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ORIGINAL ARTICLE

Efficacy of topical steroid treatment in children with severe phimosis in China: A long-term single centre prospective study

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Aim: To evaluate the efficacy of topical steroid (0.1% mometasone furoate) therapy and factors affecting long-term outcome of paediatric severe phimosis in China.

Methods: A total of 1550 patients with severe phimosis classified by Kikiros system were prospectively enrolled in the study from January 2016 to February 2020. They were prescribed with 0.1% mometasone furoate twice a day for 4 weeks. Patients were re-evaluated at the end of weeks 2, 4, 8 and 6 months follow-up.

Results: A total of 1499 patients completed the treatment, 71.1% responded at the end of week 4. The long-term success rate was 66.0% over a mean follow-up of 26.9 months. The success rate of grade 4 phimosis was significantly higher than that of grade 5 at 4, 8 weeks and 6 months ($P = 0.005$, $P < 0.001$ and $P < 0.001$, respectively). Patients with balanoposthitis had a poorer outcome compared with patients without symptoms and patients symptoms by prepuce ballooning or urinary tract infections ($P < 0.001$). Initial grade of 5 phimosis and symptom with balanoposthitis were independent risk factors for recurrence. All patients had no systemic side effects, 23 cases developed local erythema or burning sensation.

Conclusion: Topical steroid (0.1% mometasone furoate) is an effective treatment for severe phimosis in children. The recurrence was related to the grade or symptoms of severe phimosis.

Key words: children; mometasone furoate; phimosis; steroid.

What is already known on this topic

Topical steroid has been widely used. However, local steroid treatment for phimosis is at the nascent stage in mainland China. In addition, few studies have attempted to analyze the long-term outcomes, and the relationship between the treatment and phimosis-associated symptoms, such as balanoposthitis, history of UTI, and ballooning of the prepuce.

What this paper adds

It is the first report to explore the long-term efficacy and impact factors of topical steroid treatment for pediatric phimosis in mainland China. This study showed that topical application of 0.1% mometasone furoate is a safe and effective treatment for severe phimosis (Kikiros retractability grade of 4 or 5). The topical steroid could be the first choice of treatment for patients with severe phimosis, and it is recommended to apply twice a day for four weeks. Grade 5 phimosis and balanoposthitis were independent risk factors for recurrence.

Phimosis is defined as a condition with inability to retract the foreskin over the glans penis owing to a tight preputial ring distal to the glans.[1] Phimosis is normal at birth or occurs secondary to scarring of the distal foreskin when the foreskin cannot be retracted.[2] Although most cases of phimosis resolve with time without any symptoms, severe cases of phimosis may lead to urinary tract infections (UTI), balanoposthitis or urinary obstruction, which require treatment.[3]

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Traditionally, circumcision has been the main treatment choice. However, circumcision is an invasive procedure, which may lead to a financial burden and the complication rate is 0.1%–3.5%. The complications include bleeding, infection, scar stenosis and anaesthesia-related adverse events.[4] In 1993, Kikiros *et al.*[5,6] reported the effectiveness of topical steroid as the first line of treatment for symptomatic phimosis. However, few studies have attempted to analyse the long-term outcomes, and the relationship between the treatment and phimosis-associated symptoms, such as balanoposthitis, history of UTI and ballooning of the prepuce. In addition, the efficacy of the treatment was related to the patients' race. Local steroid treatment (LST) for phimosis is at the nascent stage in mainland China. The European Association of Urology (EAU) Guidelines on Paediatric Urology in 2015 proposed that treatment for phimosis usually starts after 2 years of age. Hence, we excluded patients under 2 years of age according to the guideline. Most boys will reach puberty after 12 years old in China.

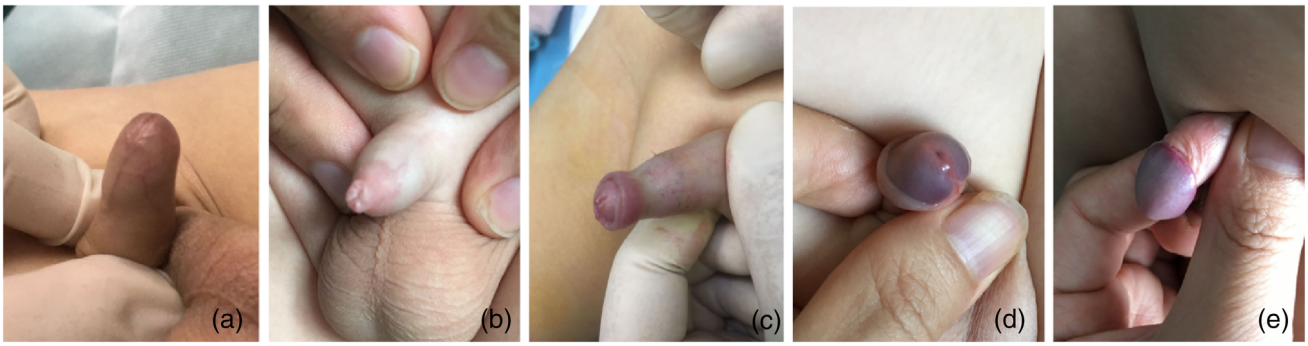

Fig. 1 Our patients with the grade of phimosis was assessed by Kikiros and Woodward: (a) grade 5 of phimosis; (b) grade 4 of phimosis; (c) grade 3 of phimosis; (d) grade 2 of phimosis; and (e) grade 0 or 1 of phimosis.

Parents of children with severe phimosis usually ask for circumcision, because they are worried that severe phimosis might affect glans hygiene and sexual function in adulthood. We had used topical steroid to treat severe phimosis before this study and found that age was negatively correlated with the success rate of topical steroid therapy. Few parents of patients older than 12 years chose the topical steroid therapy since we had told parents about the effectiveness for elder children. Hence, patients older than 12 years were excluded from our study.

The aim of this study was to evaluate the long-term efficacy and safety of topical steroid for the treatment of severe phimosis. In addition, the impact factors related to the clinical severity, age and the symptoms of phimosis for long-term outcome were explored.

Methods

Study design

This was a prospective observational study. All boys up to 12 years of age with a diagnosis of phimosis, who were referred to the children's hospital of Shenzhen from January 2016, were evaluated to determine the need for therapy. Objective grading of the tight foreskin was conducted as described by Kikiros and Woodward[5] (Grade 0: Full retraction, not tight behind the glans or easy retraction limited only by congenital adhesions to the glans. Grade 1: Full retraction of foreskin, tight behind the glans. Grade 2: Partial exposure of glans, prepuce (not congenital adhesions) limiting factor. Grade 3: Partial retraction, meatus barely visible. Grade 4: Slight retraction, but some distance between tip and glans, i.e., neither meatus nor glans can be exposed. Grade 5: Absolutely no retraction) (see Fig. 1).

Inclusion criteria

1 Age group: 2–12 years.
2 Severe phimosis (Kikiros retractability grade of 4 or 5).
3 Accepting the topical steroid or foreskin retraction treatment and completing the treatment course of 4 weeks.

Exclusion criteria

1 Pathological phimosis (failure to retract the foreskin due to distal scarring of the prepuce[1]).
2 Hypospadias or any other congenital anomaly.
3 Failure to complete steroid treatment.

Treatment evaluation criteria

1 Success was defined as downgrading of phimosis to grade 0 or 1.
2 Recurrence was defined as successful results of phimosis grade 0 or 1 at week 4, which reverted to phimosis grade >2 at follow-up.

Data on phimosis-associated clinical symptoms, such as balanoposthitis, ballooning of prepuce or a history of UTI, as well as side effects of local LST, including local erythema, burning sensation, pigmentation changes and hypertrichosis, were collected. This study was approved by the ethics committee of Shenzhen Children's Hospital (2015116).

Application of topical steroid and foreskin retraction treatment

The enrolled patients were treated by applying 0.1% mometasone furoate cream twice a day on gently stretched prepuce for 4 weeks. The instructions for the use of the topical steroid ointment were thoroughly explained and demonstrated to the parents prior to starting the treatment at home.

Follow-up cohort

The patients were re-evaluated at week 2, 4, 8 and 6 months after initial treatment. The criteria of Kikiros and Woodward classification system were used for evaluation by the same paediatric urologist. All patients with successful outcomes were required to try to gently retract the foreskin daily and maintain prepuce hygiene, and reassessed after 6 months. A final outpatient revisit was held at the end of the study period to assess the outcomes between August 2019 and February 2020.

Statistical Analysis

Statistical analysis was performed with SPSS 22.0 for Windows. Categorical variables were presented as the number of cases and percentages and compared using the χ^2 test. Continuous variables

that did not follow a normal distribution were described as median with interquartile range. Univariate analysis was performed to identify factors associated with a poor outcome. Variables with a P value <0.05 in the univariate analysis were included in the final model for multivariable analysis, and the odds ratio and 95% confidence interval were calculated. A P value <0.05 was considered statistically significant. The Bonferroni correction was applied for multiple comparisons among different age and symptom groups.

Results

Overall results

After receiving parental consent, a total of 1550 patients with a Kikiros retractability grade of 4 or 5 were enrolled into the study. A total of 1499 patients completed the treatment, and 51 boys were excluded from the study due to side effects of steroids or were lost to follow up. In terms of side effects, 23 cases developed local erythema or burning sensation, and the symptoms disappeared after cessation of steroid. The patients had no systemic side effects. The follow-up period ranged from 6 to 50 months (mean, 26.9 months), 69 cases were lost to follow up, including 28 lost to follow up within 4–8 weeks and 41 lost to follow up from 8 weeks to the final follow-up. A total of 302 children underwent surgery, of which 251 were for failures and 51 for recurrences.

Temporal response to LST

At the end of week 2, 65.7% of patients responded to treatment. Patients who had initial grade 4 phimosis, 2–4 years or asymptomatic group presented with higher response rates than those of the control groups. During therapy lasted from 2 to 4 weeks, only 15.7% responded on continuation of LST. Patients who had initial grade 5 phimosis presented with higher response rate compared with grade 4 patients, patients aged 5–7 years had higher response rate than that of other age groups, while patients with symptom of balanoposthitis presented with lower response rate compared with the other groups. The total success rates of grade 4 phimosis, 2–4 years and asymptomatic groups presented with higher response rate than those of the control groups at 2, 4, 8 weeks and long term (Tables 1–3).

Long-term efficacy of LST in different groups of phimosis

Patients with grade 4 phimosis showed better outcomes than grade 5 at different follow-up times after the initial therapy. At 4 and 8 weeks, the 8- to 12-year age group had poorer outcomes than the 2- to 4-year and 5- to 7-year age groups ($P < 0.001$). The 8- to 12-year age group had significantly poorer outcomes than the 2- to 4-year age group after 6 months (56.6% vs. 71.0%, $P < 0.001$). Patients with balanoposthitis showed lower success rates at different follow-up times, which were significantly different from the other groups (Tables 1–3).

Recurrence of severe phimosis

A total of 138 cases had recurrence of phimosis, of which 81 (58.7%) recurred within 8 weeks, while 57 (41.3%) recurred after 8 weeks, including 36 cases within 8 weeks to 6 months, 12 cases within 6–12 months and 9 cases after 12 months, as late as 29 months. Eighty-nine cases with recurrence were of initial grade 5, while 49 cases were of grade 4 group. There were 57 cases, 49 cases and 32 cases with recurrence in 2- to 4-year-old, 5- to 7-year-old and 8- to 12-year-old groups respectively; 43 cases, 21 cases, 55 cases, 19 cases with recurrence were found in asymptomatic, ballooning, balanoposthitis and history of UTI groups respectively. The multivariate analysis showed that the independent risk factors for phimosis recurrence were initial grade 5 and symptom of balanoposthitis ($P < 0.05$) (Table 4).

Discussion

Many recent studies reported 67%–95% success rates of topical steroid treatment for phimosis.[2,7] In this study, 71.1% of patients showed a successful outcome at the end of week 4 that was

Table 1 Outcomes at 4 weeks and long-term follow-up in patients with different grades of phimosis

—	Grade				
—	4	5	Total	P	χ^2
No. of boys (%)	673 (44.9)	826 (55.1)	1499	NA	NA
Success in week 2 (%)	481/673 (71.5)	504/826 (61.0)	985/1499 (65.7)	0.165 (0.005)	1.923 (7.817)
Success in week 4 (%)†	22/192 (11.58)	59/322 (18.33)	81/514 (15.7)	0.039	4.270
Total at 4 weeks (%)	503/673 (74.7)	563/826 (68.2)	1066/1499 (71.1)	0.005	7.817
Success in week 8 (%)‡	473/657 (72.0)	509/814 (62.5)	982/1471 (66.8)	<0.001	14.671
Success at last follow-up (%)§	450/630 (71.4)	469/762 (61.5)	919/1392 (66.0)	<0.001	15.006

†Calculated success rate from unresponsive cases at 2 weeks.

‡Calculated from total success rate and follow-up at 4 weeks from the initiation of therapy.

§Forty-one cases were lost to follow up between 8 weeks and last follow-up from the initiation of therapy, including 6 effective cases: 2 at grade 4 and 4 at grade 5; 38 cases underwent circumcision after 8 weeks follow-up.

NA, not applicable.

Table 2 Outcomes at 4 weeks and long-term follow-up in patients in different age groups

—	Age				
—	2–4	5–7	8–12	*P*	χ^2
No. of boys (%)	653 (43.6)	547 (36.5)	299 (19.9)	NA	NA
Success in week 2 (%)	476/653 (72.9)[a]	331/547 (60.5)[b]	178/299 (59.5)[b]	<0.001	26.584
Success in week 4 (%)[†]	12/177 (6.8)[a]	62/216 (28.7)[b]	7/121 (5.8)[a]	<0.001	47.081
Total at 4 weeks (%)	488/653 (74.7)[a]	393/547 (71.8)[a]	185/299 (61.9)[b]	<0.001	16.734
Success in week 8 (%)[‡]	454/641 (70.8)[a]	362/540 (67.0)[a]	166/290 (57.2)[b]	<0.001	16.636
Success at last follow-up (%)[§]	426/600 (71.0)[a]	342/525 (65.1)[a,b]	151/267 (56.6)[b]	<0.001	17.477

[†]Calculated success rate from unresponsive cases at 2 weeks.

[‡]Calculated from total success rate and follow-up at 4 weeks from the initiation of therapy.

[§]Forty-one cases were lost to follow up between 8 weeks and last follow-up from the initiation of therapy, including six effective cases: three in the 2- to 4-year age group, two in the 5- to 7-year age group and one in the 8- to 12-year age group. Meanwhile, 38 cases underwent circumcision after 8 weeks follow-up.

Multiple comparisons were performed among the different age groups using the Bonferroni method for all the variables. Statistically significant differences (adjusted *P* value <0.05) were identified among the 'a', 'b' and 'c' groups, but not within each group.

NA, not applicable.

Table 3 Outcomes of phimosis-associated symptoms at 4 weeks and long-term follow-up

—	Symptoms					
—	Asymptomatic	Ballooning	Balanoposthitis	History of UTI	*P*	χ^2
No. of boys (%)	529 (35.3)	282 (18.8)	480 (32)	208 (13.9)	NA	NA
Success in week 2 (%)	395/529 (74.7)[a]	206/282 (73.0)[a]	243/480 (50.6)[b]	141/208 (67.8)[a]	<0.001	86.444
Success in week 4 (%)[†]	29/134 (21.6)[a]	14/76 (18.4)[a,b]	27/237 (11.4)[b]	11/67 (16.4)[a,b]	0.062	7.325
Total at 4 weeks (%)	424/529 (80.2)[a]	220/282 (78.0)[a]	270/480 (56.3)[b]	152/208 (73.1)[a]	<0.001	76.448
Success in week 8 (%)[‡]	401/514 (78.0)[a]	209/277 (75.5)[a,b]	232/474 (48.9)[c]	140/206 (68.0)[b]	<0.001	106.693
Success at last follow-up (%)[§]	377/494 (76.3)[a]	196/268 (73.1)[a]	213/438 (48.6)[b]	133/192 (69.3)[a]	<0.001	89.336

[†]Calculated success rate from unresponsive cases at 2 weeks.

[‡]Calculated from total success rate and follow-up at 4 weeks from the initiation of therapy.

[§]Forty-one cases were lost to follow up between 8 weeks and the last follow-up from the initiation of therapy, including six effective cases: two in the asymptomatic, two in the balanoposthitis and two in the ballooning groups. Meanwhile, 38 cases underwent circumcision after 8 weeks follow-up.

Multiple comparisons were performed among the different age groups using the Bonferroni method for all the variables. Statistically significant differences (adjusted *P* value <0.05) were identified among the 'a', 'b' and 'c' groups, but not within each group.

NA, not applicable.

maintained in 66.0% of patients over a mean follow-up of 26.9 months, which was relatively low compared with other studies. There are four potential reasons for this low success rate. First, only boys with severe phimosis (Kikiros retractability grade 4 or 5) were enrolled in the present study. Second, the definition of treatment success in this study was full retraction of the foreskin, that is, Kikiros retractability grade 0 or 1. Third, 64.2% (963/1499) of boys had other symptoms, which might affect the efficacy of treatment. Fourth, this study was designed to determine the long-term effects of topical steroid treatment in phimosis, with a relatively long-term evaluation of treatment success.

The present study showed a significant difference in the long-term outcomes between grade 4 (71.4%) and 5 (61.5%) of phimosis, which was consistent with the findings of Reddy *et al.*[8] and Esposito *et al.*[9] that the long-term therapeutic success was related to the degree of phimosis. Sabino *et al.*[10] found that the changes in collagen fibres in foreskin area may be related to the site where the cream is deposited after its application, topical steroid may move it from the proximal area of foreskin to the distal area. We speculated that a corticoid ointment may not have any effect on the inner prepuce of grade 5 phimosis, and the drugs could easily fall off from the outer prepuce. In addition, the worse outcome with Grade 5 phimosis is probably due to further scarring occurring as grade 5 follows grade 4.

This study found that the long-term outcome deteriorated with increasing age, with the lowest success rate (56.6%) in the 8- to

Table 4 Logistic regression analysis for risk factors of recurrent phimosis

	Univariate analysis		Multivariate analysis	
Variables	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Initial grade	1.486 (1.006, 2.195)	0.046	ND	ND
4	ND	ND	ND	ND
5	ND	ND	1.565 (1.068, 2.294)	0.022
Age groups (years)	ND	0.125	ND	ND
2–4	Referent	ND	ND	ND
5–7	1.232 (0.797, 1.906)	0.348	ND	ND
8–12	1.717 (1.021, 2.887)	0.041	ND	ND
Symptom groups	ND	0.001	ND	ND
Asymptomatic	Referent	ND	ND	ND
Ballooning	1.047 (0.580, 1.891)	0.879	ND	ND
Balanoposthitis	2.379 (1.492, 3.793)	<0.001	2.034 (1.306, 3.166)	0.002
History of UTI	1.183 (0.652, 2.149)	0.580	ND	ND

Univariate analysis with 2–4 age group as dummy variable showed that the *P* value of 8–12 age group was 0.041, but the total *P* value of age group was more than 0.05, so the *P* value of 8–12 age group was not statistically significant.
ND, no data.

12-year age group. Changole *et al.*[11] reported poorer outcomes in boys above 5 years of age as compared to younger age group. Ku *et al.*[12] inferred that older patients were more likely to apply medication by themselves and may have a poorer compliance. Moreover, prepuce might spontaneously resolute over time in younger boys. However, Ashfield *et al.*[13] reported higher success rates with an increase in age, although without statistical significance. Zampieri *et al.*[14] studied the efficacy of topical steroid treatment on phimosis at different ages and found that the treatment was more successful in patients aged 4–8 years. In contrast, Ghysel *et al.*[15] and Ku *et al.*[12] found that the long-term outcome was not affected by the patient's age. Hence, the success rates at different ages need further study.

The present study showed that phimosis patients with a history of balanoposthitis had the lowest success rate (48.6%), compared to those with phimosis alone, ballooning of the prepuce and a history of UTI (76.3%, 73.1% and 69.3% respectively). Sabino *et al.*[10] and Zampieri *et al.*[14] reported that the patients with balanoposthitis are susceptible to developing a pathological process, and their foreskin tissue has excess collagen fibres and inflammatory cells, which might affect the efficacy of LST therapy. However, Ashfield *et al.*[13] reported no statistically significant differences among the groups of phimosis alone, balanoposthitis and history of UTI after topical steroid therapy. Chamberlin *et al.*[16] also reported no difference in treatment success based on prior history of balanoposthitis, and the number of cases of balanoposthitis not recorded. The negative results in the previous reports might be due to the small sample size, which were 194 cases and 46 cases, respectively. The success rates seemed to be influenced by the phimosis-associated clinical symptoms of patients at the beginning of steroid application.

The EAU Guidelines on Paediatric Urology in 2019[17] reported that a corticoid ointment or cream (0.05–0.1%) can be administered twice a day for 20–30 days, with a success rate of >90%. This study found that 65.7% of cases responded in the first 2 weeks. In addition, 15.7% of patients on continuous therapy for 4 weeks showed response, which was higher than the study by Reddy *et al.*,[8] which found that only 8.6% of grade 4 and 5 patients responded on further continuation to 4 weeks of therapy. The period of topical steroid application varies in different studies. Reddy *et al.*[8] concluded that continuing therapy for longer duration may not be very effective. However, Changole *et al.*[11] reported that 17.6% of patients responded between 4 and 6 weeks. Nascimento *et al.*[18] recommended to extend the treatment period to 8 weeks, since the results at 8 weeks (54.8%) were significantly better than at 4 weeks (31.3%), which was consistent with Zavras *et al.* study.[19] In addition, Chamberlin *et al.*[16] reported that success treatment response may be seen up to 12 weeks. These studies showed that the effective rates increased with prolonged therapy. Hence, further continuation of therapy may be a good option.

The reported recurrence rates of phimosis treated with topical steroid were variant, ranging from 4.0% to 34% in different studies.[12,14,20,21] In the present study, the recurrence rate was 7.6% and 12.9% at 8 weeks and 6 months after treatment, respectively. The long-term follow-up showed that the majority (58.7%) of recurrence occurred within 2 months, with 41.3% (57/138) recurrence after 6 months. Similarly, Reddy *et al.*[8] reported that 57.14% recurrence occurred within 6 months. Hence, extending the follow-up time to at least 1 year could better assess long-term efficacy of the treatment. Interestingly, history of balanoposthitis was a risk factor for phimosis recurrence in children. Zheng *et al.*[22] observed that the inhibition of proliferation of cultured human fibroblasts was transient, and there was restitution of the dermis and epidermis after cessation of steroid application. Recurrence could be related to this rebound phenomenon, which may result from the changes of pathological tissue structure in the patients. Moreover, grade 5 phimosis was an independent risk factor for recurrence.

In addition, regular daily foreskin retraction after initial treatment was also recommended. Daily foreskin retraction and hygiene were important for the sustained resolution of

phimosis.[12] Orsola *et al.*[23] found that patients with recurrent phimosis had been noncompliant with the suggested daily foreskin care. Ghysel *et al.*[15] and Zampieri *et al.*[24] demonstrated that phimosis treatment is most successful when the topical steroid is applied with gentle stretching of the foreskin.

This study had several advantages. First, it examined the efficacy of topical steroid therapy on the largest cohort of paediatric phimosis cases in China. Moreover, the study design was prospective; we collected more specific information of phimosis children before initial therapy and set up frequent follow-up visits for efficacy evaluation, which provided reliable evidence for the topical steroid treatment. Finally, we analysed the risk factors of recurrent phimosis in long-term follow-up. Patients with severe phimosis or balanoposthitis symptom might have the risk of recurrence.

This study had some limitations. The study included 1550 boys, but 97 cases were lost to follow up while 23 cases had side effects. Although the treatment arms were not compared with a placebo group in this study, it has been previously studied and well documented.

Conclusion

This study showed that topical application of 0.1% mometasone furoate is a safe and effective treatment for severe phimosis. The topical steroid could be the first choice of treatment for patients with severe phimosis, and it is recommended to apply twice a day for 4 weeks. Grade 5 phimosis and balanoposthitis were independent risk factors for recurrence.

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