Original Article

Genital molluscum contagiosum in females – therapeutic efficacy and comparative evaluation of topical 10% and 20% potassium hydroxide

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Abstract

Introduction: Molluscum contagiosum (MC) is a cutaneous viral infection caused by a poxvirus, manifested by discrete, papular, pearly lesions with central umbilication. Genital lesions are mainly transmitted sexually. Till date, several forms of medical and surgical therapies have been used with variable success. In the present study, an attempt was made to review all the female patients of genital MC attending the sexually transmitted infection (STI) clinic of the Department of Dermatology, Venereology, and Leprosy of Guru Nanak Dev Hospital, Amritsar. **Aims and Objectives:** In the present study, therapeutic efficacy and comparative evaluation of topical 10% and 20% of potassium hydroxide (KOH) were undertaken. **Materials and Methods:** A total of 30 female patients of age group 18–50 years with clinically diagnosed MC and more than ten lesions were enrolled in this study. The lesions in each patient were divided into two equal Groups A and B. Topical 10% KOH was applied over lesions of Group A and 20% over lesions of Group B with the help of 26G needle. First, two applications were done by the doctor, and subsequent applications were done twice a week at bedtime at home by the patient herself until crusting. These cases were followed up at 4th day, 1st, 2nd, 3rd, 4th, 6th, 8th, 10th, and 12th week. Results were analyzed objectively and photographically at each follow-up and at the end of the study statistically. **Results:** Mean duration of treatment ± standard deviation in normal patients, HIV-positive patients, patients with associated STIs, patients with associated non-STIs, and pregnant patients in Group A and Group B was 6.83 ± 2.692, 9.33 ± 1.633, 6.83 ± 2.887, 8.20 ± 3.347, and 8.75 ± 2.121 weeks and 5.2 ± 2.156, 7.33 ± 1.633, 5.25 ± 2.050, 6.20 ± 2.864, and 6.50 ± 1.414 weeks, respectively. **Conclusion:** Topical 20% KOH is better than 10% KOH in genital MC in females.

Key words: Females, genital molluscum contagiosum, topical 10% potassium hydroxide, topical 20% potassium hydroxide

INTRODUCTION

Molluscum contagiosum (MC) is a common cutaneous viral infection caused by MC virus belonging to the genus Molluscipox.[1] It is transmitted by close personal physical contact and also through fomites.[2] It is present in both children as well as adults. In children, the most common sites involved are the chest, arms, and face while in adults, the most

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common sites involved are genitalia. When genitalia are predominantly involved, the most common route of infection is sexual transmission.[3] The average incubation period is 2–7 weeks. Clinically, it produces discrete pearly-white umbilicated papules.[4] It is a self-limiting infection but to decrease the risk of autoinoculation and transmission, several topical and systemic treatment modalities are being used but with variable results. These include potassium hydroxide (KOH), podophyllin, trichloroacetic acid, cantharidin, cryotherapy, silver nitrate, and imiquimod.[5-7] This study was undertaken not only to evaluate the therapeutic efficacy of topical KOH but also to comparatively evaluate two varying concentrations of KOH, i.e.,10% and 20% on genital MC in females.

Aims and objectives of the study

1. To study the therapeutic efficacy of topical 10% KOH on genital MC in females
2. To study the therapeutic efficacy of topical 20% KOH on genital MC in females
3. Comparative evaluation of therapeutic efficacy of topical 10% KOH and 20% KOH on genital MC in females.

MATERIALS AND METHODS

A prospective study with a total of thirty female patients of age group 18–50 years presenting to sexually transmitted infections (STI) clinic of Guru Nanak Dev Hospital, Amritsar, with clinically diagnosed genital MC was carried out.

Inclusion criteria

1. Female patients of age group 18–50 years attending the STI clinic and clinically diagnosed MC with lesion count >10
2. Patients are willing to come for regular follow-up.

Exclusion criteria

1. All male patients and children
2. Female patients of age <18 years or more than 50 years
3. Lesion count <10
4. Patients not willing to come for follow-up.

The patients who satisfied the inclusion criteria were randomly included into the study and others were excluded from the study. All the routine tests were done. After taking informed written consent, the lesions in each patient were divided into two equal groups as follows: Group A and Group B. The lesions were cleaned with distilled water. Topical 10% KOH was applied with a 26G needle over lesions of Group A, and topical 20% KOH was applied over lesions of Group B. First, two applications were done by the doctor, and subsequent applications were done by the patient herself at home twice a week at bedtime until crusting after being properly explained about the procedure. Follow-up with clinical examination and photographic evaluation was done at the end of day 4, then weekly up to 4 weeks, and 2 weekly up to 12 weeks.

Grading of response was done as: G1 ≤25% response, G2 = 26%–50% response, G3 = 51%–75% response, and G4 ≥76% response.

Efficacy was graded as: good = complete response in <4 weeks, moderate = complete response in 4–8 weeks, and poor = complete response in >8 weeks.

RESULTS AND DISCUSSION

During the study period, thirty female patients were included into the study. Majority of the patients belonged to the age group <25 years, but the mean age of patients was 29.83 ± 9.307 years [Table 1]. Ninety percent of patients showed total duration of the disease <6 months, with a mean duration of 3.43 ± 2.932 months. Fifty percent of the patients were housewives, 20% were laborers, 13.3% were students, 6.7% were teachers and salon workers, while 3.3% were tailors [Table 2]. We divided these into high-risk and low-risk occupations. High-risk occupations were laborers, students, salon workers, and tailors. According to this, 43.3% of patients had a high risk of contracting the disease according to their occupation while 56.7% of patients had low risk of the same. Of all patients, 93.3% were married and 6.7% were unmarried. Of married patients, a history of extramarital sexual contact was present in 21.43% of the female patients and in 53.57% of their male partners, suggesting that polygamy is more prevalent in men as compared to women [Table 3]. Both the unmarried female patients had a history of premarital sexual contact. Of all, only 20% of patients were illiterate while rest 80% of patients were literate, suggesting that educational level of the patients does not affect the transmission of the STIs. About 56.7% of patients lived in rural areas, while 43.3% of patients lived in urban areas, suggesting that MC was more common in patients living in rural areas which can be attributed to lack of sexual awareness and safe sexual practices in the rural areas.

About 20% of patients were HIV positive, 16.6% of patients had associated systemic diseases and

non-STIs such as diabetes mellitus, hypothyroidism, hepatitis B, and intertrigo, and 26.7% of patients were pregnant [Table 4]. These all are states of immunodeficiency, suggesting increased prevalence of MC in the immunocompromised. Associated STIs such as vulvovaginitis, vaginocervical discharge, warts, and herpes simplex were present in 39.9% of patients, suggesting an association of other STIs predisposed the patients to contract MC or vice versa.

About 86.7% of patients had lesions over the vulva and thighs while 6.7% of each had lesions over the vulva only and over extragenital sites in addition to the vulva and thighs.

Table 1: Age group-wise distribution and mean age of the patients

Age group (years)	Number of patients	Percentage of total	Mean age±SD (years)
<25	13	43.3	29.83±9.307
26-35	11	36.7	
>35	06	20.0	

SD=Standard deviation

Table 2: Occupation of the patients

Occupation	Number of patients	Percentage of total
Housewife	15	50
Laborer	06	20
Student	04	13.3
Teacher	02	6.7
Salon	02	6.7
Tailor	01	3.3

Table 3: History of extramarital sexual contact in patients and their partners

History of extramarital sexual contact	Female partners	Male partners
Present	6/28	15/28
Not present	22/28	13/28

Table 4: Number of patients with associated other conditions

Special cases	HIV positive	Patients with associated STIs	Patients with associated non STIs	Pregnant patients
Yes	6	12	5	8
No	24	18	25	22

STIs=Sexually transmitted infections

Since patients who had more than ten lesions overall and at least five lesions in each Group A and Group B were included, it was found that majority of the patients in each group had <10 lesions on the day 0 with a mean ± standard deviation (SD) of 10.10 ± 4.759 lesions in Group A and 10.17 ± 4.786 lesions in Group B [Table 5]. Group B showed Grade 4, i.e., the complete response at as early as week 2, but Group A showed Grade 4 response at week 3. Majority of the patients in Group A, i.e., 93.3% showed complete response within 3–10 weeks [Figure 1] but in Group B, i.e., 93.3% showed complete response within 2–8 weeks [Figure 2], suggesting that Group B showed better response as compared to Group A, but this was not significant statistically. All the patients in Group B showed Grade 4 response by week 10, but in Group A, Grade 4 response was seen in all the patients by week 12. Mean total duration of treatment in Group A was found to be 6.83 ± 2.692 weeks and in Group B was found to be 5.20 ± 2.156 weeks [Table 6]. This difference in the mean total duration of treatment in both the groups was found to be statistically significant with $P = 0.012$, suggesting that topical 20% KOH is better in terms of total duration of treatment as compared to topical 10% KOH. Similarly, mean total number of applications required was 13.67 ± 5.384 applications in Group A and 10.40 ± 4.312 applications in Group B with a statistically significant $P = 0.012$, suggesting that topical 20% KOH is better than topical 10% KOH in terms of number of applications required [Table 6]. This is consistent with a study conducted by Vijay *et al*. where topical 20% KOH was found to be better than 10% KOH.[8] Efficacy was found to be good in 9 (30%) patients, moderate in 14 (46.7%) patients, and poor in 7 (23.3%) patients of Group A while it was found to be good in 16 (53.3%) patients, moderate in 12 (40%) patients, and poor in 2 (6.7%) patients of Group B [Table 7]. Even though Group B fared better than Group A in terms of efficacy, this difference was statistically not significant, suggesting that efficacy of both topical 10% and 20% KOH is comparable. Adverse effects were seen in 7 (23.3%) of patients in Group B and only 2 (6.7%) of patients in Group A. Stinging was

Table 5: Mean number of lesions in both groups on day 0

Group according to number of lesions on day 0	Group A (%)	Mean number of lesions on day 0±SD (Group A)	Group B (%)	Mean number of lesions on day 0±SD (Group B)
<10	17 (56.67)	10.10±4.759	16 (53.34)	10.17±4.786
11-20	12 (40)		13 (43.33)	
>20	1 (3.33)		1 (3.33)	

SD=Standard deviation

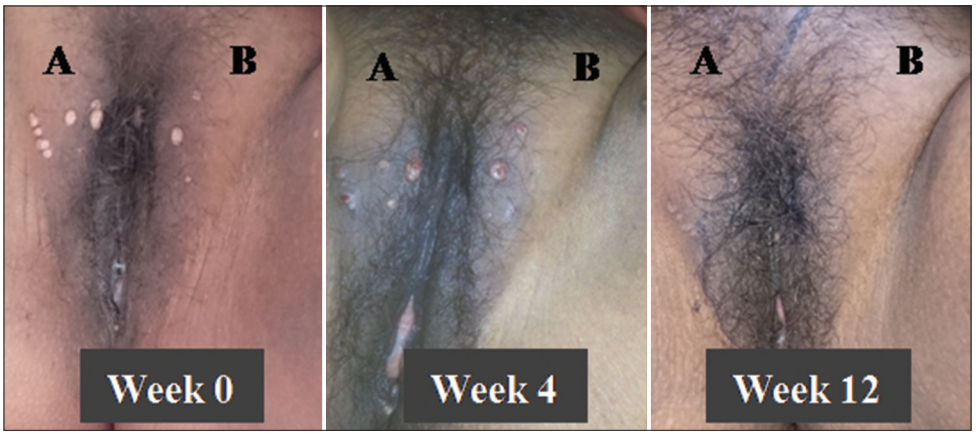

Figure 1: Clinical response in group A and B in case 1 at each follow- up

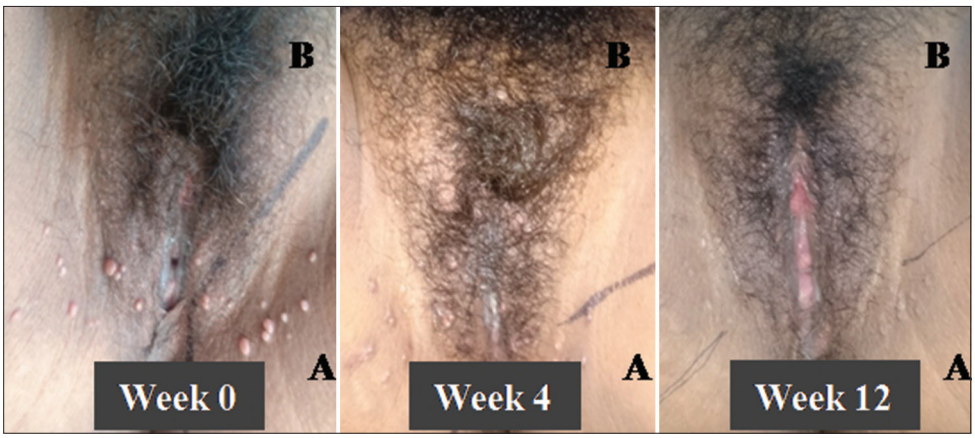

Figure 2: Clinical response in group A and B in case 2 at each follow- up

Table 6: Mean duration of treatment and mean number of applications required in both groups

Group	Mean duration of treatment (weeks)±SD	*P*	Mean no. of applications required±SD	*P*
A	6.83±2.692	0.012	13.67±5.384	0.012
B	5.20±2.156		10.40±4.312	

SD=Standard deviation

Table 7: Efficacy of both groups

Efficacy	Group A (%)	Group B (%)
Good	9 (30.0)	16 (53.3)
Moderate	14 (46.7)	12 (40.0)
Poor	7 (23.3)	2 (6.7)

found to be the most common side effect and seen in 2 (6.7%) patients in Group A and 5 (16.7%) patients in Group B, followed by secondary infection and ulceration each which were seen only in Group B in 1 (3.3%) patient [Figure 3]. However, in the study conducted by Sequeira *et al*., pigmentary anomalies were found to be the most common adverse effect which was attributed to the application with a cotton bud along with daily application in their study.[9]

Mean duration of treatment in HIV-positive patients, patients with associated STIs, patients with associated non-STIs, and pregnant patients in Group A was found to be 9.33 ± 1.633, 6.83 ± 2.887, 8.20 ± 3.347, and 8.75 ± 2.121 weeks, respectively, and in Group B was found to be 7.33 ± 1.633, 5.25 ± 2.050, 6.20 ± 2.864, and 6.50 ± 1.414 weeks, respectively. These patients showed increased total mean duration of treatment than normal patients, where it was 6.83 ± 2.692 weeks for Group A and 5.2 ± 2.156 weeks for Group B. However, a significant difference was found between Group A and Group B in case of pregnant patients only (P = 0.026), suggesting that 20% KOH is better than 10% KOH in terms of mean duration of treatment in pregnant patients.

Similarly, mean total number of applications required in HIV-positive patients, patients with associated STIs, patients with associated non-STIs, and pregnant patients in Group A was found to be 18.67 ± 1.633, 13.67 ± 5.774, 16.40 ± 6.693, and 17.50 ± 4.243 applications, respectively,

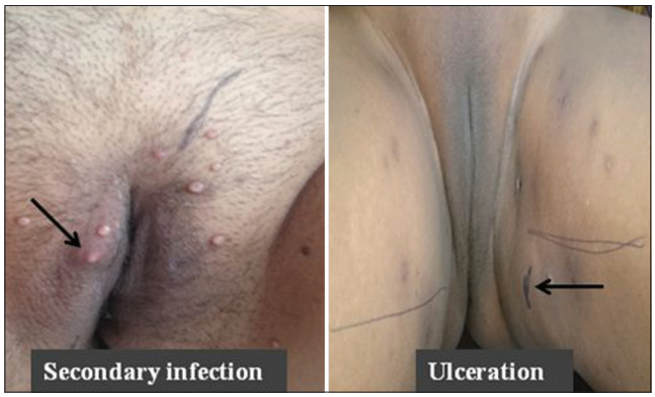

Figure 3: Adverse effects seen in Group B

and in Group B was found to be 14.67 ± 1.633, 10.50 ± 4.101, 12.40 ± 5.727, and 13.0 ± 2.828 applications, respectively. These patients showed increased total mean number of applications required than normal patients, where it was found to be 13.67 ± 5.384 applications in Group A and 10.4 ± 4.312 applications in Group B. However, a significant difference was found between Group A and Group B in case of pregnant patients only (P = 0.026), suggesting that 20% KOH is better than 10% KOH in terms of mean total number of applications required in pregnant patients.

Efficacy of 10% and 20% KOH was found to be low in HIV-positive patients, patients with associated STIs, patients with associated non-STIs, and pregnant patients as compared to patients who did not have any of these conditions. However, this difference was only significant in pregnant patients (P = 0.036 for Group A and 0.006 for Group B). This can be attributed to the fact that these conditions induce an immunocompromised state due to which the patient is unable to mount sufficient immune response to clear the MC infection leading to increase in the mean duration of treatment with increased number of applications required which in turn leads to low efficacy.

Statistical analysis used

1. Mean (Average) = $\bar{X} = \frac{\sum X}{N}$
2. Chi-square = $X^2 = \sum \frac{(O - E)}{E}$

Where O = Observed value and E = Expected value

3. SD of observation = $SD = \sqrt{\frac{\sum X - \bar{X})^2}{N - 1}}$
4. Standard Error (S. E.) = $SE_{\bar{X}} = \frac{S}{\sqrt{n}}$
5. Student test (t) = $t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{S_1^2}{N_1} + \frac{S_2^2}{N_2}}}$

All analysis was performed by Gurinder Singh, Statistician, Guru Nanak Dev University, Amritsar using SPSS (SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.) 17.0 version.

CONCLUSION

Topical KOH in both 10% and 20% concentration has been found to be an effective therapeutic modality in genital MC in females. Although both concentrations show no statistically significant difference in their efficacy, difference in their total duration of treatment and total number of applications required was found to be statistically significant, being better in 20% KOH as compared to 10% KOH. However, still further studies need to be conducted to validate these findings in immunocompetent and immunosuppressed patients.

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Conflicts of interest

There are no conflicts of interest.

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