Transdermal Oxybutynin: What Role in the Management of Overactive Bladder?

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Abstract: Overactive bladder (OAB), a bothersome condition that is frequently associated with incontinence, commonly affects middle-aged and elderly people. OAB not only has a negative effect on physical and mental well-being but also accounts for billions of dollars in health care costs and lost productivity. Although OAB can be treated effectively with muscarinic acetylcholine receptor antagonists, these agents often cause anticholinergic adverse effects, such as dry mouth and constipation, which are believed to be a major reason for low treatment persistence. Oxybutynin is an established OAB treatment that is available in oral and transdermal formulations. Oxybutynin chloride topical gel (OTG) (Gelnique®, Watson Pharmaceuticals, Corona, CA, USA.) is a new formulation that was approved by the US Food and Drug Administration in January 2009. Results of a 12-week, placebo-controlled US phase 3 study demonstrated that OTG is efficacious in patients with OAB and rarely causes anticholinergic adverse events. Only dry mouth occurred significantly more often with OTG than placebo (6.9% vs. 2.8% of patients). Furthermore, OTG showed very little propensity to cause application site skin reactions. In conclusion, the efficacy and good tolerability of OTG make it a valuable treatment option for patients with OAB.

Keywords: overactive bladder, oxybutynin chloride topical gel, antimuscarinic, urinary urgency, incontinence
Introduction

The International Continence Society defines overactive bladder (OAB) as urinary urgency with or without incontinence, usually accompanied by urinary frequency and nocturia. \(^1\) A recent population-based survey (National Overactive BBladder Evaluation [NOBLE]) estimated the prevalence of OAB in the United States at 16% in men and 16.9% in women. \(^2\) A multinational survey conducted in Canada and four European countries (EPIC study) also found that the prevalence of OAB in men (10.8%) and women (12.8%) was similar. However, the prevalence of OAB with incontinence in both studies was substantially higher for women than men. The multinational study estimated that almost 50% of women with OAB, but less than 30% of men with OAB, were incontinent. \(^3\) The NOBLE study estimated OAB with urge incontinence as present in 2.6% of all men and 7.6% of all women in the United States. Because the prevalence of OAB increases with age, OAB disproportionately affects geriatric populations. However, OAB with urge incontinence also affects a substantial percentage of middle-aged women in the United States (i.e. approximately 12% of those aged 45–54 years). \(^2\)

OAB places a substantial burden on patients in terms of reduced quality of life and on society at large in terms of its economic impact. OAB diminishes health-related quality of life (HRQoL) as a result of significant negative effects on physical and mental well-being, including quality of sleep. \(^2,4,5\) Particularly in women, OAB with incontinence is a significant cause of depression. \(^2,5\) In addition, incontinence has been associated with an increase in urinary tract infections in women, \(^2,6\) and urge incontinence in older women is independently associated with an increased risk of falls and fractures. \(^7\) A recent population-based survey among US residents aged 40–65 years suggested that OAB causes significant reductions in work productivity. \(^8\) Data from the EPIC study suggest that the total direct costs of OAB to individual European countries range from several hundred million dollars to more than $1 billion annually. \(^9\) NOBLE estimated the costs to the US economy in 2000 of treating OAB-related urinary infections and injuries from falling accidents at close to $2 billion \(^10\) and the total costs of OAB at $12 billion. \(^11\)

In most cases of OAB, the cause of the symptoms cannot be determined because of the complexity of the neuronal signaling that occurs during bladder filling and control of bladder function. \(^12–14\) Urodynamically defined detrusor overactivity, which may be the consequence of multiple signaling defects in the peripheral and central nervous system (CNS), appears to be present in the majority of patients with OAB. \(^15\) Bladder contraction is controlled primarily by the parasympathetic nervous system. The micturition reflex in adults is implemented by relay centers in the CNS that receive information about bladder filling status fromafferent signals transmitted via the pelvic and gastric nerves. \(^12\) The ultimate trigger for bladder contraction is thought to be activation of muscarinic M3 acetylcholine receptors in the detrusor muscle. \(^12\)

Currently, the best approach to the management of OAB is a combination of antimuscarinic therapy and nonpharmacologic intervention. \(^16\) The latter may include pelvic floor muscle training, bladder training, behavioral therapy, and electrical stimulation. \(^13,17\) At present, antimuscarinics are the only drugs with a clinically proven mechanism to relieve patients of the symptoms of OAB. \(^18\) Antimuscarinics have been suggested to promote detrusor smooth muscle relaxation during the storage phase by the blockade of M3 receptors. \(^19\) However, recent results from animal studies suggest that desensitization of neuronal signaling from the bladder to the CNS through afferent nerves also may be an important mechanism of antimuscarinic therapy. \(^20,21\)

A recent meta-analysis evaluated the safety, tolerability, and efficacy of all licensed antimuscarinics. \(^22\) This study confirmed the significant efficacy of antimuscarinics compared with placebo but overall found no statistically significant differences between agents. Moreover, no drug was associated with a statistically significant incidence of serious adverse events compared with placebo. However, patients receiving antimuscarinics commonly reported anticholinergic adverse effects, particularly dry mouth (29.6% vs. 7.9% on placebo). \(^22\) Most antimuscarinic drugs used for the treatment of OAB are administered orally as immediate-release or extended-release formulations. Compelling evidence suggests that the change from immediate-release to extended-release formulations has mitigated the anticholinergic adverse effects of commonly used antimuscarinic agents such as tolterodine and oxybutynin \(^23\) and consequently has improved adherence to these agents. \(^24\) However, persistence with extended-release formulations remains relatively low,
and anticholinergic effects continue to be important contributing factors. A transdermal formulation of oxybutynin (oxybutynin transdermal system [TDS]) was developed to specifically avoid anticholinergic adverse effects related to the presystemic gastrointestinal and hepatic systems and to metabolism of the oral formulations. However, although oxybutynin TDS has demonstrated excellent tolerability regarding anticholinergic effects, it may cause application site skin reactions in some patients. Recently, a new transdermal formulation of oxybutynin, oxybutynin chloride topical gel (OTG), was approved by the US Food and Drug Administration for the treatment of OAB, and several reviews of OTG have been published. This article reviews the pharmacologic and clinical properties of OTG and discusses its future place in therapy.

**Oxybutynin in the Treatment of OAB**

Oxybutynin is a well-established pharmacotherapy that has received a grade A recommendation from the Third International Consultation on Incontinence for the treatment of OAB. Oxybutynin is a tertiary amine with anticholinergic and antispasmodic properties; however, the antispasmodic effects require higher than therapeutic doses and thus generally are believed to have no clinical significance. The mechanism of action, metabolism, and pharmacokinetics of oxybutynin have been studied extensively.

Oxybutynin is a competitive inhibitor of muscarinic acetylcholine receptors in the detrusor muscle. The affinity of oxybutynin for the M3 receptor is 3–15 times that for any other receptor subtype. Despite the proven clinical efficacy of the original immediate-release oral formulation of oxybutynin, optimal use of this agent has been hampered by its propensity to cause dose-dependent anticholinergic adverse events, particularly dry mouth. In one controlled clinical study, more than 80% of patients with OAB taking immediate-release oxybutynin reported dry mouth as an adverse event. Orally administered oxybutynin is metabolized in the liver and gut by cytochrome P-450 (CYP-450), specifically CYP3A4. As a result, the plasma accumulates high concentrations of the pharmacologically active metabolite N-desethyloxybutynin (DEO), which may be up to 10 times that of oxybutynin. Several studies have shown that compared with oxybutynin, DEO has a similar or slightly higher affinity for muscarinic receptors in the salivary gland.

Together, these observations suggest that DEO may be responsible for much of the dry mouth that is associated with oxybutynin.

Extended-release oral oxybutynin represented the first successful effort to reduce the anticholinergic effects of oxybutynin. In a comparative study that consisted mostly of female patients with urge incontinence, extended-release oxybutynin compared with immediate-release oxybutynin was associated with no significant difference in efficacy but with a significant reduction in the incidence of dry mouth. Consistent with this observation, extended-release oxybutynin showed an improved steady-state pharmacokinetic profile, characterized by smaller fluctuations in plasma concentrations of DEO and oxybutynin, and reduced exposure to DEO (with an average DEO/oxybutynin ratio of approximately 4). Nevertheless, moderate to severe dry mouth was observed in 25% of patients treated with extended-release oxybutynin.

In an effort to further improve the tolerability of oxybutynin, transdermal delivery was evaluated as a strategy to avoid first-pass hepatic metabolism. In controlled clinical studies of patients with OAB, the initially developed patch oxybutynin TDS was demonstrated to have efficacy similar to that of immediate-release oxybutynin and extended-release tolterodine. Pharmacokinetic analyses in healthy adults further showed that steady-state plasma concentrations of DEO were substantially lower with oxybutynin TDS compared with oral formulations, resulting in DEO/oxybutynin exposure ratios of 1.2–1.3. In addition, saliva output in subjects taking oxybutynin TDS was significantly greater compared with that in subjects who received extended-release oxybutynin. A placebo-controlled phase 3 study of oxybutynin TDS further suggested that the occurrence of dry mouth with this formulation was similar to that seen with placebo. Moreover, in a 6-month community-based, open-label study of almost 3,000 patients, only 2.6% experienced dry mouth. These findings suggested that the transdermal formulation provided a substantial improvement in terms of anticholinergic adverse effects compared with oral formulations. However, the initial phase 2 and 3 studies and the open-label study indicated that oxybutynin TDS may cause application site skin reactions such as erythema and pruritus. In the community-based, open-label study of oxybutynin TDS, 14% of the mostly female patients reported application
site skin reactions. In the placebo-controlled phase 3 study, a notable incidence of application site pruritus was associated with the use of placebo patches (6.1%). This raised the possibility that the application site skin reactions observed with oxybutynin TDS may be inherently linked to the patch delivery system. OTG, the new, gel-based formulation of oxybutynin, was developed to avoid the adverse skin reactions associated with oxybutynin TDS while maintaining its excellent anticholinergic tolerability profile.

**Oxybutynin Chloride Topical Gel (OTG)**

OTG is a semisolid and colorless gel that is applied once daily to the abdomen, upper arm/shoulder, or thigh. Each dose of OTG is packaged in a single sachet, weighs 1 gram, and has a volume of only 1.14 mL. One gram of OTG contains oxybutynin 100 mg (10% w/w) in a hydro-alcoholic solvent that ensures effective skin penetration of the drug. Other inactive ingredients include hydroxypropyl cellulose, the gelling agent; glycerin, an emollient responsible for the soft and smooth feel of the gel; and sodium hydroxide, which maintains the gel pH at 6 to ensure optimal skin tolerability without affecting drug absorption. OTG is fragrance free, dries quickly after application, leaves no residues, and does not stain the skin.

At pH 6, oxybutynin is mostly in the form of the free base (Fig. 1), which is lipophilic and is readily absorbed by the skin. After OTG is applied to the skin, oxybutynin rapidly diffuses into the stratum corneum, the uppermost layer of the skin, and then permeates the epidermis before it reaches the capillary system located in the dermis. Oxybutynin then enters the systemic circulation. An important feature of the OTG formulation is that it does not include a permeation enhancer. On the basis of unpublished pharmacokinetic data, it appears that the release of oxybutynin into the systemic circulation is slow and gradual—an essential prerequisite for the once-daily dosing schedule. The slow release suggests that skin permeation is the rate-limiting step during drug delivery. This idea is consistent with studies of topical steroid application, indicating that the stratum corneum and the dermis may have important reservoir functions in the transdermal delivery of lipophilic agents.

**Pharmacokinetics**

The pharmacokinetics of the transdermal delivery of oxybutynin via the gel and the patch system has been compared in healthy volunteers. In a single-dose, open-label, crossover study, dose-normalized 6-day mean exposure to oxybutynin was 219 ng·hr/mL for OTG and 176 ng·hr/mL for oxybutynin TDS; the ratio of DEO and oxybutynin exposures was 0.9 for OTG and 1.1 for oxybutynin TDS. Subsequently, steady-state pharmacokinetic profiles of both transdermal delivery systems were examined in 22 healthy adults. Subjects received two treatments in random order separated by a 14-day washout period. One treatment consisted of 18 daily applications of OTG and the other treatment of five applications of oxybutynin TDS every 3.5–4 days. Both treatments resulted in stable steady-state plasma oxybutynin concentrations, with similar 4-day exposures to oxybutynin (OTG, 322 ng·hr/mL; oxybutynin TDS, 312 ng·hr/mL); the DEO-to-oxybutynin ratio was 0.8 for OTG and 1.1 for oxybutynin TDS (Fig. 2, Table 1). Another pharmacokinetic study found no clinically important influence of the application site location (abdomen, upper arm/shoulder, or thigh) on steady-state exposures to oxybutynin or DEO. This suggests that changing the application site location will not affect the efficacy or tolerability of OTG.

Because oxybutynin is readily absorbed by the skin, the possibility of drug transference to untreated persons through skin contact with treated patients was investigated. Healthy couples engaged in vigorous bare skin contact at the OTG application site for 15 minutes one hour after application. Although the study found notable exposure to oxybutynin in untreated subjects, this could be virtually eliminated by covering the application site with clothing during contact. As a precaution, it is recommended that patients cover the application site with clothing after the gel has dried if there is a possibility of skin-to-skin contact at the application site.

![Figure 1. Structural formula of oxybutynin.](image-url)
Clinical efficacy
Significant efficacy of OTG in relieving OAB symptoms has been demonstrated in a double-blind, randomized, placebo-controlled 12-week phase 3 study conducted in the United States.53 This study enrolled 789 mostly female patients with urge or mixed urinary incontinence. Slightly more than a third of the study participants were at least 65 years old, and approximately a quarter had received OAB medications before the trial.53 In both the OTG and placebo groups, the mean number of daily urinary incontinence episodes was 5.4 at the beginning of the study, indicating that a substantial proportion of patients were experiencing severe OAB symptoms. During 12 weeks of treatment, patients receiving OTG experienced a significant reduction in the number of daily incontinence episodes (mean decrease of –3.0 vs. placebo, –2.5; p < 0.0001) (Fig. 3). OTG also improved urinary frequency (mean decrease in episodes –2.7 vs. placebo, –2.0; p = 0.0017) and increased voided volume (mean increase of 21.0 mL vs. placebo, 3.8 mL; p = 0.0018). A statistically significant decrease in nocturia episodes was observed only in patients younger than 65 years (mean decrease of –0.91 vs. placebo, –0.72; p = 0.0363).53 At study end, complete continence was achieved by 28% of patients treated with OTG compared with 17% of those on placebo.

To evaluate the effects of OTG on HRQoL, the study employed two validated instruments: the 5-domain Incontinence Impact Questionnaire (IIQ) and the 10-domain King’s Health Questionnaire (KHQ) including a multi-item symptom severity scale. Compared with placebo, OTG significantly improved HRQoL in all IIQ domains (i.e. emotional health, social relationships, travel, and physical activity) (p < 0.01).54 In addition, significant HRQoL improvements were seen in the KHQ domains of incontinence impact, symptom severity, severity (coping) measures, and sleep/energy (p < 0.05).

Table 1. Steady-State pharmacokinetics of OTG and oxybutynin TDS.

<table>
<thead>
<tr>
<th>Parameter, mean (SD)</th>
<th>OTG (n = 20)</th>
<th>Oxybutynin TDS (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxybutynin AUC[0–96 h], ng·hr/mL</td>
<td>321.7 (112.3)</td>
<td>312.5 (67.6)</td>
</tr>
<tr>
<td>DEX AUC[0–96 h], ng·hr/mL</td>
<td>246.4 (97.0)</td>
<td>338.0 (116.9)</td>
</tr>
<tr>
<td>Ratio, DEX/oxybutynin [0–96 h]</td>
<td>0.77 (0.19)</td>
<td>1.07 (0.22)</td>
</tr>
</tbody>
</table>

Abbreviations: AUC, area under the plasma concentration-time curve; DEX, N-desethyloxybutynin; OTG, oxybutynin chloride topical gel; SD, standard deviation; TDS, transdermal system.
Because most of the study participants were women, the overall results of the phase 3 study would be expected to indicate the efficacy of OTG in women. This was confirmed in a prespecified subgroup analysis of only the female patients. Overall changes from baseline for all efficacy variables observed in women were similar to those in the entire study population. Results showed that 27.0% of women treated with OTG achieved complete continence during the study compared with 15.6% of those receiving placebo.

Safety and tolerability
An important property of the OTG formulation is its skin tolerability. OTG does not absorb light to any significant degree at wavelengths of 290 nm–700 nm and thus is very unlikely to cause phototoxicity. In skin sensitization studies in albino guinea pigs, OTG did not elicit dermal reactions or delayed contact sensitization. Two dermatologic studies in healthy subjects further indicated that OTG does not promote skin irritation or sensitization. Using the scale of Berger and Bowman to assess cumulative skin irritation in 41 subjects, mean scores obtained with OTG (35) and placebo (24) were well below 50, which is the lowest score that provides evidence of cumulative irritation.

In the second study, repeat insult sensitization was evaluated in 201 subjects. OTG was first applied nine times during a period of 3 weeks; after a rest period of 2 weeks, subjects received a final challenge application. During the subsequent 72-hour evaluation period, only one subject experienced a sensitization response with OTG, which was a mild case of erythema. The vast majority of subjects receiving OTG (93%) or placebo (94.5%) showed no signs of any skin reaction.

Results of the OTG phase 3 study provide further evidence of the excellent skin tolerability of this formulation. The incidence of application site skin reactions was greater for OTG (5.4%) than for placebo (1%) but was low overall. Application site pruritus occurred in 8 of 389 patients (2.1%) treated with OTG and in 3 of 400 patients (0.8%) receiving placebo (Table 2). Application site erythema was observed with similar frequency on patients treated with OTG (1.3% per visit) and those receiving placebo (0.9% per visit). At study end, 97.4% of patients treated with OTG and 98.7% of those receiving placebo were free of erythema. Among the 2.6% of patients in the OTG group who had application site erythema, most (1.8%) had mild symptoms. None of these patients had severe symptoms and few (0.8%) had moderate symptoms.

Figure 3. Mean change from baseline in daily urinary incontinence episodes. P values were derived from analysis of variance of baseline data and from analysis of covariance of postbaseline data. Last observations were carried forward for study end only. OTG, oxybutynin chloride topical gel. Adapted with permission.
The discontinuation rate attributable to application site reactions was 0.8% (three patients) for OTG and 0.3% (one patient) for placebo. No treatment-related serious adverse events were recorded, and overall discontinuation rates attributable to adverse events were low in both treatment groups (OTG, 4.9%; placebo, 3.3%).

Dry mouth was the most commonly reported adverse event in the phase 3 study, and it affected significantly more patients in the OTG group (6.9%) than in the placebo group (2.8%; p = 0.0060). Incidences of constipation, dizziness, and headache were less than 2% in both treatment groups (Table 2).

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Table 2. Adverse events reported during double-blind study treatment.

<table>
<thead>
<tr>
<th>No. of patients (%)</th>
<th>OTG (n = 389)</th>
<th>Placebo (n = 400)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-related AEs reported by ≥1% of patients in OTG group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry mouth</td>
<td>27 (6.9)</td>
<td>11 (2.8)</td>
<td>0.0060(^a)</td>
</tr>
<tr>
<td>Application site pruritus</td>
<td>8 (2.1)</td>
<td>3 (0.8)</td>
<td>0.1176(^a)</td>
</tr>
<tr>
<td>Application site dermatitis</td>
<td>7 (1.8)</td>
<td>1 (0.3)</td>
<td>0.0358(^b)</td>
</tr>
<tr>
<td>Headache</td>
<td>6 (1.5)</td>
<td>11 (2.8)</td>
<td>0.2428(^a)</td>
</tr>
<tr>
<td>Constipation</td>
<td>5 (1.3)</td>
<td>4 (1.0)</td>
<td>0.7494(^b)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>6 (1.5)</td>
<td>2 (0.5)</td>
<td>0.1719(^b)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>5 (1.3)</td>
<td>5 (1.3)</td>
<td>1.0000(^b)</td>
</tr>
</tbody>
</table>

Abbreviations: AE, adverse event; OTG, oxybutynin chloride topical gel.
\(^a\)Chi-square test.
\(^b\)Fisher’s exact test.
Adapted with permission.

The place of OTG in the Therapy of OAB
Choosing the most appropriate treatment from the range of available pharmacotherapies is an important factor in successfully managing patients with OAB. Immediate-release oxybutynin taken at night might provide optimal relief from nocturia and benefit patients who do not experience major anticholinergic adverse effects. The broad dosing options of extended-release oxybutynin may be attractive to patients who seek effective 24-hour symptom relief and do not experience or are not bothered by anticholinergic adverse effects. In contrast, transdermal delivery of oxybutynin may be the preferred route of administration for patients who are bothered by the anticholinergic adverse effects of the oral formulations. Between the two available transdermal formulations of oxybutynin, OTG has several advantages. First, it largely eliminates the occurrence of application site reactions that have been associated with the patch delivery system. Second, it provides all of the convenience of a once-daily regimen that should be easier to adhere to than the twice-weekly schedule for patch application. Third, it leaves no visible signs of application and does not require taking precautions to avoid treatment interruption, such as may result from accidental patch detachment.

In recent years, a number of new antimuscarinic agents have become available in the United States, all of which are oral formulations. In contrast to the older antimuscarinics, such as tolterodine and oxybutynin, solifenacin and darifenacin are selective for M3 receptors. Low selectivity for M1 receptors is believed to minimize the risk of treatment-related cognitive impairment, such as somnolence and dizziness. However, M3 selectivity is unlikely to reduce the incidence of the most common anticholinergic event, dry mouth, because M3 receptors are the predominant subtype in the submaxillary salivary gland but not in the bladder. In fact, darifenacin
7.5 mg per day caused dry mouth in approximately 20% of patients with OAB in phase 3 clinical trials. In addition, both solifenacin and darifenacin have been associated with a relatively high incidence of constipation in phase 3 studies (9.1%, solifenacin 10 mg/day; 14.4%, darifenacin 7.5 mg/day); only 1.3% treatment-related constipation has been reported with OTG (placebo, 1.0%). Fesoterodine is a new oral antimuscarinic that relies on metabolic activation through hydrolysis by nonspecific esterases. The active metabolite, 5-hydroxymethyl tolterodine, has no muscarinic receptor subtype selectivity. In two phase 3 studies, fesoterodine caused constipation in 3%–8% of patients and dry mouth in 16%–36% of patients. The percentages depended on the study and the administered dose (4 mg and 8 mg once daily). Trospium chloride, a quaternary amine that does not cross the blood-brain barrier, recently has been approved for the treatment of OAB. However, this agent has been in use in Europe to treat OAB for more than 20 years, and its pharmacologic properties are well established. A salient feature of the drug is its minimal metabolism independent of the hepatic cytochrome P450 system. A large multicenter phase 3 study recently conducted in the United States observed dry mouth in 8.7% and constipation in 9.4% of patients with OAB treated with trospium chloride 60 mg once daily; the corresponding percentages for placebo were 3% and 1.3%, respectively.

Conclusion

OTG, a new transdermal formulation of oxybutynin, has been shown to be efficacious and well tolerated in patients with OAB, including those with urinary incontinence. Phase 3 study results suggest that a low risk of anticholinergic adverse effects will be a hallmark of OTG therapy. Because OTG has almost no propensity to cause application site skin reactions, it represents an improvement in terms of tolerability compared with oxybutynin TDS. OTG and oxybutynin TDS have similar pharmacokinetic profiles, and both improve HRQoL. Given its efficacy, excellent tolerability, and convenience of application, OTG is a valuable addition to the current armamentarium for the treatment of OAB. As clinical experience with OTG accumulates, its relative place in therapy among the older and newer anticholinergic agents will become better defined.

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Disclosures

This manuscript has been read and approved by the authors. This paper is unique and is not under consideration by any other publication and has not been published elsewhere. The author is a consultant for Watson Pharma, Astellas, AMS and Novasys Medical.

References

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