

SAFETY AND EFFICACY OF OXYBUTYNYN CHLORIDE IN CHILDREN WITH DETRUSOR HYPERREFLEXIA: RESULTS OF THE CHOICES STUDY

Aims of Study.

Approximately 0.4 to 1.3 per 1000 newborn children suffer from spinal dysraphism with myelomeningocele as the most common form.[1] Detrusor hyperreflexia with uninhibited bladder contractions, increased detrusor pressure, decreased bladder capacity, and incontinence are frequent urologic problems in these children.[1] Approximately 70% of children with neurogenic bladder dysfunction have high intravesical pressures that can lead to upper urinary tract damage as well as urinary incontinence. The goal of urologic management is to protect the upper urinary tract and renal function and to improve continence. Clean intermittent catheterization alone and in combination with anticholinergic therapy has become the standard management of these conditions and clinical studies have demonstrated the beneficial effects. The most common anticholinergic medication used in children for the management of detrusor hyperreflexia is oxybutynin chloride.[1,2] This ongoing, multicenter study examines the safety and efficacy of oxybutynin tablets, oxybutynin syrup, and extended-release oxybutynin in children with neurogenic bladders.

Methods

The study enrolled 60 children (mean age: 9.6 years; range 4-16 years) with established detrusor hyperreflexia and currently using oxybutynin and clean intermittent catheterization as therapy. After a 3-day washout period, baseline urodynamics were performed. Children were then restarted on their respective oxybutynin therapy. After 12 and 24 weeks of treatment with the given formulation of oxybutynin, urodynamic studies were repeated. Safety data included reporting of adverse events.

Results

Children in this study received a mean dosage of oxybutynin of 13.4 mg/day (0.45 mg/kg/day). There was no significant difference in mean dosage among the three formulations of oxybutynin. The urodynamic studies showed mean cystometric capacity increased significantly from 180.4 ml at baseline to 236.6 ml at 24 weeks (or last study visit) ($p < 0.0001$). Detrusor pressures at maximal cystometric capacity decreased significantly from 44.0 cm at baseline to 35.5 cm H₂O at 24 weeks (or last study visit) ($p = 0.004$). Of the 38 children who experienced uninhibited detrusor contractions at baseline, 50% did not have these contractions after 24 weeks (or last study visit) ($p = 0.0002$). The most common adverse events were urinary tract infection (46.7%), pain (6.7%), headache (6.7%), constipation (10.0%), and rhinitis (10.0%). Six serious adverse events were reported, but none was considered to be related to oxybutynin.

Conclusions

This multicenter study demonstrated the effectiveness of oxybutynin in decreasing detrusor storage pressures and the occurrence of uninhibited detrusor contractions as well as increasing maximal cystometric capacity in children with neurogenic bladders. Generally all three formulations of oxybutynin were effective and well tolerated in children with neurogenic bladder.

References.

1. Goessl C, Knispel HH, Fiedler U, et al. *Urology* 1998; 51(1): 94-97.
2. Bauer SB. In *Cambell's Urol* Seventh Edition: Vol. 2, 1998.