Journal of Pediatric Surgery 61 (2026) 163093

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.sciencedirect.com/journal/journal-of-pediatric-surgery

Clinical Research Paper

Topical steroids are effective even in severe phimosis: Evidence from a multicenter cohort

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ARTICLE INFO

Article history:
Received 7 September 2025
Received in revised form
9 February 2026
Accepted 17 March 2026

Keywords:
Phimosis
Topical corticosteroids
Circumcision
Male
Betamethasone

ABSTRACT

Phimosis is commonly encountered in pediatric surgical practice. Despite evidence supporting topical corticosteroids for phimosis, many clinicians believe they are ineffective in certain subgroups such as severe phimosis or older children, leading to early circumcision. This study aimed to evaluate the effectiveness of topical corticosteroids across different severities and patient characteristics.

We conducted a prospective multicenter cohort study across 12 Chilean hospitals between June 2023 and August 2024. Boys under 18 years old with phimosis grades 2 to 5 (Kikiros classification) were treated with 0.05% topical betamethasone twice daily for 8 weeks. Patients were followed up between 8 and 16 weeks. Resolution was defined as improvement to Kikiros grades 0–1. Variables related to treatment outcomes were assessed using univariate and multivariate logistic regression analyses.

Out of 386 eligible patients, 235 completed follow-up and were included in the final analysis. Overall treatment success was 68%, with no significant differences across phimosis severity or age groups. The only factor significantly associated with treatment failure was altered preputial skin appearance (success rate: 72% with healthy skin vs. 29% with altered skin; $p = 0.007$). Other variables, including treatment adherence, age, symptoms, or prior balanitis, were not predictive of treatment failure.

Topical corticosteroids are effective for treating phimosis in children, regardless of severity, age or other pre-treatment variables studied. Altered preputial skin appearance may predict lower response rates. These findings support broader implementation of conservative management and may help reduce unnecessary surgical interventions.

Level of evidence: Level 2b, according to the Oxford Centre for Evidence-Based Medicine (2009).

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https://doi.org/10.1016/j.jpedsurg.2026.163093
0022-3468/

HIGHLIGHTS

- Corticosteroids are underused for phimosis due to belief they fail in some subgroups.
- Prospective study of 230+ patients from 12 hospitals across Chile.
- Topical steroids effective in 68%, regardless of severity, age and other factors.
- Altered preputial skin was the only factor linked to treatment failure.
- Findings support conservative treatment before circumcision

1. Introduction

Phimosis is a common condition in pediatrics, characterized by the inability to retract the foreskin over the glans due to a narrowed preputial opening. It is estimated that 70–80% of school-aged boys have a non-retractable foreskin [1,2]. In most children, this condition is physiological and resolves spontaneously in a high proportion of cases [3,4].

Surgical treatment via circumcision remains widely used worldwide, although its indication varies significantly across regions and healthcare systems. It is estimated that 39% of males are circumcised globally [5].

Topical corticosteroid therapy has demonstrated high effectiveness; in randomized clinical trials comparing corticosteroids to placebo, resolution rates exceed 70–80% [6–9]. These findings have been confirmed by systematic reviews and meta-analyses [10–13]. Topical corticosteroids are considered the first-line treatment for pediatric phimosis in European and Canadian guidelines [14]. In recent surveys, over 90% of specialists report prescribing corticosteroids before referring for surgery [15].

Despite this, according to a survey conducted among 118 Latin American pediatric surgeons and urologists in 2025, aimed to describe the management and treatment indications in patients with asymptomatic phimosis; only 30% of respondents routinely use corticosteroids to treat phimosis. Regarding the timing of circumcision, 80% of those surveyed recommend performing it at 4–5 years of age, regardless of symptoms (Survey by Dr. F. Yankovic, unpublished data)[25]. As a result, phimosis is the leading cause of surgical intervention in children in Chile, the second leading cause of pediatric hospital discharge before age 15, and the most common condition on surgical waiting lists. This trend may be partly attributed to the perception that corticosteroids are ineffective in certain subgroups, such as those with severe phimosis, particular morphologies, or older/postpubertal age. These beliefs may limit the implementation of less invasive management strategies in clinical practice.

The aim of this study is to evaluate the effectiveness of topical corticosteroids across different subgroups of patients with phimosis and to identify factors that may influence treatment success or failure. The study's hypothesis is that corticosteroid effectiveness is consistent across diverse phimosis subgroups.

2. Methods

Following approval from the local ethics committee, we conducted a multicenter prospective cohort study in 12 hospitals across Chile between June 1, 2023, and August 30, 2024. All participating surgeons received standardized training on the diagnosis and classification of phimosis, as well as on the application technique for topical corticosteroids. Caregivers of patients under 18 years of age referred from primary care to pediatric surgery or urology services with a diagnosis of phimosis defined as non-retractable foreskin corresponding to Kikiros grades 2 to 5 were invited to participate [16,17].

At the initial consultation, phimosis severity and foreskin skin quality were assessed by the treating surgeon using the Kikiros classification (Table 1), which grades preputial appearance and tightness from 0 to 5, with grades 0 and 1 considered normal. This classification was chosen for its widespread use in the literature and the ability to standardize assessment through diagrams and photographs. Exclusion criteria included previous treatment (corticosteroids or surgery), secondary phimosis, suspected or confirmed balanitis xerotica obliterans (BXO), congenital megaprepuce, history of paraphimosis, adverse reactions to corticosteroids, immunosuppression, or a surgical indication for other reasons.

Written informed consent was obtained from caregivers, and assent was obtained from children over 8 years old. Standardized information regarding risks and benefits was provided through a printed leaflet and an instructional video. All patients received 0.05% topical betamethasone, applied gently after foreskin retraction twice daily for 8 weeks. Betamethasone was selected due to its high demonstrated efficacy [11,13], availability, and low cost in Chile. Socio-demographic and clinical variables were collected using a pre-designed form and anonymized via a unique patient code before entering into an encrypted online database. The variables collected during the first consultation are presented in Table 2.

Follow-up was scheduled between 8 and 16 weeks post-treatment initiation to evaluate treatment success. Patients attended a clinical follow-up to assess phimosis grade and treatment adherence by the same surgeon who recruited the patient. Adherence was rated by caregivers using a Likert scale, blinded to the evaluating surgeon. Patients without documented follow-up after 16 weeks were considered lost to follow-up. Patients who missed follow-up, underwent surgery during the study, discontinued corticosteroids, or withdrew consent were excluded from the final analysis.

The primary outcome was the proportion of patients with resolution of phimosis, defined as Kikiros grades 0 or 1 at follow-up. Different variables were analyzed in relation to the success rate for each phimosis grade from 2 to 5, and results were adjusted for

Table 1
Kikiros classification.

Grade:	
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, meatus just visible.
4.	Slight retraction, but some distance between tip and glans, i.e., neither meatus nor glans can be exposed.
5.	Absolutely no retraction.
Foreskin appearance:	
0.	Normal
1.	Preputial crack
2.	Small white scar, partially circumferential.
3.	Balanitis xerotica obliterans or severe scar ± bleeding.

Table 2
Pre treatment variables collected during the first consultation.

Age	Years
Kikiros classification (preputial retraction) Kikiros classification (skin appearance)	Grades 0-5
Prior balanitis prior UTI and episodes	Grades 0-3
Atopic Dermatitis	Yes/No, number of episodes
Symptoms associated to phimosis	Yes/No
Foreskin ballooning with urination	Yes/No, which symptom
Pubertal development	Yes/No
Foreskin manipulation	Yes/No Autonomous by the patient/with aid of caregiver of physician/doesn't tolerate manipulation

age. As a secondary outcome, the resolution rate of phimosis was evaluated according to other pre-treatment variables.

Sample size was calculated assuming a 70% success rate with corticosteroids [11,13], a 5% alpha error, and 80% power to detect a reduction in effectiveness below 50%, requiring 43 patients per severity group. Accounting for four severity groups (Kikiros 2, 3, 4, and 5) and an estimated 20% loss to follow-up, a recruitment target of 215 patients was set. Descriptive statistics included frequency tables. Chi-square and Fisher's exact tests were used for qualitative variables ($p < 0.05$ considered significant). To assess the influence of potential predictors on treatment success, a multivariate logistic regression model was constructed including clinically or statistically relevant variables and covariates.

3. Results

A total of 386 patients were invited to participate in the study, of whom 3 met exclusion criteria. Of the remaining 383 patients, 119 did not attend follow-up, 3 underwent surgery during the study period, 2 withdrew their consent, and 24 discontinued treatment (10 by caregiver decision, 7 due to lack of patient cooperation, and 7 due to preputial irritation). The final cohort analyzed included 235 patients (Fig. 1).

Baseline characteristics for the overall sample and stratified by phimosis grade are shown in Table 3. The severity groups were comparable overall; the only variable with non-homogeneous distribution among grades before treatment was prior balanitis, present in 11% of Kikiros 2 patients versus 2% of Kikiros 5 patients ($p = 0.03$).

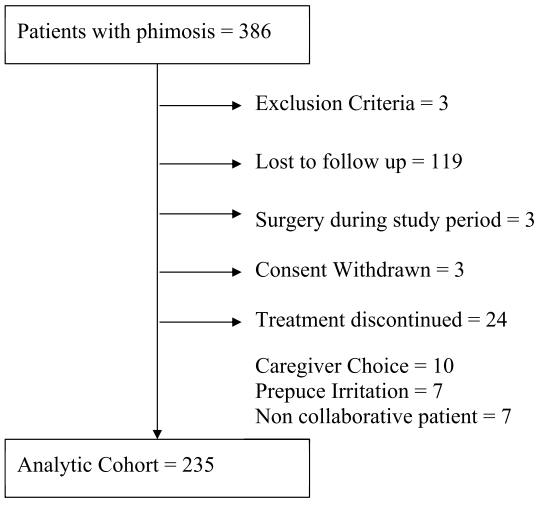

Fig. 1. Flowchart of patients with phimosis included in the analytical cohort.

As the loss to follow-up was higher than expected (31%), an additional analysis was conducted comparing baseline characteristics of patients with and without follow-up, including Kikiros classification. No significant differences were found between the groups.

Of the 235 patients who completed follow-up, 161 achieved resolution of phimosis, yielding an overall treatment success rate of 68%. Resolution rates by grade were 84% for grade 2 and 56% for grade 5, with no statistically significant differences between subgroups. Among the pre-treatment variables analyzed, the only one associated with corticosteroid response was foreskin appearance. Children with normal skin had a higher resolution rate than those with altered skin (72% vs. 29%, $p = 0.007$). No significant differences in treatment success were found regarding age, pubertal development, symptoms, or ability to manipulate the foreskin. Treatment adherence, rated as 4 or 5 on the Likert scale in 205 patients (87%), also did not influence corticosteroid effectiveness (Table 4).

Multivariate logistic regression analysis included phimosis grade, skin appearance, history of urinary tract infection (UTI), balanitis, other symptoms, and age. The only factor significantly associated with treatment success was skin appearance, consistent with the univariate analysis (Table 5).

No adverse effects were reported in the analytic cohort; nevertheless, 7 out of 386 patients (1.8%) discontinued the treatment due to irritation.

4. Discussion

The success rate of corticosteroid treatment for phimosis was 68%, regardless of phimosis grade, age, or associated symptoms. Although Kikiros grade was not independently associated with treatment failure, the odds ratios suggest a trend toward decreasing treatment success with increasing severity; however, based on our results, phimosis severity alone should not be considered a limiting factor for the effectiveness of topical steroid therapy. The only factor associated with a lower success rate was an altered appearance of the preputial skin.

This study reaffirms the effectiveness of topical corticosteroids in pediatric patients with phimosis, achieving an overall resolution rate of 68%. Our results show that this effectiveness is consistent across different severities of phimosis, as classified by the Kikiros scale, as well as across other analyzed predictors—except for preputial skin quality, which was significantly associated with lower treatment success. Multivariate analysis confirmed this observation, indicating that patients with skin graded as type 1 or 2 showed a lower response to topical treatment.

When comparing our results with previous studies, we found that several randomized clinical trials demonstrating corticosteroid efficacy included patients with varying phimosis severities. However, no statistical tests were used to detect differences among these subgroups, and most studies either did not categorize phimosis severity or used descriptive classifications developed or modified by the authors [18–24]. Furthermore, prior studies did not assess other variables included in our analysis, such as history of urinary tract infections, previous episodes of balanitis, or pubertal development.

Esposito et al. used the modified Kayaba classification and reported a significant reduction in steroid efficacy between grade III (81%) and grade V (58%; $p < 0.0042$) [6]. This difference may be attributable to the classification system used. Similarly, G. Zhou et al. found a significant decline in steroid efficacy with age, from 71% in children aged 2–4 years to 56% in those aged 8–12 years [9].

Table 3
Baseline characteristics of patients with phimosis according to phimosis grade based on the Kikiros classification.

	Total	Kikiros 2	Kikiros 3	Kikiros 4	Kikiros 5	p value
	n = 235(%)	n = 19 (%)	n = 71 (%)	n = 102 (%)	n = 43 (%)	
Age						
0-4	80 (34)	6	26	34	14	p = 0.430
5-8	133 (57)	10	36	59	133	
9-15	21 (9)	3	9	8	21	
Skin appearance						
Grade 0	211 (90)	1	2	1	3	p = 0.539
Grade 1	17 (7)	1	5	8	3	
Grade 2	7 (3)	17	64	93	37	
Balanitis	35 (15)	2 (11)	14 (20)	18 (18)	1 (2)	**p=0.03**
UTI	10 (4)	0	3	6	1	p = 0.773
Atopic dermatitis	188 (20)	4	12	25	6	p = 0.462
Symptoms	35 (15)	4	11	14	6	p = 0.827
Foreskin Balooning	85 (25)	10	23	38	14	p = 0.397
Pubertal development	15 (6)	3	6	6	0	p = 0.064
Foreskin Manipulation						
Alone	66 (28)	6	26	24	10	p = 0.402
Assisted	147 (63)	11	39	66	31	
Not tolerated	22 (9)	2	6	12	2	

Table 4
Univariate analysis.

	Resolves Phimosis n = 161 (69%)	Doesn't Resolve phimosis n = 74 (31%)	p value
Age			
0-4	57 (71)	23 (29)	p = 0.593
5-8	88 (66)	45 (34)	
9-15	16 (76)	5 (24)	
Kikiros			
grade 2	16 (84)	3 (16)	p = 0.135
grade 3	51 (72)	20 (28)	
grade 4	70 (69)	32 (31)	
grade 5	24 (56)	19 (44)	
Skin appearance			
Grade 0	**151 (72)**	**60 (28)**	**p=0.007**
Grade 1	**8 (47)**	**9 (53)**	
Grade 2	**2 (29)**	**5 (71)**	
Balanitis	25 (71)	10 (29)	p = 0.687
UTI	6 (60)	4 (40)	p = 0.512
Atopic dermatitis	34 (72)	13 (28)	p = 0.527
Symptoms	25 (71)	10 (29)	p = 0.687
Foreskin Balooning	44 (75)	15 (25)	p = 0.246
Pubertal development	12 (80)	3 (20)	p = 0.401
Foreskin Manipulation			
Alone	44 (67)	22 (33)	p = 0.509
Assisted	104 (71)	43 (29)	
Not tolerated	13 (59)	9 (41)	
Treatment adherence			
1	–	–	p = 0.205
2	6 (60)	4 (40)	
3	10 (50)	10 (50)	
4	39 (67)	19 (33)	
5	106 (72)	41 (28)	

In contrast, we did not observe such an age-related difference, possibly due to the larger sample size in this study [9].

This study has several notable strengths: it is a prospective investigation specifically designed to detect differences among subgroups, not just overall efficacy, with a sample size appropriately calculated for the planned statistical analysis. It was also conducted across multiple centers using standardized definitions and uniform evaluator training, enhancing consistency across sites. Treatment adherence was objectively assessed, further supporting the study's internal validity.

Among its limitations, the study experienced a higher-than-expected loss to follow-up (31%). However, comparison between patients with and without follow-up revealed no significant differences (including Kikiros classification distribution) reducing the risk of bias. Treatment adherence may also influence outcomes. Despite standardized instructions provided to caregivers regarding twice-daily application for eight weeks, loss to follow-up may reflect suboptimal compliance, which could have contributed to apparent treatment failure in some cases and should be informed to caregivers when offering steroids. Some definitions, such as prior UTI, were self-reported and not always confirmed in clinical records, which may introduce some subjectivity and recall bias. In addition, the short follow-up period and exclusion of recurrence analysis are limitations to consider, although previous studies have reported recurrence rates around 15%, supporting our methodological choice. Another limitation is that evaluators were not blinded to baseline classification or pre-treatment factors when assessing phimosis resolution.

Table 5
Multivariate logistic regression analysis of factors associated with topical treatment failure in phimosis.

Analyzed variables	Odds Ratio [95% Confidence Interval]	p value
Kikiros grade		
- Grade 3	2.21 [0.55–8.84]	0.26
- Grade 4	2.50 [0.64–9.75]	0.19
- Grade 5	4.05 [0.97–16.84]	0.054
Skin appearance		
- Grade 1	2.98 [1.06–8.34]	0.038*
- Grade 2	6.20 [1.06–36.32]	0.043*
Symptoms		
- UTI	1.53 [0.37–6.28]	0.55
- Balanitis	0.80 [0.33–1.92]	0.62
- Others	0.82 [0.35–1.94]	0.65
Age		
5–8 years	1.21 [0.65–2.27]	0.55
9–15 years	0.15 [0.30–3.10]	0.94

An unexpected finding was the significant influence of skin quality on treatment effectiveness. Although BXO was explicitly excluded, the low therapeutic response in patients with poorer skin quality may suggest the presence of subclinical BXO or undiagnosed cicatricial phimosis. This finding underscores the importance of careful preputial skin assessment when selecting patients for conservative management. We suggest not to delay treatment by giving steroids to patients with features of BXO or altered preputial skin quality. This result opens an interesting line of future research regarding the histological characterization of preputial skin and its clinical correlation.

5. Conclusion

In summary, this study confirms the initial hypothesis that most of the variables analyzed do not significantly affect the effectiveness of topical corticosteroid treatment for phimosis, except for specific cutaneous characteristics. The clinical relevance of this finding lies in the fact that most patients could benefit from medical treatment, thereby avoiding risks associated with surgery, such as perioperative complications, pain, and anesthetic exposure. At the healthcare system level, increasing the use of corticosteroids could help reduce surgical waiting lists and unnecessary referrals.

Future research could explore patient preferences and satisfaction regarding medical versus surgical treatment options, as well as cost-effectiveness analyses, providing valuable complementary information for clinical and policy decision-making. In conclusion, we suggest that the vast majority of children with phimosis should receive topical corticosteroid therapy before considering circumcision as a primary treatment option.

Ethics approval

The study was approved by the local ethics committees of all participating hospitals. Written informed consent was obtained from caregivers and assent from children over 8 years old.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interest

The authors declare no conflicts of interest.

Acknowledgments

We thank the Chilean Society of Pediatric Surgery and its presidents, Dr Gloria González (2021–2022) and Dr Francisca Yankovic (2023–2024), for promoting this study by leveraging their networks to recruit participating centers and interested physicians. We are also grateful to the Society for supporting the dissemination of results and for providing assistance with methodology, statistical analysis, and translation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2026.163093.

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