Original Article

Autoinoculation Versus 35% Trichloroacetic Acid for the Treatment of Molluscum Contagiosum: An Open-Label Randomized Controlled Trial

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Abstract

Background: Despite the availability of different treatment modalities, molluscum is often recurrent after the treatment. Autoinoculation in molluscum is a recently studied modality. **Objective:** The aim of this article is to evaluate and compare the efficacy of autoinoculation and trichloroacetic acid (TCA) for the disappearance of molluscum contagiosum (MC). **Methods:** This prospective, randomized controlled trial was done in which a total of 128 patients of molluscum were divided into two groups of 64 patients each: Group A treated with autoinoculation and Group B received TCA application. The patients were followed-up till 6 months for efficacy and safety. **Results:** At the end of 3 months, a statistically significant (P=0.023) complete clearance of lesions was noted in Group A (80%) when compared with Group B (62%). At the end of 6 months, the recurrence rate was significantly less in the autoinoculation group (3%) than in the TCA group (42%). **Conclusion:** We conclude that autoinoculation appears to be a safe, simple, and efficacious procedure with better clearance, minimal expertise, recurrence, and complications when compared with TCA.

Keywords: Autoinoculation, molluscum contagiosum, trichloroacetic acid

Introduction

Molluscum contagiosum (MC) is a cutaneous viral infection caused by molluscum contagiosum virus, affecting children usually. It is transmitted through direct person-to-person contact or indirectly by fomites.[1] Although the lesions are often self-limiting, cosmetic disfigurement and infectious nature of the disease are the few reasons requiring treatment.[2]

A variety of therapeutic alternatives are available for the treatment of MC either destructive (mechanical and chemical) or immunomodulatory, with variable efficacy. Destructive therapies include cryotherapy, curettage, electrodesiccation, pricking with a needle, photodynamic therapy, and lasers.[3-5] Chemical options include canthridin, salicylic acid, tretinoin, adapalene, potassium hydroxide, podophyllin, and trichloroacetic acid (TCA); nevertheless, no therapy is universally effective.[3,6-10] Immunomodulatory methods are topical imiquimod, oral cimetidine, and interferon alfa.[3,11,12] Topical cidofovir (1–3%) has been used in the immunosuppressed population, but not studied in general population.[13,14]

Autoimplantation helps in inducing a cell-mediated immune response to antigen by production of Th1 cytokines (TNF alpha and IL-1), which downregulates the transcription of genes, whereas interferon-gamma and IL-2 stimulate cytotoxic T cells and natural killer cells eradicate the infected cells.[15] It is a well-studied treatment modality for warts.[15-18] Recently, Kachhawa *et al.*[19] explained autoinoculation as an effective treatment

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modality for MC, which helped in clearance of both local and distant lesions. This prompted us to compare the efficacy of autoinoculation with TCA in MC. In order to assess the mechanism of cure, we also observed pre- and post-procedure histological findings, after 2 weeks with each therapy.

Materials and Methods

Study design

This hospital-based, randomized, controlled trial was conducted in the Department of Dermatology at a tertiary care teaching institute, over a period of 1 year from May 2019 to April 2020. The study was approved by the Institutional Review Board (EC registration no. SNMC/IEC/2019/72, dated on 11/04/2019) before commencement, and informed consent was obtained from all patients to be a part of the study.

Inclusion criteria

All patients of MC in the age group of 5–60 years of either sex, with five or more non-genital naive lesions, were recruited in this study.

Exclusion criteria

Pregnant and lactating mothers, immunosuppressed due to drug or disease, patients who had received any treatment for MC in the last 3 months, patients with tendency of keloid or hypertrophic scars, inability to come for regular follow-up, and those with genital molluscum were excluded from the study.

Sample size

The minimum sample size was calculated at 80% study power, α error of 0.05, and expected standard deviation of 2.

Study subjects

Clinically diagnosed (dome-shaped pearly white lesions, 1–5 mm in diameter with an umbilicated center) 128 patients of MC were recruited in the study. Demographic data and patients' clinical data including number, size, site, duration, and presence or absence of distant MC were noted at the start of the study and at each follow-up visit, in a prestructured proforma. Routine baseline investigations were done to rule out any hematological abnormality, immunosuppression, active viral or bacterial infection, renal or hepatic dysfunction, bleeding time, clotting time, prothrombin time, random blood sugar levels, urine pregnancy test, and an HIV TRI-DOT test. Photographic records were maintained prior to treatment (at baseline) and at each subsequent visit.

Patients were randomly allocated into two groups of 64 patients each using a computer-generated randomization method. Concealment of randomization was done by opaque sequentially numbered and sealed envelopes. Group A patients received treatment with autoinoculation technique, whereas Group B patients were treated with TCA.

Procedure

(A) Autoinoculation

A well-formed lesion was selected as a donor. After disinfection and topical anesthesia, the donor lesion was pierced using an insulin syringe from a site just adjacent to the lesion, followed by repeated puncturing of the lesion from within five to seven times to expose the contents of the molluscum body to the dermis. It inoculated and exposed the viral antigen to the immunological surveillance system. Fusidic acid ointment was applied over the punctured site, after the procedure. Single session of autoinoculation was performed.

Before autoinoculation procedure, the lesion was demarcated on the basis of following criteria:

a. Six watershed areas in the body for lymphatic drainage;
b. One vertical midline divides body into right and left and two horizontal lines on each side divide the area into three zones on each side: the first zone lies above the line of clavicle, the second between line of clavicle and line at the umbilical level, and the third below the umbilical line. The face region was further subdivided into three zones on the basis of drainage of parotid, submandibular, and submental lymph nodes.
c. Number and site of lesions were calculated by the above criteria, and then one per five MC lesions from each site was taken as representative lesion and intervention was done on that lesion only.

(B) Chemical cautery by TCA

About 35% TCA solution was applied with the help of pointed end of a wooden applicator to the center of all the MC lesions until a white frost appeared.

Follow-up

Patients were followed up fortnightly for 3 months to check clearance and thereafter monthly for next 3 months to check for recurrence. Any local side effects such as redness, swelling, infection, hyperpigmentation or hypopigmentation, and scarring were recorded during this period. During the follow-up visit, biopsy of interventional site was taken to monitor histopathological changes.

Assessment

Response to treatment was evaluated by a decrease in the number of lesions along with photographic comparison. The response to therapy was graded as complete clearance, partial clearance, and no clearance.

Statistical analysis

Statistical analysis was done using SPSS 23 software. The data on categorical variables were presented as percentages

and the data on continuous variables were presented as mean± standard deviation (SD). For analytic statistics, continuous variables were compared by using unpaired Student's *t*-test and categorical data were analyzed by using the χ^2 test.

P-value of less than 0.05 was considered statistically significant.

Results

A CONSORT flowchart showing flow of study participants was shown in Figure 1. One hundred and twenty-eight patients were randomized equally into two groups. Seven patients were lost to follow-up (three in Group A and four in Group B).

The mean age in Group A and Group B was 12.40±5.40 years (range 5–38 years) and 13.30±7.50 years (range 6–36 years), respectively. The female-to-male ratio was 1.13:1 in Group A and 0.93:1 in Group B. Most of the patients in both the groups were students, i.e., 45 (72.58%) in Group A and 48 (77.42%) in Group B.

Majority of the patients in both the groups (Group A 45.16% and Group B 41.13%) had lesions for 7–12 weeks. The mean number of lesions in Group A was 15.80±7.02 (range 5–34) and in Group B was 14.40±6.03 (range 5–30).

Lesions were distributed on different parts of body but face was the predominantly affected site in both the groups, 35 (54.68%) and 30 (46.87%) patients in Groups A and B, respectively, followed by trunk and lower limb. Most of the patients in both the groups, 90% (n = 115), had not taken any kind of treatment for MC before participating in the study. More details regarding the clinical characteristics of both the groups are mentioned in Table 1.

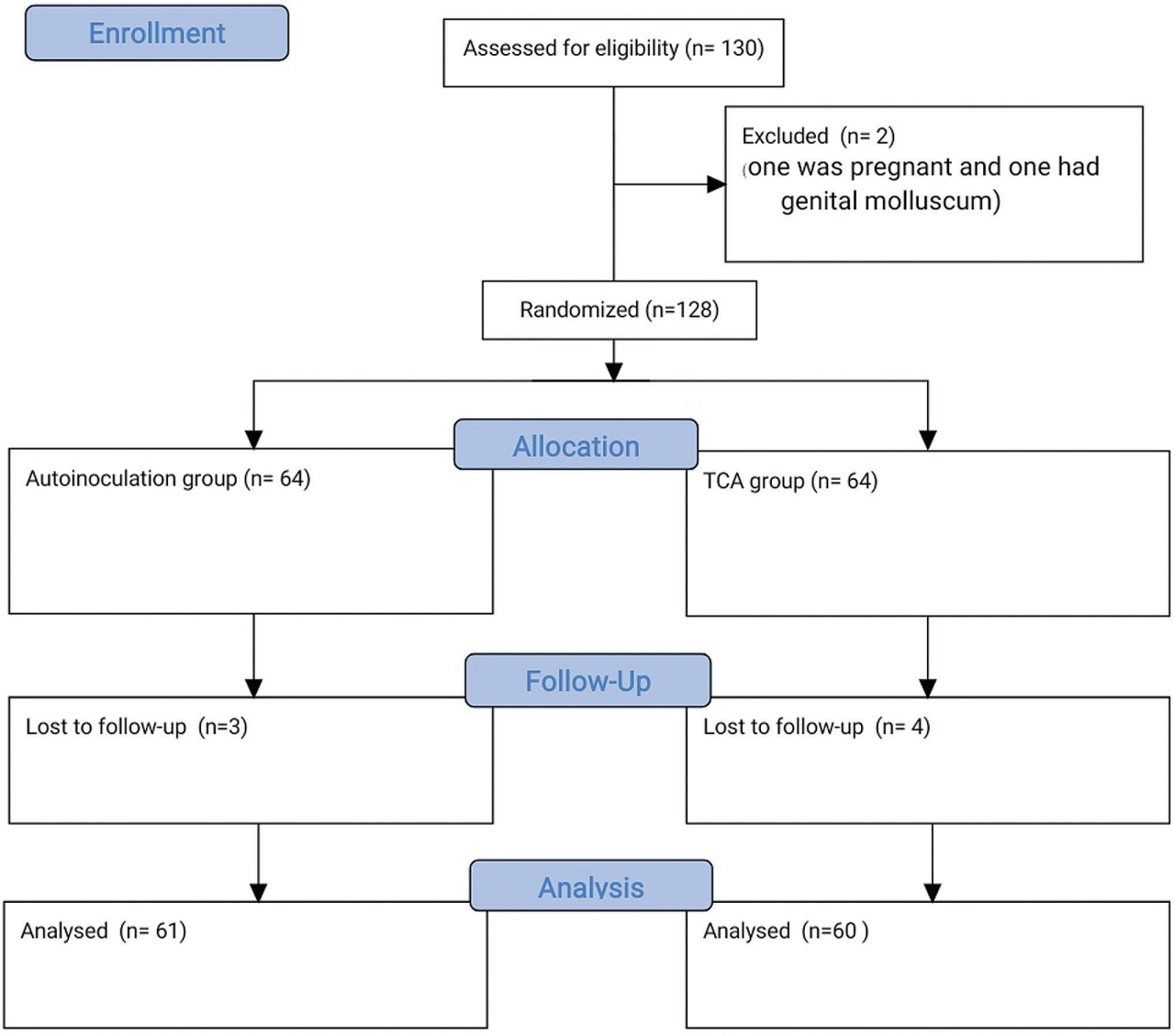

Figure 1: Consort flow diagram of study participants

In both the groups, at the end of 3 weeks, no patient showed lesion clearance. At the end of 3 months, a statistically significant difference was observed between these groups with better outcome in Group A, in which 49 (80%) patients had complete clearance, whereas in Group B, 37 (62%) patients had complete clearance (P = 0.023) [Figure 2]. Group A had partial clearance in 18% (n = 11) and no clearance in 2% (n = 1); however, Group B had partial clearance in 33% of the (n = 20) patients and no clearance in 5% (n = 3) of the patients [Table 2].

Table 1: Demographic and clinical characteristics of autoinoculation (Group A) and TCA (Group B)

	Group A (n = 64)	Group B (n = 64)
Age (years)		
≤10	40 (62.5%)	33 (51.56%)
11–30	21 (32.81%)	24 (37.5%)
>30	3 (4.6%)	7 (10.93%)
Mean age (years)	12.40±5.40	13.30±7.50
Median age (years)	10	9
Age range (years)	5–38	6-36
Gender		
Male	30 (46.87%)	33 (51.56%)
Female	34 (53.12%)	31 (48.43%)
No. of lesions		
≤10	18 (28.12%)	24 (37.5%)
11–20	31 (48.43%)	32 (50%)
>20	15 (23.43%)	8 (12.5%)
Site of lesions		
Face	35 (54.68%)	30 (46.87%)
Trunk	16 (25%)	14 (21.87%)
Upper limb	4 (6.25%)	2 (3.125%)
Lower limb	9 (14.06%)	18 (28.12%)
Treatment history		
Yes	4 (6.25%)	9 (14.06%)
No	60 (93.75%)	55 (85.93%)

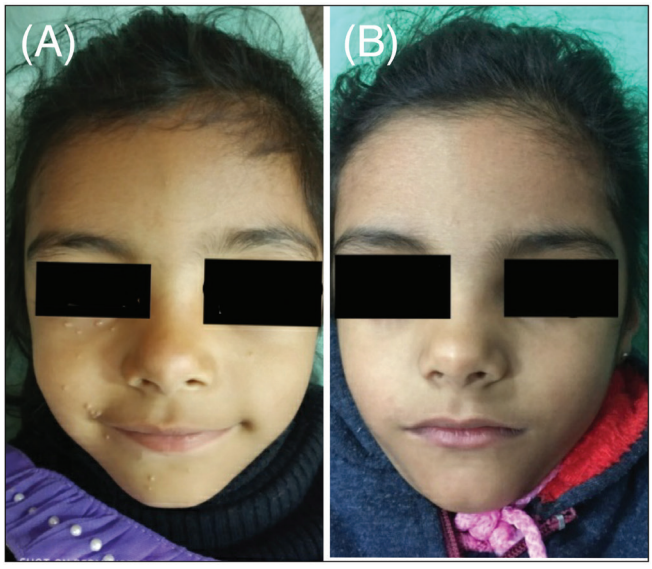

Figure 2: Pre- and post-autoinoculation photographs showing complete clearance of MC lesions

At the end of 6 months, in Group A only, 3% of the (n = 2) patients showed recurrence at 16th and 24th weeks. Both patients showed complete clearance before recurrence. In Group B, out of the 37 patients who showed complete clearance, 12 patients showed recurrence and out of the 20 patients who showed partial clearance 13 patients showed recurrence. This difference in both the groups was statistically significant (P < 0.0001).

With autoinoculation therapy, maximum response of complete clearance was seen between 5 and 7 weeks, whereas in the TCA group, it was between 9 and 12 weeks. In the autoinoculation group, the mean time of complete clearance was 7.04±2.74 weeks, which was significantly better than the mean time (10.13±2.41 weeks) of Group B (P < 0.0001).

Adverse events following autoinoculation and TCA have been shown in Table 3. Majority of the patients (92%) in the autoinoculation group did not show any complications compared with the TCA group (45%), and this difference was highly significant (P=0.0001). Overall, the most common side effect, i.e., post-inflammatory hyper/hypopigmentation, was noted in 15 patients; out of them 13 were Group B patients and 2 were Group A patients (P = 0.02). The second common side effect was pain observed in eight patients of Group B and four patients of Group A. Burning and scarring were only seen in TCA group patients (P-value = 0.0009 and 0.04, respectively) [Figure 3].

Discussion

Despite the availability of numerous destructive or immunomodulatory treatment options, a single universally reliable and effective therapeutic modality is yet to emerge. Most of them are inconvenient, have side effects, and cannot prevent recurrence.

There are a number of studies proving the role of cell-mediated immunity in the resolution of warts.[15-18] Autoimplantation and different intralesional immunotherapeutic agents (*Candida* antigen, BCG vaccine, MMR vaccine, Mycobacterium w vaccine) have proven useful in warts.[20] Similarly, cell-mediated immunity also plays a most important role in MC by modulating and controlling the infection, supported by multiple studies.[21-23]

Hence, this randomized controlled trial was done to assess and compare the efficacies of autoinoculation and TCA for the treatment of MC.

The most common age group was ≤10 years (57%) in this study because the spread of the virus among children is rapid and easy; similar findings were observed by Metkar *et al.*[24] and Goyal *et al.*[25] In our study, male-to-female

Table 2: Therapeutic response of both treatments at 3 months: autoinoculation (Group A) and TCA (Group B)

	Group A (n =64)	Group B (n = 64)	Applied test	P-value
Complete clearance	49 (80.33%)	37 (61.67%)	χ^2 5.464	0.023
Partial clearance	11 (18.03%)	20 (33.33%)	$\chi^2$3.484	0.053
Non-clearance	1 (1.64%)	3 (5.00%)	Fisher's exact	0.364
Total	61	60		

Table 3: Side effects

	Group A (n = 62)	Group B (n = 62)
Pain	4	8
Burning	0	9
Scaring	0	3
Hyper/hypopigmentation	2	13
No complications	55	27
Total	61	60

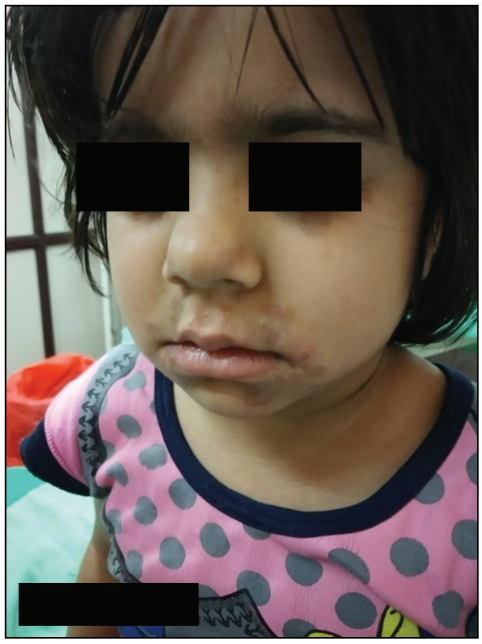

Figure 3: Hyperpigmentation and scarring following TCA application

ratio was approximately 1:1 in both the groups, similar to a study by More *et al.*[26]

The commonest group affected was students (75%), followed by housewives (6%) in our study. Metkar *et al.*[24] and Goyal *et al.*[25] reported similar findings. Overall 49% (n = 63) of the patients had lesions in the range of 11–20 in number, followed by 32.8% had lesions ≤10 in number and 17.9% of the patients had lesions >20 in number. These results were in accordance to the study by Gupta *et al.*[27] and Goyal *et al.*[25]

In our study, face was affected the most, i.e., in 54.68% in one group and 46.87% patients in other group followed by trunk (Group A 25% and Group B 21.87%) and lower limbs. This distribution was almost similar to the study by Kashif *et al.*,[10] Rajouria *et al.*,[28] and Al-Mutairi *et al.*[29]

At the end of 3 months, complete clearance was seen in 80% post-autoinoculation when compared with 62% following TCA application. Similar to this study, Gupta *et al.*[27] reported 77.3% clearance rate. They removed molluscum body and implanted into the dermal pocket extending up to the deep dermis, which can cause unintentional contamination of normal epidermis, thereby increasing the chance of newer lesions inevitably.[27] Kachhawa *et al.*[19] reported complete clearance in 55.2% of the cases. We found improvement with autoinoculation therapy in 5th week, which contrasts the findings of Shivakumar *et al.*[30] (autoimplantation in warts) wherein response was as early as 3 weeks. Complete clearance was noted within 7 weeks, which was similar to the study by Shivakumar *et al.*[30] and Kachhawa *et al.*[19]

The clearance rate in the TCA group was 62%, i.e., comparable to the results of the study by Goyal *et al.*[25] (60%). However, Kashif *et al.*[10] and Al-Hamzawi and Al-Shammari[31] reported higher clearance rates and could be due to multiple applications of TCA.

At the follow-up visits, in the autoinoculation group, only 3% of the patients showed recurrence, whereas 42% of the patients showed recurrence in the TCA group, which can be due to its immunomodulatory action. In contrast, Gupta *et al.* reported higher recurrence rates, i.e., 9.1%. However, Shivakumar *et al.*[30] (autoimplantation in wart) and Kachhawa *et al.*[19] (autoinoculation in mc) have reported no recurrence. The recurrence rate in the TCA group was in accordance with the study by More *et al.*[26] In contrast to our study, Kashif *et al.*[10] and Al-Hamzawi and Al-Shammari[31] reported 16.7% and 11.9% recurrence rates, respectively. This difference could be due to multiple weekly applications of TCA.

The autoinoculation group showed less complication when compared with the TCA group, and these results were statistically significant. Overall, the most common side effect is post-inflammatory hyper/hypopigmentation (12.39%), followed by pain (9.91%). Burning (15%) and scarring (5%) were observed only in the TCA group. Goyal *et al.*[25] observed similar side effects which were in accordance with our TCA group findings.

Clinical and histopathological comparison of both groups

The histopathological features of MC are lobulated endophytic hyperplasia of keratinocytes, which contain very large intracytoplasmic inclusion bodies with minimal dermal infiltration. Interestingly, the biopsy reports

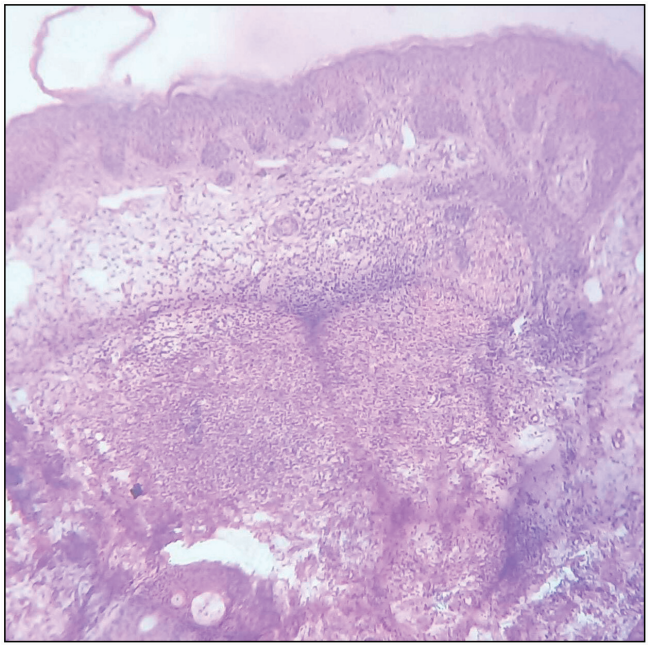

Figure 4: Mildly hyperplastic squamous epithelium with marked mixed inflammatory infiltrate in upper and mid dermis (hematoxylin and eosin stain, 40x)

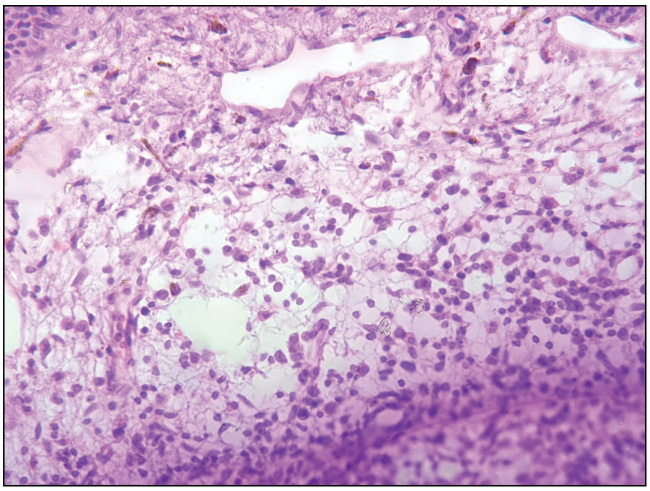

Figure 5: Inflammatory infiltrate consisting of mainly histiocytes and lymphocytes in upper and mid dermis (hematoxylin and eosin stain, 400x)

of MC treated with autoinoculation therapy showed histiocytes when compared with TCA therapy which showed lymphocytes.

Clinical and histopathological comparison of both groups proves the role of immune system in disease clearance. In the TCA group, this histopathological response was seen over the procedure site only. Whereas in the autoinoculation group, clearance of distant lesions and presence of histiocytes in histopathology were suggestive of more extensive inflammation [Figures 4 and 5]. However, we could not check the cytokine levels (Th1) to ascertain their role in autoinoculation.

Previously, no work has been done specifically for comparing the efficacy of autoinoculation and TCA for treatment of MC. This study may indicate that autoinoculation could be considered as a safe and tolerable technique for the treatment of MC. The procedure does not require much expertise or expense, providing the patient a clinically efficacious treatment modality. Faster clearance rate and lesser recurrence rate with minimal complications are the advantages of autoinoculation when compared with TCA application.

This study has certain limitations. This was a single-centered trial conducted in a limited population size. Larger double-blinded trials with longer follow-up are needed to determine the accurate efficacy.

Conclusion

In conclusion, we can say that autoinoculation is a safe, simple, and efficacious technique without the need of extensive surgical instruments and minimal complications. Autoinoculation is a type of immunotherapy which appears to be a better method in view of lesion clearance and recurrence rate when compared with TCA applications.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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