



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

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Abstract

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.

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Phimosis, from the Greek word *phimos*, meaning muzzle, usually describes “a covered glans that cannot be retracted” [1,2]. Its treatment by circumcision, one the earliest surgical procedures, mentioned in the Bible, Talmud, and Torah, and also depicted in Egyptian tombs from 2400 BC, may have been performed as early as the Paleolithic age, according to cave drawings. Yet, this surgical procedure remains controversial until today [2-4].

On the other hand, in 1993, Kikiros et al [5], introduced a new, nonsurgical approach to phimosis treatment that has been widely adopted because of the many advantages relative to the surgical treatment, that is, less trauma and lower cost, avoidance of anesthetic risk, and surgical complications such as hemorrhage, pain, infection, urinary obstruction, and esthetic problems [6-8].

As a variable number of topical cream treatment nonresponders has been reported in different series, we decided to carry out a randomized double-blind clinical trial to test the efficacy of a new medium-potent corticoid cream for the treatment of phimosis.

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1. Method

Boys aged 2 to 13 years (mean age, 4.6 years), all of them with symptomatic phimosis and referred to surgery, presenting with degree 5 phimosis (Fig. 1) according to the classification of Kikiros et al [5] (Table 1) were entered in the study. After cleaning of the prepuce, it was gently retracted to identify the phimotic ring that was then measured with a pachimeter before and after the treatment.

The patients were examined by one of the investigators.

Topical treatment was applied twice daily for 8 weeks, on a double-blind fashion. For this purpose, numbered cream tubes were provided. A moisturizing cream was used as placebo. During the first 4 weeks, parents were instructed to add just a light prepucial retraction maneuver to avoid fissuring the prepuce. During the ensuing 4 weeks, prepucial traction was increased to a moderate degree, to attain phimotic ring widening.

Once the treatment was completed, the boys showing total absence of prepucial ring and adhesions (Kikiros grade 1) or only prepucial adhesions in the absence of ring (Kikiros grade 2) were considered cured, whereas patients with a persistent prepucial ring, comprising Kikiros degree 3, 4, or 5 cases, were considered nonresponders and entered another 8-week-long treatment session with the test corticoid cream. This new treatment was included after an ethic committee consideration because the children from the placebo group could undergo an unnecessary surgery.

Nonresponders to the second treatment session were scheduled to undergo postectomy.

At the end of the study, after the second treatment, the tubes were decoded and the patients were classified into 4 groups:

Group PC Cured placebo-treated children after the initial 8-week treatment.

Group PNC Placebo treatment nonresponders.

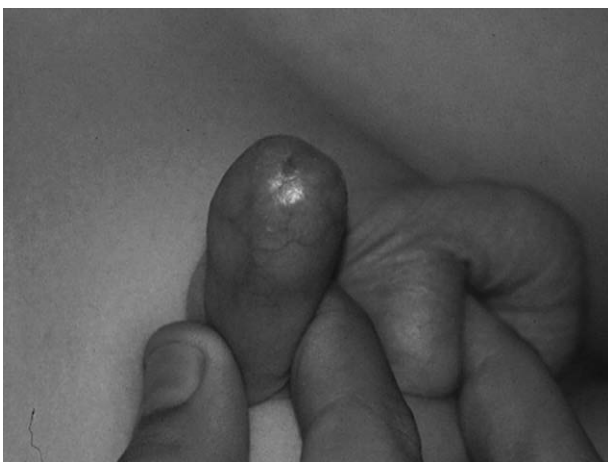


Fig. 1 A typical degree 5 phimosis case according to Kikiros, Beasley, and Woodward classification.

Table 1 Kikiros, Beasley, and Woodward phimosis classification

Foreskin retractability	
0	—Full retraction, not tight behind glans, or easy retraction limited only by congenital adhesions to the glans.
1	—Full retraction of foreskin, tight behind the glans.
2	—Partial exposure of glans, prepuce (not congenital adhesions) limiting factor.
3	—Partial retraction, the meatus just visible.
4	—Slight retraction, but some distance remains between tip and glans, that is, neither meatus nor glans can be exposed.
5	—Absolutely no retraction is possible (Fig. 1).
Foreskin appearance	
0	—Normal.
1	—Prepucial crack.
2	—Small white scar, partially circumferential.
3	—Balanitis xerotica obliterans or severe scar ± bleeding.

Group MC Cured mometasone furoate cream-treated children after the first 8-week treatment.

Group MNC Mometasone furoate cream treatment nonresponders.

Statistical analysis was performed using Fisher and Mann-Whitney tests, at a *P* significance level of less than .05.

2. Results

Of 130 children eligible to the study, 6 could not be reassessed by the designated investigator and were excluded.

Of the remaining 124 children, 7 from the placebo group and 7 from the drug group interrupted the treatment and were also excluded. From the 110 cases who completed the investigation, 54 belonged to the placebo group and 56 to the corticoid group.

Children's age distribution was similar with ages 5 and younger predominating in both groups (Fig. 1).

The phimotic ring diameter ranged from a pin hole to 2.0 cm, with a similar distribution in both groups.

The corticoid cream was statistically more effective than the placebo as 49 (88%) of the 56 boys in the

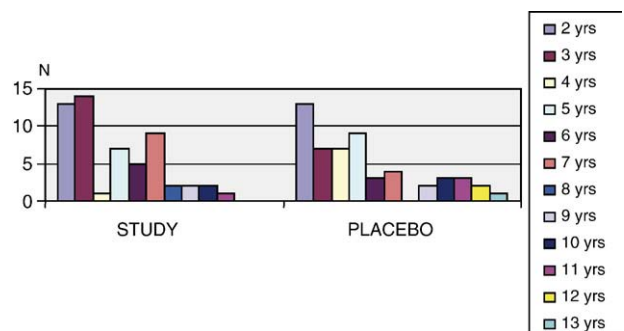


Fig. 2 Age distribution in corticoid and placebo groups.

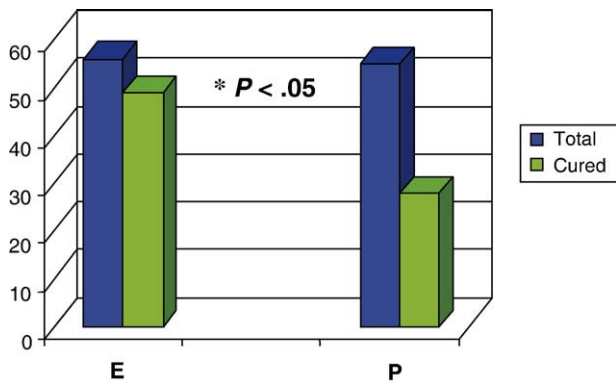


Fig. 3 Treatment effectiveness in corticoid vs placebo group.

corticoid group were cured as compared to only 28 (52%) of the 54 placebo group patients during the first 8 weeks of treatment (Fig. 2).

The phimotic ring disappeared in 19 of the 26 PNC group children and in 5 of 7 children from the MNC group (Fig. 3) after the second treatment. Postectomy was performed in 6 children, 4 from the placebo group and 2 from the corticoid group.

Phimotic ring augmentation was more marked in the corticoid group as compared to the placebo group (Fig. 4), but phimotic ring augmentation was similar between the MC and PC groups (Fig. 5). This finding was also observed when groups PNC and MNC were compared after 0.1% mometasone furoate was applied in all of them for another 8-week treatment period.

3. Discussion

In 1930, approximately one third of the boys from England were circumcised during the neonatal period. By 1975, this rate dropped to 6%, most certainly in response to Gairdner's [9] finding, published in 1949, that in the general population, most boys gain gland exposure by the age of 5 years [4].

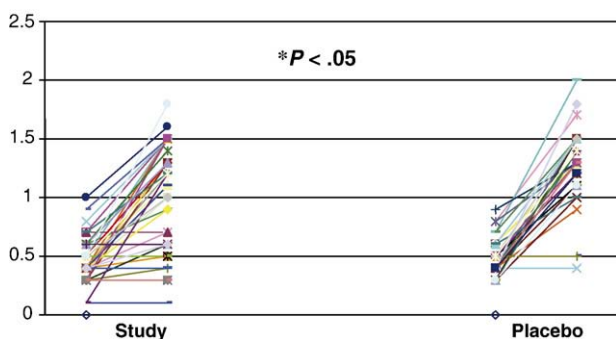


Fig. 4 Phimotic ring augmentation (centimeters) after the first 8 weeks of treatment with corticoid or placebo.

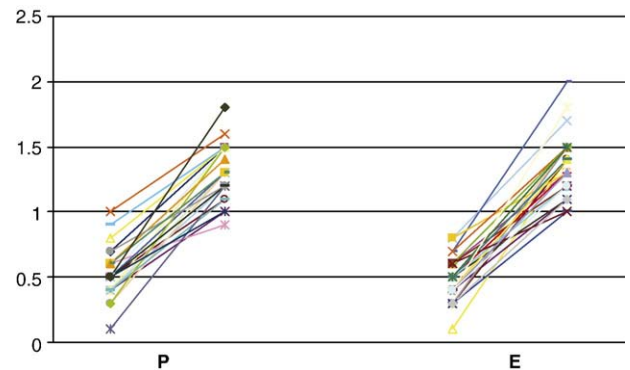


Fig. 5 Phimotic ring augmentation (centimeters) in placebo and corticoid group responders.

As phimosis until the age of 3 years [3,9,10] is taken as physiological by some, and considering that the American Academy of Pediatrics [11] and the Australian College of Pediatrics positioned against postectomy, pediatricians and surgeons now tend to preserve the prepuce, particularly in the neonatal period [4,5].

This lead to the introduction of conservative phimosis treatment with topical corticoid cream application once or twice daily, for a period of 4 to 8 weeks, with excellent ring widening results and the adjuvant benefit of both preputial hygiene and repeated forced retraction.

Although success strongly depends on parental adherence to the treatment protocol, a sometimes temporary effect of the topical corticoid treatment has been emphasized because the phimotic ring may recidivate if preputial hygiene is not maintained after treatment completion [12,13].

Golubovic et al [7], in 1996, and Dahlman-Ghozlan et al [6], in 1999, demonstrated that a 0.05% betamethasone topical cream, a highly potent corticoid presentation, was effective and safe in children and adults, without interfering in the morning cortisol levels.

In 1991, Kelly et al [8] compared 0.05% betamethasone with 0.1% mometasone furoate for the topical treatment of dermatoses and detected no changes in the morning cortisol level and in the hypothalamic-hypophyseal axis. Nonetheless, local skin atrophy was noticed 4 to 12 weeks after the treatment was initiated.

A medium-potent corticoid was selected for this study based on the theoretical advantage of safety concerning side effects, notwithstanding the known small drug absorption of even highly potent topical corticoid creams. In fact, in the present investigation, no side effects, either topical (skin atrophy and hyperemia) or systemic (Cushing syndrome), were found.

Considering the usually good results of phimosis clinical treatment, a second rescue treatment was deemed indispensable on an ethical basis, before disclosing the double-blind study. The secondary treatment was intended to prevent the first treatment nonresponders (PNC group) from undergoing unnecessary surgery because they could

have responded to the drug treatment as opposed to the placebo cream.

The more than 50% placebo group phimosis cure rate casts some doubt on corticoid cream phimotic ring treatment and certainly highlights the importance of adjunct repeated prepuce retraction.

As 96% of the children administered the 26-week corticoid treatment as opposed to 88% in the MC group showed ring opening, the extension of the medication use period seems advocated. However, this recommendation should be made only when more concrete data confirm the absence of side effects from the extended use of topical corticoid on the prepuce.

Our data suggesting the effectiveness of topical corticoid for treating the phimotic ring are in agreement with the literature.

The statements of ring regression afforded only by local hygiene and prepuce retraction, as well as the fact that in ancient Greece physicians deemed circumcision a superfluous procedure, set forth some questions. "Would both the diagnosis and the indication for surgical treatment of phimosis be overestimated? Would surgeons be operating on children unnecessarily?" [5,14,15].

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 on the disappearance of the phimotic ring as well. Therefore, new studies are necessary to clarify this detail.

References

- [1] Braz A. Curso de patologias cirúrgicas do Pênis e Escroto na criança. *Pediatr Atual* 1998;11(6):54-66.
- [2] Hodges FM. Phimosis in antiquity. *World J Urol* 1999;17(3):133-6.
- [3] Nasrallah PF. Circumcision: pros and cons. *Prim Care* 1985;12(4):593-605.
- [4] Warner E, Strashin E. Benefits and risks of circumcision. *CMAJ* 1981;125:967-76.
- [5] Kikiros CS, Beasley SW, Woodward AA. The response of phimosis to local steroid application. *Pediatr Surg Int* 1993;8:329-32.
- [6] Dahlman-Ghozlan K, Hedblad MA, von Krogh G. Penile lichen sclerosus et atrophicus treated with clobetasol dipropionate 0.05% cream: a retrospective clinical and histopathological study. *J Am Acad Dermatol* 1999;40(3):451-7.
- [7] Golubovic Z, Milanovic D, Vukadinovic V, et al. The conservative treatment of phimosis in boys. *Br J Urol* 1996;78(5):786-8.
- [8] Kelly JW, Cains GD, Rallings M, et al. Safety and efficacy of mometasona furoate cream in the treatment of steroid responsive dermatoses. *Australas J Dermatol* 1991;32:85-91.
- [9] Gairdner D. The fate of the foreskin. A study of circumcision. *Br Med J* 1949;2:1433-7.
- [10] Simpson ET, Barraclough P. The management of the paediatric foreskin. *Aust Fam Physician* 1998;27(5):381-3.
- [11] American Academy of Pediatrics. Report of the Task Force on Circumcision. *Pediatrics* 1989;84(4):388-91.
- [12] Ng WT, Fan N, Wong CK, et al. Treatment of childhood phimosis with a moderately potent topical steroid. *ANZ J Surg* 2001;71(9):541-3.
- [13] Wright JE. Further to "the further fate of the foreskin". Update on the natural history of the foreskin. *Med J Aust* 1994;160(3):134-5.
- [14] Celsus de Medicina, 7.25.2. In: Spencer WG, editor. *Celsus. De Medicina*, vol 3. Cambridge: Harvard University Press; 1938. p. 422.
- [15] Rickwood AM, Hemalatha V, Batcup G, et al. Phimosis in boys. *Br J Urol* 1980;52(2):147-50.