208

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Title: EARLY EFFICACY WITH HIGH DOSE OXYBUTYNIN XL IN SPINAL CORD INJURED PATIENTS

Aims of Study:

Evaluate effects and tolerability of controlled release oxybutynin chloride on the voiding or catheterization frequency in spinal cord patients with defined detrusor hyperreflexia (DH).

Methods:

This 12 week, prospective, dose titration study of controlled release oxybutynin was approved by the University's IRB. Spinal cord injury (SCI) subjects with urodynamically defined DH were recruited for this study. After a 7-day washout period patients were evaluated via video-urodynamics study and then initiated at a dose of 10 mg oxybutynin controlled release. Doses were increased by 5 mg in weekly intervals to a maximum dose of 30 mg per day. Micturition frequency diaries were completed at baseline and at 6 and 12 weeks. Urodynamic studies were repeated at week 12. Tolerability information was collected at each follow up visit.

Results:

Fourteen patients (mean age = 38.3 ± 5.9 years) with both, complete and incomplete SCI were enrolled. Subjects reported clinical improvement with decreased urinary frequency and incontinence episodes after dosing was escalated to 30 mg. Within one week, a decrease of 2 voids or catheterizations per day was seen. All 14 patients chose a final effective does greater than 10mg with 6 patients talking 30 mg per day. Mean cystometric bladder capacity increased from 245±59 to 359±64 ml [p=0.02]. No patient experienced serious adverse events during the course of the 12-week study. The percent of patients with moderate or severe dry mouth did not statistically increase up to 30 mg dosage. Frequency of bowel movement per week ranged from 1-6 but did not alter drug effect.

Conclusions:

Oxybutynin controlled release is safe and effective in SCI patients with detrusor hyperreflexia. The onset of clinical efficacy occurs within one week and daily doses up to 30 mg, if indicated in selective patients, are well tolerated. Neurogenic bowel dysfunction did not affect drug efficacy.

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