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ORIGINAL ARTICLE

Outcome and recurrence in treatment of phimosis using topical betamethasone in children in Hong Kong

Wai-Hung Ku, Becky S-K Chiu and Kwai-Fun Huen

Department of Paediatrics and Adolescent Medicine, Tseung Kwan O Hospital, Hong Kong SAR, China

Aim: To study the efficacy of treating phimosis with topical steroid, and its long-term outcome and side effects. We also looked into the effect of daily retraction and cleansing of prepuce on preventing recurrence of phimsosis.

Methods: This prospective study comprised 138 boys who were prescribed 0.05% betamethasone ointment (Diprocel) during 1 August 2001–31 July 2004. Five boys were excluded because of non-compliance. Of the remaining 133 boys, 108 were followed-up and assessed. Age ranged from 0.03 to 12.9 years (mean = 3.38, SD = 2.79). The number of treatment course received, short-term and long-term outcome, side effects and the effect of daily foreskin retraction were studied.

Results: The success rate of first treatment course was 81.5%, and 60.2% of boys remained free from phimosis upon latest assessment. The follow-up period ranged from 0.4 to 4.4 years (mean = 2.45, SD = 0.90). There were no side effects noted. We found a significant and linear relationship between daily foreskin retraction and sustained resolution of phimosis.

Conclusion: Topical steroid is an effective and safe treatment for phimosis, especially when combined with a good hygiene practice of the foreskin with daily cleansing and retraction. A trial of topical steroid treatment should be offered upon considering circumcision.

Key words: betamethasone; paediatric; phimosis; topical steroid.

Over the past decade there has been an increasing interest all over the world to use topical steroid for treatment of phimosis. Different articles had been published and the results were promising. The reported successful rate was 67%[1]–100%.[2] In Hong Kong, Ng *et al*. had also concluded the effectiveness of topical trimacinolone to treat phimosis.[3] There were no local or systemic adverse effects being reported.[4] The risk of surgery as well as those associated with general anaesthesia could also be avoided. However, so far there was no study focused on the long-term outcome and side effects, the recurrence of phimosis and importance of daily retraction after the treatment. In our study we aimed to look into the above aspects, and to provide more information and evidence in the use of topical steroid in treatment of phimosis in children in Hong Kong.

Key Points

1 Topical steroid is a safe and effective treatment for phimosis.
2 The importance of good hygiene practice including daily cleansing and retraction must be emphasized.
3 A trial of topical steroid treatment should be offered upon considering circumcision.

Correspondence: Dr Wai-Hung Ku, Department of Paediatrics and Adolescent Medicine, Tseung Kwan O Hospital, 2 Po Ning Lane, Hang Hau, Tseung Kwan O, New Territories, Hong Kong SAR, China. Fax: +86-852-2174-9956; email: kuwh2002@yahoo.com.hk

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Methods

From 1 August 2001 to 31 July 2004, there were 138 boys with phimosis being treated with topical steroid in the Department of Paediatrics and Adolescent Medicine, Tseung Kwan O Hospital. The patients were recruited from the paediatric ward as well as the paediatric outpatient clinic. Phimosis was examined because of urinary tract infection, parents' concern or during routine physical examination. Phimosis was defined as a cone-shaped foreskin with a fibrotic circular band which forms the most distal and narrowest part of the prepuce during attempted gentle retraction of the prepuce (Fig. 1). In contrast to a normal non-retractable foreskin, during the same gentle retraction results in pouting of the distal prepuce, with narrow portion proximal to the tip of prepuce (Fig. 2).[5] Exclusion criteria were current active balanoposthitis, recurrent urinary tract infections, balanitis xerotica obliterans (BXO), buried penis, and phimosis secondary to incomplete circumcision. The topical steroid used was 0.05% betamethasone ointment (Diprocel, Schering-Plough Corporation, Kenilworth, NJ, USA).

The treatment options for phimosis using topical steroid or surgery were discussed with the parents and/or guardian and/or patients. A verbal consent was obtained if they agreed for the steroid treatment. The parents and/or guardian and/or patients were instructed to apply the ointment twice daily, after washing or bathing, for 4 weeks to the foreskin. After the foreskin became retractable, patients and/or their parents were asked to retract the foreskin gently without causing any pain. They were also instructed to wash the prepuce daily during bathing once it became retractable. Patients were followed up

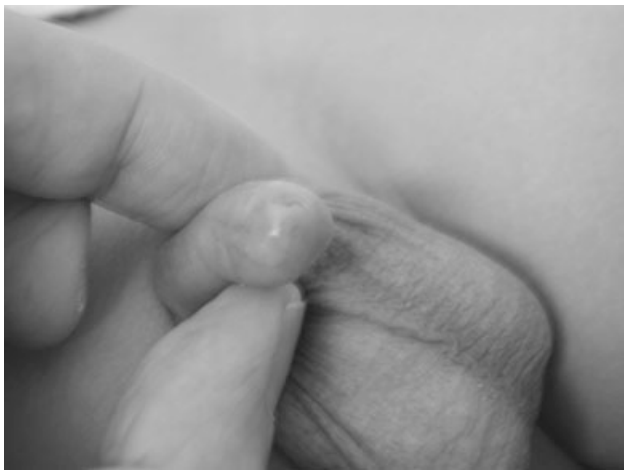

Fig. 1 True phimosis. The narrowest portion formed the most distal part of the prepuce upon retraction.

Fig. 2 Non-retractile prepuce. Note the proximally located narrow portion.

at 4 weeks' time for treatment effect. If the phimosis did not resolved, the patient would be offered another course of 4-week treatment. The maximum consecutive treatment period was limited to 8 weeks. Upon further follow-up in the outpatient clinic, further treatment courses of topical steroid were offered to parents if there were recurrences of phimosis.

During January to March 2005, all of the patients being treated with topical steroid were called back for assessment. A complete patient list was obtained from the Pharmacy Department of Tseung Kwan O Hospital which contained all patient names who were prescribed Diprocel (included inpatient and outpatient), in order to prevent missing data. The patients were examined for phimosis using the same definition as before. Criteria for response to steroid treatment were complete exposure of the glans with or without a tight ring behind the glans, or partial exposure of the glans limited by the adhesion of the inner surface of the foreskin to the glans (Fig. 3).[6] Any presences of possible local side effects were also looked for, including striae, pigmentation, hypertrichosis and telangiectasia. For each treatment course, the patients or their parents were asked whether they had daily retraction and cleansing of the retractable foreskin, and any episodes of balanitis occurred during the treatment.

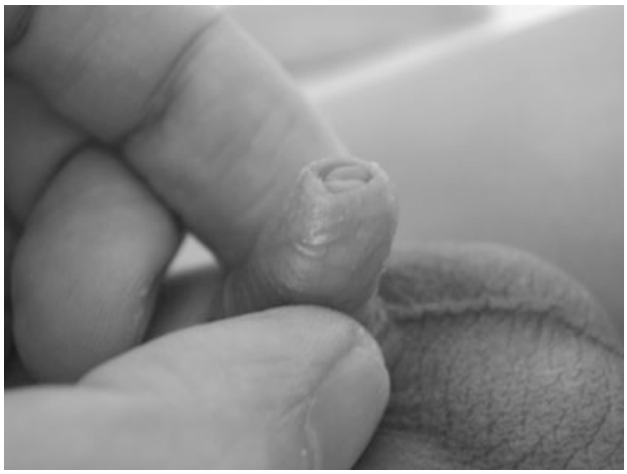

Fig. 3 Retractable prepuce after 4 weeks of treatment.

The effect on the long-term outcome by the number of treatment courses, age of start of the first treatment and the follow-up period were analysed. The effectiveness of treatment (first treatment and long-term outcome) in boys <3 years were compared with those boys ≥3 years old. We had also looked into the effect of daily retraction on the long-term outcome. The χ^2-test and the Spearman's rank correlation test in the SPSS (Statistical Package for the Social Sciences, SPSS Inc., Chicago, IL, USA) version 13.0 were used for data analysis.

Results

Of the 138 boys who underwent treatment, five boys were excluded from the study because of non-compliance. The remaining 133 boys were called back for follow-up. One hundred and eight boys had attended the follow-up and were analysed. For the 25 defaulters, eight had lost contact, 10 parents thought their child's prepuce was well and not required follow-up, and seven were unable to come back during our follow-up period. The outcome of the boys was shown in Figure 4.

The age of first treatment ranged from 0.03 to 12.9 years (mean = 3.38, SD = 2.79). Fifty per cent of the boys (54/108 boys) were younger than 3 years old. There were 27 boys who had history of urinary tract infection, in which six of them had vesico-ureteric reflux. Two boys had nocturnal enuresis; another two boys had history of balanitis before treatment. The number of treatment course received ranged from one to four, 73 boys had received one treatment course, 24 boys received two treatment courses, nine boys received three treatment courses, and two boys received four treatment courses. The total number of treatment course was 156; in average each boy received 1.44 treatment courses. The maximum consecutive

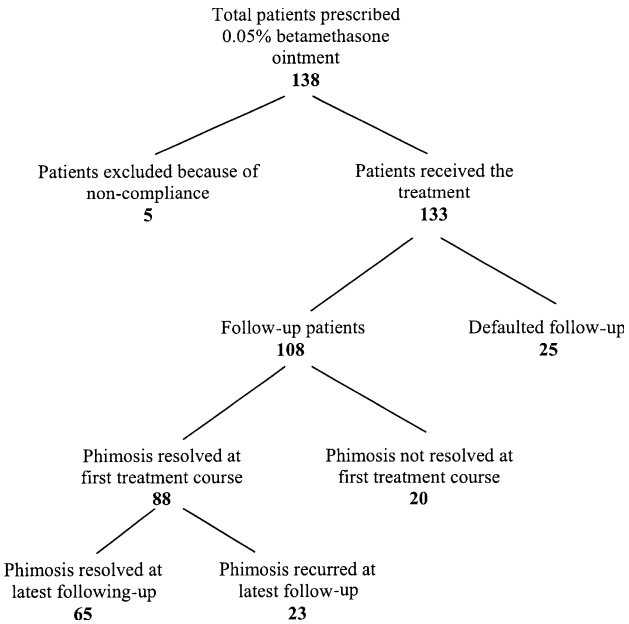

Fig. 4 Outcome of the boys with phimosis treated with topical steroid.

Table 1 Number of treatment courses received and the latest treatment outcome

Treatment courses received	Latest treatment outcome		Total
	Phimosis persisting	Phimosis resolved	
1	31	42	73
2	8	16	24
3	3	6	9
4	1	1	2
Total	43	65	108

$r = 0.088$; $P = 0.367$.

Table 2 Latest treatment outcome in patients younger and older than 3 years old

Age (year)	Latest treatment outcome		Total
	Phimosis persisting	Phimosis resolved	
<3	18	36	54
≥3	25	29	54
Total	43	65	108

$\chi^2 = 1.89$, $P = 0.169$.

Table 3 First treatment outcome in patients younger and older than 3 years old

Age (year)	First treatment outcome		Total
	Phimosis persisting	Phimosis resolved	
<3	4	50	54
≥3	16	38	54
Total	20	88	108

$\chi^2 = 8.84$; $P = 0.003$.

treatment period was 8 weeks (which was two consecutive treatment courses). For the 156 treatment courses, phimosis resolved with topical steroid in 129 treatment courses, that is, a success rate of 82.7%.

In 88/108 boys (81.5%), their phimosis resolved after the first treatment course. Upon our final outcome assessment, 65/108 boys (60.2%) remained free from phimosis. The sustained time of resolution of phimosis was 1 to 43 months (mean = 24.3 months, SD = 11.7 months). In 54/65 boys (83.1%) the sustained time of resolution was 12 months or longer. Of 108 boys, 16 (14.8%) had undergone circumcision either because of failure of treatment or recurrence of phimosis.

The age upon final outcome assessment was 1.4 to 14.1 years (mean = 5.84, SD = 2.90). The follow-up period ranged from 0.4 to 4.4 years (mean = 2.45, SD = 0.90 years).

We analysed the data with χ^2-test and Spearman's rank correlation test. All the tests were 2-tailed and the level of significance was set at 0.05 level. The results of Spearman's rank correlation tests showed that there were no significant relationships between the number of treatment courses and the long-term outcome ($r = 0.088$, $P > 0.05$) (Table 1), the age of start of treatment and the long-term outcome ($r = -0.026$, $P > 0.05$), the follow-up period and the long-term outcome ($r = -0.048$, $P > 0.05$).

Chi-squared test indicated that there were no significant differences on the *latest* treatment outcome between boys <3 years and those ≥3 years old ($\chi^2 = 1.89$, $P > 0.05$) (Table 2). There were significant differences on the *first* treatment outcome between boys <3 years and those ≥3 years old ($\chi^2 = 8.84$, $P < 0.05$). The results showed that in the younger group, 50/54 boys (92.6%) responded to the first treatment, compared with 38/54 boys (70.4%) in the older group (Table 3).

For the comparison between the characteristics of two groups, χ^2-test indicated that there were no significant differences on the number of treatment courses received ($\chi^2 = 3.79$, $P > 0.05$) or follow-up period ($\chi^2 = 38.88$, $P > 0.05$) between boys <3 years and those ≥3 years old.

The results of Spearman's rank correlation tests showed that there was a significant and linear relationship between daily foreskin retraction and sustained resolution of phimosis ($r = 0.76$, $P < 0.01$).

There were no local side effects noted upon our final assessment, including striae, pigmentation, hypertrichosis, and telangiectasia. There was no report of balanitis during the steroid treatment. In one patient his mother reported an episode of balanitis, but she could not recall the detail and the date of

the incidence, and was not sure whether the balanitis occurred during the steroid treatment or after the recurrence of the phimosis. It was worth to note the boy was found to have recurrence of phimosis upon our final assessment. As she did not bring the boy to see any doctor, we were not able to trace back the detail and the date of the balanitis.

Discussion

Physiological versus pathological phimosis

The incomplete separation of the prepuce from the glans is common and normal in male neonates and infants, and their separation will continue till adolescence.[7] Attempted retraction of the foreskin will be limited by the congenital adhesions between the prepuce and the glans, with the exposure of the urethral meatus and the adjacent glans penis.[8] Sometimes the condition is called physiological phimosis, which means asymptomatic non-retractable foreskin. In pathological phimosis, however, the hindrance upon retraction is distal to the glans penis, so often the urethral meatus and the glans may not be visible.[8]

Incidence of phimosis

In England the incidence of pathological phimosis was estimated to be 0.4 cases per 1000 boys per year.[9] In Australia Kikiros *et al*. found about 3% to 5% of uncircumcised boys will develop phimosis.[8] In other studies the reported incidences of phimosis varied at 0.2% to 0.3%,[10] 1.7%[11] and 2.94%.[12] Krueger and Osborn studied 28 boys who were more than 4 years and found 10.7% of them had phimosis.[13] In New Zealand Fergusson *et al*. followed a cohort of 1265 boys, reported the incidence of phimosis under 8 years of age was 16%.[14]

Studies review

We did a computer search in the MEDLINE database using the headings 'phimosis', 'topical steroid' and 'circumcision' from 1979 to 2005. There were four randomised controlled trials, in which two studied the effect of topical steroids versus placebo,[15,16] one studied the effectiveness of steroid with different potencies,[17] and one studied the effectiveness of a topical non-steroidal anti-inflammatory drug.[18] There was another randomised controlled trial focused on the treatment of BXOs using topical steroid.[19] Fourteen non-randomised clinical trials were recruited, 13 of them studied topical steroid[1–4,6,8,20–26] and the remaining one studied a topical conjugated equine estrogen in treating phimosis.[27]

The most commonly studied topical steroid in the clinical trials was betamethasone, in the form of 0.05% cream,[1,4,16,20–23] 0.06% cream,[6,17] 0.05% ointment,[8] or 0.1% ointment.[24] Of note, the concentration of betamethasone in Wright's report was misprinted as 0.5% instead of 0.05%.[21] Other agents included 0.05% clobetasol,[15,17,25,26] 0.02% triamcinolone,[2,3] 1% and 2% hydrocortisone.[8] Atilla *et al*. studied the effectiveness of diclofenac sodium ointment which was a non-steroidal anti-inflammatory drug.[18] Yanagisawa *et al*. used topical 0.1% conjugated equine estrogen to treat phimosis.[27]

The reported success rate was 67%[1]–100%.[2] Golubovic *et al*. reported the significant difference of treatment effect of 0.05% betamethasone cream from the placebo with the success rate of 95% (19/20).[16] Lindhagen reported the success rate of 89% (24/27) using 0.05% clobetasol propionate.[15]

The sample size ranged from 15[27] to 276[6] boys (mean = 78.1), with only four out of 18 reviewed studies the sample size was greater than 100 boys. The follow-up period was reported in 16 studies, ranged from 4 weeks[1,6,16,18] to 16 months[20] (mean = 17.4 weeks). However, the 16th month follow-up was conducted by phone. If excluding this study the longest follow-up period would be 13 months.[3]

Cost of topical steroid versus circumcision

The cost of treating phimosis using topical steroid has been compared with circumcision. For the medical treatment the cost includes the medication and the fees corresponding to two consultations by a specialist (paediatrician or urologist) before and after the treatment. The cost of circumcision comprised of the price of the hospital stay, consultation fees and pharmacy. Additional cost has to be included if there is any complications.[28] Van Howe has concluded the overall cost of therapy by topical steroid is approximately 25% of circumcision. It was recommended to initiate a course of topical steroid before deciding for circumcision, which may save up to 75% of the treatment cost.[29]

Mechanism of topical steroid

Topical steroid has anti-inflammatory, immunosuppressive and skin thinning effect.[5] In the treatment of phimosis the steroid may make the foreskin thinner, improves its elasticity, and reduce any inflammatory component. It allows the foreskin to be retracted and daily hygiene to be performed.[4] In one of the two randomised controlled trial comparing topical steroid with placebo, the effect of topical steroid appeared to be significantly better than that of placebo.[16] In another trial the result was not statistically significant, in which may be the sample size was too small.[15]

The 0.05% betamethasone dipropionate ointment used was classified as a potent corticosteroid. Hepburn *et al*. has reviewed the efficacy and safety profile of the topical steroids, and reported the side effects are very rare.[30] We had reported no local side effects during our follow-up period. The 0.05% betamethasone appeared to be more effective than the 1% hydrocortisone in treating phimosis.[5]

While Golubovic *et al*.[16] used topical steroid for phimosis with cut-off points of patient age of 3 years, Elmore *et al*.[20] and Yang *et al*.[17] have proven the therapeutic effect of topical steroid for phimosis in children younger than 3 years old. Monsour *et al*. has successfully administered the topical steroid in two boys younger than 3 years.[1] There was no side effect reported. In our study 50% of the boys were 3 year old or younger, and we found no local side effects. Although with the adherence between the prepuce and the glans is considered as physiological phimosis, the boys at these age are often referred to urologists for circumcision. Topical steroid can be offered as an alternative to avoid unnecessary circumcision.[17] In addition, in

young infants who have history of urinary tract infection phimosis will make the urine surveillance more troublesome. With a retractable prepuce, the peri-meatal region can be cleaned and the possibility of contamination of urine sample can be reduced.

Failure of treatment and recurrence of phimosis

In our results the success rate of 81.5% was comparable with other studies (67%[1]–100%[2]). Wright and Orsola *et al*. had suggested the key factor in predicting successful treatment was the compliance of the patients and parents.[4,21] Chu *et al*. had the similar conclusion.[6] We found the long-term outcome was not affected by the patient's age, but the initial treatment was more effective in younger patients. In older patients the medication was more likely to be applied by patient themselves, who had a poorer compliance.[1] Upon offering the option and explaining the treatment of phimosis using topical steroid, the compliance and method of steroid application should be given in detail to the parent and/or the patient.

The reported recurrence rate of phimosis treated with topical steroid was 13% to 19%. Ruud and Holt had reported the recurrence rate of 34%.[26] The most important factor in preventing recurrence is the regular daily routine foreskin retraction and hygiene. Orsola *et al*. found all patients with persistent or recurrent phimosis were non-compliant to the suggested daily foreskin care.[4] The recurrence may be related to the rebound phenomenon described by Zheng *et al*.[31] They observed the inhibition of proliferation of cultured human fibroblast was transient, and there was restitution of the dermis and epidermis after cessation of steroid. With the understanding of the rebound phenomenon, it is important to commence daily retraction together with daily cleansing once the phimosis is resolved in order to prevent recurrence.

In our study, the long-term success rate was 60.5% with the mean follow-up period of 2.45 years (SD = 0.90), the longest follow-up period was 4.4 years. We had shown the significant difference of daily retraction of the prepuce in prevention of recurrence of phimosis. The finding of no significant difference in the latest treatment outcome between the younger and older group suggested the main determinant of long-term outcome was daily prepuce retraction rather than spontaneous resolution with age. We believed that the topical steroids only act temporarily in treating phimosis, and the key to long-term success is the modification of the local handling and hygiene practice of the foreskin.[4]

There are groups of boys who are not good candidates for steroid treatment. Chu *et al*. had reported the unsatisfactory treatment response in boys with buried penis. It is difficult to retract the foreskin along a short penile shaft, which may obscure the application of steroid over the phimotic ring and retraction of foreskin.[6]

The presence of BXOs was considered as an absolute indication for circumcision.[5,21] It comprised of atrophic and sclerotic pathological changes of the prepuce.[19] It is thought to occur in about 1% of boys, and is extremely rare under the age of 5 years. The etiology is unknown but it commonly occurs as a result of forceful retraction of the prepuce.[32] Monsour *et al*. suggested that patients who failed the topical steroid treatment and eventually underwent circumcision were more likely to have BXO, although they did not confirmed their observation.[1] Shankar *et al*. had reported the rate of BXO found on excised prepuce histological examination was 14%, which was close to the failure rate of topical steroids (19%).[9] Although we did not performed histological examination on the excised prepuce, our rate of circumcision (14.8%) was comparable with the failure rate of topical steroid treatment (18.5%).

Kiss *et al*. had conducted a randomised controlled trial in treatment of BXO using 0.05% mometasone furoate ointment in 40 boys aged 5–15 years. He concluded the steroid treatment was effective when there was active inflammation and before occurrence of irreversible tissue damage, which included the early and intermediate histological form of BXO.[19]

Side effects

The side effects could either be local or systemic because of steroid absorption. Studies reported the topical steroid was well tolerated and there was no local side effect noted.[4] The hypothalamus-pituitary-adrenal axis could be suppressed if there was excessive steroid absorption. Golubovic *et al*. studied the early morning blood spot cortisol levels and there were no significant difference between the 0.05% betamethasone cream and the placebo group.[16] He suggested because the foreskin comprised of less than 1% of the total body surface area and thus the systemic effects are very unlikely. We found no local side effects during our follow-up period. In another study there was a boy developed gynaecomastia after treatment with topical conjugated equine estrogen.[27]

The treatment period of the studies ranged from 4 to 8 weeks. Ng *et al*. has reminded the safety of prolonged treatment course resulted from slow responders or recurrent phimosis.[3] In our patients, the maximum number of treatment course received was four, and the longest consecutive treatment period was limited to 8 weeks.

Recommendations and Conclusion

We found topical steroid is an effective and safe treatment for phimosis, especially when combined with a good hygiene practice of the foreskin consisting of daily retraction and cleansing. A trial of topical steroid treatment should be offered upon considering circumcision, with proper and sufficient information provided to parents before they decided for surgical or medical management of their child's phimosis.

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