



Conservative treatment of phimosis with fluticasone propionate 0.05%: A clinical study in 1185 boys

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Abstract *Objective:* Circumcision has been the traditional method of choice in the treatment of boys with phimosis. Recently, several published studies worldwide have focused their interest on more conservative approaches in management of this condition. These studies advocate the use of topical steroids in the phimotic foreskin. We aimed to investigate the efficacy and safety of a medium potency corticosteroid in boys with different types of prepuce retractability.

Patients and methods: A prospective study was performed involving boys referred to our hospital for possible phimosis between January 2004 and February 2008. All were treated initially with fluticasone propionate 0.05% for a period of 4–8 weeks. Patients were reassessed after 6 months of follow up.

Results: A total of 1185 boys with a diagnosis of phimosis were treated with fluticasone propionate 0.05%. Successful results were achieved in 1079 (91.1%) patients including boys with mild balanitis xerotica obliterans. No side effects were noticed.

Conclusion: Our results show that fluticasone propionate 0.05%, a mild potent corticosteroid, is effective and safe in the treatment of boys with different types of phimosis.

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Introduction

The Greek term phimosis (φίμωσις, muzzling) implies the inability of the distal prepuce to be drawn back over the glans penis [1], and is a common cause of referral of boys to the paediatric surgeon. Essentially, two entities of phimosis

are recognized: congenital and acquired. Congenital phimosis is considered a normal biological process [2] and refers to the wholly or partially non-retractable prepuce due to a tight distal preputial ring, as a result of persistent developmental adherence between the glans and the foreskin [3]. The majority of neonates have a non-retractable prepuce, with an incidence of about 96% [2], which falls to up to 10% and 1% at the age of 4 and 14 years respectively, without special treatment [4]. This small percentage represents the true incidence of congenital phimosis. Acquired phimosis refers to the inability of the

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prepuce to be retracted over the glans penis as a result of balanitis xerotica obliterans (BXO) [5], previous forceful retraction with subsequent scarring, post-traumatic, recurrent balanitis and/or balanoposthitis, ammoniacal dermatitis, or as a postoperative complication after circumcision [6].

Regardless of the aetiology, circumcision has been considered the treatment of choice for boys aged >3 years with a diagnosis of phimosis [7]. Although its effectiveness is well established, circumcision carries the risk of surgical complications, which may vary from minor ones such as bleeding and meatal stenosis to major ones such as glans amputations and urethrocuteaneous fistulae [8].

Since Kikiros et al. [6] introduced steroids for the treatment of phimosis, several articles have supported this new conservative approach as an effective and safe alternative to surgical intervention, with a success rate ranging from 67% to 95%, and no side effects [4,8–10]. Reasons for this preference include surgical complications, as mentioned above, in addition to the risk of anaesthesia, financial cost, family preference and perioperative stress [4].

The aim of the present study was to evaluate the efficacy of fluticasone propionate 0.05% cream administered to boys with different types of exposure of the glans, and the length of application needed for the foreskin to become fully retractable.

Patients and methods

Patients

Between January 2004 and February 2008, a total of 1230 consecutive boys aged 3–14 years were referred for consideration of phimosis and possible circumcision. Phimosis was defined as the inability of the prepuce to be retracted because of a tight distal preputial ring [4], and was graded according to the classification of Kayaba et al. [11] (Fig. 1) as: type I, no retraction of prepuce; type II, non-retractable prepuce but the external urethral meatus could be visualized; type III, glans exposure halfway to coronal sulcus; and type IV, incomplete exposure of the glans due to preputial adherence to the coronal sulcus.

Five (0.4%) boys with a diagnosis of mild BXO were included in the study. The diagnosis was based on the appearance of a thickened non-retractable foreskin with a white porcelain discoloration but without cicatrization [12].

Methods

Enrolled patients were treated with fluticasone propionate 0.05% for a period of 4 weeks, twice daily. The boys who did

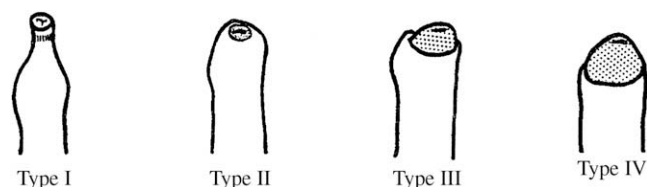


Figure 1 Classification of prepuce type according to Kayaba et al. [11].

not have a satisfactory result underwent a second course for another 4 weeks. For boys under 8 years, parents were instructed to expose the foreskin gently and to apply a thin layer of cream over the stenotic opening of the prepuce twice daily. Boys older than 8 years usually performed the retraction by themselves. No occlusive dressings were used. Parents were advised about potential signs of toxicity (e.g. vomiting, headaches), especially for those receiving a second course. The outcome was defined as successful if the prepuce was retractable with complete exposure of the glans after 4–8 weeks of treatment and there was no recurrence at 6-month follow up. Exclusion criteria included: evidence of balanoposthitis at presentation, boys who were referred for religious circumcision and boys lost to follow up.

Data collection

The patients were reassessed at 4 and 8 weeks following initiation of treatment at the outpatient service. Parents of responders were contacted by telephone or email at 6 months, in order to assess any recurrence of phimosis. In the case of non-responders and patients with recurrence, the protocol was not repeated and they were referred for surgery. Patients were enrolled in the study with approval from the relevant institutional review boards and after informed consent was received from either parent.

Statistical analysis

The results were analysed using the Chi-square test. Children who were not available to follow up were excluded from the analysis. A *P*-value less than 0.05 was statistically significant. All statistical analyses were computed by SPSS for windows (Version 8.0, 1997, SPSS Inc., Chicago, IL, USA).

Results

Forty-five patients were excluded from the study for various reasons (lost to follow up, religious circumcision, balanoposthitis at presentation). Of the remaining 1185, (median age 5.1 years), 460 (38.8%) were considered to have type I phimosis, 370 (31.2%) (including patients with mild BXO) type II, 245 (20.6%) type III, and 110 (9.2%) type IV (Table 1).

Independently of the classified type, a successful result, after 4 or 8 weeks treatment with fluticasone propionate

Table 1 Characteristics of the study group.

Prepuce type	No. of patients	Median age (years)	%
Type I	460	4 (Range: 3–7)	38.8
Type II including 5 with BXO	370	6 (Range: 3–9)	31.2
Type III	245	7 (Range: 3–14)	20.6
Type IV	110	9.25 (Range: 4–14)	9.2
Total	1185	5.1	100

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