Comparative Evaluation of Topical 10% Potassium Hydroxide and Intralesional MMR Vaccine in Pediatric Molluscum Contagiosum: A Prospective Interventional Study

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Abstract

Background: The infection called Molluscum contagiosum (MC) is caused by a virus called a poxvirus and is characterized by small dome-shaped bumps on a child's skin. MC is often treated with various treatments (some have been around for a long time) however, the best possible options will be safe, effective, easy to apply and tolerated well by children. This study was performed to compare the efficacy and safety of the use of topical 10% Potassium Hydrate (KOH) to the use of intralesional measles, mumps and rubella (MMR) vaccination when using those two treatments for caregivers who have a child with Molluscum contagiosum.

Methods: This prospective study was conducted on 60 children (1-12 years old) with clinically diagnosed molluscum contagiosum and randomly assigned them to two groups of 30. Group A had topical 10% KOH applied, while Group B was treated using intralesional MMR vaccine. Following up for two years, including six months after treatment, the researchers assessed and compared the two groups on treatment response, lesion clearance rate, recurrence rate, and adverse effects associated with the respective treatments.

Results: A complete clearance of the lesions occurred in 86.7% of the patients who received the MMR treatment; however, only 70% had total lesion clearance in the KOH group ($p<.05$). All MMR-treated lesions will resolve within an average of four weeks; however, many KOH-receiving lesions will have a longer resolution time. Patients who had an intralesional injection of MMR had fewer adverse events (pain, redness, hyperpigmentation) compared to KOH-treated patients. Additionally, patients who received intralesional injection of MMR had fewer instances of recurrence of the lesion.

Conclusion: The use of the MMR vaccine injected under the skin has been proven to be a better treatment than using a topical solution of (potassium hydroxide) KOH 10%, and is therefore considered superior. There is evidence that the MMR vaccine will clear more molluscum faster, have less reoccurrence, and be better tolerated than topical treatments, thereby supporting its use in patients who have multiple lesions or who have not responded to previous treatments.

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1. Introduction

Molluscum contagiosum (MC) is a benign, self-limiting cutaneous infection of the skin caused by the molluscum contagiosum virus (MCV) which is a member of the double-stranded DNA viruses in the Poxvirus family [1]. The individual most frequently infected by MC is a child between the ages of 1 to 10, due to their immature immune function, frequent peer-to-peer contact and

propensity for minor skin trauma, all create the ability for quick transmission between children [2]. Lesions of MC are small, dome-shaped, pearly papules with a central umbilication, and commonly found on the trunk, face and limbs [3].

MC is transmitted via direct skin-to-skin contact, autoinoculation or via contaminated fomites such as towels or toys [4]; while MC is known to be a self-limiting infection, resolving spontaneously in the 6-18 months, there are instances where persistent or widespread lesions cause significant cosmetic disfigurement, psychosocial stress and result in high levels of concern for parents thus requiring intervention in a timely manner [5]. Treatment options include destructive physical methods (curettage, cryotherapy, and electrocautery), topical chemical agents (salicylic acid, tretinoin, imiquimod and potassium hydroxide), and immunotherapeutic modalities (intralesional vaccines and interferons). There is no universally accepted first-line therapy for MC; therefore it is important that comparison of these different modalities is conducted in an appropriate scientific manner [6].

The cheap, easy application of 10% potassium hydroxide (KOH) as a topical keratolytic agent has led to its widespread use in clinical practice. At the same time, the use of the measles-mumps-rubella (MMR) vaccine has developed as an immunotherapeutic option, being able to create both local and peripheral anti-viral immunity [7, 8]. Unfortunately, there are still no direct comparisons between these two interventions on children. This study evaluates this literature gap.

2. Aim and Objectives

To assess and compare the effectiveness and safety of topical 10% potassium hydroxide (KOH) with intralesional measles-mumps-rubella (MMR) in treating children with molluscum contagiosum. To compare the results of both treatment modalities in regard to clearances, time to resolution, adverse effects, and recurrence rate. To assess the clinical response to topical 10% KOH; and to assess the clinical response to intralesional MMR vaccine.

3. Review of Literature

Various studies have looked at different treatment options for molluscum contagiosum (MC). For example, Rajouria, *et al.* showed that potassium hydroxide (KOH) was more effective than tretinoin in terms of speed of lesions clearing up (Rajouria, *et al*., 2010). Handjani, *et al*. demonstrated that KOH also clears MC lesions at a rate similar to that of cryotherapy but has fewer side effects related to pigmentation (Handjani, *et al*., 2005). Furthermore, Metkar, *et al.* suggested that KOH and imiquimod are equally effective but that KOH works faster than imiquimod to clear MC lesions (Metkar, *et al*., 2006).

Increasingly, immunotherapy has received attention for the treatment of MC. Chauhan, *et al*. reported that the majority of patients who received an intralesional administration of the MMR vaccine (live or inactivated) had complete clearance of their lesions without any serious adverse effects (Chauhan, *et al*., 2003). When reviewing multiple studies, it was found that immunotherapy has been shown to achieve clearance rates between 36% and 100% and is generally well tolerated (Lareau, *et al*., 2007). However, due to a lack of available studies that have directly compared the use of KOH versus MMR vaccination in children, these findings strengthen the clinical need for the current study (Duvall, *et al*., 2010; Roper, *et al*., 2004).

4. Materials and Methods

4.1. Study Design and Setting

The Outpatient Department of Dermatology, Venereology, and Leprology of the Saraswathi Institute of Medical Sciences in Hapur, Uttar Pradesh, conducted a two-year prospective interventional comparative study, after approval by the applicable institutional ethics committee and receipt of written consent from the parents/guardians.

4.2. Sample Size and Participants

Sample sizes were determined according to established statistical equations using a population prevalence of 8%, a 95% confidence level, and a 5% margin of error which results in 30 subjects in each group (N=60). Patients were children of between 1 and 12 years of age with a clinically diagnosed case of molluscum contagiosum, and patients were excluded if they had a concurrent skin infection, had a known allergy to KOH or components from the MMR vaccine or had received any + treatment within four weeks of the study start date.

4.3. Intervention

Group A (n=30): 10% KOH topical solution applied directly to lesions every 12 hours until clear or for a maximum of 12 weeks. Group B (n=30): Intralesional MMR Vaccine (0.1 mL) injected into the largest lesion every other week, four total treatments.

4.4. Outcome Assessment and Statistical Analysis

Participant responses were categorized as either complete (clearance 100%), good (clearance 75-99%), moderate (clearance 50-74%), or mild/no response (clearance ≤49%). Patients were monitored for six months following treatment for the recurrence of tumor. All data were analyzed using SPSS v26; Chi-square test, Fisher's exact test, and independent t-test were utilized. A p-value of less than 0.05 was considered statistically significant.

5. Results

See Table 1 for baseline demographic data. Both groups were comparable in age, sex, and lesion distribution ($p>0.05$). The predominant age group was 6–10 years (53.3%), with slight male preponderance.

Table 1: Baseline Demographic Characteristics of Study Participants (N=60)

Parameter	Group A – KOH (n=30)	Group B – MMR (n=30)	p-value
Mean Age ± SD (years)	6.8 ± 2.4	7.1 ± 2.6	0.62
Age Group 1–5 years	9 (30%)	8 (26.7%)	0.78
Age Group 6–10 years	16 (53.3%)	16 (53.3%)	>0.99
Age Group 11–12 years	5 (16.7%)	6 (20%)	0.74
Male : Female	17:13	18:12	0.81
Mean Lesion Count ± SD	8.4 ± 3.2	9.1 ± 3.7	0.40
Duration of Lesions (weeks)	6.3 ± 2.9	6.8 ± 3.1	0.51

Table 2 provides treatment summary tables. 86.7% of patients in the MMR group reached complete clearance, whereas only 70% of patients in the KOH group achieved complete clearance (p=0.04). MMR group patients reached resolution within 4 weeks on average, while the KOH group took 8 weeks to reach resolution (median). During the 6 month follow-up period, recurrence rates were 6.7% for the MMR group compared with 20% for the KOH group (Table 3). There were significantly higher rates of adverse effects reported by patients in Group A compared with Group B (p<0.05), namely, burning (60%); erythema (53.3%); hyperpigmentation (36.7%); and secondary infection (13.3%). In Group A, the majority of adverse events recorded mild/transient fevers (16.7%) and no significant localized complications were reported.

Table 2: Comparison of Treatment Response Between Groups

Response Category	Group A – KOH n (%)	Group B – MMR n (%)	p-value
Complete (100% clearance)	21 (70%)	26 (86.7%)	0.04*
Good (75–99% reduction)	5 (16.7%)	3 (10%)	0.43
Moderate (50–74% reduction)	3 (10%)	1 (3.3%)	0.30
Mild/No Response (<50%)	1 (3.3%)	0 (0%)	0.31
Median Time to Clearance	8 weeks	4 weeks	<0.001*
Sessions Required (mean)	3.8 ± 0.7	2.3 ± 0.6	<0.001*

Table 3: Adverse Effects and Recurrence Rates

Parameter	Group A – KOH n (%)	Group B – MMR n (%)	p-value
Burning Sensation	18 (60%)	2 (6.7%)	<0.001*
Erythema	16 (53.3%)	3 (10%)	<0.001*
Post-inflammatory Hyperpigmentation	11 (36.7%)	1 (3.3%)	0.001*
Secondary Infection	4 (13.3%)	0 (0%)	0.04*
Transient Fever	0 (0%)	5 (16.7%)	0.02*
Recurrence at 6 Months	6 (20%)	2 (6.7%)	0.03*

*Statistically significant (p<0.05)

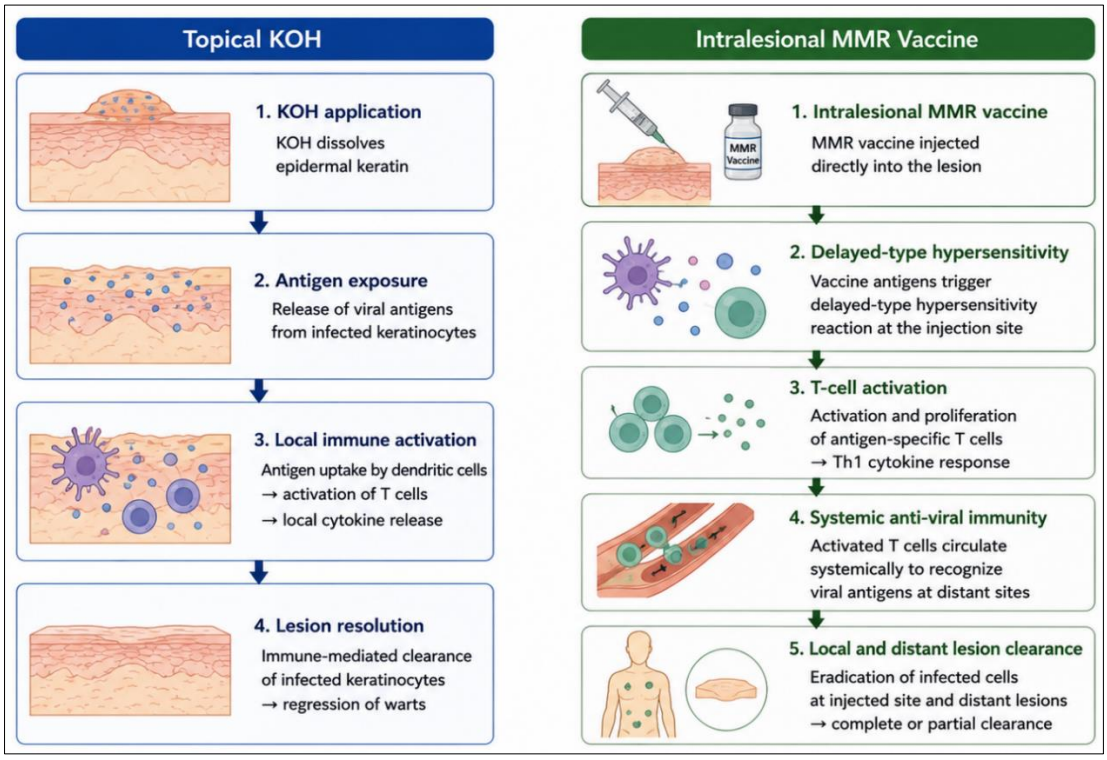

Fig 1: Mechanism of Action – Topical KOH vs. Intralesional MMR Vaccine

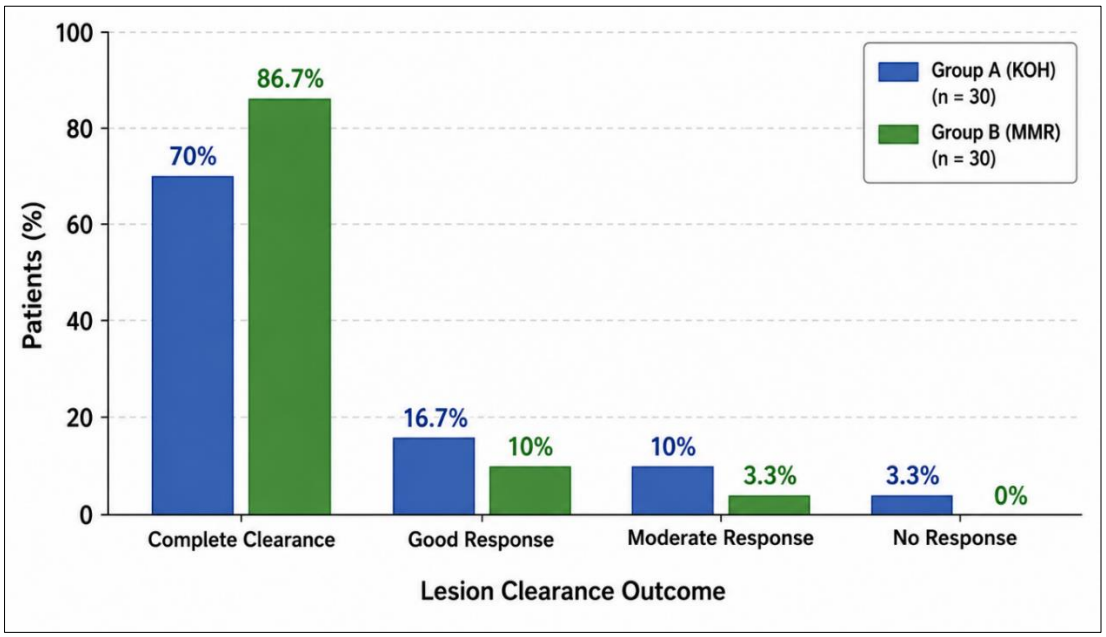

Fig 2: Comparative Lesion Clearance Rates – Group A (KOH) vs. Group B (MMR)

6. Discussion

This research showed that topical 10% KOH and the use of the MMR vaccine as an injection are both effective ways to treat children with molluscum contagiosum (MC); however, the MMR vaccine had better results on both the primary and secondary outcome measures than the topical KOH. The rate of complete clearance was 86.7% in the MMR immunotherapy group, which is consistent with Chauhan *et al*. [12] and supported by systematic review data showing clearance rates between 85-100% through intralesional immunotherapy [13]. The greater effectiveness of the MMR vaccine was likely due to the vaccine causing an immune response that produced systemic anti-viral cells (cell-mediated immunity) from the initial site of an injection as a delayed type hypersensitivity, where the immune response would also proceed to resolve any distant MC lesions, which would not happen with the KOH because it only works locally by effecting a keratolytic disruption [7, 8]. The lower recurrence rate with the MMR (6.7% vs.20%) further confirms that immunotherapy treatments will result in longer-term anti-viral memory than topical treatments such as KOH. In the KOH group, there are multiple adverse effects (e.g., hyperpigmentation and burning), which can be a substantial clinical barrier in the pediatric population (e.g., those with darker skin tones) because post-inflammatory pigmentation changes last longer inpeople with darker skin [9]. There were very few adverse effects reported by the MMR (none were noted in the MMR group), which would be acceptable when treating children.

The study has many limitations including the single-centre design, a relatively small sample size, and the use of clinical grading without quantitative measures for the viral load. There is a need for new multicentre randomized controlled trials that use larger cohorts and molecular outcomes in order to validate these findings further.

7. Conclusion

Both topical 10% KOH and intralesional MMR vaccine (www.cdc.gov) are effective treatments for molluscum contagiosum in children. However, the intralesional MMR vaccine has much higher rates of complete clearance (86.7% vs. 70%), quicker resolution of lesions, a better safety profile, and a significantly lower rate of recurrence during the six-month follow-up period, demonstrating that intralesional MMR immunotherapy is the preferred treatment for pediatric patients with multiple, widespread, or resistant-to-treatment molluscum contagiosum lesions. The authors recommend conducting large, multicenter, randomized controlled trials to validate these findings, as well as to develop appropriate dosages and dosing intervals, and to investigate long-term immunologic outcomes following MMR immunotherapy.

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