Original Research Article

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Efficacy of Neosporin hydrocortisone cream versus preputial dilatation in children with phimosis: a comparative study

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ABSTRACT

Background: Physiological phimosis, a common complaint in the pediatric surgery outpatient department presenting as non-retractile foreskin is due to adhesions between the inner layer of the prepuce with glans penis or due to tight tip of the prepuce. These patients are managed with circumcision, preputial dilatation. In this study, we compare different outcomes measures in children treated with dilatation and those with application of Neosporin-hydrocortisone ointment.

Methods: This prospective comparative study was conducted in the department of pediatric surgery outpatient department between 2015 and 2017. We followed up 50 patients who underwent only dilatation and other 66 patients who were advised to apply only hydrocortisone impregnated antibiotic cream twice daily over a period of six weeks. We recorded basic demographic features, parent anxiety, parental compliance, parent satisfaction, complete response and persistence of phimosis at the end of the treatment. All statistical tests were done using R statistical software.

Results: Of the 116 children recruited to the study, 50(43%) belonged in the dilatation group and rest (66%) to the Neosporin-hydrocortisone (NH) group. The median age of the patients was 36 with inter-quartile range (23-48) months. Baseline characteristics were comparable across the groups. At the end of six weeks, there was statistically significant difference between the two groups with regard to all outcome measures namely parent compliance, parent satisfaction, symptom resolution with the NH group showing a better result (P value<0.0001). Moreover, Phimosis persisted in 18 (36%) of the patients treated with dilatation compared to 4 (6%) in Neosporin hydrocortisone ointment group which was statistically significant.

Conclusions: Present study shows that local application of Neosporin-hydrocortisone ointment is a better alternative to using the painful preputial dilatation in children with phimosis.

Keywords: Dilatation, Foreskin, Hydrocortisone, Phimosis, Prospective studies

INTRODUCTION

Phimosis is a frequent presenting complaint in the Paediatric surgery outpatient department. Physiological Phimosis otherwise called non-retractable foreskin is different from pathological phimosis, and is due to adhesions between the inner layer of the prepuce with the glans or having a tight tip of the prepuce. Physiological phimosis is usually self-limiting and resolves

spontaneously by the first few years of life with 99% resolution by 16 years of life.³ While most of the patients who present with the same are asymptomatic, a small proportion of children does have symptoms like ballooning, dribbling, balanoposthitis or even urinary tract infections.⁴ Older children may present differently with pain during erection.³ Children who are symptomatic have been traditionally managed with circumcision or foreskin sparing operative procedures.³

The invasiveness of surgery along with the unpredictable results of foreskin sparing procedures have stimulated the look for alternative non-surgical options.^{5,6} In addition, preputial dilatation results in discomfort and pain which make parents uncomfortable with this procedure.⁷ Moreover, compliance with regular preputial dilatations in non-cooperative children is also an issue.8 In recent years preputial dilatation done as an outpatient procedure has gained popularity. This dilatation is followed by gentle daily retraction of the prepuce by the child or by the parents in younger children. Another option which has been evaluated is local steroid cream therapy, which loosens the tight foreskin.⁹⁻¹⁴ This is applied for a period of six weeks and has shown good response.14 The proposed mechanism is by reducing the local inflammatory and immune responses and also by thinning of the preputial skin.³

Widespread use of these non-surgical managements could potentially lead to better parent satisfaction. In addition, this will result in Surgical options for treatment being reserved only for those in whom medical treatment has failed or when cultural issues are involved. However, there is lack of with a prospective design in our area. In this study we aimed to compare, the efficacy of locally applied hydrocortisone impregnated antibiotic cream to traditional preputial dilatation in symptomatic phimosis in children in our setting.

METHODS

We conducted this prospective comparative study at the department of pediatric surgery clinic between January 2015 and January 2017. We started recruiting to the study after getting clearance from the institutional ethics committee. A prior sample size calculation was done. Only those parents giving informed consent were included in the study. All consecutive prepubertal boys who presented to the Pediatric Surgery Clinic because of a foreskin problem with symptoms related to unretractable foreskin were included in the study formed the study participants. We excluded those with pathological phimosis, and those detected incidentally.

This study involved 116 patients. We followed up 50 patients who underwent only dilatation and another 66 patients who were advised to apply only hydrocortisone impregnated antibiotic cream (NH) twice daily over a period of 6 weeks. Each gram of the ointment contained 10mgm of Hydrocortisone with Polymyxin (5000 units), Bacitracin (400 units) and Neomycin sulphate (3400 units). Approximately 2 grams were used for each application. The responses of all the patients were evaluated at 2, 4 and 6 weeks and findings recorded. In addition to this parental anxiety at presentation, parental compliance and parental satisfaction after treatments were also recorded. All statistical analysis was done in R statistical software. Continuous data were summarized as median and inter-quartile range and categorical data were reported as absolute numbers and percentages. Outcomes

measures in the two groups were compared with chisquare test. A P-value of less than 0.05 was taken as statistically significant.

RESULTS

Of the 116 children recruited to the study, 50 (43%) belonged to the dilatation group and rest (66%) to the Neosporin-hydrocortisone group.

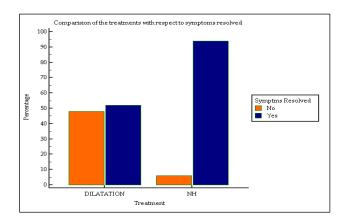


Figure 1: Symptoms relief in dilatation group versus Neosporin-hydrocortisone group.

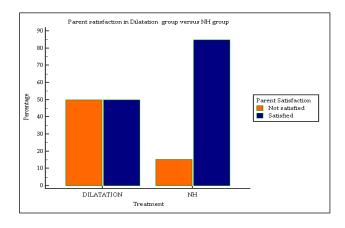


Figure 2: Parent satisfaction in dilatation versus NH group.

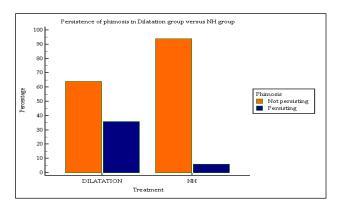


Figure 3: Persistence of phimosis in dilatation group versus NH group.

Baseline features are comparable across the two groups except for the differential distribution of dribbling in the

two groups (Table 1).

Table 1: Baseline comparison of the dilatation and Neosporin-hydrocortisone (NH) ointment groups.

	(All) N=116	Dilatation N=50	NH ointment N=66	P. overall
Age	36.0 (23.0;48.0)	24.0 (12.0;46.5)	36.0 (24.0;48.0)	0.004
Parenteral anxiety				0.827
Absent	95 (81.9%)	40 (80.0%)	55 (83.3%)	
Present	21 (18.1%)	10 (20.0%)	11 (16.7%)	
Balanoprosthitis				0.061
Absent	76 (65.5%)	38 (76.0%)	38 (57.6%)	
Present	40 (34.5%)	12 (24.0%)	28 (42.4%)	
Ballooning				0.001
Absent	68 (58.6%)	20 (40.0%)	48 (72.7%)	
Present	48 (41.4%)	30 (60.0%)	18 (27.3%)	
Dribbling				0.854
Absent	86 (74.1%)	38 (76.0%)	48 (72.7%)	
Present	30 (25.9%)	12 (24.0%)	18 (27.3%)	
Meatus				0.005
Not visualized	49 (42.2%)	29 (58.0%)	20 (30.3%)	
Visualized	67 (57.8%)	21 (42.0%)	46 (69.7%)	
Constriction ring				0.001
Absent	101 (87.1%)	37 (74.0%)	64 (97.0%)	
Present	15 (12.9%)	13 (26.0%)	2 (3.03%)	

Table 2: Outcomes in dilatation group versus NH group.

	(All) N=116	Dilatation N=50	NH N=66	P. overall
Parent compliance				0.013
Absent	5 (4.31%)	5 (10.0%)	0 (0.00%)	
Present	111 (95.7%)	45 (90.0%)	66 (100%)	
Parent satisfaction				< 0.001
Not satisfied	35 (30.2%)	25 (50.0%)	10 (15.2%)	
Satisfied	81 (69.8%)	25 (50.0%)	56 (84.8%)	
Complete resolve				< 0.001
Not resolved	30 (25.9%)	26 (52.0%)	4 (6.06%)	
Resolved	86 (74.1%)	24 (48.0%)	62 (93.9%)	
Symptoms resolved				< 0.001
Not resolved	28 (24.1%)	24 (48.0%)	4 (6.06%)	
Resolved	88 (75.9%)	26 (52.0%)	62 (93.9%)	
Phimosis				< 0.001
Not persisting	94 (81.0%)	32 (64.0%)	62 (93.9%)	
Persisting	22 (19.0%)	18 (36.0%)	4 (6.06%)	

At the end of treatment, there was statistically significant difference between the two group with regard to all outcome measures namely parent compliance, parent satisfaction, symptom resolution (Figure 1 and 2). Phimosis persisted in 18 (36%) of the patients treated with dilatation compared to 4 (6%) in Neosporin hydrocortisone ointment group which was statistically significant (Table 2) (Figure 3).

DISCUSSION

This study was designed to compare the different outcomes of preputial dilatation versus local application of hydrocortisone impregnated Neosporin ointment in children with symptomatic phimosis in our setting. Present study shows that the Neosporin hydrocortisone group fared better with respect to all outcome measures

like parent compliance, parent satisfaction, resolution of symptoms at the end of the treatment period.

In present study, the success rate as measured by complete resolution of symptoms was 94% percent in the NH group compared to 52% in the dilatation group. Our results are on the higher side compared to 70% reported by Jorgensen et al. in 1993.15 Comparison of topical Clobetasol with placebo in the treatment of unretractable foreskin was published by Lindhagen et al in 1996, with a success rate of 67%.² Another randomized controlled study by Lund et al. in 2000 quoted a success rate of 74%. ¹³ Various other studies been done. All together they show success rates varying between 67% to 90% with a mean of around 85%. 3,6,10,11,14 This higher results in present study could be due to combination we used. Another potential reason for the higher results could be due to selection bias inherent in the nature of the cohort design. The parent compliance was 100% in the NH group in present study compared to 90% percent in the dilatation group. This is reasonable in view of the painful nature of the dilatation process. In addition, phimosis persisted in 36% of children who were treated with dilatation compared to only 6% in the NH group. These show the topical application of Neosporin-hydrocortisone cream as the better option compared to the dilatation.

CONCLUSION

One of the limitations in present study is the observational design of the study. The better results in the outcomes compared with those reported in the literature could lie in the design of the study. Future studies need to be planned as randomized controlled study. Present study shows that local application of Neosporin-hydrocortisone ointment can be a better alternative to using the painful preputial dilatation in children with phimosis.

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