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Original Article

The efficacy of DemoJet infiltration using normal saline versus bleomycin in the treatment of recalcitrant wart: A comparative therapeutic study

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Abstract

Background Warts are one of the most common benign tumours caused by the human papillomavirus (HPV), and treating them is still difficult, especially when the lesions don't respond to treatment. There are now a number of intralesional therapies available. For example, needle-free high-pressure jet injection systems (DemoJet) offer a new way to deliver drugs intradermally, subcutaneously, or intramuscularly. Intralesional bleomycin has previously shown significant efficacy, particularly in resistant periungual and palmoplantar warts.

Objective To compare the efficacy of DemoJet infiltration utilizing bleomycin versus normal saline in the treatment of recalcitrant viral warts.

Methods An interventional comparative study involving 40 patients with 173 clinically diagnosed viral warts. Patients were allocated into two groups: Group A (20 patients, 102 warts) treated with 1-2 ml of bleomycin solution via DemoJet, and Group B (20 patients, 71 warts) treated with normal saline using the same technique. Sessions were repeated every two weeks for up to 12 weeks or until complete resolution. Assessment included the number and size of warts, pain intensity (visual analogue scale), and patient satisfaction at baseline, 2, 6, and 12 weeks.

Results Group A demonstrated a significantly lower mean number of sessions to achieve cure, fewer residual warts, and greater reduction in lesion size compared to Group B. However, pain scores were higher in the bleomycin group.

Conclusion Bleomycin delivered through DemoJet provides a more active management choice for persistent warts than normal saline, despite sharp pain levels.

Keywords Recalcitrant wart; Bleomycin; DemoJet; Periungual wart.

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Introduction

Viral warts are common benign epithelial proliferations that present as firm, small, rough growths, often similar in color to the surrounding skin; it affects about 10% of the general population. In most cases, they are asymptomatic, though plantar warts may cause pain or discomfort when located on weight-bearing areas of the feet.[1] These lesions occur predominantly on the hands and feet, but they may appear on any part of the body. Warts are particularly frequent in adults, and among children, they rank as the third most common dermatologic problem. They are caused by more than 200 types of human papillomavirus (HPV) and affect individuals

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of all races. Clinically, HPV-induced warts are classified into two major groups: genital and non-genital, with the ratio of non-genital to genital lesions reported as 9:1.[2] Palmoplantar warts are among the most frequent non-genital forms. Since the identification of HPV as the causative agent, numerous therapeutic approaches have been developed.[3] Warts happen because of a number of host and environmental factors. Age, gender, race, and immune status are significant factors, while behavioral patterns, seasonal variations, geographical distribution, and socioeconomic status also influence the observed differences in incidence.[4] It is estimated that 3-5% of individuals infected with HPV will develop visible warts, rendering them the most prevalent manifestation of HPV infection. Even though it is very common, only about 2% of people who have it go to the doctor each year.[5] Several topical and systemic treatment options have been explored. Salicylic acid, often considered first-line therapy, may be compounded up to 60% strength for wart management.[6-8] Other agents include 5-fluorouracil (5-FU), which inhibits cellular proliferation and has been used off-label for warts, cantharidin, which demonstrates efficacy particularly in combination with podophyllotoxin and salicylic acid and imiquimod, an immune response modifier approved by the U.S. Food and drug administration for genital warts.[9-12] Dinitrochlorobenzene, though once used with cure rates up to 80%, has been abandoned due to its mutagenic potential.[10] Antivirals such as cidofovir cream have shown promise in resistant cases.[11] Podophyllotoxin, a purified derivative of podophyllin resin, has been applied in genital and plantar warts, particularly in immunocompromised patients.[12] More recently, intralesional therapies have emerged as a promising modality for resistant or difficult-to-treat warts, particularly those in periungual and palmoplantar sites.[13] A wide range of agents-including vitamin D3, purified protein derivative (PPD), Candida antigen, the measles-mumps-rubella (MMR) vaccine, and others-have demonstrated efficacy as immunotherapies. Additional combinations, such as digoxin-furosemide and antivirals, have also been studied.[14] For the past several years, high-pressure needle-free jet injection systems (such as DemoJet) have been utilized to deliver drugs intramuscularly, subcutaneously, and intradermally, like bleomycin. The mechanism is bleomycin-binding free radical formation and subsequent breakages of DNA strands, leading to cell death of the infected system's keratinocytes, and no replication of HPV occurs. In different studies, patients obtained complete healing after a single infiltration of equal parts of 0.9% saline solution, in a mean post-treatment time of 4 weeks. it is unclear whether this effectiveness is due to the composition of the product or to the pressure, which may also provoke cell necrosis and destruction of the virus. These devices are also used in dermatology and cosmetic procedures for mesotherapy. Although DemoJet is suitable for both adults and children, it carries potential adverse effects, including local bleeding, erythema, swelling, and an increased risk of secondary infection due to skin barrier disruption. The DemoJet infiltration technique was by pressing the trigger several times to ensure that the pressure was sufficient to ensure penetration of the preparation into the skin tissues. Disinfection of the skin with an antiseptic solution and superficial paring was done to remove the callus surrounding, followed by infiltration with the preparation depending on the size of the lesion. The DemoJet was applied until the lesion whitened.[15] The aim of the study is to compare the efficacy of DemoJet infiltration using normal saline versus bleomycin in the treatment of recalcitrant warts: a comparative therapeutic study. Previous studies used a DemoJet in the delivery of bleomycin, but there were no previous studies comparing the use of a DemoJet in the delivery of different treatment modalities for the resistant warts because of limited studies about the treatment of resistant warts. The DemoJet gives us many benefits for wart treatment that make it superior to other therapies, such as increased effectiveness, decreased discomfort, accurate administration, and the ability to treat cases that are resistant. In comparison between both types, it has been argued that intralesional bleomycin is an

effective and low risk treatment and the studies comparing both therapies are scarce.

Methods

This was an interventional comparative study carried out in the Department of Dermatology and Venereology at Al-Kindy Teaching Hospital, Baghdad, Iraq, between November 2023 and September 2024. Ethical approval was obtained from the hospital authority as well as the Scientific Council of the Arab Board of Dermatology and Venereology (approval was granted during committee's meeting No. 13 Ref. Nil dated 26.05.2025). All patients received a full explanation of the study and provided verbal consent prior to enrolment. A total of 40 patients, all attending the dermatology outpatient clinic fulfilling the inclusion criteria with 173 clinically diagnosed viral warts (by visual inspection of hyperkeratotic papules, a characteristic finding in the diagnoses of viral warts is the appearance of tiny black dots that show pinpoint bleeding when the wart is pared) were recruited. Diagnosis was established through history and careful visual inspection. Eligible participants included patients with common or palmoplantar warts that were unresponsive to prior therapies, patients who use more than two different modalities of treatment for more than three months without achieving remission and had not received any treatment in the preceding month. Exclusion criteria were pregnancy, lactation, known hypersensitivity to bleomycin, refusal to participate, or any systemic disease and those who had a documented history of chronic autoimmune disease or immune suppression by taking detailed information from the patient.

The sample size was calculated with G*Power software version 3.1 by estimating the difference between two treatment groups of a moderate effect size (d=0.80) at a two-sided significance level (α) of 0.05 and a statistical power of 80%. We calculated the minimum number of samples to be 18 participants per group. Each group consisted of 20 patients for a total sample size of 40 patients, to account for possible dropouts and incomplete follow-up.

Patients were randomized based on numbering order: those with odd numbers were assigned to Group A, while those with even numbers were placed in Group B.

- Group A: 20 patients with 102 viral warts treated with DemoJet infiltration of bleomycin solution (1–2 ml per session).
- Group B: 20 patients with 71 viral warts treated with DemoJet infiltration of normal saline.

Intervention Protocol: Sessions were performed every two weeks for a maximum of 12 weeks or until complete clearance. In both groups, lesions were pared superficially and disinfected with an antiseptic before injection.

For Group A, bleomycin (Bleokine®, 15 IU/vial) was reconstituted with 5 ml of saline to yield a stock solution of 3 IU/ml, stored at 4-8°C for up to 60 days. Before use, the stock was further diluted with 2% lidocaine to a final concentration of 1 IU/ml. The maximum amount of 2 ml per session and 1 ml into a single wart was used to treat each lesion until it turned white.

For Group B, normal saline was mixed with 2% lidocaine in equal amounts and given by DemoJet using the same method and limits. Preparation of normal saline solution with equal parts of 0.9% saline and 2% lidocaine, with no vasoconstrictor. The DemoJet® was purged by pressing the trigger several times to ensure that the pressure was sufficient to ensure penetration of the preparation into the skin tissues, Disinfection of the skin with an antiseptic solution and superficial paring was done to remove the callus surrounding, followed by infiltration with the preparation depending on the size of the lesion and The DemoJet® was applied until the lesion whitened.

Patients were evaluated at baseline and at 2, 6, and

12 weeks. The following outcomes were recorded:

- Lesion characteristics: number and size of warts.
- Pain severity: measured using a 100 mm Visual Analogue Scale (VAS), ranging from "no pain" to "worst imaginable pain" (16).
- Patient satisfaction: rated on a five-point Likert scale (1=not at all satisfied, 5=very much satisfied).

All data were analyzed using SPSS version 26. Results were expressed as mean±standard deviation and range. Categorical data were presented as frequencies and percentages. Between-group comparisons were performed with the independent t-test, while within-group changes before and after treatment were assessed using the paired t-test. A *P*-value <.05 was considered statistically significant.

Result

There were 40 study participants in total, and there were 173 viral warts. Two groups were formed out of them: Twenty patients in group A had 102 viral warts treated with bleomycin injection, and twenty patients in group B had 71 viral warts treated with normal saline infiltration. **Table 1** displays the distribution of research groups by general characteristics.

With a mean age of 24.5 years and a standard deviation (SD) of ±12.8 years, the study participants ranged in age from 7 to 48 years. Half of the study participants in group A were between the ages of 20 and 39, and half of the participants in group B were under 20. In this study, 40% of patients in group A and 55% of group B had periungual type of viral warts, the most common site of viral warts was foot in groups A and B (55% and 35% respectively), number of viral warts was >4 in 50% of group A and 40% of group B, and size of viral warts was between 1-2 cm in 47.1% of viral warts in group A and in 54.9% of viral warts in group B. As shown in **Table 2**, the mean of number of viral warts in each patient was significantly higher in group A than that in group B (5.77±3.1 versus 3.37±2.6, P=.019).

Table 1 General characteristics of study groups.

General	*Study group*		*P-Value*
	A (%) n= 20	*B (%) n= 20*	
Age (Year)			
< 20	8 (40.0)	10 (50.0)	
20 – 39	10 (50.0)	6 (30.0)	.388
≥ 40	2 (10.0)	4 (20.0)	
Gender			
Male	12 (60.0)	11 (55.0)	.749
Female	8 (40.0)	9 (45.0)	
Type of wart			
Common	6 (30.0)	4 (20.0)	
Plantar	6 (30.0)	5 (25.0)	.617
Periungual	8 (40.0)	11 (55.0)	
Site of wart			
Foot	11 (55.0)	7 (35.0)	
Hand	5 (25.0)	7 (35.0)	.595
Elbow	2 (10.0)	4 (20.0)	
Foot and Hand	2 (10.0)	2 (10.0)	
Duration of lesion (Months)			
< 6	4 (20.0)	8 (40.0)	
6 – 12	14 (70.0)	9 (45.0)	.269
> 12	2 (10.0)	3 (15.0)	
Number of viral warts			
One	2 (10.0)	7 (35.0)	
2 – 4	8 (40.0)	5 (25.0)	.157
> 4	10 (50.0)	8 (40.0)	
Size of viral warts (cm)			
< 1	36 (35.3)	22 (31.0)	
1 – 2	48 (47.1)	39 (54.9)	.584
> 2	18 (17.6)	10 (14.1)	

Table 2 Comparison in general characteristics between study groups.

Variable	*Study group (Mean±SD)*		*P-Value*
	Group A	*Group B*	
Age (Year)	23.6±10.6	25.45±14.9	.653
Duration of lesion (Month)	10.7±5.5	8.05±5.3	.129
Number of viral warts	5.77±3.1	3.37±2.6	.019
Size of wart (cm)	1.33±0.7	1.13±0.6	.089
Number of total sessions	2.6±0.5	5.3±2.0	.001

No statistically significant differences (P=.653) in age, duration of lesion, and size of viral warts between study groups. The mean number of sessions needed to cure the patients was significantly lower in group A than that in group B (2.6 versus 5.3, P=.001).

As shown in **Table 3**, the number of viral warts left

Table 3 Comparison in number of viral warts after each session between study groups.

Variable	*Study group (Mean±SD)*		*P-Value*
	Group A	*Group B*	
Age (Year)	23.6±10.6	25.45±14.9	.653
Duration of lesion (Month)	10.7±5.5	8.05±5.3	.129
Number of viral warts	5.77±3.1	3.37±2.6	.019
Size of wart (cm)	1.33±0.7	1.13±0.6	.089
Number of total sessions	2.6±0.5	5.3±2.0	.001

in group A was significantly lower than that left in group B (P<.05) after 6 and 12 weeks. No significant difference in number of viral warts left after 2 weeks between study groups (P=.111).

The difference in mean size of viral warts during visits in group A and B compared to baseline size is shown in **Table 4**. In this study, the size of viral warts after 6 weeks were significantly decreased than before treatment (0.44 versus 1.26, P=.001). The difference in the mean size of viral warts during visits in group B compared to baseline size is shown in **Table 4**. Size of viral warts after 6 and 12 weeks were significantly decreased than before treatment (0.68 versus 1.16, P=.001 and 0.52 versus 1.21, P=.001 respectively).

After 6 and 12 weeks of treatment, the mean size of viral warts decreased more significantly (P<.05) in group A than in group B when compared to before treatment; however, it indicates that there was no significant difference in the amount of decrement in the mean size of viral warts after 2 weeks of treatment (P=.326). The VAS score of pain was significantly higher (P<.05) in group A than that in group B after 2 and 6 weeks of treatment as shown in **Table 5**. No side effects other than pain were reported.

After 2 weeks, in Group A, most patients were either somewhat satisfied (40%) or undecided (40%).

In contrast, in Group B, the majority were undecided (55%), and 20% were not at all satisfied. After 6 weeks, satisfaction improved in Group A, with 30% very satisfied and 35% somewhat satisfied. In Group B, only 5% were very satisfied, while 30% were somewhat satisfied, and 25% were not really satisfied **(Table 6)**.

Table 4 Comparison of mean size of viral warts during treatment in Group A and B.

Time (Sessions)	*Size of wart (cm) Mean±SD*	*P-value*
Group A		
Baseline	1.33±0.7	.221
After 2 weeks	1.23±0.7	
Baseline	1.26±0.52	.001
After 6 weeks	0.44±0.1	
Group B		
Baseline	1.13±0.6	.625
After 2 weeks	1.08±0.4	
Baseline	1.16±0.6	.001
After 6 weeks	0.68±0.3	
Baseline	1.21±0.7	.001
After 12 weeks	0.52±0.1	

Table 5 Percentage change in size of viral warts during treatment compared to baseline and VAS score of pain after treatment in both groups.

	Group A Mean±SD	*Group B Mean±SD*	*P-value*
Comparison with before treatment (%)			
After 2 weeks	-9.4±2.3	-7.31±2.1	.326
After 6 weeks	-34.2±9.6	-21.7±7.4	.001
After 12 weeks	-100.0±0	-36.9±8.5	.001
VAS score of pain			
After 2 weeks	5.7±1.7	4.6±0.94	.018
After 6 weeks	5.8±0.6	4.45±1.0	.001

Table 6 Patients' satisfaction during treatment in study groups.

Patients' satisfaction	*Group A (n=20)*	*Group B (n=20)*
After 2 weeks		
Somewhat satisfied	8 (40.0)	3 (15.0)
Undecided	8 (40.0)	11 (55.0)
Not really satisfied	3 (15.0)	2 (10.0)
Not at all satisfied	1 (5.0)	4 (20.0)
After 6 weeks		
Very much satisfied	6 (30.0)	1 (5.0)
Somewhat satisfied	7 (35.0)	6 (30.0)
Undecided	4 (20.0)	6 (30.0)
Not really satisfied	2 (10.0)	5 (25.0)
Not at all satisfied	1 (5.0)	2 (10.0)

Discussion

Viral warts are a common problem in the clinical

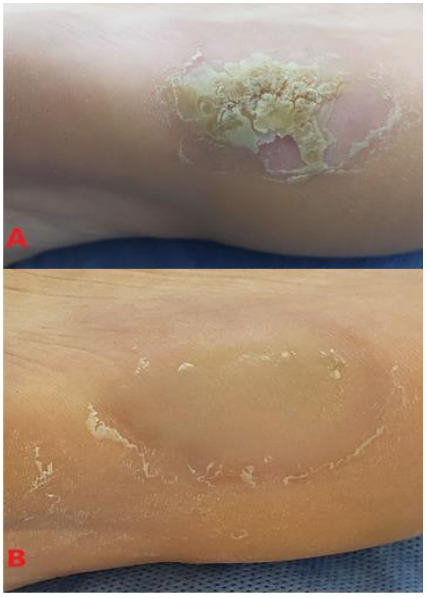

Figure 1 Patient received bleomycin: A: Before treatment, B: After treatment

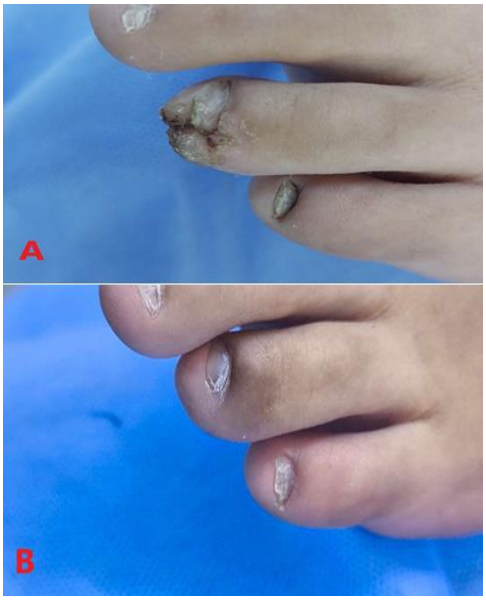

Figure 2 Patient received normal saline: A: Before treatment, B: After treatment

Figure 3 Patient received bleomycin: A: Before treatment, B: After treatment

practice affecting 10% of worldwide population. While many lesions disappear by themselves, many patients show up with warts that don't respond to standard treatments. This requires the search for more effective treatment strategies. Intralesional bleomycin has been widely studied in this context and achieves cure rates of 59-100%, with an acceptable side effect profile which is predominantly confined to transient local discomfort.[17] The therapeutic response is particularly impressive with periungual as well as extremity warts with clearance rates of about 94-95%, but not so much for plantar lesions in which the average rate is approximately 60%.[18] In the present study, the number of sessions required for clearance was significantly shorter in the bleomycin group compared to saline group (*P*=.001). This result is in line with Ngo T *et al*. who also found a high relationship between the effectiveness of treatment and number of sessions. They concluded that a reduced number of treatment visits and less duration of the disease were associated with reduced number of lesions.[19] Kruter *et al*. also noted that majority of the warts resolved after three sittings of DemoJet-administered bleomycin and there was an insignificant advantage with fourth sitting.[20] Our findings demonstrate that a DemoJet applicator for bleomycin acts faster than other treatment modalities. With respect to warts numbers, we found that the number of remaining lesions was significantly lower in the bleomycin group at 6 weeks but not at 2 weeks. This is consistent with the findings of Agius *et al*; who reported cumulative clearance rates of 51.5% after one treatment, increasing to 77.5% at fourth treatment, with approximately 90% of lesions showing some degree of clearance.[21] Orosa AM *et al*. described high-pressure saline delivery by DemoJet that afforded 78.4% of clearance after one exposure, suggesting plausible activation of local immune mechanisms to help in resolution of the lesions.[22] In our group, it was also more effective than bleomycin in reducing warts in size. Mean Size decreased sharply after a 6 week period, equivalent to the finding of Agius *et al*. was observed by these authors when they demonstrated that the skin area was diminishing proportionally to the number of DemoJet injections bleomycin at each session, being 1.27 cm^2 initially and 0.03 cm^2 at fifth.[21] These reports suggest, therefore, that bleomycin has a strong effect in inducing keratinocytes apoptosis and in early reduction of the lesions. The DemoJet itself appears to be therapeutic. Its needle-free,

which enables precise administration into thick acral and curved areas and minimize leakage to surrounding tissue for patient comfort. Singal *et al*. confirmed these advantages in their substantial series of periungual and subungual warts, and the pain being mostly moderate, pigmentary changes minor and temporary with minimal severe side effects including necrosis which was uncommon and reversible.[23] So, DemoJet makes a safe and sound route to deliver drugs, particularly for warty lesions where other forms of treatments fail.[24] Bleomycin as the active ingredient also matters. Kumar *et al*. treated 703 warts with bleomycin, and found a complete cure in 94.2% of periungual lesions within 12 week.[25] Aziz-Jalali *et al*. reported similar findings showing an overall response rate of complete clearance in 73% but particularly high for periungual, hand lesions.[26] In the present study, the bleomycin group demonstrated higher pain scores at two and six weeks post-treatment. This aligns with previous reports by Agius *et al*. that moderate pain was frequent which did not sustain or prevent patients from completing treatment.[21] Mehta *et al*. also reported that 5 to 9% of the patients experienced mild to severe pain for two days after treatment, which was considered acceptable and controllable.[27] The pain profiles of needle injections versus DemoJet comparisons are strikingly in their contrast with sources pointing to the risks associated with deep infiltration and sloughing while these can be reduced through a superficial pressurized route using the DemoJet.[28] Finally, the choice of treatment must be based on clinical presentation, patient tolerance, and the desired balance between efficacy and convenience.[29] Such Results of the present study validate bleomycin in DemoJet as an effective weapon for resistant warts, the DemoJet provides several benefits for wart therapy that made it superior to other techniques, such as increased effectiveness, decreased discomfort, accurate administration, and the ability to treat cases that are resistant. Additionally, DemoJet delivers the drugs precisely and with high pressure into the lesion, enhancing its cytotoxic effects on diseased cells while reducing the discomfort and any adverse effects that come with typical needle injections.

However limits of this study must be acknowledged. The sample size was somewhat limited, however, which might limit the generalizability of the findings. The duration of follow-up was short casting the main spotlight on short-term recurrence rates that still remained a problem in treatment of warts. The viral warts were diagnosed clinically without histopathological diagnosis as usually done. Finally, patient-reported outcomes such as pain and satisfaction are subjective; this could introduce variation. Further studies in larger series, long-term follow-up, comparison with other well accepted therapies would provide us with more comprehensive information regarding the real efficacy of DemoJet bleomycin.

Conclusion

In clinical practice, bleomycin injection using the DemoJet device to treat viral warts has produced encouraging outcomes. Bleomycin delivered through DemoJet provides a more active management choice for persistent warts than normal saline, despite sharp pain levels.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Conflict of interest No conflict of interest.

Author's contribution

MMR, MYA: Substantial contributions to study design, acquisition of data manuscript writing.

SHM: Substantial contributions to concept, study design, critical review.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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