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RESEARCH ARTICLE
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"COMPARISON OF 10% POTASSIUM HYDROXIDE (KOH) SOLUTION V/S 5% IMIQUIMOD CREAM V/S ORAL RANITIDINE IN THE TREATMENT OF MOLLUSCUM CONTAGIOSUM"

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Abstract:
Context: The majority of treatment options in molluscum contagiosum traumatise the lesions and must be performed in a hospital, making patients anxious.
Aims: This study aims at comparing 10% potassium hydroxide (KOH) solution, 5% imiquimod cream and oral ranitidine in the treatment of MC in search for an alternative therapy.
Settings and Design: The study was carried out at a tertiary care hospital in the Department of Dermatology, Venereology and Leprosy, Jaipur, Rajasthan, India, from January 2021 to September 2022; with triple group cohorts.
Methods and Material: Patients having atleast three MC lesions aged between 5-54 years were enrolled in the study and were allocated into three groups, A, B, and C, each with 30 patients. Group A patients were instructed to apply the 10% KOH solution, group B received 0.25 g sachets of 5% imiquimod cream and group C received oral ranitidine at a dose of 5 mg/kg/day in two divided doses for eight weeks.
Statistical analysis used: To compare the groups of data, ANOVA test was used.
Results: At the end of this study, complete clearance of lesions was seen in 36% (9/25) patients in group A, 33.33% (7/25) patients in Group B and 15.80% (3/19) patients in group C. 48% (12/25) patients in Group A showed adverse effects in contrast to Group B with only 50% (6/12) patients showing adverse effects. No adverse events were reported among the patients in Group C.
Conclusions: It would seem reasonable to use 10% KOH solution because it is effective and affordable, albeit with a few minor side effects.

Key-words: 5% imiquimod, 10% potassium hydroxide, Molluscum contagiosum, Oral ranitidine, children, immunomodulatory

Key messages: This study highlights 10% KOH solution for treating lesions of Molluscum contagiosum as it is an effective, affordable and home-based modality.

Text

Introduction

Children frequently develop Molluscum Contagiosum (MC), a cutaneous viral infection characterised by spontaneous resolution.[1] Despite the benign nature of the condition, active therapy may be recommended to stop the spread of the disease, treat symptoms, avoid scarring, and for social and cosmetic reasons.[2] Although there are many treatment options available, no single therapy has been unanimously approved for the treatment of MC. While mechanical removal of lesions is the simplest treatment for adults, it is not often used on children due to their lower pain tolerance and fear.[3] Parents also dislike frequent hospital trips because they cause children to experience high levels of anxiety. Consequently, there is a need for a painless, at-home treatment approach.[4]

Potassium hydroxide works by dissolving the keratin and damaging the skin. For the treatment of MC, it has been utilised at a range of concentrations, namely 5%, 10%, and 20%.[5] The advantages of 10% KOH are safety and effectiveness.[6] A tissue response modifier called imiquimod generates interferon, a powerful antiviral drug. It has been demonstrated to have a very good safety profile while treating cutaneous viral infections.[7,8] Histamine receptor antagonists like cimetidine and ranitidine are typically used to treat peptic ulcer disease by reducing gastric acid secretion.[9] However, they have also been reported to have immunomodulatory effects by inducing delayed type hypersensitivity. In light of this, we conducted a randomised comparative study to evaluate and compare the efficacies of 10% KOH aqueous solution, 5% imiquimod cream and oral ranitidine for the treatment of Molluscum contagiosum.

Materials and methods

90 patients between the ages of 5-54 years with at least three MC lesions were enrolled in the study after receiving approval from the institutional ethics committee. The study was done between January 2021 to September 2022. Patients having involvement of the eyelids, subsequent infections, or a history of imiquimod hypersensitivity were not allowed to participate in the trial. A written informed consent of the patients was taken. Patients' symptoms and duration, family history, location and number of lesions were noted.

The patients were allocated into three groups, A, B, and C, each with 30 patients, using the lottery technique. The patients in Group A were instructed to apply the 10% KOH solution using a toothpick after coating the surrounding area with petrolatum and to prevent any leakage onto healthy skin. Patients in Group B received 0.25 g sachets of 5% imiquimod cream, and patients were instructed to apply a thin coating of the cream every other night until it was no longer noticeable. In case of children >15years of age their parents were instructed the same. For eight weeks, patients in Group C received oral ranitidine at a dose of 5 mg/kg/day in two divided doses. For 8 weeks or until the lesions cleared up, whichever came first, groups A and B were instructed to apply their respective agents at night and every other night respectively wash them off in the morning. Before and after the procedure, pictures were taken with consent.

At the second, fourth, sixth, and eighth weeks of treatment, patients were checked on. Clinical response to treatment, effectiveness and tolerability characteristics were assessed on each visit. Size of lesions and number of lesions was assessed. Complete clearance, partial clearance, and no change were the three clinical response categories assigned to the treatment. In order to compare the groups of data, ANOVA test was used.

Results

90 patients were included in this study for the treatment. Out of all the patients, 5 patients in Group A, 9 patients in Group B and 11 patients in Group C were lost to follow-up. The age of the patients ranged from 5 to 54 years (mean age of 18.80). In this study, 34(52.80%) cases were males and

31(47.70%) were females. Maximum numbers of patients were having molluscum contagiosum since less than 4 months. The minimum duration of infection was 17 days, and maximum duration was 9 months. At the end of this study, Group A showed complete clearance of lesions in 36% (9/25) patients, out of which 3 patients showing clearance by 4th week, 2 patients showing clearance by 6th week and the 4 patients showing clearance by 8th week [Figure 1A, 1B and 1C]. Group B showed complete clearance of lesions in 33.33% (7/21) patients, out of which 3 patients showing clearance by 6th week and the rest by 8th week [Figure 2A, 2B and 2C]. Group C showed complete clearance of lesions in 15.80 % (3/19) patients, out of which 1 showing clearance by 6th week and rest by 8th week [Figure 3A, 3B and 3C].

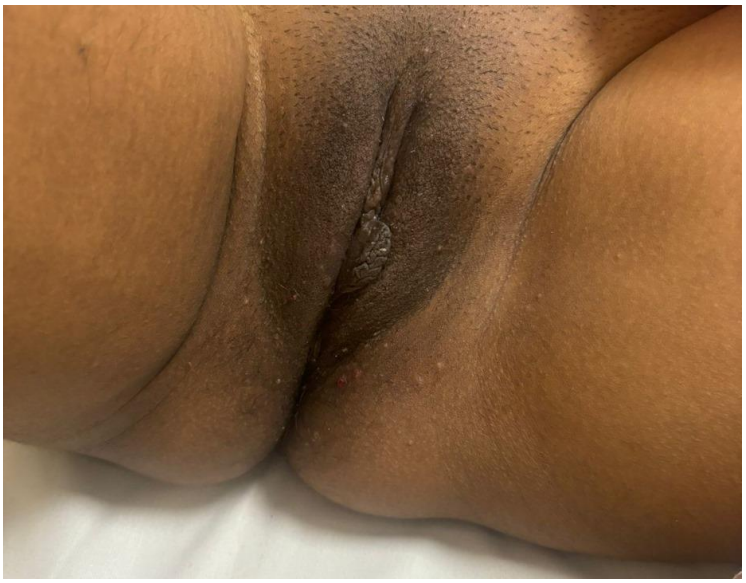

Figure 1A. Molluscum contagiosum: Before 10% KOH therapy

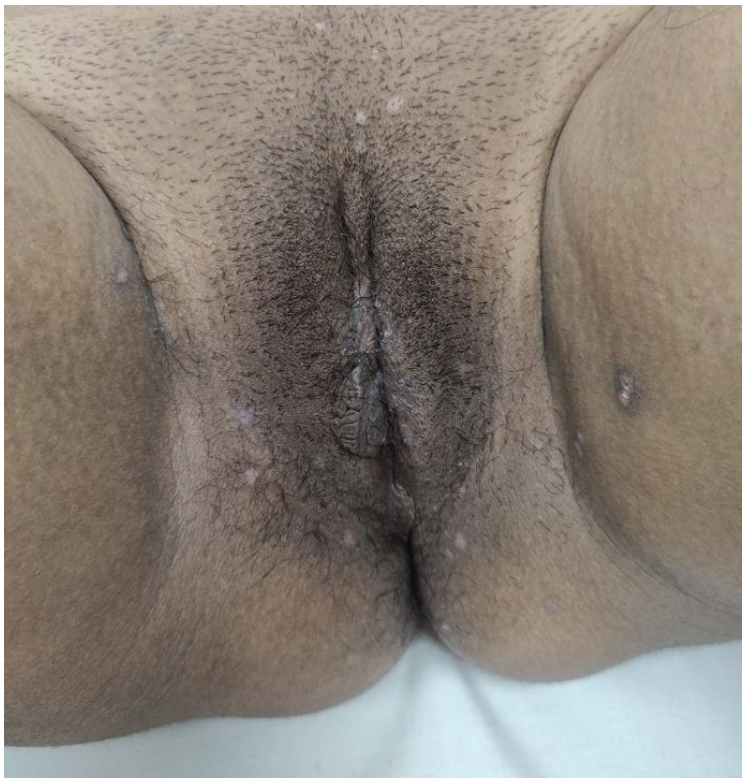

Figure 1B. Molluscum contagiosum: At 4 weeks during 10% KOH therapy

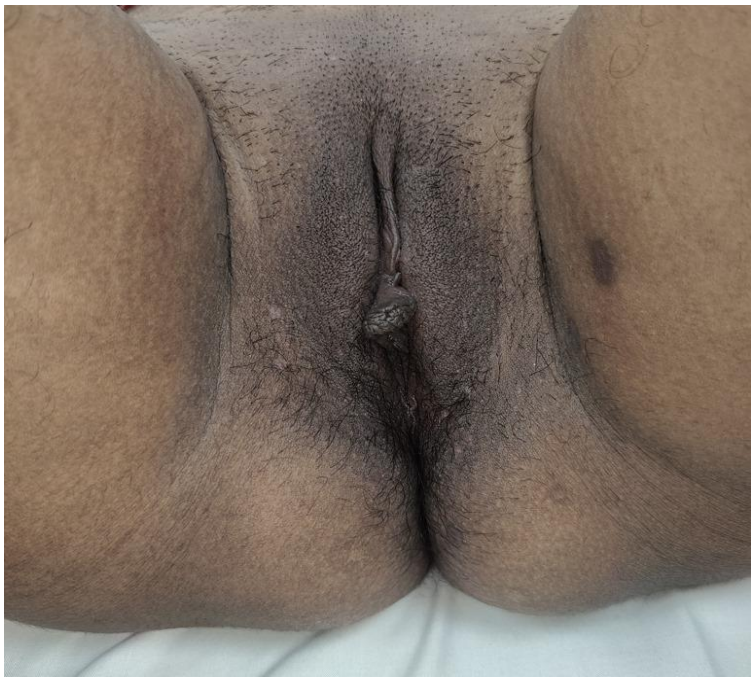

Figure 1C: Molluscum contagiosum: At 8 weeks during 10% KOH therapy

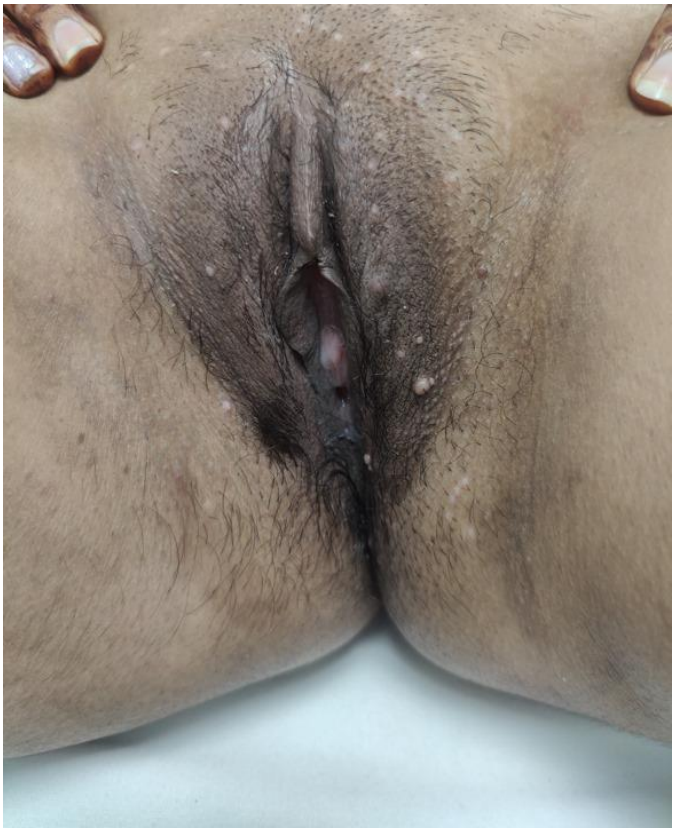

Figure 2A. Molluscum contagiosum: Before imiquimod therapy

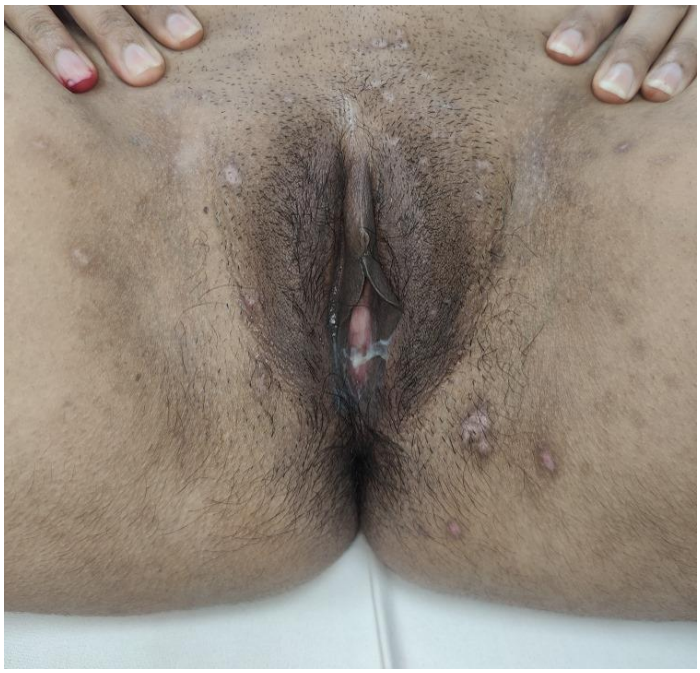

Figure 2B. Molluscum contagiosum: At 4 weeks during imiquimod therapy

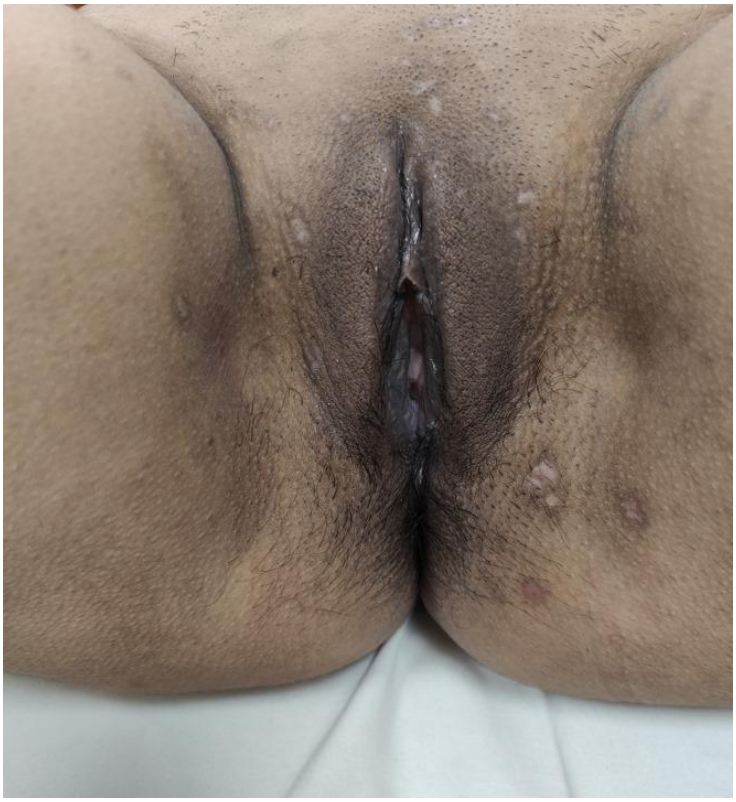

Figure 2C. Molluscum contagiosum: At 8 weeks during imiquimod therapy

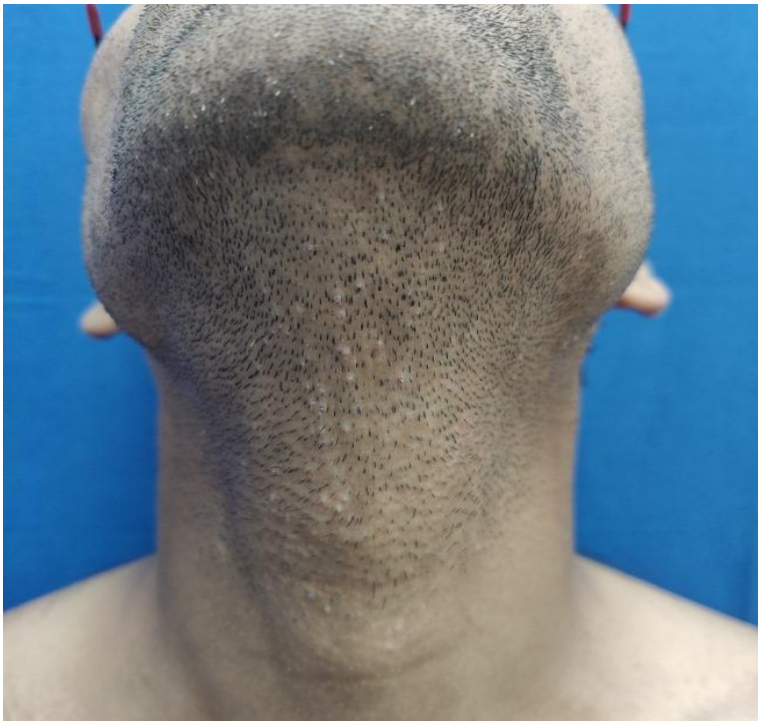

Figure 3A. Molluscum contagiosum: Before intake of oral rantidine

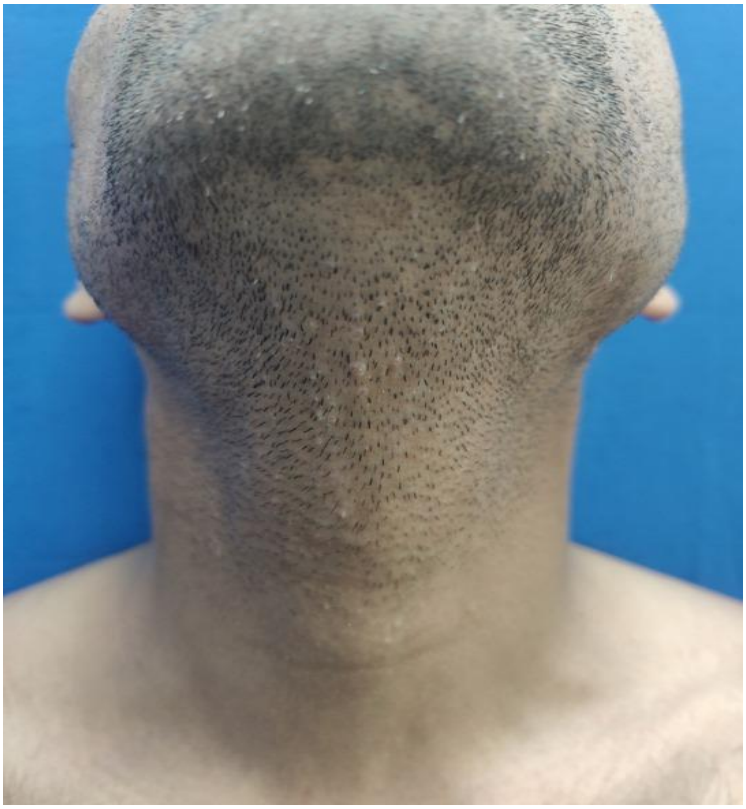

Figure 3B. Molluscum contagiosum: At 4 weeks during oral rantidine therapy

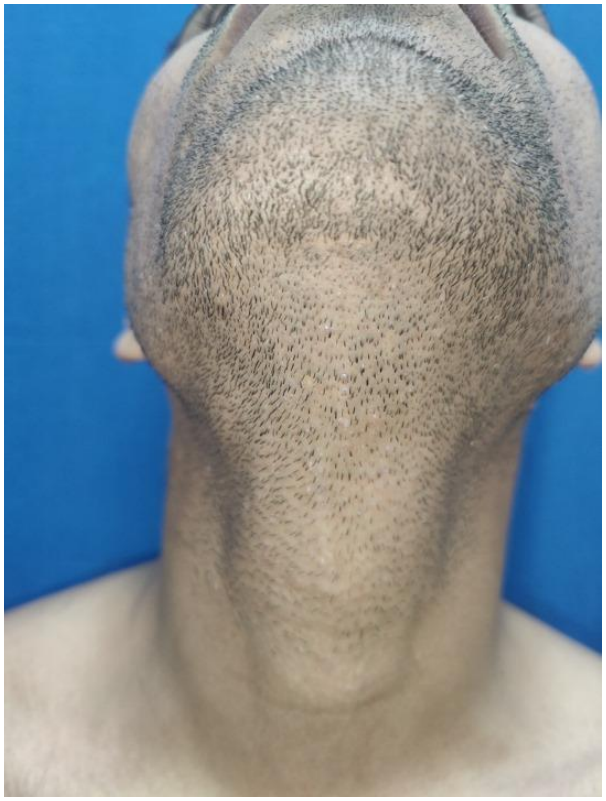

Figure 3C. Molluscum contagiosum: At 8 weeks during oral rantidine therapy

As represented below in tables 1, 2 and 3, the number of lesions were compared between baseline and each follow up visit and analysed by paired t test. The comparison between the number of lesions at baseline (week 0) and the number of lesions at week 6 and 8 were found to be statistically significant (P value-0.01 and 0.001 respectively) in group A patients [Table 1]. Similarly, the comparison between the number of lesions at baseline (week 0) and the number of lesions at week 6 and 8 were found to be statistically significant (P value-0.02 and 0.002 respectively) in group B patients [Table 2]. While in group C, comparison of number of lesions at week 0 was done with week 2, 4 ,6 and 8 respectively and there was no difference seen [Table 3].

In our study comparing the adverse effects of KOH solution, imiquimod and ranitidine, it was found that 12 out of 25 patients who received KOH solution experienced adverse effects. The most common adverse effect was pigmentary changes, seen in 7 patients, followed by erythema and burning sensation. On the other hand, 6 out of 21 patients who received imiquimod experienced adverse effects, with erythema being the most common, seen in 3 patients, followed by pigmentary changes. No adverse events were reported in patients who received ranitidine [Figure 4].

Table 1: Comparison of reduction in the lesional counts in Group A; SD- Standard deviation, S- Significant, NS- Non-significant

		Mean	SD	P value (S/NS)
Comparison between-	Week 0 Week 2	7.08 6.60	4.22 4.28	0.69 NS
Comparison between-	Week 0 Week 4	7.08 4.80	4.22 4.08	0.06 NS
Comparison between-	Week 0 Week 6	7.08 4.08	4.22 3.71	0.01 S
Comparison between-	Week 0 Week 8	7.08 3.20	4.22 3.70	0.001 S

Table 2: Comparison of reduction in the lesional counts in Group B

		Mean	SD	P value (S/NS)
Comparison between-	Week 0 Week 2	7.48 7.38	3.90 4.36	0.94 NS
Comparison between-	Week 0 Week 4	7.48 5.76	3.90 4.26	0.19 NS
Comparison between-	Week 0 Week 6	7.48 4.42	3.90 3.96	0.02 S
	Week 0 Week 8	7.48 3.42	3.90 3.84	0.002 S

Table 3: Comparison of reduction in the lesional counts in Group C

		Mean	SD	P value (S/NS)
Comparison between-	Week 0 Week 2	7.11 6.68	3.63 3.43	0.71 NS
Comparison between-	Week 0 Week 4	7.11 6.26	3.63 3.42	0.47 NS
Comparison between-	Week 0 Week 6	7.11 5.42	3.63 3.50	0.15 NS
Comparison between-	Week 0 Week 8	7.11 4.84	3.63 3.53	0.06 NS

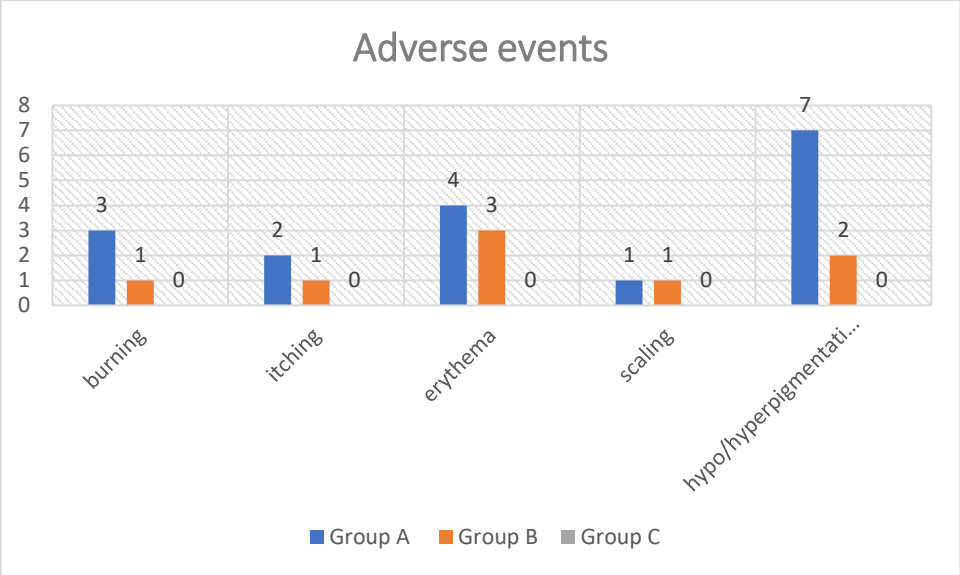

Figure 4. Comparison of adverse effects between group A, B and C

Discussion

Due of its powerful tissue-destructive capabilities, 10% KOH has a quicker onset of action and greater effectiveness than imiquimod, which has a delayed reaction because it functions by triggering cell-mediated immunity.[10] This may also explain why patients taking imiquimod rather than KOH continued to develop new lesions; as Potassium hydroxide works by dissolving the keratin and damaging the skin which may produce early destruction that could preclude autoinoculation. On the other hand, Imiquimod cream works by inducing cell-mediated immunity, which helps in the regression of mollusca, similar to what is observed in viral warts. The cream induces the production of the principal antiviral cytokine, interferon-γ, as well as other inflammatory cytokines.[11,12] Ranitidine functions as an H_2 receptor antagonist and has a molecular structure that is different from both histamine and cimetidine.[13] It has the added benefit of not having any of cimetidine's

antiandrogenic or hepatic enzyme-inhibiting properties, making it a more effective inhibitor than cimetidine.[14] Its safety profile is better for infants, women who are pregnant or nursing, and the elderly. The medication is very well tolerated and has not been associated with any severe side events or clinically significant drug interactions.[15] Oral ranitidine was selected as the treatment option in this trial due to its superior availability than cimetidine and favourable efficacy, tolerability profile, and safety profile.

In our study at the end of 8 weeks, Group A showed complete clearance of lesions in 36% (9/25) patients, Group B showed complete clearance of lesions in 33.33% (7/25) patients and Group C showed total clearance of lesions in 15.80 % (3/19) patients. The results were similar to the study by Seo et al. who found absolute clearance of lesions in 8 (57%) of 14 patients treated with imiquimod and in 10 (77%) of 13 patients treated with KOH.[16] In contrast to our study, at the end of 12 weeks, 8 (57%) out of 14 patients receiving imiquimod and 8 (42.1%) out of 19 patients receiving KOH had completely cleared off lesions, according to Metkar et al.[17] The study by Mahajan et al. instructed 27 patients to apply 20% KOH solution once daily before bed. All of the kids were cleared after an average of 17 days.[18] Puri observed complete clearance of genital MC lesions in 27 (75%) of the 36 patients with once daily application of 5% imiquimod.[19]

In conclusion, both 10% KOH solution and 5% imiquimod cream are effective, safe, and easy to use at home for treating Molluscum contagiosum. Oral ranitidine may be a safe and effective alternative for immunocompetent children with extensive MC. Curettage is a good option in resource-poor countries, but may be painful and frightening for patients specially of younger age group. 10% KOH solution is effective and affordable with minor side effects, while 5% imiquimod cream has virtually no side effects but may be more expensive. More research is needed on different KOH concentrations and standardized drug administration methods.

Conflict of Interest: Nil

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