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Topical treatment for phimosis: Time span and other factors behind treatment effectiveness

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Abstract *Objective:* To study the factors that may influence the effectiveness of 0.2% betamethasone/hyaluronidase cream in the treatment of phimosis.
Methods: We treated 427 patients (3—10 years old, mean 6.33) in a prospective, randomized, blind study, with 214 patients on a 4-week and 213 patients on an 8-week course. All patients were seen once monthly at least for 6 months after the end of treatment. The penis was photographed to allow objective evaluation of treatment response. The therapeutic response was graded as total success when there was complete exposure of the glans; partial success when there was exposure of half of the glans, impeded by balanopreputial adherence or ring fibrosis at the prepuce; and therapeutic failure when patients had no or less than 50% glans exposure.
Results: After treatment 92.1% of patients showed total or partial success, but during follow up (mean 9.36 months, range 6—13) 29.5% failed to maintain this (22.6% and 37.6% for 8- and 4-week treatment, respectively). During treatment, 13.6% presented side effects or complications: prepuce ardor (6.1%), hyperemia (4.6%), paraphimosis (0.0098%). Intervention or interruption of treatment was unnecessary. The two groups were statistically similar in all parameters, but time of treatment = 8 weeks, previous urethral meatal exposure and no previous balanoposthitis increased the chance of total success. Surgery was indicated for failure or relapse in 181 patients (42.38%).
Conclusion: Treatment with topical 0.2% betamethasone/hyaluronidase cream for 8 weeks is effective and safe, especially if the urethral meatus is exposed and there is no previous balanoposthitis. Rescue treatment is not recommended, as the results were not encouraging.

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Introduction

Phimosis is an affliction commonly seen by urologists and pediatricians, being defined as the incapacity of retraction of the foreskin, impeding exposition of the glans [1]. Only 4% of newborns have a fully retractable prepuce but at 3 years 90% of boys can easily expose the glans, and for this population no especial kind of treatment is advisable.

Circumcision is one of the oldest known surgical procedures, being performed for centuries by the Jews, with references to it in the Bible (Genesis, Ch. 17), and also in Egyptian tombs [1–3]. This procedure in the US is performed in 61% of the male population, and relative costs are estimated at 140 million US dollars per year [2,5]. The American Academy of Pediatrics (AAP) [6] recommends no absolute indication for neonatal circumcision, since some advantages, but also some potential risks, are involved in this process. Topical steroidal treatment has been reported as an alternative, non-surgical, approach for treating classical phimosis. We studied factors that may influence the effectiveness of topical corticosteroid treatment with a 0.2% betamethasone plus hyaluronidase formula in patients aged 3–10 years with classical phimosis who were recruited from a 'waiting list' for circumcision in our institution.

Materials and methods

We performed a prospective, randomized by a list with a deciphered code, blind study to evaluate clinical response to a 0.2% betamethasone plus hyaluronidase cream for patients with classical phimosis. The study had been approved by the Ethics Committee of our University and was conducted from January 2004 to March 2005.

We treated 417 patients: 214 for 4 weeks and 213 for 8 weeks in a one-nocturnal-application regimen. Patients were eligible if they were 3–10 years old and had 'true or classical' phimosis, consisting of a fibrous foreskin ring and no exposition of the glans. One investigator (RGF) examined each patient blindly, photographed the genitalia and dictated his impressions to a second investigator (YDN), who filled in the medical records and had no influence in the clinical analysis of the patient. Patients were taught to use a 0.25 finger dose unit (FDU = 0.5 g) of the cream applied for 30 s in the foreskin after mild retraction.

We selected as important input investigation parameters: previous urethral meatal exposure; previous history of balanoposthitis characterized by hyperemia, edema and foreskin secretion; UTIs previously documented by urinalysis (Table 1). Clinical response to the treatment was defined as total if easy and complete exposure of the glans was observed without a persistent fibrous ring. Partial response was defined if half of the glans could be retracted and the other half was attached to the foreskin either secondary to balanopreputial adherences or due to a fibrous ring. No response was defined when less than half of the glans was exposed.

This study was not placebo-controlled because the efficiency of corticosteroid topical treatment has been previously established and documented [7,8,9]. Statistical analysis of the data was done using the Chi-square and Fisher tests. When the obtained value was significant we calculated the odds ratio and its 95% confidence interval. The significance level was $P \leq 0.05$. Due to the fact that the dependent variable was a dichotomic variable, we used in the multivariate analysis the method of multivariable logistic regression analysis, with the objective of checking the influence of the independent variables (or predictors): previous urethal meatus exposure, therapy length, presence of pretreatment of ring fibrosis at the prepuce meatus, smegma, banalitis and UTI, simultaneously over the dependent variable (or success).

We used 0.25 FDU/day (0.5 g), which allowed us to control the total dosage of the substances used for the entire treatment course, equivalent to 7.5 g for patients treated for 4 weeks and 15.0 g for patients treated for 8 weeks. We used a total of 932 5-g tubes. At the end of the treatment course, and after at least 6 months of follow up, we printed for each patient a record with the pictures of the genitalia documenting all medical visits, which are archived in the papers of the study.

Results

From the series of 427 patients, 19 were excluded either for inadequate use of the cream (6) or for

Table 1 First physical examination data and previous medical history

Clinical presentation	No. of patients ($n = 408$)
Without previous meatal exposure	205 (50.24%)
Puncture prepuce meatus	202 (49.5%)
Previous balanophostitis	210 (51.4%)
Previous UTI	97 (23.77%)
Ring fibrosis at the prepuce meatus	357 (87.5%)