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Original Article

Paediatric Molluscum Contagiosum treatment in South Asia: Evaluating Cryotherapy against topical KOH

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Abstract

Background Molluscum contagiosum is a viral skin infection in children, often causing cosmetic concerns and requiring treatment because of its contagious nature. Various treatment modalities are available, but an ideal therapy should provide effective lesion clearance with minimal pain and adverse effects.

Objective To compare the effectiveness and safety of cryotherapy vs. 10% KOH solution in treatment of paediatric Molluscum contagiosum patients in a South Asian tertiary care centre.

Methods A total of 70 patients fulfilling the inclusion criteria were enrolled from OPD of dermatology department, Mayo Hospital. Participants were divided into two equal groups. Group A received cryotherapy every 15 days while group B applied 10% KOH solution, twice daily at home until clearance of lesions. Follow-up assessments were conducted at weeks 2, 4, 6, 8, 10 and 12. Treatment response was categorized as complete (100%), moderate (50-99%), or mild (1-49%) clearance of lesions.

Results All the patients completed the study. Complete response was achieved by the 3rd visit in group A and by 4th to 5th visit in group B. Mean cure time was significantly shorter in the cryotherapy group compared to the KOH group (56 vs. 84 days, *P*<.001). Pain was the most common adverse effect and was significantly more frequent in the cryotherapy group than in the KOH group (62.8% vs. 31.4%; *P*=.0004; 95% CI: 1.2-2.8). Hyperpigmentation and scarring were also observed more commonly with cryotherapy, although no serious adverse effects or treatment discontinuation occurred. The difference in treatment efficacy between the two groups was statistically significant during follow-up visits (*P*<.05).

Conclusion Topical 10% KOH solution is a better therapeutic option as compared to cryotherapy in the treatment of MC in terms of pain and regional side effects.

Keywords Molluscum contagiosum; Cryotherapy; Potassium hydroxide; Paediatric dermatology.

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Introduction

Molluscum contagiosum (MC) is a self-limiting viral infection of the skin quite prevalent in paediatric age group.[1] It is caused by Molluscipox virus (Poxvirus) which is a human specific double stranded DNA virus. It presents with 1 to 10mm, dome-shaped papules with central umbilication, on the trunk and extremities.[2] However, lesions may also be present on face, neck and genitals. Contact with affected people or autoinoculation leads to formation of these papules after an incubation period of 3-12 weeks. It is more common in patients with

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history of atopy, immunosuppression and is also sexually transmitted.[3] The lesions are asymptomatic in majority of patients and usually the disease waves off in a period of around 8 months. However, these may cause cosmetic disfigurement and parents specially in female children are highly concerned about disease course and outcomes like pigmentation and scarring.[4]

Multiple treatment options are available like physical elimination, topical treatment and systemic agents. Physical treatment options are curettage, cryotherapy, pricking with a sterile needle, electrodessication and laser ablation.[5] However, all of these cause pain resulting into poor tolerance by children. Topical therapies include Salicylic acid, tretinoin, cantharidin and podophyllotoxin.[6] All these treatment regimens usually require a longer duration of treatment and most of them cause local side effects like irritation, redness and inflammation when applied to the lesion.[7] All these regimes have limited and variable efficacy and it is very difficult to establish that any treatment is more effective than benign neglect of lesion until clearance.[5]

Cryotherapy with liquid nitrogen spray is very effective and most commonly used technique. Liquid nitrogen which boils at -196°C, is quite effective for clinical use.[8] It produces tissue destruction by ice crystallization. Lesions of MC usually clear within 4-6 weeks but pain, scarring and higher rate of post inflammatory hyperpigmentation are major side effects.[3]

Potassium hydroxide (KOH) is a strong alkali and due to its keratolytic property, causes local destruction of the skin. It has also been used successfully as a topical application, in a concentration of 5-10% for the treatment of MC.[9] KOH is easily available and relatively safer treatment option for MC.[9]

This study was designed to compare outcome and safety of cryotherapy versus topical 10% KOH solution for the treatment of MC in terms of effectiveness, cure time and side effects like pain, burning, pigmentation and scarring. There are a few previous studies that compare the two therapeutic approaches, but we have taken sample size of 70 patients in order to get more accurate results. Additionally, this study calculates the pain score and the cure time for both groups, which hasn't been done in any prior researches.

Methods

This study was approved by the Institutional Review Board/ Ethical Review Committee of Mayo Hospital (vide Ref. No No.890/RC/KEMU dated 31.10.2022) prior to commencement of data collection. Written informed consent was obtained from the parents or legal guardians of all participating children. Confidentiality and anonymity of patient data were maintained throughout the study.

The sample size of 70 patients (35 in each group) was calculated using a 95% confidence level, 80% study power and expected difference in treatment efficacy based on previously published studies comparing cryotherapy and topical potassium hydroxide in molluscum contagiosum treatment.

This Randomized controlled trial was conducted in Outpatient Department of Dermatology, Unit II, Mayo Hospital Lahore from January, 2023 to July, 2023. Patients fulfilling the inclusion criteria were recruited consecutively from the outpatient department of dermatology during the study period. Baseline demographic and clinical characteristics including age 2 to 14 years, both genders, number of lesions ranging from 5-40 in number at any site of body, history of atopy and previous treatment history were recorded on a structured proforma. Patients with sensitivity to either therapy included in the study, receiving any topical or systemic therapy in last 2 months, with known immunodeficiency or on immunosuppressive drugs, with superadded infection and history of peripheral vascular disease were excluded. Patients were randomly divided into two treatment groups (group A and group B) using

computer generated random number table. Group A patients were treated with cryotherapy performed with liquid nitrogen spray, 2 weeks apart for a maximum of 6 sessions or till clearance of lesion, whichever was achieved first. Liquid nitrogen was applied with spray from cryogun for a single freeze-thaw cycle of 5-10 seconds. USA made, hand held, mini cryogun with model no. 1007006 was used for our study. It was applied with cotton tip applicator at difficult to approach areas like lesions on or near eyelids. Group B was treated with 10% KOH solution. 1st application was done at hospital. Parents were guided about twice daily application at home with a cotton tip applicator, for 12 weeks or till clearance of lesion, whichever was achieved first. Advice was given regarding application of white soft paraffin on the surroundings of lesions to be treated to avoid irritation or contact dermatitis. Pain score was calculated at 1st application of both treatments in hospital at o and 6 hours post procedure. Treatment in either group was discontinued if inflammation or superficial erosion occurred. Follow-up evaluations were conducted at 2-week intervals for 12 weeks by the same researcher to ensure consistency in assessment. Clinical photographs were obtained at baseline and during follow-up visits after parental consent.

Pain assessment was performed using the validated Faces Pain Scale, which is commonly used in paediatric patients for reliable assessment of pain intensity. Treatment response was assessed through percentage reduction in lesion count, a standardized and objective clinical outcome measure frequently used in previous dermatological studies. Effectiveness of both treatments was measured in terms of response. Complete response was considered as efficacious. Patients were also inquired about any local side effects like hypo/ hyperpigmentation, burning, stinging, scarring or pain on each visit. Consistent assessment by the same researcher throughout the study minimized inter-observer variability.

Data analysis

Collected data was transferred to Statistical Package for Social Sciences (SPSS) version 26 for data entry and analysis. Results were presented in the form of graphs and tables for categorical variables. Quantitative variables like age, duration and effectiveness were measured with mean±SD and qualitative variables like gender, site, and safety of treatment with frequency and percentage. Efficacy of the two treatment groups were compared with independent sample t-test at each follow up (from baseline till last visit). However, efficacy of treatment within group before and after treatment was assessed with the help of paired sample t-test. *P*-value ≤.05 was considered statistically significant.

Result

Total number of patients included in the study was 70; 34 (48.6%) males and 36 (51.4%) females. The participants in this study ranged in age from 2 to 14 years. Most of the patients were 6-9 years of age, which was 16 (45.7%) in group A and 16 (45.7%) in group B. Baseline demographic characteristics, including age and gender distribution, were comparable between both groups (*P*>.05).

Lesions were distributed most commonly over the trunk, followed by upper and lower limbs, face and neck respectively as shown in **Figure 1**.

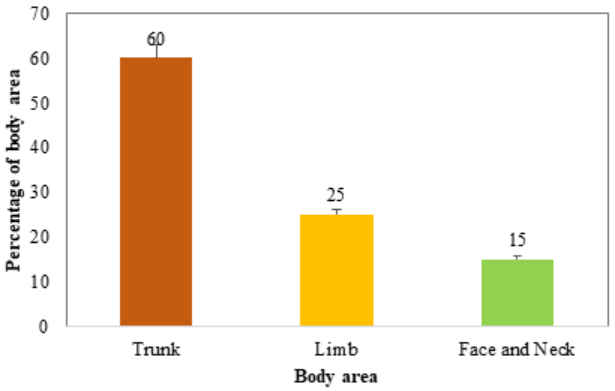


Figure 1 Distribution of Molluscum contagiosum lesions on different body areas in both cryotherapy (A) and topical 10% KOH (B) solution treated Groups.

Table 1 Comparison of effectiveness of both groups at each visit.

Sr#	*No of Patients*	*Visit No.*	*Group A Cryo Mean±SD*	*Group B KOH Mean±SD*
1	35	1	6.94	6.89
2	35	2	5.94	6.06
3	35	3	4.81	4.74
4	35	4	3.93	3.39
5	35	5	2.77	2.51
6	35	6	2.06	2.23
7	35	7	1.54	2.19
P Friedman test			<.001	<.001

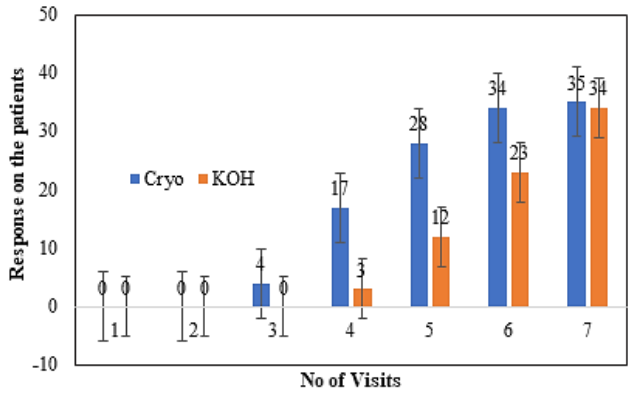


Figure 2 Comparison of response among two groups in relation to number of visits.

Total number of patients in each treatment group is 35. Data is presented as mean rank. Treatment was performed for up to 7 Visits. Effectiveness of individual treatment was recorded using Friedman Rank test and comparison of two treatments on each visit was performed using Wilcoxon Sign Rank test. Both treatments were effective. Significant differences between treatments were recorded on visit 4, 5 and 6. Cryotherapy treatment was more effective when compared with KOH.

100% reduction of lesion was considered as efficacious. Cryotherapy demonstrated earlier lesion clearance compared with topical 10% KOH solution. Complete response was achieved by the 3rd-4th visit in the cryotherapy group, whereas patients treated with KOH showed complete response between the 4th and 6th visits. The difference in treatment response between the two groups became statistically significant during later follow-up visits (*P*<.001) as shown in **Figure 2**, **Table 1**.

Average cure time was significantly shorter in the cryotherapy group (56 days) compared with the KOH group (84 days) (*P*<.001) (**Figure 3)**.

Pain was the most frequently reported adverse effect and occurred significantly more often in the cryotherapy group than in the KOH group (62.8% vs. 31.4%, *P*<.001). Hypopigmentation/scarring was also significantly more common among patients receiving cryotherapy (*P*=.003). Although hyperpigmentation was observed more frequently in the cryotherapy group, the difference was not statistically significant (*P*=.341). No serious adverse effects or treatment discontinuation were reported in either group **(Table 2)**.

Pain score was calculated at 1st application of both treatment modalities in group A and group B at 0 and 6 hours post procedure. 35 out of 35 patients in group A experienced pain at 0 hour of 1st application of cryotherapy with a pain score range of 2-10. Most of the patients reported it between score 4-6 (little to more hurt). While in group B, 26 patients out of 35 had no pain at 1st application of KOH solution and 9 patients reported pain score of 2 at 1st application. A statistically significant *P*-value of .026 was obtained **(Table 3)**. None of the patient reported pain at 6 hours post procedure in both groups. The mean age of the study population was 22.75±4.03.

Table 2 Safety percentage after treatment of Cryotherapy and KOH in Group A and Group B patients.

Safety	*Group A (Cryotherapy) n (%)*	*Group B (KOH) n (%)*
Burning	31 (88.6%)	16 (45.7%)
Hyperpigmentation	8 (22.8%)	4 (11.4%)
Hypopigmentation/ scarring	14 (40%)	7 (20%)

Table 3 Mean pain score calculation through Mann-Whitney test of Group A and Group B.

Groups Name	*Pain Score*	*Mean Rank*	*Sum Ranks*	*P-value*
Group A	6	8.83	53.00	.26
Group B	6	4.17	25.00	

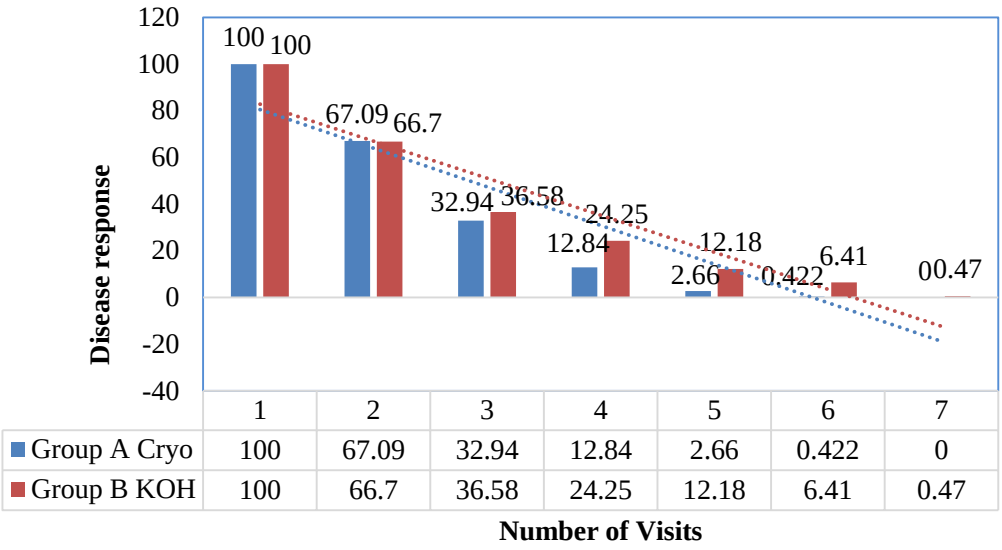


Figure 3 Comparison of cure time of both treatment groups in relation to number of treatment.

Discussion

In a disease like molluscum contagiosum, which impairs the quality of life due to its cosmetic disfigurement and fear of being contagious, the majority opts for a treatment rather than waiting for spontaneous resolution. So, a treatment option with easy availability, rapid response, cost effectiveness, feasibility of application, better efficacy, and fewer side effects is essential. The present study compares the outcome and safety of cryotherapy versus topical 10% KOH solution for the treatment of MC in terms of effectiveness, cure time and side effects.

Total number of patients enrolled in this study was 70 and they were divided in 2 groups A and group B with each having 35 patients. Group A was treated with cryotherapy and group B with KOH solution. A similar study was conducted by Farhan, 2011,[10] but total number of patients was less than in our study.

In our study, out of total 70 patients, 34 (48.6%) were males and 36 (51.4%) were females. In group A, 16 patients were male and 19 were females out of 35. Similarly, group B had 18 males and 17 females. *P*-value was .811 which was statistically insignificant. A similar equal distribution of the disease in both genders was described by 11. Another research conducted by Faid *et al.* 2025 also showed similar equal gender distribution.[12]

In our study, age distribution was 2-14 years including both males and females. However, most patients were 2-9 years old. This age distribution was in accordance with a previously reported literature by Hebert *et al.* 2023, Olsen, Gallacher, Piguet, and Francis, 2014.[13,14] Similar age distribution was also reported by Farhana, 2011.[10]

Lesions were distributed most commonly over the trunk, followed by upper and lower limbs, followed by face and neck. Similar distribution of lesion was also supported by Hebert *et al*; 2023.[14] However this study did not report any of the patients with lesion on face or neck which can be attributed to a limited sample size of 53 patients.

In our study, we observed that complete clearance of lesions (effectiveness) was achieved at 3rd-4th visit in group A with an average cure time of 56 days while it was achieved at 4th-6th visit in group B (KOH) with an average cure time of 90 days which was statistically significant with a statistically significant (*P*<.001) **Figure 3**. 35 out of 35 patients achieved complete clearance of lesions in group A. While in group B, 34 out of 35 patients achieved completed

clearance. One patient in group B exhibited moderate response (92%) at the end of study. This is in accordance to another study by Farhana, 2011[10] but limitation of that study was the limited sample size of 40 patients.

Pain score was calculated at 0 and 6 hour of 1st application of both therapeutic modalities at hospital. FACES pain score was used for pain assessment. In group A, pain score was significantly higher at 0 hour ranging from score 2 to score 6 in most of the patients. However, both groups had pain score of 0 by all participants at 6th hour of 1st application. It was statistically significant among both groups with a *P*-value of .026. Similarly, study conducted by Chapa, Mavura, Philemon, Kini, and Masenga, 2021[15] showed similar results in terms of side effects and by Farhana, 2011.[10] These results were comparable with our study as pain, burning and hypopigmentation are commonly documented side effects of cryotherapy.

Burning was also temporary but a major side effect. It was experienced by 31 patients in group A while by 16 patients in group B with a statistically significant *P*-value of .0004. Other side effects observed were pigmentary changes including both hyper and hypopigmentation/ scarring. Percentage of pigmentary changes was also higher in patients of group A. For hyperpigmentation, 8 patients among group A and 4 patients among group B developed it with a statistically insignificant *P*-value of .341. Hypopigmentation/ scarring was observed in 20 patients of group A and 7 patients of group B with a statistically significant *P*-value of .003. Similar results were also supported by Chapa *et al;* 2021; Farhana, 2011.[10,15] However, these pigmentary changes resolved in both treatment groups when patients were followed for additional 3 months after therapy. No patient developed any serious side effect causing study cessation.

Despite these important findings, the study has certain limitations. The study was conducted at a single tertiary care centre with a relatively small sample size, which may limit the generalizability of the results. In addition, the follow-up duration was limited, and long-term recurrence rates could not be fully assessed. Blinding of participants and investigators was also not feasible because of the visible differences between treatment modalities, which may have introduced observer bias. Furthermore, treatment response was primarily based on clinical assessment without the use of dermoscopic or histopathological confirmation.

Future multicenter studies with larger sample sizes and longer follow-up periods are recommended to validate these findings further. Comparative studies involving different concentrations of potassium hydroxide and other emerging therapeutic modalities may also help establish standardized treatment guidelines for paediatric molluscum contagiosum. Additionally, assessment of patient satisfaction and quality-of-life outcomes would provide further insight into the overall effectiveness of these treatment approaches.

Conclusion

The findings of the present study demonstrate that both cryotherapy and topical 10% KOH solution are effective treatment modalities for paediatric molluscum contagiosum. Cryotherapy showed a comparatively faster clinical response and shorter cure time; however, it was associated with significantly greater pain, burning sensation, and pigmentary changes. In contrast, topical 10% KOH solution provided comparable efficacy with fewer adverse effects and the added advantage of easy domiciliary application, making it a more tolerable option for children and their caregivers. These findings support the use of topical KOH as a safe, cost-effective, and practical therapeutic alternative in routine clinical practice.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Conflict of interest No conflict of interest.

Author's contribution

AI: Have made substantial contributions to conception and design, acquisition of data and revising the manuscript critically.

SM,AS,US: Have made substantial contributions to analysis and interpretation of data, drafting and revising the manuscript critically.

TAC: Have made substantial contribution acquisition of data, revising the manuscript critically.

SF,MNA: Have made substantial contribution acquisition of data, revising the manuscript critically.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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