



Effectiveness of Topical Steroid in Phimosis: A longitudinal Observational Study

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Abstract

Introduction: Most non-retractile foreskins have been diagnosed with phimosis and referred for circumcision. However, many patients can be managed with corticosteroid cream. This study evaluates the effectiveness of the topical application of corticosteroid cream and manual prepuce stretching in the treatment of phimosis.

Methods: This was a longitudinal observational study carried out among children aged six months to 10 years with the diagnosis of phimosis between 1st September 2019 to 31st August 2020. The patients were advised to apply 1% Hydrocortisone cream together with manual prepuce stretching twice daily for four weeks. Patients were assessed at four weeks and six months at the outpatient clinic using Kirkos grading for retractability.

Results: A total of 110 patients were diagnosed with phimosis during the study period. Fourteen patients had pathological phimosis out of which four had balanitis xerotica obliterans and were excluded from the analysis. Ninety-six patients with physiological phimosis were treated conservatively with 1% hydrocortisone and manual prepuce stretching. Among them, 87 cases were successfully treated whereas five patients had a partial response with treatment failure in four cases. Those five cases with partial response underwent adhesiolysis while circumcision was performed in the remaining four patients with treatment failure. Prepuce retraction was possible in four weeks in most of the patients with physiological phimosis with successful results in 90.6% of cases.

Conclusions: All non-retractile prepuce are not pathological phimosis and doesn't need circumcision. Local application of a potent corticoid cream and foreskin stretching is a safe, simple, and effective long-term treatment for physiological unretractable foreskin in children.

Introduction

Phimosis is a condition with a failure to retract the foreskin, which may be due to either a narrowness of the opening of the prepuce, congenital adhesions between the glans and prepuce, or both.¹ Almost all boys (96%) are born with an unretractable foreskin.

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Prepuce gradually becomes retractile by three years of age but can extend into older age groups (Physiological phimosis).² There is ongoing controversy regarding the use of neonatal circumcision for phimosis.³ The American Academy of Pediatrics has adopted a neutral or anti-circumcision stance on neonatal circumcision.⁴

Physiological phimosis is more appropriately managed by conservative measures, such as "tincture of time", or topical steroid therapy.⁵ Topical steroids have now become an alternative to circumcision for the treatment of phimosis with high success rates^{1,6,7} since its introduction in 1993.⁸ Pathological phimosis is defined as failure to retract the foreskin due to distal scarring of the prepuce that is seen as a contracted white, indurated, fibrous ring around the preputial orifice during physical examination. On the contrary, physiological phimosis lacks this scarring process and is a normal developmental phase of the prepuce and many physicians continue to have difficulty distinguishing one form from the other.^{3,4,9}

The standard treatment for pathological phimosis is circumcision^{6,9} but dorsal slit and preputioplasty under general anesthesia and adhesiolysis under topical anesthetics are other modes of treatment. Phimosis creates major concerns for parents and is responsible for significant numbers of consultations, referrals to paediatric surgeons, and circumcisions.¹⁰⁻¹² Recently alternative to circumcision and prepuce plasty, conservative treatments for phimosis with topical corticosteroids applied to the stenotic distal portion of the prepuce for four to eight weeks have been published with high rates of resolution. Three large studies have recommended the initial treatment of phimosis with topical corticosteroids before any surgical intervention.^{6,13,14}

The study aims to evaluate the effectiveness of the topical corticoid cream and manual prepuce stretching for non retractile prepuce.

Methods

This longitudinal observational study was conducted at KIST Medical College and Teaching Hospital from 1st September 2019 to 31st August 2020 after ethical approval from Institutional Review Committee (IRC NO 2076/77/15). Children aged six months to 10 years, who were diagnosed with phimosis in the outpatient clinic of Surgery and Paediatrics were included in the study while children with current active balanoposthitis, recurrent urinary tract infections, balanitis xerotica obliterans, buried penis, and phimosis secondary to incomplete circumcision were excluded from the analysis. Written informed consent was taken from the parents of the children after explaining the study.

The treatment options for phimosis using topical steroids or surgery were discussed with the parents. Grading of the degree of retractability of the foreskin was recorded at presentation and during follow-up visits at four weeks and six months after the corticosteroid treatment using Kirkos grading.⁵ The parents and / or the patients were instructed to wash prepuce and apply 1% hydrocortisone ointment at the tip of the foreskin together with manual prepuce stretching twice daily for four weeks without stopping even if the foreskin became retractable without causing any pain. The patients were then followed up at four weeks to analyze the treatment effect. At four weeks of treatment, all patients were examined for phimosis using the

same Kirkos grading. The maximum duration of corticosteroid treatment was limited to four weeks. Successful treatment at four weeks was defined as a retractile prepuce, patient / or parent satisfaction, and clinical examination suggesting circumcision was unnecessary. These patients were then followed again six months after treatment. Those patients who did not come for follow-up were interviewed by telephone. Failure of therapy at four weeks was defined as persistent phimosis with the inability to retract the outer foreskin and advised for circumcision. Side effects such as striae, pigmentation, hypertrichosis, and telangiectasia as well as weight gain, and behavioral changes were recorded. During the treatment course, the patients or their parents were asked if the daily regime of retraction and cleansing of the retractable foreskin was diligently followed and whether there was an episode of balanitis during treatment. Demographic data, age, and clinical data of patients were recorded in predesigned proforma and the same proforma was used to record the treatment outcomes during the follow-up. The data were entered and analyzed using the Statistical Package for Social Sciences (SPSS) Version 27. Frequencies and percentage values were calculated for the various variable using descriptive analysis.

Results

A total of 110 patients ranging from six months to 10 years (Mean = 4.28 years) were diagnosed as having phimosis during the study period. Out of 110 patients, 14 (12.7%) patients had pathological phimosis of which four had balanitis xerotica obliterans. These 14 patients were excluded from the study and underwent circumcision. Among 96 patients eligible for corticosteroid ointment therapy, 39.58% of patients had a grade 2 phimosis, 5.21% patients had grade 3 phimosis, 34.37% patients had grade 4 phimosis, and 20.83% patients had grade 5 phimosis at initial presentation as shown in Table 1. During the study period, no patient had grade 0 and grade 1 phimosis.

Table 1. Grades of phimosis of the study population

Grade	Number of patients	Percentage
Grade 0	0	0
Grade 1	0	0
Grade 2	38	39.58%
Grade 3	5	5.21%
Grade 4	33	34.37%
Grade 5	20	20.83%

None of the patients were practicing daily retraction of their foreskin before entering the study. Ninety-six patients were treated with 1% hydrocortisone cream and manual prepuce stretching according to protocol. Four weeks after enrollment, 90.6% (87 patients) had a successful treatment while 5.21% (Five patients) had a partial response, and 4.17% (Four patients) were considered failures (Table 2). The five patients with partial response to treatment were found to have symptomatic physiological preputial adhesion and were managed by simple adhesiolysis in the outdoor clinic under xylocaine spray. Circumcision was performed for four treatment failure patients. At six months of follow-up, two patients were lost

to follow-up while 88.5 % (85 / 96 patients) had a retractable prepuce without recurrence of phimosis.

In all the cases, the treatment was well tolerated without evidence of adverse effects. In general, boys older than six years performed the retraction by themselves while parents performed the retraction procedure in younger boys.

Table 2. Putcome of phimosis in Kirko's grades after steroid therapy

Grade	Number of patients	Percentage
Grade 0	87	90.62%
Grade 1	0	0
Grade 2	4	4.17%
Grade 3	5	5.21%
Grade 4	0	0
Grade 5	0	0

Discussion

This study found that local application of 1% Hydrocortisone cream with manual prepuce stretching is an effective, safe treatment in patients with physiological phimosis. This finding was similar to several articles published recently on the treatment of phimosis using topical steroids with success rates from 70% to 90%.^{6,13,14} In a study, 233 patients received eight-week treatment with 0.02% clobetasol propionate cream, among which 181 (77.68%) showed full retraction of the foreskin, 28 (12.01%) experienced improvement (Disappearance of the phimotic ring), and 24 (10.30%) failed to respond, with a total effectiveness rate of 89.70%.¹⁵ Our result of 90.6 % success rate is similar to the above studies. Moreover, this study followed patients and found that there was no recurrence in a six months follow-up.

This study highlights that four weeks of conservative treatment could be tried before circumcision reducing the risk of anesthesia¹⁶ as well as complications associated with surgery.^{16,17} A tight foreskin may manifest with symptoms such as itching, smegma deposits, straining, ballooning, balanoposthitis, dysuria, or urinary infection termed as symptomatic or pathological phimosis. Recently the general trend emerging all over the world is to perform circumcisions only in symptomatic cases and in possible cases to perform a prepuce conserving surgery like Prepuceplasty, V-Y plasty, etc.¹⁸ The dorsal slit has been known to cause scarring of the dorsal prepuce leaving an inadequate amount of ventral foreskin in 55% of the boys four years after the operation.¹⁹ Surgical alternatives to circumcision, such as preputial plasty, also require anesthesia which has up to a 4% recurrence rate.¹⁸

The exact mechanism of action of topical steroids in phimosis is unknown. However proposed mechanisms are inhibition of prostaglandin release, downregulation of collagen synthesis, and moisturizing effect of steroids improving the elasticity of prepuce acid.^{1,5,7} Steroids applied only to the foreskin (less than 0.1% of the total body surface area) have very minimal systemic side effects even in young boys less than four years of age^{5,7} and also topical steroid treatment for phimosis did not change morning cortisol levels.⁷ No local or systemic side effects with

corticosteroid cream and foreskin stretching were noticed in our study. The risk of side effects is unlikely since the quantity of cream applied and the treated surface of the prepuce is very small. Nevertheless, the parents and patients were informed accordingly and possible signs of toxicity such as headaches and vomiting were mentioned. The overall cost of topical steroid treatment is 25 to 35% of circumcision and preputial plasty, therefore cost-effective.^{6,13}

Sometimes prepuce adhesion may be misdiagnosed as pathological phimosis and subjected to circumcision when it could have easily been managed by adhesiolysis as an outdoor procedure.¹⁰⁻¹² Gentle retraction of the prepuce, known as physiotherapy, was suggested as an important factor in the spontaneous resolution of physiologic phimosis.¹⁷ Although forcible retraction of the prepuce should be avoided because of pain, bleeding, adhesion, and cicatrix formation, which might lead to secondary phimosis, careful and gentle retraction has been encouraged for the more rapid resolution of severe physiologic phimosis.^{6,17} A previous study found that gentle retraction of the foreskin with topical application, reported a 50% success rate even with placebo cream and physiotherapy and suggested that physiotherapy per se would be effective to resolve physiologic phimosis.⁶ In concurrence to these researches, we also found that steroid therapy would be an effective therapy for physiological phimosis. The limitation of this study is that it is a single-site study with a small number of children from the local region. Hence the study should be further carried out in a large population from various centers to confirm the finding of this study to extrapolate to the general population.

Conclusions

This study has shown that not all non-retractile prepuces are pathological phimosis and require circumcision. Local application of 1% hydrocortisone cream along with foreskin stretching is a safe, simple, and effective long-term treatment for physiological unretractable foreskin in children.

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