

**Phimotic ring topical corticoid cream (0.1% mometasone furoate) treatment in children**

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**Background/Purpose:** Phimosis, owing to the presence of a preputial fibrotic ring, is surgically treated in 1% of children. During the last decade, however, topical steroid treatment has been proposed for phimosis.

**Methods:** We present a double-blind study comparing 0.1% mometasone furoate topical cream vs moisturizing cream (placebo) for the treatment of phimosis. Children aged from 2 to 13 years (n = 110) presenting with phimosis (Kikiro's classification grade 5) and scheduled for circumcision were included in this trial. The patients were evaluated after 8 weeks of topical treatment with moisturizing cream (n = 54) or steroid cream (n = 56). Nonresponders from both groups received an additional 8 weeks of steroid cream treatment.

**Results:** In the steroid group, the ring disappeared and glans exposure was obtained in 49 (88%) of 56 patients vs 28 (52%) of 54 patients in the placebo group (P < .05). After a second treatment, in the steroid group, 5 of the 7 patients were finally cured vs 22 of the 26 in the placebo group (P < .05). Two children with persisting phimosis (Kikiro's retractability grade 5 and appearance grade 3) in the steroid group (4%) vs 4 children in the placebo group (7%) ended up receiving postectomy.

**Conclusions:** The present investigation adds up and supports the effectiveness of phimosis topical corticoid treatment. Nevertheless, hygiene and preputial traction, when appropriately performed, seem to play an important role in the disappearance of the phimotic ring as well. New studies are necessary to confirm if this is true or not.

**Editorial Comment**

These authors did a double-blind placebo controlled study on boys 2-13 years-of-age with a mean of 4.6 years, with symptomatic phimosis with degree 5 phimosis according to the classification of Kikiros (1). An eight

week trial was undertaken with either mometasone or a placebo moisturizing cream, being lightly applied to the preputial ring and during the first four weeks, parents were instructed to add “just a light preputial retraction maneuver” and during the second four weeks, the preputial retraction was “increased to a moderate degree”. After eight weeks, boys showing total absence of preputial ring, Kikiros grade 1 or 2 were considered cured and degrees 3, 4, and 5 were considered non-responders and entered a second eight-week-long treatment session, all with mometasone. Four groups were then examined. The placebo group that were cured in the first eight weeks, the placebo group that were non-responders in the first eight weeks and treated with mometasone for another eight weeks. Group 3, the mometasone cured group in the first eight weeks and then Group 4 was mometasone treatment for an additional eight weeks.

Results - Of the initial 130 patients, 110 were available at the end of the study. 88% of the steroid cream patients were considered successes, while 52% of the placebo group patients were considered successes. 19 of the 26 placebo failures responded during the second treatment period to the corticosteroid and 5 of 7 of the mometasone failures were cured with a second eight weeks of treatment.

Comments - The mometasone is a moderate-strength topical corticosteroid and this study shows that it may be a good alternative to the betamethasone that has been reported in the literature and with less side effects. None of these patients had any side effects. It is interesting to note that 52% of the placebo group had success with gentle to more moderate retraction of the foreskin without the benefit of any steroids. It is likely that this is an important adjunct to the treatment regimen, regardless of the medication chosen. I believe that one of the important aspects of this study is that the patients who were chosen for the study were severely phimotic and are often thought not to be good candidates for medical treatment, and yet the success rates were excellent. It is refreshing to see physician scientists doing high quality double-blind placebo studies and they should be applauded for their efforts.

#### Reference

1. Kikiros CS, Beasley SW, Woodward AA: The response of phimosis to local steroid application. *Pediatr Surg Int.* 1993; 8: 329-32.

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#### **Do holding exercises or antimuscarinics increase maximum voided volume in monosymptomatic nocturnal enuresis? A randomized controlled trial in children**

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Purpose: We assessed prospectively the efficacy of holding exercises and/or antimuscarinics (oxybutynin chloride and placebo) for increasing maximum voided volume in prepubertal children with monosymptomatic nocturnal enuresis.

Materials and Methods: We randomly allocated 149 children to 5 groups, namely holding exercises with placebo (group A), holding exercises with oxybutynin (group B), placebo alone (group C), oxybutynin alone (group D)

and alarm treatment (controls, group E). Maximum voided volume was the greatest voided volume from a 48-hour bladder diary, and holding exercise volume was the greatest volume produced with postponement of voiding after a fluid load, once daily for 4 days. Study medication, holding exercise procedures and alarm treatment were administered for 12 weeks.

Results: Holding exercises combined with placebo or oxybutynin significantly increased holding exercise volume and maximum voided volume, by 25% ( $p < 0.001$ ) and 21% ( $p < 0.01$ ), respectively, in group A, and by 43% ( $p < 0.001$ ) and 41% ( $p < 0.001$ ), respectively, in group B. Medication without holding exercises (groups C and D) did not increase holding exercise volume or maximum voided volume, and in these groups oxybutynin was not significantly superior to placebo. A borderline increase in holding exercise volume did not affect maximum voided volume in group E. Monosymptomatic nocturnal enuresis response was significantly lower with all 4 holding exercise volume modulating treatments (7%) compared to alarm therapy (73%).

Conclusions: In the treatment of children with monosymptomatic nocturnal enuresis maximum voided volume can be increased significantly through holding exercises, but not with oxybutynin chloride alone. Compared to controls, increasing maximum voided volume had a minimal effect on monosymptomatic nocturnal enuresis.

### Editorial Comment

The authors performed a randomized prospective controlled study selecting patients who had at least 14 wet nights out of 28 nights. Patients were excluded if they had previously been treated with an alarm, desmopressin or anticholinergics within three months of the start of the study. If the patients were younger than age 5 or greater than Tanner stage I. They were randomized into a 12 week trial with group A having holding exercises with a placebo, group B holding exercises with oxybutin, group C placebo alone, group D oxybutin alone, and group E 12 weeks of alarm therapy. End points of the study were a maximum voiding volume compared to a cystographic bladder capacity and compared to holding exercise volume. The holding exercise was done and baseline maximum bladder volume was obtained from a 48 hour frequency-volume chart including voided volumes while asleep. Holding exercises were done with a 20m L/kg body weight oral loading during 30 minutes, with voiding being postponed as long as possible and then voided volume noted. During the 12 week study, patients had normal fluid intakes and voiding regimens and were to note wet and dry nights in a diary for 12 weeks. Holding exercises were to be done 4 days per week during the 12 week treatment span. Oxybutin was to be administered twice daily at 4 pm and immediately before bedtime, with the placebo medication being administered on the same schedule. 149 children were randomly allocated to treatment groups, ages ranging from 5.9-12.7 years, with 108 boys and 41 girls.

Results - The holding exercise volume at the end of the study increased significantly in the two groups that did the holding exercises and had either placebo or oxybutin. In the two groups without the holding exercise studies during the 12 week, there was no statistical change. Maximum voided volumes increased by 21% in the holding exercise with placebo group and 41% in the holding exercise with oxybutin group. In the two groups without holding exercises the changes were insignificant. In the 5th group with wetting alarms alone, a full response was found in 73% and the holding exercise volume was significantly increased, but there was no change in the maximum voided volume. Multi-factorial logistic regressions showed that the holding exercises had no significant influence on the rate of response of monosymptomatic nocturnal enuresis with success being only about 7%, with or without holding exercises.

Comments - Many years in the past, holding exercises for nocturnal enuretic patients were encouraged in hopes that the bladder capacity would increase and the patients would be able to go all night without wetting. The treatment was abandoned because of lack of success and this randomized controlled trial suggests that this was good judgment by former urologists. It is no surprise that oxybutin was not effective in reducing nighttime wetting, as other studies have shown, and for monosymptomatic nocturnal enuresis that it is not effective. It also suggests that antimuscarinic effects are greatest on abnormal bladders and that in patients with normal daytime

bladder function oxybutinin does not make a significant difference. There may be a slight advantage of encouraging holding exercises in conjunction with other nocturnal enuresis treatments but this study does not lend a strong support to this. I believe this study may be a significant foundation for further studies but it shows in a controlled randomized fashion that treatments that have been given up in the past are not effective in the combinations that were used.

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