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Original Article

Intralesional Injections of Vitamin D3 Versus 2% Zinc Sulfate for the Treatment of Palmoplantar Warts: A Comparison of Efficacy and Safety

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ABSTRACT

Background: Warts are benign epithelial tumors due to several human papillomavirus strains affecting people of all age groups. Warts give an unappealing look and mostly remain asymptomatic. However, they can become painful, as is the case with palmoplantar warts. For warts, different treatment approaches are available, but all the treatments are very expensive, time-consuming, and painful, and recurrence is very common. This study aimed to compare the efficacy and safety of intralesional injections of vitamin D3 and 2% zinc sulphate solution in the treatment of palmoplantar warts.

Methods: In this prospective comparative interventional study (non-randomized trial), done from January 2023 to July 2023, patients with warts from the Outpatient Department of Dermatology of Services Hospital, Lahore, were included. Patients were alternately divided into two groups. Group A patients were given intralesional vitamin D3, while Group B patients were injected with a 2% zinc sulfate solution. Follow-up was done fortnightly for 8 weeks, and then after 12 weeks. Complete response was considered when there was a complete resolution of warts, partial response; if there was >50% and less than 100% reduction in the original width of warts, poor response; if the reduction in the original width of warts was <50%, and no response if there was no recovery after four treatment sessions. Data was collected through a predesigned proforma and entered and analyzed using SPSS version 27.0. The chi-square test was used to compare the percentage reduction in the two treatment groups, while the Student's t-test was applied for quantitative variables. *P*-value <0.05 was considered significant.

Results: The study comprised a total of 90 patients. Both groups comprised 45 patients each, with 100% compliance and similar demographics. Among group A (vitamin D3) patients, 73.3% had a complete response, 11.1% had a partial response, and 6.7% had a poor response, while 8.9% patients had no response after 12 weeks of treatment. Regarding side effects, only 6.7% of patients had scarring at the end of 12 weeks of treatment. Among 45 patients of Group B (2% Zinc Sulfate), 62.2% had a complete response, 20.0% had a partial response, and 6.7% had a poor response, while 11.1% patients had no response after 12 weeks of treatment. Among these patients, 4.4%, 2.2%, and 11.1% at the end of 12 weeks of treatment had erythema, dryness, and scarring, respectively. However, except for the assessment at the end of week 2 ($P < 0.001$),

no statistically significant differences were observed between treatments at 4 weeks (P = 0.067), 6 weeks (P = 0.058), 8 weeks (P = 0.803), and after 12 weeks (P = 0.645) of the treatment period.

Conclusions: Both 2% zinc sulfate solution and vitamin D3 were found to be efficacious and safe in the treatment of palmoplantar warts without a statistically significant difference. Therefore, both treatment modalities can be utilized in patients with palmoplantar warts.

Key words: Safety, intralesional injection, palmoplantar, vitamin D3, warts, zinc sulfate

INTRODUCTION

Verrucae or warts are the benign epidermal proliferation of skin and mucosae due to human papillomavirus (HPV). [1] About 40% of the global population is infected with HPV, with a 14% annual prevalence of plantar warts. [2] Warts are most commonly seen on hands, feet, and face. [3] These warts can be single or multiple, painful or painless, depending on their site. [4] Infection occurs via direct contact with the virus, either through infected surfaces or contaminated skin, and is favored by humid, warm conditions. Risk factors include barefoot walking in public places, hyperhidrosis, poor hygiene, swimming in warmed pools, tropical climates, and a weak immune system. [5] These lesions could have a significant impact on skin appearance, quality of life, and, in severe cases, mobility. [6] Plantar warts are often self-limiting. [7, 8] The spontaneous resolution rate for warts is around 65% to 78%. [9] Diagnosis is primarily clinical. Frequent clinical signs include hyperkeratosis due to proliferation of mutated foot cells, thrombosed capillaries, hemorrhagic dots upon delamination of hyperkeratosis, and loss of normal dermatoglyphics. Pain on lateromedial compression of the plantar wart is also common. [10]

For warts, several treatment options are available, for example: cryotherapy, topical 5-fluorouracil, topical salicylic acid, laser, and electrocoagulation, etc. The response to treatment is greatly variable and patient-dependent, and recurrence is very common. Plantar warts' cure rates are still low, possibly caused by a thicker cornified layer as well as subsequent reduced penetration of therapy to the underlying epidermis. [11] Most treatments face challenges such as the threat of residual scar, depigmentation, or increased risk of recurrence, and, hence, a window of opportunity is opened for the subsequent treatment, such as intralesional immunotherapy. [12] Immunotherapy works by activating cell-mediated immunity for the clearance of the warts. [13]

Intralesional vitamin D3 (Vit D3) has successfully been utilized in the treatment of warts. [14] Vitamin D3 is a prohormone and a fat-soluble vitamin that is produced in the skin by ultraviolet rays. It is quite accepted that vitamin D3 applies its genomic effects through interaction with the vitamin D receptor (VDR), involved in cell proliferation, differentiation, as well as mineral homeostasis. [15] Vit D3 regulates (inhibits) the proliferation of epidermal cells. Secondly, it may also stimulate pro-inflammatory anti-virus cytokines such as interferon-gamma by upregulating Vit D3 receptors and hydroxylase genes. [16] In addition, Vit D3 is postulated to be engaged in the formation of peptides that activate an innate immune response. [17] There is another school of thought that says that vitamin D3 somehow invokes a cell-mediated response to kill the virus. Vit D3 is not known for having antigenic property, whether it is given as a topical treatment or intradermal (except if it acts as a hapten). Therefore, this treatment has been found useful for patients with multiple refractory warts with efficacy equal to other first-line treatments. Moreover, these injections regress not only the target warts, but they also have the ability to regress distant warts. [18]

Zinc, on the other hand, plays a crucial role in immune regulation by promoting the activity of leucocytes and natural killer cells. Studies have revealed a deficiency of zinc in patients suffering from multiple or recurrent warts. Consequently, zinc has been extensively investigated for its efficacy in treating warts, with various studies exploring its use through topical, systemic, and intralesional administration. [19] Nofal and coworkers demonstrated the efficacy of zinc sulphate in treating the recalcitrant warts. [20] The deficiency of zinc leads to thymic hypoplasia with its consequent impact on the T cell maturation, causing immune deficiency, which favors subsequent infections. [21] In the past few years, 2% zinc sulfate solution (ZSS) has been utilized for the treatment of viral warts. The results of the studies are very encouraging, for example, El Sayed and coresearchers reported complete response in 71.4% patients after multiple sessions of intralesional 2% ZSS. [22] Since both Vit D3 and 2% ZSS as intralesional interventions possess anti-wart potential, it is pertinent to conduct a study to evaluate their comparative efficacy and safety in the treatment of palmoplantar warts. Since direct comparative studies are limited worldwide, we conducted this study to improve patient care and develop effective treatment strategies for complex cases where treatment options are restricted, for example, due to limited availability, personal preferences, or resistance. As the costs of both approaches are similar, comparing their efficacy and safety will facilitate treatment decisions. Consequently, this study was designed to compare the efficacy and safety of intralesional injections of vitamin D3 and 2% zinc sulphate solution in the treatment of palmoplantar warts.

MATERIALS AND METHODS

Study Design and Setting

It was a prospective comparative interventional study (non-randomized trial), conducted on 90 patients chosen using a non-probability purposive sampling.

Eligibility Criteria

Patients of either gender, with an age range of 15 to 70 years, with a clinical diagnosis of palmoplantar warts (limited to up to 5 palmoplantar warts per patient) were included. Pregnant or lactating women, immunocompromised or immunosuppressed patients (either due to drug intake or medical illness), those with known allergy to Vit D3 or zinc

sulfate, and patients having bacterial or fungal infection of involved skin, were excluded. Patients with prior treatment of warts during the last month were also excluded since this may affect the outcome of the drugs under trial.

Sample Size Calculation

The sample size of 90 (45 in each group) was calculated by the following formula, keeping the power of the study equal to 90% and the level of significance equal to 5% in reference to a similar study by Abd El Magid et al. [14]

$$n = \frac{\left\{ Z_{1-\alpha}\sqrt{2\bar{P}\left(1-\bar{P}\right)} + Z_{1-\beta}\sqrt{P_1\left(1-P_1\right)+P_2\left(1-P_2\right)} \right\}^2}{\left(P_1 - P_2\right)^2}$$

α = desired level of significance = 5% = 1.28

β = desired power of study = 90% = 1.96

P1 = anticipated proportion of swelling in intralesional injections of Vit D3 (Group A) = 0%

P2 = anticipated proportion of swelling in zinc sulfate 2% (Group B) = 15%

n = calculated sample size for each group = 45

Patient Recruitment and Allocation

All participants provided written informed consent before inclusion after being informed about the study objectives. Participants were assured of confidentiality, and they were free to leave the study at any time. An alternating allocation method was used for dividing the patients into study groups. The study was non-blinded.

Intervention Protocol

The patients were observed in two equal groups. In group A, the patients were treated with intralesional injection of 0.3 ml of Vit D3 200,000 IU (5 mg per mL) in each lesion, using a 27-gauge insulin syringe. [14] All patients received 4 sessions at 2 weekly intervals. In group B, patients were treated with intralesional injections of 2% zinc sulfate solution (0.1–0.3 mL depending on the size of each lesion). [23] Participants were advised not to use any topical or systemic therapy for warts during sessions. Clinical assessment was carried out by two dermatologists. The number of warts as well as diameter were evaluated before intervention and at each subsequent session, as well as three months after the last session. The cure rate of warts after a maximum of four treatment sessions was considered the primary outcome of the study. Photographic evaluation was performed at the same intervals. Complete response was considered when there was a complete resolution of warts, partial response if there was >50% and less than 100% reduction in the original width of warts, poor response if the reduction in the original width of warts was <50%, and no response if there was no recovery after four treatment sessions. Recurrence was defined as the reappearance of lesions after complete disappearance.

Statistical Analysis

All the data was entered, and statistical analysis was performed by using Statistical Package for Social Sciences (SPSS) version 27. Tables and graphs were made. The quantitative variables, such as age and number of palmoplantar warts, were calculated as means ± SD. The qualitative variables, such as gender, efficacy, and safety, were calculated as frequencies and percentages. Chi-square test was utilized to compare the grades of %age reduction in two treatment groups, while for quantitative variables, Student's *t*-test was applied. *P*-value ≤0.05 was considered significant.

Ethical Approval

The study was conducted after getting approval from the institutional review board (Ref No. IRB/2022/1010/SIMS) at the Department of Dermatology, SIMS/Services Hospital, Lahore, Pakistan.

RESULTS

The demographic and clinical characteristics of the total 90 patients were generally well balanced between Group A and Group B. There was no statistically significant difference regarding gender distribution between the groups, with males comprising 68.9% in Group A and 64.4% in Group B (*P* = 0.655). Among Group A patients, 28 (62.2%) were 15 to 40 years old, and 17 (37.8%) were 41 to 70 years old, while the average age was 37.27 + 12.174 years. Among Group B patients, 30 (66.7%) were 15 to 40 years old and 15 (33.3%) were 41 to 70 years old, while the average age was 38.38 + 9.815 years (*P*-value = 0.635).

The mean number of warts in Group A patients was 3.33 + 0.826, while in Group B it was 3.18 + 1.051 (*P*-value = 0.437). Regarding the type of warts, the majority had plantar warts in both groups, 37 (82.2%) in Group A and 34 (75.6%) in Group B (*P*-value = 0.438).

Regarding treatment efficacy at 2 weeks, there was a significantly better response with vitamin D compared to ZSS (*P*-value ≤ 0.001), as shown in **Table 1**. However, later on throughout the treatment and follow-up period, although the response was better in the Vit D group, this was not statistically significant (*P*-values >0.05).

Regarding the safety profile of both treatment modalities, more patients in Group B reported irritation/burning, erythema, dryness, and swelling compared to Group A (**Table 2**). Pre- and post-treatment photographs were also taken for follow-up and comparison (**Figures 1 and 2**).

DISCUSSION

This study compared the efficacy and safety of intralesional vitamin D3 versus 2% zinc sulfate for palmoplantar warts and found that vitamin D3 produced higher and earlier complete clearance rates with fewer and less severe adverse effects. At 12 weeks, 73.3% of patients in the vitamin D3 group achieved a complete response versus 62.2% in the zinc group; vitamin D3 also produced a significantly greater proportion of complete responses at the first follow-up (2 weeks). These results indicate that intralesional vitamin D3 is a promising, well-tolerated option for palmoplantar warts.

Patient demographics and baseline characteristics were broadly comparable between groups, with most patients aged 15 to 40 years and a predominance of male participants.

Table 1: Comparison of efficacy between the treatment groups.

Time point	Response type	Group-A: vitamin D3 (freq, %)	Group-B: zinc sulfate (freq, %)	P value
2 weeks	Complete response	6 (13.3%)	0 (0.0%)	<0.001
	Partial response	1 (2.2%)	9 (20.0%)	
	Poor response	3 (6.7%)	11 (24.4%)	
	No response	35 (77.8%)	25 (55.6%)	
4 weeks	Complete response	14 (31.1%)	7 (15.6%)	0.067
	Partial response	7 (15.6%)	15 (33.3%)	
	Poor response	5 (11.1%)	9 (20.0%)	
	No response	19 (42.2%)	14 (31.1%)	
6 weeks	Complete response	25 (55.6%)	14 (31.1%)	0.058
	Partial response	11 (24.4%)	23 (51.2%)	
	Poor response	5 (11.1%)	5 (11.1%)	
	No response	4 (8.9%)	3 (6.7%)	
8 weeks	Complete response	33 (73.3%)	29 (64.4%)	0.803
	Partial response	5 (11.1%)	7 (15.6%)	
	Poor response	3 (6.7%)	3 (6.7%)	
	No response	4 (8.9%)	6 (13.3%)	
12 weeks	Complete response	33 (73.3%)	28 (62.2%)	0.645
	Partial response	5 (11.1%)	9 (20.0%)	
	Poor response	3 (6.7%)	3 (6.7%)	
	No response	4 (8.9%)	5 (11.1%)	

Complete response = 100% of clearance; partial response ≥ 50% and <100% of clearance; poor response = <50% of clearance; no response = 0% of clearance.

The mean number and distribution of warts were similar across arms, limiting confounding from baseline wart burden. Differences in mean age compared with some previous studies, for example, Abd El Magid et al. [14], likely reflect local population characteristics and referrals to our tertiary center; such variability underlines the importance of context when comparing outcomes across studies. The predominance of plantar warts in our cohort is consistent with prior series from similar settings. [22]

The superior clinical response observed with vitamin D3 is biologically plausible. Vitamin D modulates both innate and adaptive immunity, promotes keratinocyte differentiation, and can induce local antiviral activity—mechanisms that may facilitate wart clearance. Intralesional administration delivers a high local concentration that likely augments these immunomodulatory effects without systemic toxicity. [24] Zinc, while also an immunomodulator with antiviral properties and documented efficacy in some reports, may produce more local irritation at the concentration used here, potentially limiting tolerability and repeated dosing. [14]

Our safety data also favor vitamin D3. Adverse events such as irritation, erythema, dryness, swelling, and scarring were consistently more frequent and often more intense in the zinc group at all follow-ups. These findings align with other reports that intralesional zinc can produce substantial injection-site pain and local reactions. [14, 25] The better tolerability of vitamin D3 is clinically relevant because reduced discomfort may improve adherence and allow completion of treatment courses, thereby enhancing effectiveness in routine practice.

Comparisons with prior literature show both consistencies and differences. Several studies have reported complete clearance rates for intralesional vitamin D3 in the range observed here, supporting our efficacy findings. [14] Reports on 2% zinc sulfate have been mixed, with some studies demonstrating high clearance and others reporting more modest results and notable adverse events. A study undertaken by El Sayed and collaborators (2020) reported that both treatments have similar efficacy. Authors confirmed that 71.4% patients in the Vit D3 group and 70.0% patients in the Zinc group had a complete response. [22] A study carried out by Ali and teammates (2023) elucidated that among patients treated with intralesional vitamin D3, 70.8% had a complete response. [26] A study done by Javed and colleagues (2022) also confirmed the better efficacy of intralesional vitamin D3, supporting our findings. [27] They reported in their study that 72.6% patients had a complete response regarding clearance of warts. Raghukumar and comrades (2017) reported that 90.0% patients had a complete response and the treatment was effective, safe, and not expensive for warts. [28] Aktaş and companions (2016) demonstrated in their study that wart's complete resolution was observed among 80.0% patients. [29] The results of a study conducted by Sharquie and Al-Nuaimy (2002) confirmed that among patients treated with 2% zinc sulfate solution, the clearance rate was 98.2%. [25]

It is significant to mention here that at last follow-up (12 weeks of treatment), the findings of our study also confirmed that intralesional injections of Vit D3 was safer than 2% zinc sulfate solution because only 6.7% patients in Vit D3 group had scarring, while in zinc group 4.4% patients had erythema, 2.2% had dryness and 11.1% had scarring. The findings of a study carried out by Abd El-Magid and coworkers (2021) also confirmed that vitamin D3 was better tolerated than Zinc.

Table 2: Comparison of safety profiles of the treatment modalities.

Time point	Adverse effect	Group-A: vitamin D3 (Freq, %)	Group-B: zinc sulfate (Freq, %)	*P* value
2 weeks	Irritation/burning	13 (28.9%)	27 (60.0%)	0.003
	Photo sensitivity	0 (0.0%)	0 (0.0%)	–
	Erythema	17 (37.8%)	25 (55.6%)	0.091
	Dryness	5 (11.1%)	13 (28.9%)	0.035
	Infection	2 (4.4%)	4 (8.9%)	0.398
	Scarring	0 (0.0%)	0 (0.0%)	–
	Swelling	11 (24.4%)	17 (37.8%)	0.172
4 weeks	Irritation/burning	15 (33.3%)	24 (53.3%)	0.056
	Photo sensitivity	0 (0.0%)	0 (0.0%)	–
	Erythema	19 (42.2%)	24 (53.3%)	0.291
	Dryness	3 (6.7%)	11 (24.4%)	0.020
	Infection	0 (0.0%)	3 (6.7%)	0.078
	Scarring	0 (0.0%)	0 (0.0%)	–
	Swelling	9 (20.0%)	16 (35.6%)	0.099
6 weeks	Irritation/burning	3 (6.7%)	21 (46.7%)	0.001
	Photo sensitivity	0 (0.0%)	0 (0.0%)	–
	Erythema	11 (24.4%)	21 (46.7%)	0.028
	Dryness	0 (0.0%)	15 (33.3%)	0.001
	Infection	0 (0.0%)	0 (0.0%)	–
	Scarring	0 (0.0%)	0 (0.0%)	–
	Swelling	3 (6.7%)	13 (28.9%)	0.006
8 weeks	Irritation/burning	1 (2.2%)	19 (42.2%)	0.001
	Photo sensitivity	0 (0.0%)	0 (0.0%)	–
	Erythema	7 (15.6%)	17 (37.8%)	0.017
	Dryness	0 (0.0%)	9 (20.0%)	0.002
	Infection	0 (0.0%)	1 (2.2%)	0.315
	Scarring	3 (6.7%)	5 (11.1%)	0.459
	Swelling	3 (6.7%)	11 (24.4%)	0.020
12 weeks	Irritation/burning	0 (0.0%)	0 (0.0%)	–
	Photo sensitivity	0 (0.0%)	0 (0.0%)	–
	Erythema	0 (0.0%)	2 (4.4%)	0.153
	Dryness	0 (0.0%)	1 (2.2%)	0.315
	Infection	0 (0.0%)	0 (0.0%)	–
	Scarring	3 (6.7%)	5 (11.1%)	0.459
	Swelling	0 (0.0%)	0 (0.0%)	–

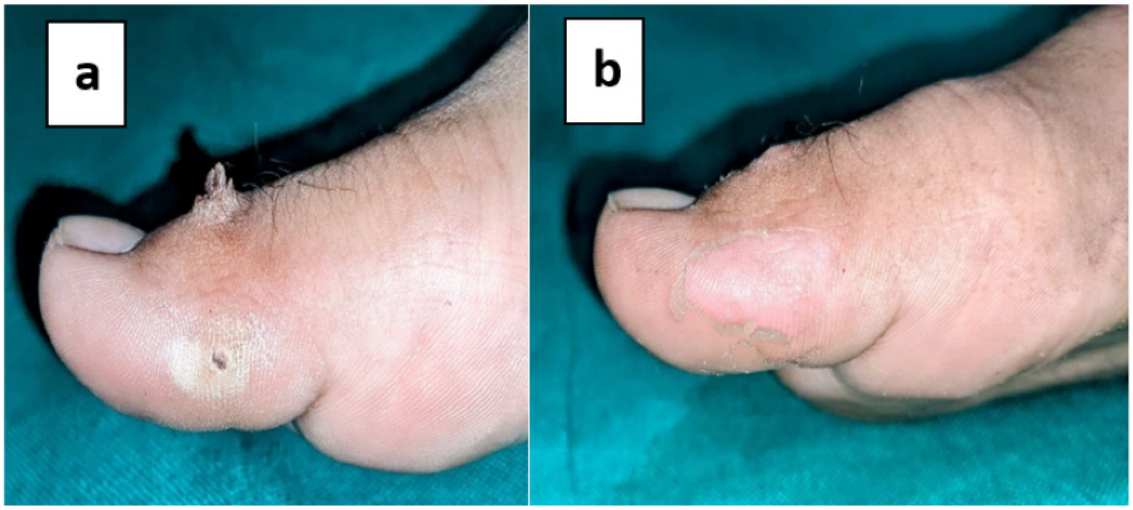

Figure 1: Plantar warts of a 32-year-old patient, before (a) and after (b) treatment with vitamin D3.

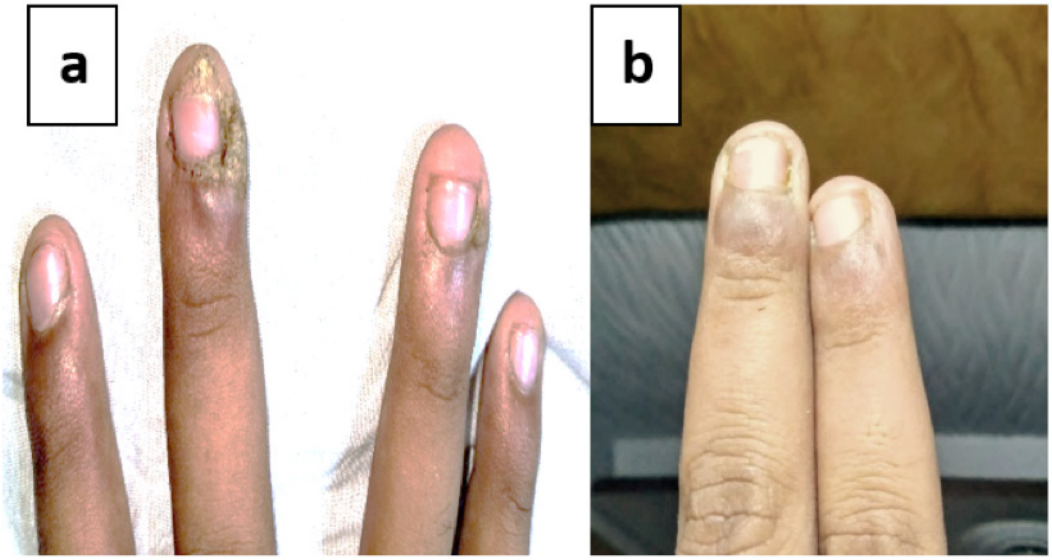

Figure 2: Warts of a 42-year-old patient, before (a) and after (b) treatment with zinc sulphate 2% solution.

[14] In the vitamin D3 group, 5.0% patients had mild pain, and 5.0% patients had hematoma, while in the zinc group, 45.0% patients had mild pain, 55.0% had moderate pain, 55.0% had hematoma, and 15.0% patients had swelling. Another study carried out by El Sayed and collaborators (2020) reported that 48.6% in the zinc group had severe pain, while the majority of patients (80.0%) in the vitamin D3 group had mild pain, highlighting the better safety of Vit D3. [22]

In summary, this study demonstrated that intralesional vitamin D3 is slightly more effective and safer than 2% zinc sulfate for treating palmoplantar warts. It showed a higher complete clearance rate and fewer adverse effects. However, this difference was not statistically significant.

Study strengths include a well-defined palmoplantar wart cohort and systematic assessment of efficacy and adverse events at multiple time points. However, limitations should be acknowledged. Follow-up was limited to 12 weeks, which restricts the assessment of long-term recurrence rates. The single-center design and moderate sample size may limit generalizability. Blinding could have been done. Finally, we did not perform virological typing of HPV strains, which could influence response and help explain inter-study differences.

Clinical Implications

Given their favorable balance of efficacy and tolerability in this trial, both intralesional vitamin D3 and Zinc sulfate can be considered viable first-line or adjunctive options for palmoplantar warts, particularly when patient comfort and rapid response are priorities.

Future Research

Larger, multicenter, blinded trials with longer follow-up are needed to confirm the durability of response and recurrence rates. Comparative studies evaluating different concentrations and schedules for zinc, as well as head-to-head comparisons with other established modalities (e.g., cryotherapy, salicylic acid, intralesional immunotherapy agents), would help refine treatment algorithms. Investigation of HPV typing, local immune markers, and patient-reported outcomes would further clarify mechanisms of response and the patient-centered benefits of each treatment.

CONCLUSIONS

In this study, both intralesional vitamin D3 and 2% zinc sulfate demonstrated early clearance and a favorable safety profile in the treatment of palmoplantar warts. These findings support their use in clinical practice while highlighting the need for longer-term and larger-scale studies to confirm durability and optimize treatment protocols.

AUTHORS' CONTRIBUTION

Each author has made a substantial contribution to the present work in one or more areas, including conception, study design, conduct, data collection, analysis, and interpretation. All authors have given final approval of the version to be published, agreed on the journal to which the article has been submitted, and agree to be accountable for all aspects of the work.

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None.

CONFLICT OF INTEREST

None.

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