), oxybutynin IR is not significantly different from tolterodine ER (HR = 1.09; 95% CI, 0.88-1.35) in the initial 30-day period (**Table 2**). Table 2 shows the HRs of non-

Table 2. Hazard Ratios of Nonpersistence and Nonpossession-Cox Time-dependent Survival Analysis, Adjusted for Drug, Age, Race, and Sex

Variable	Ratio of hazard for nonpersistence			Ratio of hazard for nonpossession		
	Point estimate	95% confidence interval		Point estimate	95% confidence interval	
Oxybutynin IR vs tolterodine ER						
≤30 days	1.09	0.88	1.35	1.07	0.84	1.35
>30 days	1.13	0.84	1.51	0.99	0.74	1.32
Oxybutynin ER vs tolterodine ER						
≤30 days	0.96	0.60	1.53	0.94	0.59	1.50
>30 days	1.47	1.01	2.14	1.24	0.86	1.79
Age						
<18 vs 18-39	1.56	1.33	1.82	1.38	1.18	1.62
≥40 vs 18-39	0.85	0.74	0.97	0.75	0.65	0.86
Race (vs Caucasian)						
African American	1.22	1.09	1.36	1.20	1.07	1.34
Other/unknown	1.35	1.08	1.68	1.50	1.20	1.88
Sex						
Men vs women	1.00	0.88	1.13	1.04	0.92	1.18
≤30 days	1.16	1.01	1.34			
>30 days	0.74	0.59	0.94			

IR indicates immediate release; ER, extended release.

persistence of oxybutynin IR and oxybutynin ER compared with tolterodine ER. Because of the large drop in persistence for any of the 3 drugs in the first 30 days, the analysis is stratified by time period, differentiating between trends in the first 30 days and trends in the period after 30 days. The effects are also shown on nonpersistence of age, sex, and race. In the first 30 days, the oxybutynin ER and tolterodine ER do not differ statistically, in both adjusted (HR = 0.96; 95% CI, 0.60-1.53) and unadjusted models (HR = 1.04; 95% CI, 0.80-1.35). However, of the users who continue past 30 days, oxybutynin ER has a higher risk of discontinuation in both the adjusted (HR = 1.47; 95% CI, 1.01-2.14) and unadjusted models (HR = 1.50; 95% CI, 1.03-2.18).

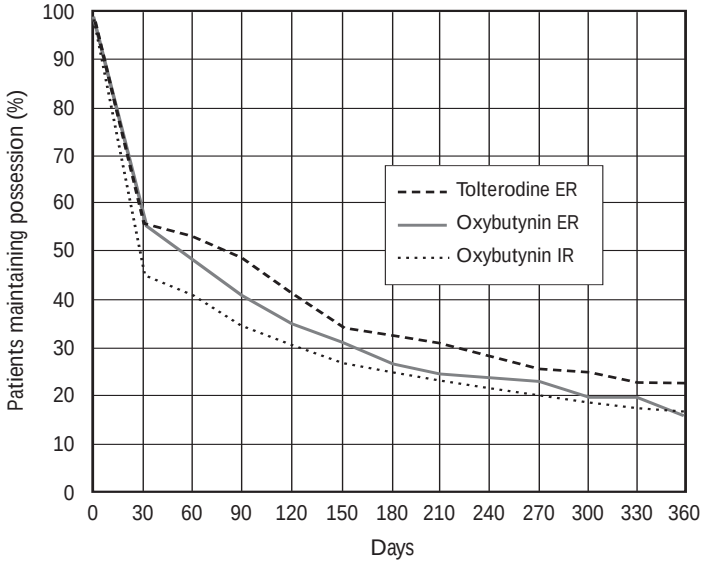
Possession Time. The survival curves for patient possession time with an MPR >30% are shown by index drug in **Figure 2.** About 45% of those starting on oxybutynin IR and 55% of those starting on either tolterodine ER or oxybutynin ER maintain possession after 30 days. At 1 year, 16%, 22%, and 15% are maintaining possession of oxybutynin IR, tolterodine ER, and oxybutynin ER, respectively. The shape of the possession-time survival curve points to a time-dependent model that can handle different HRs before and after 30 days of possession time.

No drug shows significantly different hazard risk than another in either time period, in both unadjusted and adjusted Cox models. Detailed HR results are included in Table 2.

In a comparison of the distributions for persistence and possession time, it was found that possession time is just 30 days longer than persistence for 80% of patients. On average, tolterodine ER and oxybutynin ER users possess medication approximately 40 days longer than they persist. The mean difference is greater for oxybutynin IR users, which is approximately 60 days.

Switching. About 6% of the cohort switched drugs before they were determined to be otherwise nonpersistent or reached the end of the enrollment period, with little difference by index drug. Of those who did

Figure 2. Possession Time by Drug*



*Unadjusted for covariates.
ER indicates extended release; IR, immediate release.

switch, 44%, 56%, and 20% (tolterodine ER, oxybutynin ER, and oxybutynin IR, respectively) switched in the first 30 days. The corresponding rates by 120 days were 50%, 80%, and 60%.

Demographic and Clinical Predictors. Table 2 includes HRs from the Cox multivariate model, indicating how age, race, and sex affect persistence and possession time. Younger patients are half as likely to discontinue their original therapy compared with young adults aged 18 to 39 years (HR = 1.56; 95% CI, 1.33-1.82). Patients aged 40 to 64 years are significantly less likely to discontinue therapy than the younger adults (HR = 0.85; 95% CI, 0.74-0.97). Age has a similar effect on possession time.

African Americans and other minorities were more likely than Caucasians to discontinue or switch (HR = 1.22; 95% CI, 1.09-1.36). At 90 days, only 15% of African Americans remain persistent compared with 27% of Caucasians. Similar racial effects held for possession time. Sex did not affect long-term persistence; however, an interesting difference shows up in the first 30 days. If men were going to discontinue, they were more likely than women to stop therapy in the first 30 days (HR = 1.16; 95% CI, 1.01-1.34). Men who continue past 30 days are less likely than women to stop (HR = 0.74; 95% CI, 0.56-0.94).

As might be expected, patients who had a qualified diagnosis for OAB in the 6 months before initiating medication were less likely to discontinue than others (HR = 0.80; 95% CI, 0.72-0.89; n = 715).

Discussion

Because patients eligible for Medicare were excluded and there is a high prevalence of children in most Medicaid plans, the cohort of OAB patients identified here was younger than what might be expected in terms of more typical OAB patients. Among the 3 products of interest, oxybutynin IR use is predominant at 76% of users. This is likely a result of the preferred use of generic drugs as a cost-containment measure in many Medicaid plans.

Rates of persistence with OAB drugs were found to be low among these Medicaid MCO patients, with only 32% of the oxybutynin IR users and 44% of users of either once-daily agent refilling their first prescription at 30 days. The difference is associated with the greater number of young adults in the oxybutynin IR cohort, whose persistence is significantly less than older adults. Of those patients who did fill a second prescription, persistence was significantly better for patients receiving tolterodine ER compared with oxybutynin ER; the significant difference persists after adjusting for demographic variables (HR = 1.47; 95% CI, 1.01-2.14). In 2 clinical trials comparing the 2 longer-acting agents over a 12-week period, results on relative efficacy were mixed, whereas fewer tolterodine ER users experienced dry mouth than did oxybutynin ER users.[17,18] Thus, this difference may be a result of fewer patients experiencing adverse effects, such as dry mouth; however, a specific study that tests this hypothesis would be needed for confirmation.

After the initially poorer persistence for oxybutynin IR users, those who do continue after 30 days adhere at about the same rate as tolterodine ER users. It is possible that these patients experience more side effects at the initiation of therapy. However, those who do not experience these side effects are

able to persist without problems later. There was less difference between index drugs, and possession time lasted 1 to 2 months longer than persistence on a mean basis. Like persistence, possession time was lower among younger or minority individuals.

Little data on persistence with OAB medication has been published in peer-reviewed journals, but research abstracts of other claims studies also report low rates of persistence. For immediate-release formulations, Juzba and colleagues[19] found that nearly half (48.2%) of the patients in their 1999 claims study failed to refill their first prescription, and that continuation was more likely for patients taking tolterodine ER than oxybutynin IR (n = 436). Boccuzzi et al found 12-month persistence rates of 24% for tolterodine ER patients, and 17% for oxybutynin IR patients (n = 36 142).[12] Chui et al[9] and Yu et al[10] reported similar 12-month results also from studies of claims data. Zhou et al reported an adjusted odds ratio of discontinuation for tolterodine ER versus oxybutynin IR users as 0.66 (P <.001; n = 11 893).[8]

Poor compliance can be attributed to a variety of factors, including low levels of formal education, cultural factors, side effects, and financial barriers.[15,16,20] Clinical studies and patient surveys are necessary to better understand reasons for nonpersistence with OAB medications and to develop interventions to improve persistence. Clinical trials of transdermal patches for administration of oxybutynin ER have indicated reduced incidence of side effects, and studies of these new therapies in routine clinical practice are needed to replicate these findings in the real world.[21,22]

A good patient education program favorably impacts patient behavior, including compliance with short-term therapies, long-term management of chronic conditions, and preventive lifestyle recommendations.[23] It can also build trust between healthcare providers and reduce anxiety, thus favorably impacting health outcome and patient satisfaction.[24] Patient education programs have been carried out in various settings and proved to be successful in improving patient compliance.[25-27] Because of its chronic nature, unpleasant side effects, and chronic treatment, a behavior-modifying education program would be of essential value to patients with OAB, particularly among those with lower educational status. Further efforts are called for to design an effective educational program specifically targeted to this population.

There are limitations to assessing persistence patterns from claims data, as done in this study. Different methods are used to measure persistency in patient populations. The most commonly used method involves obtaining information on pharmacy refill records, often from third-party institutions. These records are beneficial as an economical method for tracking compliance on large numbers of patients. However, they may overestimate compliance in that they represent prescriptions filled or refilled and not medications actually taken.

Conclusion

It can be concluded that persistence with OAB therapy in a Medicaid MCO population is low. Research is needed to understand the reasons for low persistence, so that interventions can be developed to improve persistence and compliance. Medicaid managed care plans will continue to face demands for reduced budgets and will continue to explore different approaches to optimize care and reduce risk. If low persistence with OAB therapies increases total cost of care for patients with OAB, it is critical that managed Medicaid plans understand and address this problem. Further studies are needed to understand OAB drug treatment compliance patterns in these populations as well as the factors influencing these patterns.

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Appendix.

OAB diagnoses considered to be a primary, secondary, or tertiary diagnosis coded as:

595.3	Trigonitis
596.51	Hypertonicity of bladder
596.59	Other functional disorder of bladder
597.81	Urethral syndrome NOS
788.30	Unspecified urinary incontinence
788.31	Urge incontinence
788.33	Mixed incontinence, urge and stress
788.34	Incontinence without sensory awareness
788.36	Nocturnal enuresis
788.41	Urinary frequency
788.43	Nocturia
788.4	Frequency of urination, unspecified

Study exclusion criteria: diagnoses primary, secondary, or tertiary diagnosis coded as:

365.23	Chronic angle-closure glaucoma
530.0	Achalasia, aperistalsis of esophagus
530.1	Esophagitis
530.10	Esophagitis, unspecified
530.11	Reflux esophagitis
530.3	Stricture of esophagus
537.0	Pyloric stenosis
537.2	Chronic duodenal ileus, persistent obstruction between pylorus and jejunum
560	Intestinal obstruction without mention of hernia
560.1	Paralytic ileus
560.8	Other specified intestinal obstruction
560.81	Intestinal or peritoneal adhesions with obstruction
560.89	Unspecified intestinal obstruction
788.1	Dysuria
788.2	Retention of urine
788.20	Retention of urine, unspecified
788.21	Incomplete bladder emptying
788.29	Other specified retention of urine

OAB indicates overactive bladder; NOS, not otherwise specified.