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Original Article

# Comparison of 5% Potassium Hydroxide with 10% Potassium Hydroxide Solution in Treatment of Molluscum Contagiosum

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## ABSTRACT

***Objective***: To compare the efficacy of 5% potassium hydroxide against 10% potassium hydroxide solution in the management of molluscum contagiosum.

***Study Design***: Randomized Controlled Trial (ClinicalTrials.gov:NCT05634460).

***Place and Duration of Study***: Department of Dermatology, Combined Military Hospital, Abbottabad Pakistan, from Mar to Aug 2022.

***Methodology***: We enrolled 60 patients, aged between 2-14 years, by using non-probability consecutive sampling. All patients having molluscum contagiosum were randomly assigned to one of two groups, where Group-A received 5% KOH, and Group-B received 10% KOH solution, which was applied to patient's lesions, by their parents, once daily, for two weeks, or until inflammatory manifestations. All patients were monitored for side effects after Week 2, 4, 8, and 12. Efficacy classification was based on complete remission (>90%), partial remission (60-90%), and insignificant improvement (<60%). Demographic information and frequency percentages were calculated for qualitative variables. The chi-square test was applied to establish statistical significance, with *p*-value ≤0.05 considered significant.

***Results***: In Group-B, after Week 12, 19(63.3%) patients had complete remission while 11(36.7%) patients had partial remission ($p<0.05$). In Group-A, only 1(3.3%) patient had complete remission, but partial remission was observed in 22(73.3%) patients. In Group-A, erythema was noted in 17(56.7%) patients and burns in 13(43.3%) patients, but in Group-B, 30(100%) patients complained of burning and erythema, 14(46.6%) had pruritis and 12(40%) developed crusting ($p<0.05$).

***Conclusions***: In treating molluscum contagiosum, a 10% KOH solution was found to be more efficacious than a 5% KOH solution.

**Keywords**: Drug Efficacy, Molluscum Contagiosum (MC), Potassium Hydroxide (KOH).

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## INTRODUCTION

Molluscum contagiosum (MC) is a virus-related skin infestation, commonly seen among children, caused by the Molluscipoxvirus, the largest human virus, which often causes asymptomatic lesions but in immuno-competent individuals, single or multiple dome-shaped, shiny, pearly white papules with a central dimple can occur on the skin with spontaneous resolution usually ensuing within 18 months, however, the lesion may persist for several years with an elevated risk of transmission in general populations over the years.[1,2] Patients may seek therapy for social and cosmetic reasons, and also to avoid spreading the disease to others, for which numerous treatment modalities are currently available, including potassium hydroxide (KOH), curettage, cryotherapy, disinfected needle pricking, photodynamic therapy,[3] laser,[4] salicylic acid, and glycolic acid, among others.[5,6] Potassium hydroxide is a topical treatment for Molluscum contagiosum[7] with dermatologists routinely using potassium hydroxide (KOH) in varying concentrations, as it is a strong alkali with keratolytic characteristics and due to it being inexpensive and widely accessible, it has the potential to be a useful method to treat MC in resource-constrained countries.[8,9] Thus, the purpose of this study was to examine two different concentrations of potassium hydroxide (5% KOH vs 10% KOH) on patients with MC, in order to determine the most effective concentration for use in children.

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## METHODOLOGY

A randomized controlled trial was done at the Department of Dermatology, Combined Military Hospital (CMH), Abbottabad Pakistan, from March to August 2022, after gaining Ethical Review Board approval via letter Reg# CMHAtd-ETH-04-Derm-22 and issuance of RCT registration number from Clinical

Trials.gov (NCT05634460). We enrolled 60 patients, aged between 2-14 years, by using non-probability consecutive sampling, after obtaining informed consent of their parents. To calculate the sample size, confidence interval was set at 95%, power at 80%, anticipated cure rate of 20% for 5% KOH and 77% for 10% KOH.[10] The calculated sample size was 26 patients, with 13 in each group, however, we enrolled a sample size of 60, with 30 in each group, to increase the validity of the study.

**Inclusion Criteria**: Patients belonging to either gender with <100 lesions and no previous therapy within the preceding one month, were included.

**Exclusion Criteria**: Patients with known immuno-deficiency and hypersensitivity to the treatment modality were excluded.

After randomization into one of two groups, either Group-A (5% KOH) and Group-B (10% KOH solution), KOH solution was prescribed, to be applied to the patient's lesions by the parents, once daily for two weeks, or until inflammatory manifestations became evident (erythema). The researcher counted MC lesions to assess treatment response at the end of Weeks 2, 4, 8, and 12. Efficacy was classified as complete when clearance of lesions ≥90%, partial upon 60-90% of clearance and insignificant when <60% clearance was observed. Patients were also queried and evaluated for any local side effects, such as itching, burning, discomfort, erosion, crusting, pigmentary changes or scarring. Patients who attained complete clinical clearance before the completion of this study were reevaluated one month later, and those who showed post-inflammatory pigmentary change were followed for an additional three months. Data was analyzed by using Statistical Package for the Social Sciences (SPSS) version 26.0. Mean+SD were calculated for continuous variables while frequency and percentage were calculated for categorical variables. To determine statistical correlations, chi-square test was applied with $p$-value≤0.05 considered as significant.

## RESULTS

In total, 60 patients were allocated to two equal groups, with Group-A (5% KOH) having a mean age of 4.81+2.18 years, and Group-B (10% KOH) having a mean age of 4.32+1.96 years. Table-I lists the demographic characteristics of both treatment groups. In terms of preliminary clinical symptoms, the two groups were quite similar, however, as 44(76.6%) patients were less than 8 years old with 55(91.6%) patients having a disease duration of less than 9 months. Family history was found to be positive in 6(10%) patients. The number of lesions ranged from 2 to 32, and on examination, 24(40%) lesions were found to be located on the face, 23(38.3%) on the limbs, and 12(20%) on the trunk. Table-II shows comparison between efficacy at final follow-up at Week 12, where 1(3.3%) patient in Group-A had complete remission, however, in 22(73.3%) patients, partial remission was observed, with no significant difference in efficacy observed in the rest. In contrast, complete remission was noted in 19(63.3%) patients of Group-B, while 11(36.7%) had partial remission ($p$<0.05). Figure-1 shows the number of side-effects observed during treatment, where erythema was noted in 17(56.7%) patients and burning in 13(43.3%) patients from Group-A but in Group-B, 30(100%) patients complained of burning and erythema, 14(46.6%) had pruritic and 12(40%) developed crusting ($p$=0.00), however, following repeated treatment, these negative effects gradually diminished. Transient post inflammatory hypopigmentation was seen in only 2(6.6%) patients, which was cured 1.5 months after the final follow up.

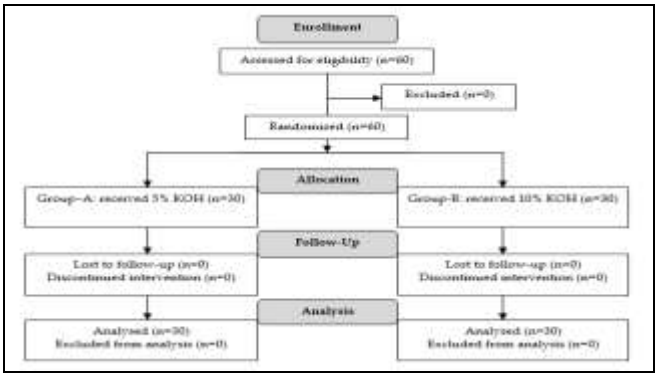


**Figure: Patient Flow Diagram (n=60)**

**Table-I: Baseline Clinical Findings in Both Treatment Groups (n=60)**

| Variables | | Group-A 5%KOH (n=30) | Group-B 10%KOH (n=30) |
|---|---|---|---|
| Gender | Male | 16(53.3%) | 19(63.3%) |
| | Females | 14(46.7%) | 11(36.6%) |
| Age (years) | Mean+SD | 4.80+2.18 | 4.32+1.96 |
| Duration of MC Lesions (months) | | 1-9 | 1-20 |
| Sites of Involvement | Face | 12(40%) | 12(40%) |
| | Limbs | 10(33.3%) | 13(43.3%) |
| | Trunk | 08(26.7%) | 4(13.3%) |
| | Genitals | 0(0%) | 1(3.3%) |
| Number of Lesions (range) | | 2-32 | 2-29 |
| Family history of MC | | 4(13.3%) | 2(6.6%) |

**Table-II: Comparing Efficacy in the 12th Week of Treatment (n=60)**

| Remission | Group-A 5% KOH (n=30) | Group-B 10% KOH (n=30) | *p*-value (≤0.05) |
|---|---|---|---|
| Complete | 01(3.3%) | 19(63.3%) | 0.00 |
| Partial | 22(73.4%) | 11(36.7%) | |
| Failure | 07(23.3%) | 0 | |

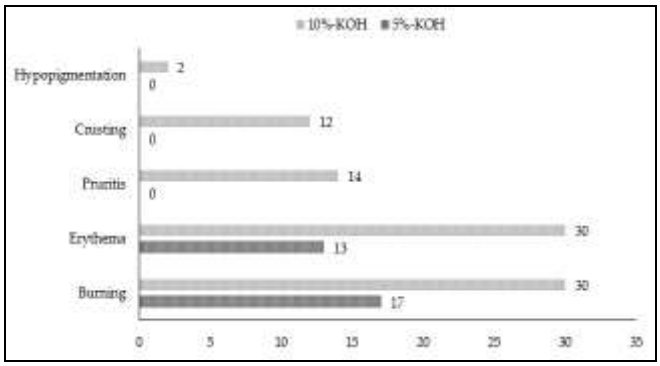


**Figure-1: Side Effects observed in Group-A (5% KOH) and Group-B (10% KOH)**

## DISCUSSION

While MC remains a self-limiting disorder in children, in some cases, cosmetic disfigurement, the risk of autoinoculation, and worsening health can cause parents to seek medical treatment which, ideally, should cause minimal pain and disfigurement in patients. The findings of this study show that 10% KOH is more efficient than 5% KOH solution in the treatment of MC, as by Week 12 of our study, 19(63.3%) patients treated with 10% KOH showed complete remission compared to only 1(3.3%) patient in complete remission, when treated with 5% KOH solution. These findings are similar to the findings reported in published literature,[11-13] especially as one study reported 91.4% patients treated with 10% KOH solution showed complete recovery.[14] However, our results are different from another study which noted complete remission in both treatment groups, with 5% KOH solution considered better.[15] Another study, when comparing 5% KOH with 10% KOH solution, also concluded that 5% KOH solution as considerably more effective.[16] We hypothesize that the impact of KOH is concentration dependent, with greater concentration producing better outcomes. In terms of KOH treatment tolerability, all patients in the 10% KOH group and over 56% in the 5% KOH group suffered minor side effects, similar to other studies,[17,18] as the keratolytic impact of KOH can cause erythema and burning, however, the advantages of KOH, which are that it is inexpensive, readily accessible, and reasonably well endured by patients, far outweigh the risk of its dose dependent side effects.

## LIMITATION OF STUDY

The present study's main limitation was that it was conducted over a comparatively short period of time as large, randomized, multicenter trials, with relatively long follow-ups, are required for assessing efficacy. Additionally, this study was based on pediatrics population so these results cannot be generalized to the rest of the population.

## CONCLUSION

We found 10% KOH to be safer and more effective than 5% KOH for treatment in pediatric patients diagnosed with molluscum contagiosum patients.

**Conflict of Interest:** None.

**Funding Source:** None.

**Authors' Contribution**

Following authors have made substantial contributions to the manuscript as under:

HF & BM: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MH & MAS: Conception, data analysis, drafting the manuscript, approval of the final version to be published.

SA & KG: Data acquisition, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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