RESEARCH PAPER

EVALUATION OF EFFICACY AND SAFETY OF INTRALESIONAL INJ BLEOMYCIN AND INJ 5- FLUOROURACIL IN THE TREATMENT OF PALMOPLANTAR WARTS

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ABSTRACT

Background: Palmoplantar warts are benign proliferative lesions caused by human papillomavirus (HPV) and are often difficult to treat due to recurrence and resistance to conventional therapies. Intralesional immunotherapy has emerged as an effective treatment modality.

Objectives: To compare the efficacy and safety of intralesional Bleomycin and intralesional 5-Fluorouracil (5-FU) in the treatment of palmoplantar warts.

Materials and Methods: A randomized controlled study was conducted in the Department of Dermatology, Venereology, and Leprosy at Adichunchanagiri Hospital and Research Centre over 18 months. Thirty patients with palmoplantar warts were enrolled and randomly allocated into two groups: Group A received intralesional Bleomycin (n=15) and Group B received intralesional 5-FU (n=15). Clinical response was assessed based on reduction in wart number, size, and height, along with adverse effects.

Results: The mean age of participants was 27.07 years, with a male predominance in both groups. Both treatments significantly reduced wart number, size, and height. Complete response was achieved in 81.3% of patients in the Bleomycin group compared to 46.23% in the 5-FU group. Partial response was observed in 5.6% and 18.27% of patients, respectively. Pain was the most common adverse effect, reported by all patients, while swelling occurred in 16.67% of Group A and 10% of Group B. No serious systemic adverse effects were noted. The difference in treatment response between groups was statistically significant (p=0.0003).

Conclusion: Intralesional Bleomycin demonstrated superior efficacy and a better safety profile compared to intralesional 5-FU in the treatment of palmoplantar warts.

Keywords: Palmoplantar warts, Bleomycin, 5-Fluorouracil, Intralesional therapy, Human papillomavirus (HPV)

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INTRODUCTION

Warts (verrucae) are benign epidermal proliferations caused by infection with the human papillomavirus (HPV), a DNA virus belonging to the Papovaviridae family. The virus infects basal keratinocytes through microabrasions, resulting in hyperproliferation and hyperkeratosis of the epidermis [1]. Clinically, warts are classified into several types, including verruca vulgaris, verruca plana, plantar warts, filiform warts, digitate warts, and anogenital warts. Common and plantar warts are among the most frequently encountered lesions in dermatology practice and commonly affect the hands and soles, where repeated trauma facilitates viral inoculation and persistence [1].

The persistence and recurrence of cutaneous warts are influenced by viral immune evasion and host immune status. HPV remains confined to the epidermis, limiting immune recognition and contributing to chronic or treatment-resistant infections, particularly in immunocompromised individuals [2]. Numerous treatment modalities have been used for wart management, including cryotherapy, electrocautery, laser ablation, keratolytic

agents, antiproliferative agents, and immunotherapy [3]. However, recurrence, pain, pigmentary changes, scarring, and the need for repeated treatment sessions remain significant limitations of conventional therapies [4,6].

5-Fluorouracil (5-FU), a pyrimidine analogue that inhibits thymidylate synthase and DNA synthesis, has demonstrated effectiveness in dermatological conditions characterized by rapid keratinocyte proliferation [7]. While topical 5-FU has shown moderate efficacy in warts, limited penetration through hyperkeratotic lesions may reduce its therapeutic effectiveness [8]. Intralesional administration provides higher local drug concentration with minimal systemic absorption and has shown encouraging cure rates in previous studies [9,10]. Bleomycin, another intralesional agent, has also demonstrated promising results in resistant palmoplantar warts.

Considering the limitations of existing therapies and the need for effective, safe, and minimally invasive treatment options, this study was undertaken to compare the efficacy and safety of intralesional Bleomycin and intralesional 5-Fluorouracil in the treatment of palmoplantar warts.

MATERIALS AND METHODS

This randomized controlled study was conducted in the Department of Dermatology, Venereology and Leprosy, over a period of 18 months. Thirty patients aged ≥18 years with palmar or plantar warts attending the dermatology outpatient department were enrolled after obtaining Institutional Ethics Committee approval and written informed consent.

Patients who were pregnant or lactating, immunocompromised, receiving immunosuppressive therapy, or had significant systemic illness, peripheral vascular disease, Raynaud's disease, active infection, hypersensitivity to study medications, or a history of keloids, hypertrophic scars, or vitiligo were excluded.

Participants were randomly allocated into two groups of 15 patients each. Group A received intralesional bleomycin and Group B received intralesional 5-fluorouracil (5-FU). Baseline demographic and clinical details, including number, size, and site of warts, were recorded, and clinical photographs were obtained before treatment and during follow-up.

In Group A, bleomycin was administered intralesionally at a final concentration of 1 mg/mL after superficial paring of the lesion. In Group B, intralesional 5-FU was administered at a concentration of 40 mg/mL. In both groups, injections were given strictly intralesionally until blanching was observed. A maximum of five lesions were treated per session, and sessions were repeated every two weeks for a maximum of four sessions or until complete clearance.

Patients were followed for two months after the final treatment session to assess recurrence and adverse effects. Treatment response was categorized as complete response (100% clearance), partial response (>50% reduction in lesion size or number), or no response (<50% improvement). Adverse effects such as pain, swelling, pigmentary changes, crusting, and local tissue reactions were documented.

Data were analyzed using Epi Info software. Qualitative variables were analyzed using the chi-square test, and quantitative variables were assessed using appropriate parametric tests. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 30 patients with palmoplantar warts were enrolled in this prospective randomized study, with 15 patients each allocated to the intralesional Bleomycin group (Group A) and intralesional 5-Fluorouracil (5-FU) group (Group B). All participants completed the study without dropouts. A total of 90 verrucae were evaluated during the study period.

The mean age of patients in Group A was 25.13 ± 3.58 years, while the mean age in Group B was 29 ± 6.22 years. The majority of patients in both groups belonged to the 21–30 years age group. Male predominance was observed in both groups, with males accounting for 56.7% of the overall study population. Most participants were students, and the occupational distribution was comparable between groups. Baseline demographic and clinical characteristics, including duration of lesions, number of warts, and site involvement, were similar between the two treatment groups. The majority of patients presented with multiple lesions, and palmar warts were more common than plantar warts. These baseline characteristics are summarized in Table 1.

Table 1. Baseline characteristics

Variable	Group A (Bleomycin) n=15	Group B (5-Fluorouracil) n=15	Total (N=30)
Age Group (Years)			
18–20	3 (20%)	2 (13.3%)	5 (16.7%)
21–30	11 (73.3%)	10 (66.7%)	21 (70%)
31–40	1 (6.7%)	2 (13.3%)	3 (10%)
41–50	0	1 (6.7%)	1 (3.3%)
Mean Age (years)	25.13 ± 3.58	29 ± 6.22	27.07 ± 5.27
Gender			
Male	8 (53.3%)	9 (60%)	17 (56.7%)
Female	7 (46.7%)	6 (40%)	13 (43.3%)
Occupation			
Student	5 (33.3%)	4 (26.7%)	9 (30%)
Housewife	4 (26.7%)	3 (20%)	7 (23.3%)
Agricultural Worker	1 (6.7%)	2 (13.3%)	3 (10%)
Unskilled Worker	3 (20%)	4 (26.7%)	7 (23.3%)
Skilled Worker	2 (13.3%)	2 (13.3%)	4 (13.3%)
Duration of Warts (Weeks)			
0–4	3 (20%)	5 (33.3%)	8 (26.7%)
4–8	4 (26.7%)	3 (20%)	7 (23.3%)
8–12	3 (20%)	2 (13.3%)	5 (16.7%)
12–16	2 (13.3%)	4 (26.7%)	6 (20%)
16–20	3 (20%)	1 (6.7%)	4 (13.3%)
Mean Duration (weeks)	9.47 ± 5.83	8.13 ± 5.63	8.80 ± 5.73
Number of Lesions			
Single	2 (13.3%)	1 (6.7%)	3 (10%)
Multiple	13 (86.7%)	14 (93.3%)	27 (90%)
Mean Number of Warts	3.73 ± 1.16	4.20 ± 1.47	3.97 ± 1.31
Site of Involvement			
Palmar	9 (60%)	9 (60%)	18 (60%)
Plantar	6 (40%)	6 (40%)	12 (40%)
Mean Size of Largest Wart (mm)			
Diameter	5.47 ± 0.92	5.87 ± 0.99	5.67 ± 0.96
Height	2.60 ± 0.94	2.92 ± 0.63	2.76 ± 0.79

At baseline, 46 verrucae were treated in the Bleomycin group and 44 in the 5-FU group. During the first follow-up, complete response was observed in 63% of lesions treated with Bleomycin compared to 31.8% in the 5-FU group. No response was observed in 8.7% and 45.5% of lesions, respectively. The difference in treatment response between the two groups was statistically significant (p=0.0002). During the second follow-up, Bleomycin continued to demonstrate superior therapeutic response, with significantly fewer non-responding lesions compared to the 5-FU group (p=0.002). Subsequent follow-up assessments included only residual lesions that had not achieved complete clearance in the previous visit . These findings are presented in Table 2 and while representative post-treatment evaluation at first follow-up is illustrated in Figure 1.

Table 2. Comparison of Therapeutic Response Between Intralesional Bleomycin and 5-Fluorouracil Across Follow-Up Assessments

Follow-up / Response Pattern	Group A – Bleomycin n (%)	Group B – 5-Fluorouracil n (%)
Initial Response Assessment		
Complete Response	29 (63%)	14 (31.8%)
Partial Response	13 (28.3%)	10 (22.7%)
No Response	4 (8.7%)	20 (45.5%)
Total	46 (100%)	44 (100%)
Second Follow-up		
Complete Response	10 (21.7%)	8 (18.18%)
Partial Response	6 (13.04%)	6 (13.63%)
No Response	1 (2.17%)	16 (36.36%)
Total	17 (38.6%)	30 (68.18%)
Third Follow-up		
Complete Response	3 (6.5%)	8 (18.18%)
Partial Response	2 (4.3%)	6 (13.63%)
No Response	2 (4.3%)	8 (18.18%)
Total	7 (15%)	22 (50%)

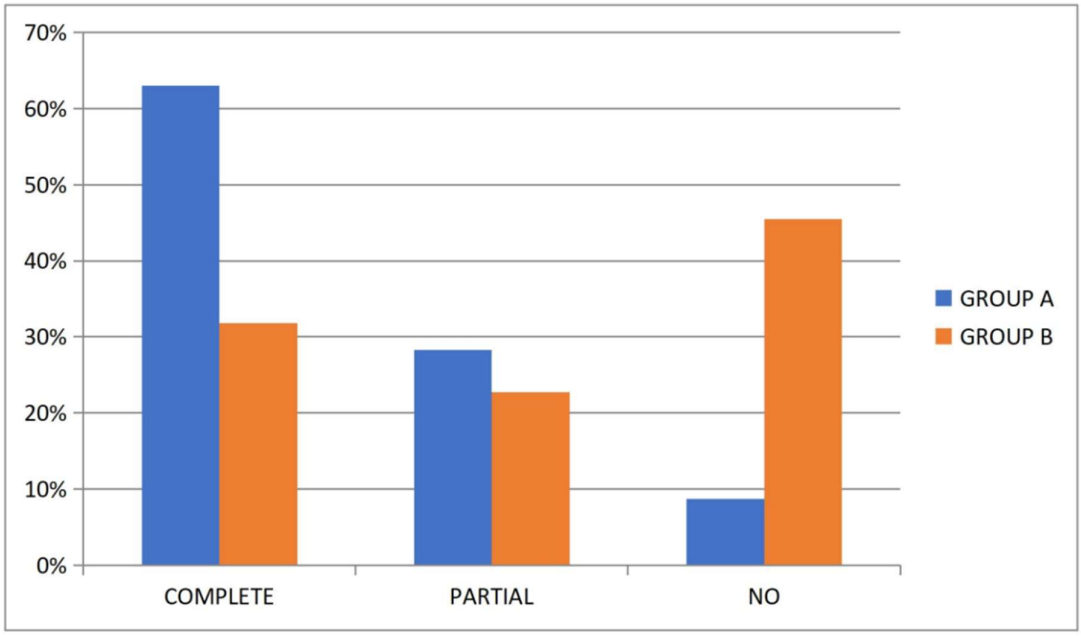

Figure 1: Post treatment evaluation on 1st follow up

At the final follow-up, intralesional Bleomycin demonstrated superior efficacy compared to intralesional 5-FU. Complete clearance was achieved in 91.3% of lesions treated with Bleomycin, whereas 68.18% of lesions treated with 5-FU showed complete response. Partial response and no response were observed more frequently in the 5-FU group. The difference in overall treatment response between the two groups was statistically significant (p=0.000003). Plantar lesions in the Bleomycin group showed complete clearance in 88.88% of cases, while palmar lesions showed 92.85% clearance. In the 5-FU group, complete clearance was achieved in 72% of plantar lesions and 63.15% of palmar lesions. Overall treatment outcomes are summarized in Table 3 and represented in Figure 2 and 3.

Table 3. Comparison of Response According to Type of Verruca Between Group A (Bleomycin) and Group B (5-Fluorouracil)

Type of Verruca	Response Pattern	Group A – Bleomycin n (%)	Group B – 5-Fluorouracil n (%)
Plantar Verruca	Complete Response	16 (88.88%)	18 (72%)
	Partial Response	1 (5.55%)	3 (12%)
	No Response	1 (5.55%)	4 (16%)
	Total	18	25
Palmar Verruca	Complete Response	26 (92.85%)	12 (63.15%)
	Partial Response	1 (3.57%)	2 (10.52%)
	No Response	1 (3.57%)	5 (26.31%)
	Total	28	19
Overall Total	Complete Response	42 (91.3%)	30 (68.18%)
	Partial Response	2 (4.3%)	5 (11.36%)
	No Response	2 (4.3%)	9 (20.45%)
	Total	46	44

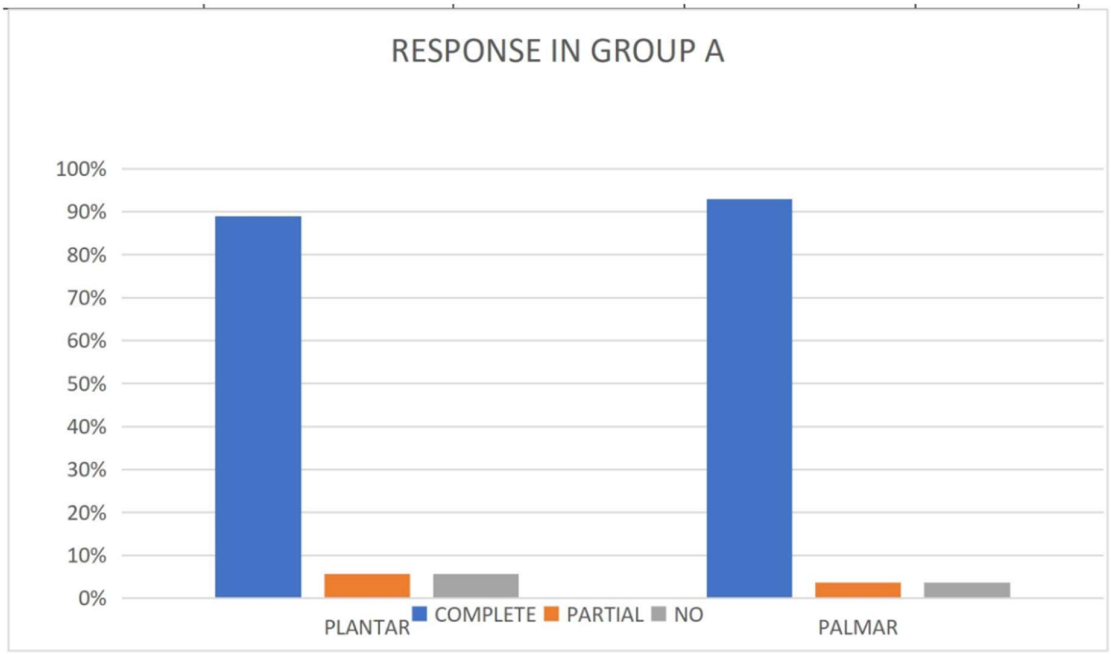

Figure 2: Response in GROUP A

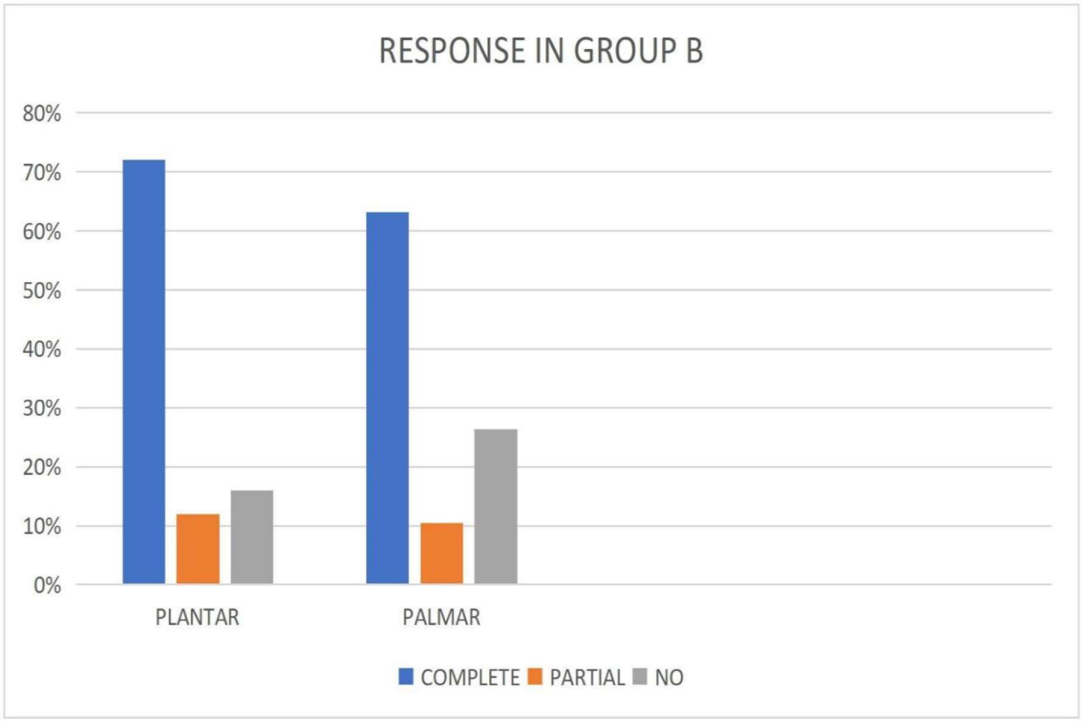

Figure 3: Response in GROUP B

Both treatment modalities resulted in a reduction in wart size and height during follow-up. The mean diameter of the largest wart at the final follow-up was lower in the Bleomycin group (4.7 ± 2.7 mm) compared to the 5-FU group (6.7 ± 5.0 mm), although the difference was not statistically significant (p=0.20). Similarly, the mean wart height was 3.3 ± 2.7 mm in the Bleomycin group and 2.4 ± 2.0 mm in the 5-FU group (p=0.29). Reduction in lesion size during follow-up is shown in Figure 4.

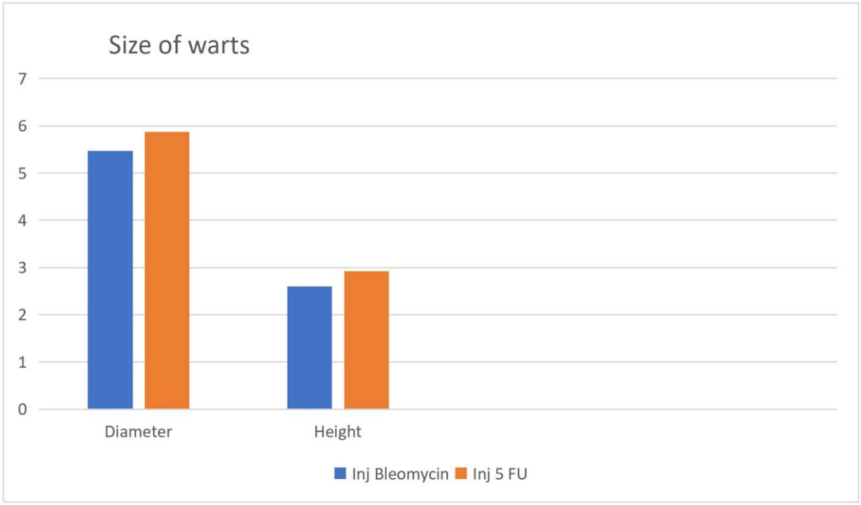

Figure 4: Size of warts in Group A and Group B

Pain during injection was reported by all patients in both groups. Perilesional hyperpigmentation was observed in 33.3% of patients in each group. Superficial ulceration occurred in 6.7% of patients treated with Bleomycin, while swelling was observed in 6.7% and 13.3% of patients in the Bleomycin and 5-FU groups, respectively. Oozing and crusting were noted only in the 5-FU group. Hemorrhagic eschar was observed in one patient treated with Bleomycin. No serious adverse effects, systemic complications, or necrosis were reported in either group. The adverse effects observed during the study are summarized in Table 4 and depicted in Figure 5.

Table 4. Comparison of Adverse Effects Between Intralesional Bleomycin and 5-Fluorouracil

Adverse Effects	Inj. Bleomycin n (%)	Inj. 5-Fluorouracil n (%)
Pain	15 (100%)	15 (100%)
Superficial Ulcer	1 (6.6%)	0
Swelling	1 (6.7%)	2 (13.3%)
Oozing and Crusting	0	1 (6.7%)
Perilesional Hyperpigmentation	5 (33.3%)	5 (33.3%)
Hemorrhagic Eschar	1 (6.6%)	0

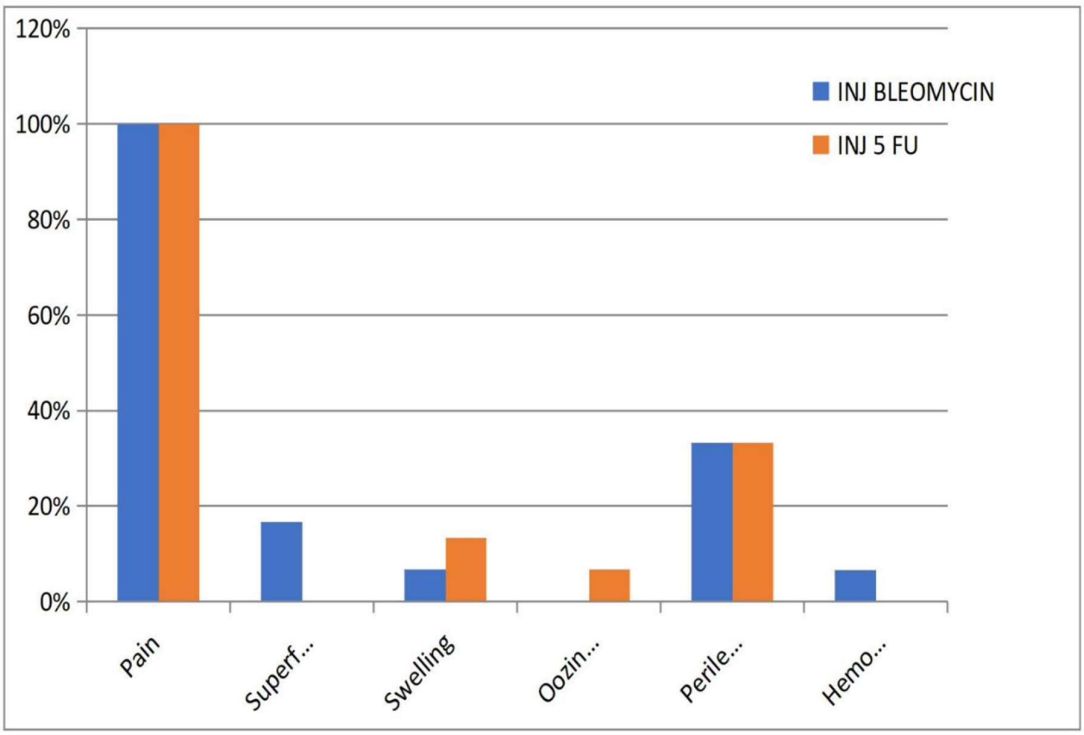

Figure 5: Adverse events in Group A and Group B

DISCUSSION

Warts, or verrucae, are benign epidermal proliferations caused by infection with human papillomavirus (HPV). These lesions commonly affect the palms and soles and are often associated with pain, cosmetic concerns, functional impairment, and recurrence. Although several therapeutic modalities are available for the treatment of verrucae, no single therapy has been universally effective. Intralesional therapies have gained increasing importance because they deliver the drug directly into the lesion, thereby improving therapeutic response while minimizing systemic adverse effects. The present study was conducted to compare the therapeutic efficacy and safety of intralesional Bleomycin and intralesional 5-Fluorouracil (5-FU) in the management of palmoplantar verrucae.

In the present study, the mean age of patients was 27.07 ± 5.27 years, with the majority of patients belonging to the 21–30 years age group. Similar findings were reported by Sachan P et al., who observed a mean age of 27.20 years among patients with verruca.[110 In both treatment groups of the present study, the highest proportion of patients belonged to the 21–30 years age category, which is in agreement with previous studies conducted by Sachan et al. [11] The higher prevalence of verrucae in younger adults may be attributed to increased outdoor activity, occupational exposure, repeated minor trauma, and frequent interpersonal contact facilitating viral transmission.

A slight male predominance was observed in the present study, with males accounting for 56.7% of the study population and a male-to-female ratio of approximately 1.3:1. Similar observations were reported by Sachan et al.,[11] Soni et al.,[12] and Singal and Grover et al [13] all of whom demonstrated a higher prevalence of verruca among males. Marahatta et al. [14] also reported male predominance in patients with palmoplantar and periungual warts. However, Kamal et al.[15] reported a relatively higher proportion of female patients, indicating variation in demographic distribution across different study populations. The male predominance observed in the present study may be related to greater occupational exposure, outdoor activity, and repeated trauma to palms and soles.

The baseline distribution of lesions was comparable in both treatment groups. Most patients presented with multiple lesions, with mean lesion counts of 3.73 ± 1.16 in the Bleomycin group and 4.20 ± 1.47 in the 5-FU group. Multiple lesions are frequently encountered in verruca due to autoinoculation and progressive spread of HPV infection. Similar findings were reported by Sachan et al and Soni et al., where the majority of patients presented with multiple lesions at baseline.

In the present study, palmar warts were more common than plantar warts in both treatment groups. Palmar involvement was observed in 60% of patients in both groups, whereas plantar lesions accounted for 40% of cases. Similar observations were reported by Sachan et al.and Soni et al.,who also noted increased involvement of palmoplantar regions. Repeated friction, minor trauma, and pressure over these sites may facilitate viral inoculation and persistence of infection.

The present study demonstrated that intralesional Bleomycin was significantly more effective than intralesional 5-Fluorouracil in achieving complete clearance of palmoplantar verrucae. At the final follow-up, complete response was achieved in 91.3% of lesions treated with Bleomycin compared to 68.18% of lesions treated with 5-FU. Partial response and non-response were more commonly observed in the 5-FU group. The difference in therapeutic response between the two groups was statistically significant, indicating superior efficacy of Bleomycin.

The findings of the present study are comparable with those reported in previous literature. Sachan et al. reported complete clearance in 81.3% of lesions treated with intralesional Bleomycin, while Marahatta et al. [14] observed complete response rates of approximately 89.47%. Soni et al. demonstrated an even higher complete response rate of 96.47% following intralesional Bleomycin therapy. The complete response rate of 91.3% observed in the present study is therefore consistent with previously published studies and supports the high therapeutic efficacy of Bleomycin in verruca management.

With regard to intralesional 5-Fluorouracil, Kamal et al. [15] reported complete clearance rates of approximately 75%, which is comparable to the 68.18% complete response observed in the present study. Although 5-FU demonstrated appreciable therapeutic benefit, its efficacy was lower than that of Bleomycin. The comparatively reduced response with 5-FU may be related to differences in mechanism of action, tissue penetration, and cytotoxic effect on infected keratinocytes.

The present study also demonstrated marked reduction in wart size and height in both treatment groups following therapy. In the Bleomycin group, the mean wart diameter decreased from 5.47 mm at baseline to 4.7 mm at final follow-up, while wart height reduced from 2.6 mm to 3.3 mm. Similarly, in the 5-FU group, wart diameter and height also reduced substantially during follow-up. However, reduction in lesion size and complete clearance were more pronounced in the Bleomycin group, further supporting its superior efficacy.

Plantar and palmar lesions both responded favorably to intralesional Bleomycin. Complete clearance was achieved in 88.88% of plantar lesions and 92.85% of palmar lesions treated with Bleomycin. In contrast, the 5-FU group demonstrated complete clearance in 72% of plantar lesions and 63.15% of palmar lesions. These findings suggest that Bleomycin may provide more consistent therapeutic outcomes irrespective of lesion location.

The adverse effects observed in the present study were generally mild and self-limiting. Pain during injection was the most common adverse effect and was reported by all patients in both treatment groups. Similar findings have been reported by Sachan et al. [16] Marahatta et al.,[17] and Soni et al.,[18] where pain was noted as the most frequent adverse effect associated with intralesional therapy. Pain is expected because of the intralesional injection procedure and the inflammatory response induced within the lesion.

Swelling was observed in one patient treated with Bleomycin and two patients treated with 5-FU. Similar inflammatory reactions have been described in previous studies by Marahatta et al.[17] and are considered part of the normal post-treatment response. Perilesional hyperpigmentation was observed in five patients in each group. Comparable findings were reported by Marahatta et al. [17] and by Singal and Grover, [19] who described transient post-inflammatory hyperpigmentation following intralesional Bleomycin therapy that resolved spontaneously without permanent sequelae.

Hemorrhagic eschar formation was observed in one patient in the Bleomycin group. Similar findings have been documented in earlier studies evaluating intralesional Bleomycin and are attributed to its cytotoxic and necrotizing action on infected tissue. Importantly, no serious systemic adverse effects, necrosis, secondary infection, or treatment discontinuation were observed in the present study, indicating that both treatment modalities are relatively safe and well tolerated.

Overall, the present study demonstrates that both intralesional Bleomycin and intralesional 5-Fluorouracil are effective therapeutic modalities for palmoplantar verrucae. However, intralesional Bleomycin showed significantly higher complete clearance rates, lower recurrence of residual lesions, and better overall therapeutic response compared to intralesional 5-Fluorouracil. The findings of the present study are consistent with previously published literature and support the use of intralesional Bleomycin as a superior therapeutic option for palmoplantar verrucae. Further studies with larger sample sizes

and longer follow-up duration may help establish standardized treatment protocols and assess long-term recurrence rates.

CONCLUSION

Both intralesional bleomycin and intralesional 5-fluorouracil were effective and safe in the treatment of palmoplantar warts, producing significant reductions in wart count, size, and height. However, intralesional bleomycin demonstrated superior therapeutic efficacy, with higher complete clearance rates and lower residual lesion counts compared to intralesional 5-fluorouracil.

The adverse effects observed with both treatments were mild, localized, and self-limiting, with pain during injection being the most common complaint. No serious systemic adverse effects or complications were noted in either group, indicating good tolerability and safety of both treatment modalities.

Overall, intralesional bleomycin appears to be a more effective therapeutic option for palmoplantar warts while maintaining a comparable safety profile to intralesional 5-fluorouracil. Further studies with larger sample sizes and longer follow-up durations are recommended to validate these findings and assess long-term recurrence rates.

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