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OXYBUTYNIN TRANSDERMAL *(OXYTROL)* FOR OVERACTIVE BLADDER

A patch formulation of oxybutynin (*Oxytrol* – Watson) is now available for treatment of overactive bladder. It is claimed to be as effective as the oral drug, with less dry mouth.

DRUGS FOR OVERACTIVE BLADDER — Oral anticholinergic drugs are the mainstay of treatment for overactive bladder, the primary cause of incontinence in the elderly. Oxybutynin and tolterodine are available in both immediate-release and extended-release oral formulations (Medical Letter 2001; 43:28). Dry mouth has been the limiting adverse effect.

DOSAGE AND COST

Drug	Dosage	Cost*
Tolterodine tartrate – *Detrol* (Pharmacia)	1-2 mg PO bid	$108.25
Detrol LA	2-4 mg PO once/day	89.96
Oxybutynin chloride – average generic price	5 mg PO bid or tid**	25.58
Ditropan (Alza)		58.28
Ditropan XL	5-30 mg PO once/day**	87.95
Oxytrol (Watson)	39 cm^2 patch 2x/week (3.9 mg/day)	81.88

* Cost of one month's treatment with the lowest recommended adult dosage according to AWP listings in *PriceAlert*, April 15, 2003.

** Oral oxybutynin should be started at the lowest dosage and increased by 5 mg a week.

THE NEW FORMULATION — *Oxytrol* is marketed in a 39 cm^2 patch, which releases an average daily dose of 3.9 mg of oxybutynin. Average serum concentrations over 24 hours with one 96-hour patch were about 2.5 ng/mL of oxybutynin and 3.9 ng/mL of an active metabolite (N-desethyloxybutynin). When oxybutynin is taken orally, serum concentrations of the active metabolite are about 5-6 times higher, presumably because the transdermal route of application avoids first-pass metabolism; *in vitro* the metabolite has a higher affinity for parotid cells than it does for bladder cells (K Waldeck et al, J Urol 1997; 157:1093).

CLINICAL STUDIES — A 12-week study in 247 patients (mostly women) with urge incontinence found that the 3.9-mg/day patch decreased incontinence episodes per week from an average of 34.3 to 13.3 (a decrease of 21), compared to a reduction from 37.7 to 18.5 (a decrease of 19.2) with placebo (RR Dmochowski et al, J Urol 2002; 168:580). A second 12-week study, still unpublished, compared the patch with oral long-acting tolterodine 1-10 mg/day and placebo. The average number of incontinence episodes per day decreased from 4.7 to 1.9 with the patch (median decrease 3), from 5.0 to 1.9 with oral tolterodine (median decrease 3), and from 5.0 to 2.9 with placebo (median decrease 2) (RR Dmochowski et al, J Urol 2003, in press). In both studies, using an analysis of covariance with rank transformation, the authors found these small differences from placebo statistically significant.

ADVERSE EFFECTS — The most common adverse effect of the patch has been pruritus at the application site, which occurred in about 15% of patients in the 2 studies. Dry mouth was only slightly more frequent with the patch than with placebo (9.6% vs 8.3% in one study, and 4.1% vs. 1.7% in the other). One study in 76 patients comparing transdermal with immediate-release oral oxybutynin found dry mouth in 34% of patients using the patch and 94% of those taking the oral drug. Patients using the transdermal formulation also had lower rates of constipation (21% vs. 50%), somnolence (18% vs. 33%) and blurred vision (18% vs. 29%) (GW Davila et al, J Urol 2001; 166:140).

CONCLUSION — Oxybutynin delivered transdermally may cause less dry mouth than when it is taken orally, but it may also be less effective for incontinence, and itching at the application site can be a problem. As the Medical Letter has said before, none of these drugs are as effective as advertisements to the public have suggested.