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To Compare the Outcome of Estrogen and Betamethasone Cream in the Treatment of Labial Adhesion in Pre-pubertal Girls

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Abstract

Background: *Labial adhesion is a condition of prepubertal girls where the labia are fused over the vaginal opening and/or urethra.*

Objective: *The purpose of the study was to compare the outcome of estrogen and betamethasone cream in the treatment of labial adhesion.*

Materials and methods: *This prospective comparative study was conducted among 100 pre-pubertal girls with labial adhesion where at least 50% vaginal opening was fused. Patients previously treated with estrogen or betamethasone for labial adhesion was excluded from the study. Fifty patients were treated with betamethasone cream (group 1) and fifty patients with estrogen cream (group 2) after randomization. All patients were followed at 3rd week, 6th week, 3rd month, 6th month and then release of adhesion and adverse effects were noted.*

Results: *Within 3 weeks no adhesion was found in 84.0% participants in group 1 and 64.0% participants in group 2, which showed significant statistical differences (p=0.023). Within 6 months recurrence of adhesion was found in 2.2% participants in group 1 and 23.4% in group 2, which also showed highly significant statistical differences (p=0.004). Success rate was 90.0% and 72.0% within 6 months in group 1 and in group 2 respectively and the difference was statistically significant (p=0.022).*

Conclusion: *Betamethasone cream appears to be a superior agent in terms of effectiveness, safety and cost than estrogen cream in the treatment of labial adhesion in pre-pubertal girls.*

Key words: *Labial adhesion, betamethasone cream, estrogen cream*

Introduction

Labial adhesion is a condition of prepubertal girls in which the labia are fused over the vaginal opening and/or urethra. Labial adhesions are estimated to occur in 22% of prepubertal girls and are most frequent in ages 3 months to 6 years.[1] The cause of labial adhesion appears to a mild inflammatory condition in a child with a thin layer of labial epithelial cells secondary to a low estrogen level.[2] Most children with minor agglutination of the labia are asymptomatic. When symptoms occur, they are often related to interference with voiding, such as dysuria or altered urinary stream, or symptoms related to the accumulation of urine behind the agglutination predisposing to vaginal or urinary tract infections.[3] Although topical estrogen has traditionally been considered first line therapy, this method of treatment can be associated with side effects including breast budding and vaginal bleeding.[1] An alternative topical treatment considered recently is 0.05% betamethasone. Using 1 to 3 courses of twice-daily betamethasone for 4 to 6 weeks showed promising results in 19 children who failed previous treatments.[4]

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The present study was undertaken to compare the outcome of estrogen and betamethasone cream in the treatment of labial adhesion in pre-pubertal girls.

Materials and methods

This prospective comparative study was carried out on pre-pubertal girls who came for treatment of labial adhesion at the Out Patient Department of Dhaka Shishu (Children) Hospital from January 2015 to December 2017. The study was conducted among 100 pre-pubertal girls with labial adhesion where at least 50% vaginal opening was fused. Patients previously treated with estrogen or betamethasone for labial adhesion was excluded from the study. Routine & microscopic examination with culture sensitivity test of urine was done for patients. If the labial adhesion was severe with only a small pin-point opening on the labia, it was termed as complete labial adhesion. After randomization fifty patients were treated with betamethasone cream (group 1) and fifty patients with estrogen cream (group 2). The parents of the children were instructed to apply a thin layer of cream to the raphe along the adhesion line twice daily. A single course of treatment was defined as a 3-week course. All children were treated with 1 to 2 courses. All patients were followed at 3rd week, 6th week, 3rd month, 6th month. During each follow up visit, release of adhesion and adverse effects such as pigmentation of genitalia, redness and breast budding were noted. Associations of continuous data were assessed using student t- test. Associations of categorical data were assessed using Chi-square test and Fisher's exact test. For both tests, $p<0.05$ was considered significant.

Results

Age, weight, types of labial adhesion and presence of associated symptoms between two groups showed no statistical differences (table I). In group 1, 13 participants had UTI, 4 had poly urea and 5 had post void dripping where as in group 2, 16 participants had UTI, 5 had poly urea and 6 had post void dripping (figure 1). In group 1, 84.0% participants had no adhesion within 3 weeks whereas in group 2, 64.0% which showed significant statistical differences (p=0.023). In group 1, 92.0% participants had no adhesion within 6 weeks whereas in group 2, 94.0% which did not show any significant statistical differences (p=1.000) (table II). In group 1, 92.0% participants developed no side effects whereas it was 86.0% in group 2. In group 1, 8.0% participants developed local irritation. In group 2, 8.0% participants developed breast budding and 6.0% participants developed hyperpigmentation (figure 2). Recurrence of adhesion within 6 months was found in 2.2% participants in group 1, & 23.4% in group 2, which showed highly significant statistical differences (p=0.004) (table III). Success rate was 90.0% in group 1 and 72.0% in group 2 within 6 months which showed significant statistical differences (p=0.022) (table IV). The cost of one tube Betamethasone was 35 taka whereas the cost of one tube estrogen was 1000 taka (table V).

Table-I

Comparison of baseline characteristics of the participants between two groups

Baseline characteristics	Group 1 (n=50)	Group 2 (n=50)	P value
Age (in months) Mean SD	11.90	11.06	0.426
Weight (in kg)	8.91	8.36	0.399
Complete adhesion	22(44.0%)	26(52.0%)	0.423
Presence of symptom	22(44.0%)	27(54.0%)	0.317

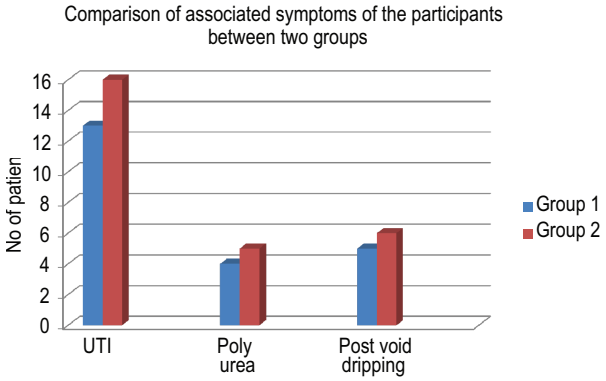

Fig.-1: *Comparison of associated symptoms of the participants between two groups*

Table II

Comparison of release of adhesion between two groups

Release of adhesion	Group 1 (n=50) No. (%)	Group 2 (n=50) No. (%)	P value
Within 3 weeks	42(84.0%)	32(64.0%)	0.023
Within 6 weeks	46(92.0%)	47(94.0%)	1.000

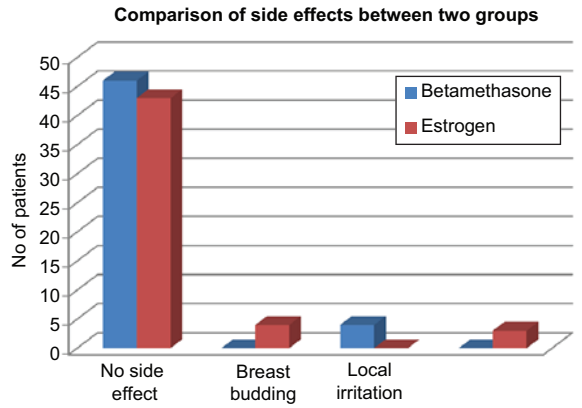

Fig.-2: *Comparison of side effects between two groups*

Table-III

Comparison of recurrence of adhesion within 6 months between two groups

Recurrence of adhesion	Group 1 (n=46) No. (%)	Group 2 (n=47) No. (%)	P value
Yes	1(2.2%)	11(23.4%)	0.004
No	45(97.8%)	36(76.6%)	

Table IV

Comparison of success within 6 months between two groups

Success within 6 months	Group 1 (n=50) No. (%)	Group 2 (n=50) No. (%)	P value
Yes	45(90.0%)	36(72.0%)	0.022
No	5(10.0%)	14(28.0%)	

Table V

Comparison of cost of cream between two groups

	Amount in per tube	Cost in taka
Group 1	10 gm	35
Group 2	10 gm	1000

Discussion

Labial adhesion is a phenomenon recognized by many pediatricians.[2] Complications of labial adhesion are usually minor and include dysuria and local inflammation in the labial area; however, labial adhesion can also be associated with urinary tract infections, and this is the main reason to treat this condition.[5] While adhesion is a concern to families, the first line of therapy is reassurance, as close to 80% of labial adhesions will resolve spontaneously within a year after they are diagnosed. Other measures are estrogen cream and manual or surgical opening of the labia.[6] This prospective study was done to compare the outcome of estrogen and betamethasone cream in the treatment of labial adhesion in pre-pubertal girls. In this study near about half of the respondents had associated symptoms other than labial adhesion which were UTI, poly urea and post void dripping. Although UTI occurs in 3-5% of girls in the normal population, the rate in those with labial adhesion can be as high as 20-40%.[7] In group 1, 26% and in group 2, 32% respondents were suffering from UTI which is similar with the findings of Sanfilippo.[7] Melek et al. found that there was a marked association between the presence of UTI and the type of adhesions. The percentages of UTIs in girls with complete and partial LA were 84.0% and 28.6%, respectively ($P < 0.05$). The percentages of UTIs in girls with thick and thin LA were 100% and 44.1%, respectively ($P < 0.05$).[8]

Significant statistical difference was found between the groups regarding release of adhesion within 3 weeks. At the end of 6 months 2.2% participants had recurrence of adhesion in betamethasone group & 23.4% in estrogen group. Mayoglou L et al in their study found recurrence rate in betamethasone and estrogen group as 15.8% and 35% respectively.[9]

Side effect of betamethasone was found local irritation which developed in 8.0% patients. The side effects of estrogen were found breast budding and hyperpigmentation which developed in 8.0% and 6.0% patients respectively. Mayoglou L et al. in their study reported that short-term side effects of topical estrogens include breast budding, rash or irritation, and vaginal bleeding and short-term side effects of betamethasone include erythema, folliculitis, pruritus, vesiculation, fine hair growth, and skin atrophy.[9]

The result of the present study indicated that the success rate of the treatment was 90.0% in betamethasone group and 72.0% in estrogen group. A retrospective study was conducted in Turkey to compare estrogen and betamethasone where the success rate of the betamethasone treatment exceeded that of the topical estrogen (89.4% and

80%, respectively).[10] The present study also found that the success rate of the betamethasone treatment exceeded that of the topical estrogen.

In a low income country like Bangladesh the cost burden of health care is likely to be significant for most citizens. The cost of one tube Betamethasone was 35 BDT (Bangladeshi taka) whereas that of estrogen was 1000 BDT. This supports that betamethasone is more cost effective than estrogen in treatment of labial adhesion.

Conclusion

Betamethasone cream appears to be a superior agent in terms of effectiveness, safety and cost than estrogen cream in the treatment of labial adhesion in pre-pubertal girls.

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