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ORIGINAL ARTICLE

Safety and Efficacy of Intralesional Polidocanol Sclerotherapy in the Treatment of Plantar Warts : A Pilot Study

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Abstract

Background: ***Benign lesions called warts can develop on the skin and mucosa. These are among the most prevalent skin conditions, and their severity can vary from a small quantity of annoyance that goes away on its own to a bothersome chronic ailment.***

Aim and objectives: ***To cure plantar warts, this study assesses the safety and effectiveness of intralesional polidocanol sclerotherapy.***

Patients and methods: ***This is a prospective, open-label pilot research involving 80 plantar wart patients. They were chosen from Al-Azhar University Hospitals' Outpatient Dermatology Clinics. In addition to a clinical and dermatological examination, every patient had a thorough history-taking procedure (including age, sex, length of disease, history of drug use, and history of other related diseases) and images of their lesions during the initial and follow-up appointments.***

Results: ***Regarding the response, there were statistically significant differences (P<0.0001) between the analyzed groups. Patients in groups A and B had the highest complete response rates (60%), group C had the lowest (45%), and the control group had the lowest percentage (10%). Patients in the control group had a much higher rate of no response (70%) than those in groups A, B, and C, which were 15%, 10%, and 20%, respectively. Additionally, the response rate in the sclerotherapy groups (A, B, and C) was substantially more significant than in the control group (p<0.05; all), according to the current study.***

Conclusion: ***Because intralesional polidocanol sclerotherapy is easy to use and does not require any additional equipment, it is a cost-effective and safe treatment option for plantar warts.***

Keywords: Intralesional polidocanol sclerotherapy; plantar warts; Safety; Efficacy

1. Introduction

Verrucae, or warts, are a common benign skin malignancy affecting people of all ages and genders[1] About 30% of cutaneous warts are plantar warts, which affect the plantar areas of the foot [2], having a roughly 14% yearly incidence. Human Papillomavirus (HPV) types 1, 2, 4, 10, 27, and 57 are frequently linked to them.[3] Plantar warts hurt when you walk or stand, in contrast with warts that affect other body parts, such as the feet, which are often asymptomatic. Usually, this concerns where they are on the foot's weight-bearing sections.

Thus, successful therapy for plantar warts can enhance patients' quality of life.[4] Plantar warts can be treated with a variety of therapy approaches. However, plantar warts remain a therapeutic challenge because of their high recurrence rates and resistance to therapy.[5]

Polidocanol is a non-ionized detergent sclerosant that attaches itself to phospholipid membranes and causes structural disruption.[6]

Polidocanol lyses blood cells, platelets, and endothelium at high doses. At low concentrations, polidocanol generates a negative charge on the outside of cell membranes, promoting coagulation and forming muscular clots resistant to fibrinolysis. Eventually, endovascular fibrosis and effective lumen obliteration result from thrombotic occlusion at the site of endothelial damage.[7]

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Polidocanol comes in a liquid formulation, and the vessel diameter determines the amount of polidocanol needed to cause vascular sclerosis in vivo. For telangiectatic leg veins, polidocanol at a concentration of 0.5% is suitable. For veins 1 to 2 mm, 2%, and larger, 4 to 8 mm and 3% are the recommended concentrations. [7]

This study aims to assess the safety and effectiveness of intralesional polidocanol sclerotherapy in treating plantar warts.

2. Patients and methods

This study is a pilot study that is open-label and prospective. It involves 80 participants who have plantar warts. The participants were selected from the Outpatient Dermatology Clinics of Al-Azhar University Hospitals from February 2023 to November 2023. Every patient underwent a comprehensive assessment that included gathering detailed information on their age, gender, duration of illness, medication history, and other relevant medical conditions. A thorough examination of general health and dermatological conditions followed this. Photographs of the skin lesions were taken during the initial and subsequent follow-up visits.

2.1.Inclusion criteria: Healthy adult patients with clinical diagnoses of planter wart. Exclusion criteria: Bleeding diathesis, vasoocclusive or thromboembolic disorders, concurrent use of systemic or topical treatments of warts, patients with immunosuppression, and pregnant or lactating women.

2.2.Ethical consideration: Before beginning the study, each participant gave informed consent, which the Medical Research Ethics Committee approved.

2.3.Treatment protocol:

Four equal groups of twenty patients were randomly assigned to receive intralesional polidocanol injections at concentrations of 1%, 2%, 3%, and 0.9% normal saline (control group), respectively. Prior to injection, the skin was topically anesthetized with lidocaine cream. A 27-gauge needle was then used to slowly inject the solution into the lesion's base until the lesion blanched, with a maximum of 1 ml injected in a single session. Every two weeks or every two weeks for a maximum of three months, six injection sessions were administered till resolution. Sterile gauze was used to provide pressure to stop any seeping after injection treatment. No topical medicine or dressing was applied. Patients were advised to take analgesics as needed, clean the injection site often with soap and water, and try to prevent trauma to the area.

2.4.Treatment evaluation and follow-up

Each group's wart size (measured with a ruler) was used to assess the therapeutic efficacy. Serial digital photographs taken in the same conditions (room lighting, patient positioning, camera settings) were taken at baseline (the first visit before beginning treatment) and every two weeks. Weekly patient follow-ups were conducted, and any side effects were noted. The following will be used to rate the response to treatment: complete response (wart cleared 100%; ordinary skin marking appears), partial response (wart size reduced by 50% to 99%), and no response (wart size less than 50%). Patients were monitored for any adverse reactions, such as discomfort or bruises.

2.5.Data analysis

The SPSS software, version 22, entered and analyzed the gathered data. Frequencies were used to show the data and the means and standard deviation (SD). Comparison of control and study groups by their clinical data, separately and collectively, was done using chi-square, Fischer exact, Mann-Whitney test, and one-way ANOVA analysis as appropriate. The control and study groups were compared by the amount of injection and response (complete, partial, and no response), number of sessions, and side effects using chi-square and ANOVA analysis. The study groups were compared according to their response, amount of injection, number of sessions, and side effects using chi-square and ANOVA analysis. Finally, each study group was compared with the control group regarding the response variables. P values ≤ 0.05 were used as a level of statistical significance.

3. Results

Table 1. Clinical characteristics of studied planter wart patients.

CHARACTERISTICS*	N= 80
AGE IN YEARS, MEAN ±SD (RANGE)	25.3 ± 10.3 (5-53)
SEX	
MALE	37 (46.2)
FEMALE	43 (53.8)
MEAN NUMBER OF WARTS , MEAN ±SD (RANGE)	1.8 ± 1.5 (1-10)
MEAN DURATION IN MONTH , MEAN ±SD (RANGE)	5.0 ± 9.8 (1-24)
GROUPS OF THE STUDY	
GROUP A (3% INJECTION)	20 (25.0)
GROUP B (2% INJECTION)	20 (25.0)
GROUP C (1% INJECTION)	20 (25.0)
GROUP D (CONTROL GROUP)	20 (25.0)

*Data are presented by mean ± SD or by n (%).

The mean age of the studied patients was 25.3 ± 10.3, of them 46.2 % were male and 53.8% were female. The mean number of planter warts among the studied patients was 1.8 ± 1.5 and the mean duration was 5.0 ± 9.8 months. Of the studied 80 planter wart patients, 20 were represented control group, Twenty people made up study groups A (3% injection), B (2% injection), and C (1% injection).

Table 2. Comparison of the studied groups by their clinical data

CLINICAL DATA	GROUPS				P VALUE
	Control group	Group A	Group B	Group C	
AGE IN YEARS	23.1 ± 10.3	27.9 ± 10.8	23.1 ± 10.3	22.1 ± 7.2	0.92
SEX MALE FEMALE	9 (45.0) 11 (55.0)	11 (55.0) 9 (45.)	12 (60.0) 8 (40.0)	11 (55.0) 9 (45.0)	0.81
MEAN NUMBER OF WARTS	2.3 ± 1.5	1.7 ± 1.1	1.9 ± 2.1	1.4 ± 0.9	0.15
MEAN DURATION IN MONTH	3.3 ± 1.9	7.7 ± 7.8	4.8 ± 3.4	4.2 ± 3.2	0.70

*Significant

The studied groups were comparable and there were no significant differences among them regarding all the studied clinical data. However, the patients in group A were found to have the higher mean age (27.9 ± 10.8 years) and the mean duration of warts in months (7.7 ± 7.8). Group B were more females (60%), and group C were found to have the lower mean age (22.1 ± 7.2 years). The higher mean number of warts, however, was found among the control group (2.3 ± 1.5).

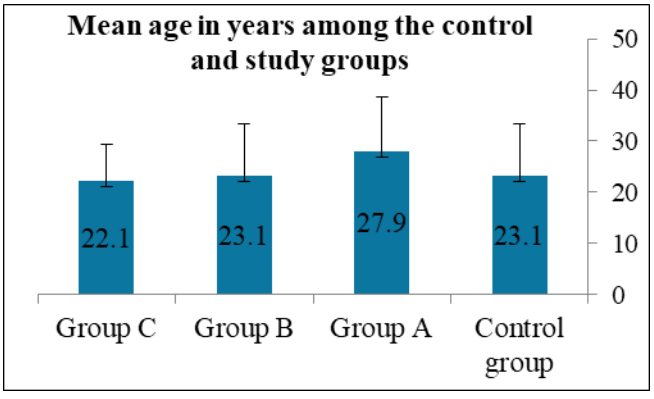


Figure 1. Mean age in years among the control and study groups.

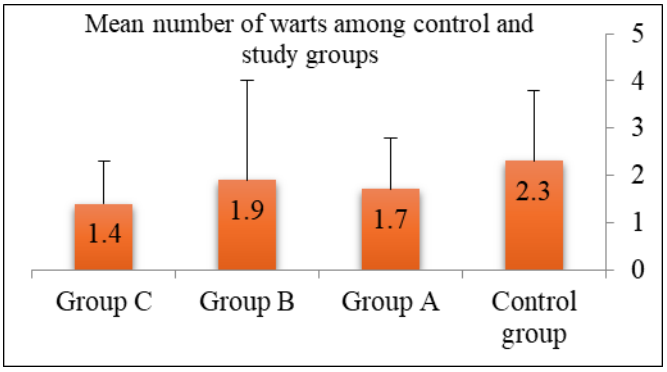


Figure 2. Mean number of warts among the control and study groups.

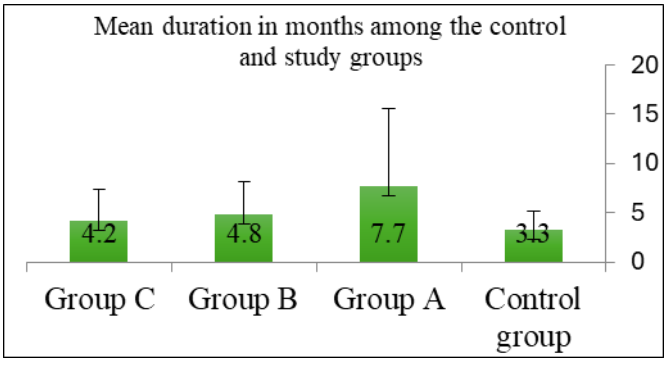


Figure 3. Mean duration in months among the control and study groups.

Table 3. Comparison of the study groups by procedures, response and side effects.

	GROUPS				P VALUE
	Control group	Group A	Group B	Group C	
AMOUNT OF INJECTION (VOLUME)	0.22 ± 0.12	0.13 ± 0.10	0.15 ± 0.10	0.14 ± 0.10	0.36
NUMBER OF SESSION	3.9 ± 0.8	3.1 ± 1.6	3.8 ± 1.3	4.3 ± 1.1	0.40
RESPONSE COMPLETE PARTIAL NO	2 (10.0) 4 (20.0) 14 (70.0)	12 (60.0) 5 (25.0) 3 (15.0)	12 (60.0) 6 (30.0) 2 (10.0)	9 (45.0) 7 (35.0) 4 (20.0)	<.0001*
SIDE EFFECTS NO PAIN BRUISES	10 (50.0) 6 (30.0) 4 (20.0)	9 (45.0) 9 (45.0) 2 (10.0)	8 (40.0) 9 (45.0) 3 (15.0)	5 (25.0) 10 (50.0) 5 (25.0)	0.65

*Significant

Statistically significant differences were found among the studied group regarding the response (P<0.0001), where the complete response was the highest among patients in group A and group B (60%). A significant high rate of no response was found among patients in the control group (70%). For other studied factors, no significant differences were found among the studied groups, although pain rate was the high in patients of the study group A (45%), B (45%) and C (50%). The bruises rate was high in patients of group C (25%) and in the control group (20.0). The amount of injection and the mean number of sessions were comparable among all studied groups with no statistically significant differences.

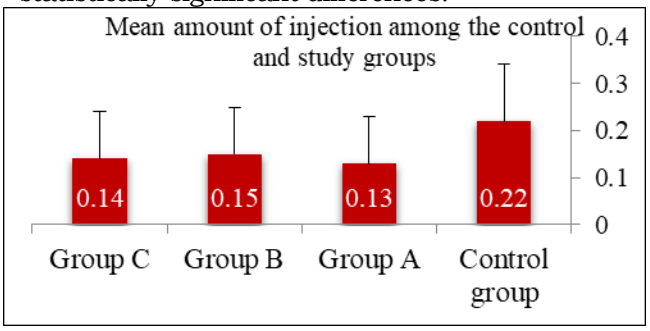


Figure 4. Mean amount of injection among the control and study groups.

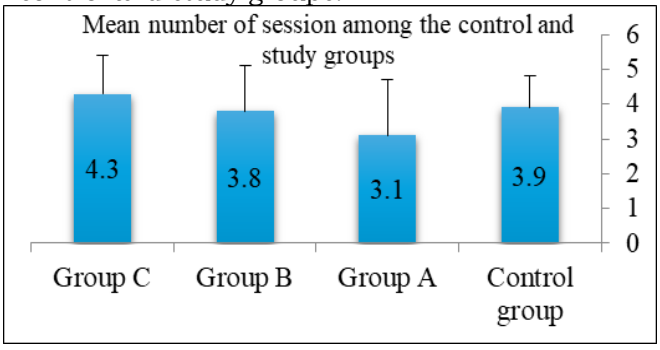


Figure 5. Mean number of sessions among the control and study groups.

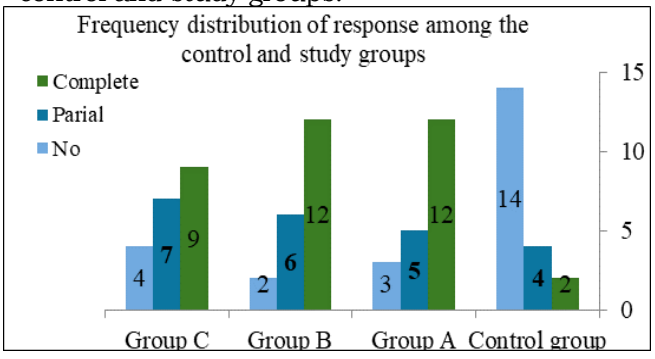


Figure 6. Frequency distribution of response among the control and study groups

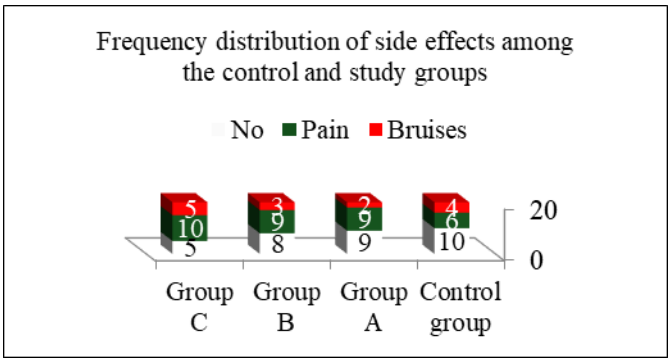


Figure 7. Frequency distribution of side effects among the control and study groups.

4. Discussion

Extensive research from the internet for this type of treatment has not been found, which means that the current study is considered a novel approach Zoheir et al.,8 The study compared the effectiveness of intralesional methotrexate and 5-fluorouracil in treating plantar warts. The results showed that in the methotrexate group, 35% of patients experienced complete resolution, 40% had partial resolution, and 25% showed no response. These outcomes were lower than those observed in the current study. In the 5-fluorouracil group, 80% of patients achieved complete resolution, 15% had a partial resolution, and 5% showed no response. These results were better than those observed in the current study. A notable disparity was seen between the two groups (P-value=0.01). 55% of patients experienced discomfort and moderate bruising as side effects from methotrexate, while 50% experienced the same side effects from 5-fluorouracil.[8]

Also, higher than the current outcome, Muhammad et al., [9] A study was conducted to compare the effectiveness of intralesional bleomycin and cryotherapy in treating plantar warts among 160 patients (80 in each group). The results showed that the intralesional bleomycin group had a 90% efficacy rate, while the cryotherapy group had a 72.5% efficacy rate. The statistical analysis indicated a highly significant difference between the two groups (P=0.005). [9]

Gamil et al. [10] Distributed 54 cases among three groups, each consisting of 18 patients. The initial group underwent micro-needling treatment with topical bleomycin every two weeks, while the second group received intralesional bleomycin every three weeks. The control group was given intralesional saline for a maximum of four weeks. The study found that the micro-needling group had a higher rate of total clearance of warts, with 16 out of 18 patients (88.9%) achieving this outcome. In comparison, the intralesional bleomycin group had 15 out of 18 patients (83.3%) achieving complete clearance, while the

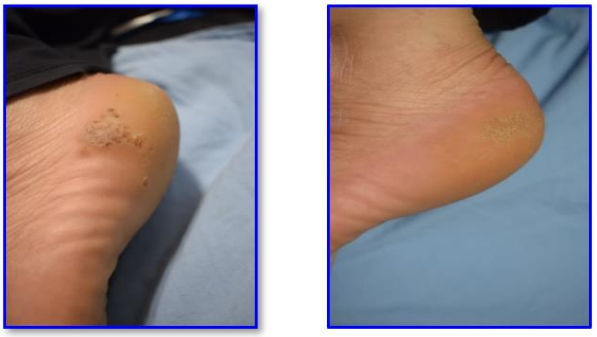
control group had only one out of 18 patients (5.6%) achieving complete clearance. [10]

Elsayed et al., [11] This study assessed the effectiveness and safety of injecting acyclovir directly into the warts of 31 patients. Nineteen patients were given intralesional acyclovir (70mg/ml), while twelve patients received a saline solution as a control for two weeks. The study's results revealed that 52.6% of the individuals in the acyclovir group experienced complete clearance of their warts, 36.8% had a partial response, and 10.5% showed no response to the treatment. 16.7% of the individuals in the control group showed a partial reaction, whereas 83.3% showed no response. A considerable and highly statistically significant difference was seen comparing the treatment as well as control groups ($P < 0.01$). The patients experienced discomfort during injection in 89.5% of cases, blistering in 52.6%, and erythema in 5.3% of cases. No instances of recurrence were observed throughout the follow-up period.[11]

In addition, Ghaly et al., [12] An assessment was conducted to determine the effectiveness and safety of injecting PPD directly into plantar warts. The results indicated that 50% of patients experienced full recovery in the treated area. Three patients (30%) obtained this response following three intralymphatic purified protein derivative (IL PPD) treatment sessions. Nevertheless, two patients (20%) exhibited an identical reaction after undergoing only two therapy sessions, while one (10%) displayed a partial response. Additionally, two patients (20%) showed limited improvement, and two patients (20%) did not exhibit any discernible progress after completing three treatment sessions. The therapy group exhibited a statistically significant improvement compared to the control group. Regarding side effects, 70% of individuals had discomfort, 50% experienced symptoms resembling the flu, 40% experienced erythematous edema, and 10% experienced hyperpigmentation.[12]

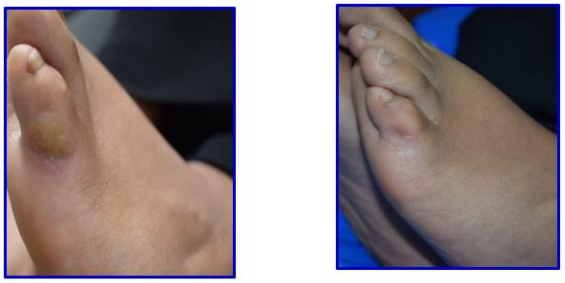
Also, inferior to the current treatment, Abd-Elaal et al.,.[13] This study aimed to assess the effectiveness of intralesional vitamin D3 in treating plantar warts, comparing it to the use of candida albicans antigen. The Candida group exhibited a total reaction in 9 individuals (45%), a partial response in 6 individuals (30%), and no response in 5 individuals (25%). Similarly, the Vitamin D3 group showed a complete response in 8 individuals (40%), a partial response in 6 individuals (30%), and no response in 6 individuals (30%). No significant difference was observed between the two groups.[13]

The above-mentioned literature, compared to the current study, suggested that intralesional polidocanol sclerotherapy with different doses (1%, 2%, and 3%) was reliable in treating plantar warts, as it resulted in an acceptable response rate without significant adverse effects compared to other intralesional agents.



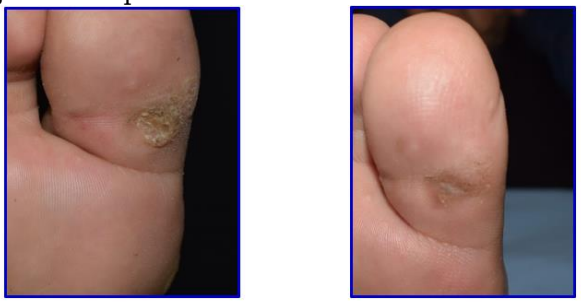
(a): Before injection. **(b):** After injection.

Figure 8. A 33-year-old female patient with numerous plantar warts experienced complete remission after undergoing four sessions of intralesional injection with polidocanol 3%.



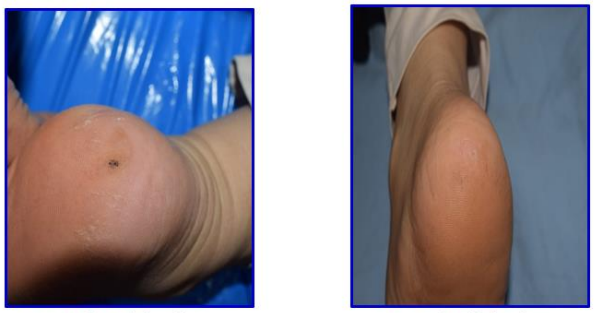
(a): Before injection. **(b):** After injection.

Figure 9. A 20 -year- old female patient with a planter wart experienced complete remission after undergoing five sessions of intralesional injection of polidocanol 2%.



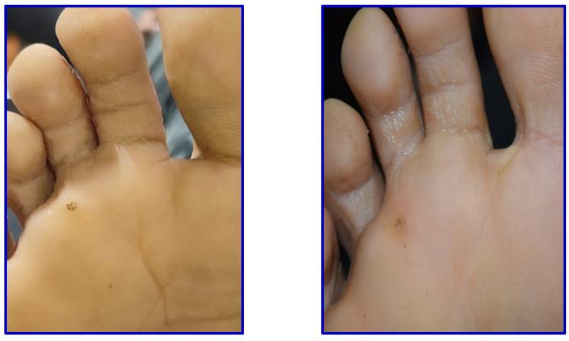
(a): Before injection. **(b):** After injection.

Figure 10. A 18 -year- old male patient with a planter wart experienced partial remission after undergoing six sessions of intralesional injection of polidocanol 2%.



(a): Before injection. **(b):** After injection.

Figure 11. A 32 -year- old female patient with a planter wart experienced complete remission after undergoing four sessions of intralesional injection of polidocanol 1%.



(a): Before injection. **(b):** After injection.

Figure 12. A 22 -year- old male patient with a planter wart experienced no remission after undergoing six sessions of intralesional injection of polidocanol 1%.

4. Conclusion

Intralesional polidocanol sclerotherapy is a new, secure, and efficient method for treating plantar warts. It is economically feasible because it is easy to manage and requires no specialized equipment. There is no notable influence on the response rate and adverse effects when the dosage of polidocanol is increased. The adverse events observed were localized reactions characterized by pain and bruising, and no significant side effects were reported.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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