

**Abstract Reproduction Form B-1**Author(s): G. Kramer, P. Walter, J. Grosse, U. Schwantes¹, H.-U. Schulz², M. Stöhrer

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Title (type in
CAPITAL
LETTERS)**PLASMA LEVELS OF TROSPIUM CHLORIDE AFTER A SINGLE
INTRAVESICAL INSTILLATION**Aims of study

Trospium chloride is an effective anticholinergic for oral treatment of detrusor overactivity and hyperreflexia. The patient's individual tolerance for the maximal daily dose is restricted mainly by its adverse effects (dry mouth, accommodation disorders). The side effects might be reduced by intravesical application. This prospective phase-I study reports the absorption of trospium chloride after a single dose intravesical instillation of 15 mg or 30 mg.

Patients and methods

Six male patients with detrusor hyperreflexia were treated by intravesical instillation of 15 mg or 30 mg trospium chloride in 40 ml 0.9% NaCl. Catheterisation was postponed for at least three hours after instillation and fluid intake was not allowed during the first four hours. Before instillation and 12 times after instillation (every ½ hour until 3 hours, 4, 4½ hours; every 2 hours between 6 and 12 hours post-instillation) blood samples were taken and the plasma level of trospium chloride was assessed. The minimum detectable plasma level of trospium chloride was 0.1 ng/ml.

Results

In only 4 of 72 post-treatment samples a minor level of trospium chloride was found in the plasma. This did not correlate with the applied dosage: in fact 2 of 3 patients with positive findings were treated by 15 mg instillations. Three patients reported side effects, but those were not related to the drug in 2 of them: one (15 mg) indicated disturbed temperature sensitivity in the left leg and the other (30 mg) increased spasticity in the legs. The third patient reported a dry mouth, which is a general anticholinergic effect. This patient, however, had significantly less fluid intake during the study

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period than normally. In only one of his blood samples trospium chloride was present, so the dry mouth cannot be unequivocally associated with the treatment.

Patient	Dosage	Positive samples	
		Time	Concentration
1	15 mg	2½ hours	0.13 ng/ml
5	30 mg	30 minutes	0.24 ng/ml
5	30 mg	6 hours	0.70 ng/ml
6	15 mg	1 hour	0.10 ng/ml

Conclusion

Trospium chloride appears to be absorbed only minimally after intravesical application. Thus, intravesical application will clearly be a favourable treatment alternative in patients who have serious problems with adverse effects during oral treatment and who empty their bladder by intermittent catheterisation. Amelioration of detrusor overactivity after intravesical instillation of 40 mg trospium chloride is reported [1].

Reference

1. Intravesical trospium chloride, oxybutinin and verapamil for relaxation of detrusor muscle: A placebo-controlled, randomised clinical trial [in German]. *Arzneim Forsch/Drug Res* 1998; 48 (Pt 1): 486-491.