

Original Research

Assessment of efficacy of Bleomycin solution in managing patients with anogenital warts

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ABSTRACT:

Background: Anogenital warts (AGWs), caused by the human papillomavirus (HPV), are among the most common sexually transmitted infections, particularly involving HPV types 6 and 11. Intralesional bleomycin is a relatively new treatment modality being explored. Hence; the present study was undertaken for assessing the efficacy of Bleomycin solution in managing patients with anogenital warts. **Materials & methods:** This prospective interventional study, 20 patients clinically diagnosed with anogenital warts was enrolled. All participants underwent intralesional needling using bleomycin, reconstituted with 5 mL of sterile water to ensure optimal therapeutic concentration. The primary outcome was defined by complete or near-complete clearance of lesions, while secondary outcomes included patient tolerance and recurrence rate. Data were systematically entered in Microsoft Excel and analyzed using SPSS statistical software. **Results:** Mean age of the patients was 39.5 years. Mean duration of disease was 11.5 months. Mean number of warts at baseline, 4 weeks, 8 weeks, 12 weeks, 16 weeks, 20 weeks and 24 weeks was 7.85, 6.99, 4.45, 2.36, 1.85, 1.75 and 1.69 respectively. Mean percentage improvement in terms of number of warts was 78.47 percent. Mean percentage improvement in terms of size warts was 82.36 percent. Pain, erythema, swelling and ulceration was seen in 20 percent, 15 percent, 20 percent and 30 percent of the patients respectively. **Conclusion:** Intralesional bleomycin proved to be a highly effective treatment modality for anogenital warts, showing substantial reduction in both size and number of lesions. Its favorable efficacy, coupled with manageable side effects, supports its role as a valuable therapeutic option in resistant or recurrent cases.

Key words: Warts, Bleomycin

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INTRODUCTION

Anogenital warts (AGWs), caused by the human papillomavirus (HPV), are among the most common sexually transmitted infections, particularly involving HPV types 6 and 11.¹ These lesions typically present as soft, flesh-colored growths affecting the perianal region, external genitalia, or perineum and are often asymptomatic, though they may cause discomfort, itching, or psychosocial distress. Transmission occurs through direct skin-to-skin contact during vaginal, anal, or oral intercourse, and subclinical infections are common, particularly among immunocompromised individuals. The incubation period can vary from weeks to months, making it difficult to ascertain the time of infection. Epidemiological data prior to 2010 indicated increasing trends in AGW incidence,

particularly in populations with early sexual debut, multiple sexual partners, and inconsistent condom use.^{2,3}

Treatment modalities included patient-applied therapies like podophyllotoxin and imiquimod, and provider-administered options such as cryotherapy, trichloroacetic acid (TCA), electrosurgery, and laser ablation.⁴ Recurrence was common due to latent viral persistence in adjacent epithelium. The introduction of prophylactic HPV vaccines—especially quadrivalent vaccines targeting types 6, 11, 16, and 18—marked a significant preventive milestone, showing reductions in AGW incidence among vaccinated populations in early clinical trials.⁴ The emphasis on early immunization, particularly before sexual debut, was based on data suggesting near-complete protection

against vaccine-type AGWs in naïve individuals.⁵Intralesional bleomycin is a relatively new treatment modality being explored. Hence; the present study was undertaken for assessing the efficacy of Bleomycin solution in managing patients with anogenital warts.

MATERIALS & METHODS

This prospective interventional study, 20 patients clinically diagnosed with anogenital warts were enrolled from the outpatient department of Dermatology, Venereology, and Leprology. All participants underwent intralesional needling using bleomycin, reconstituted with 5 mL of sterile water to ensure optimal therapeutic concentration. The procedure was performed under aseptic conditions, targeting the lesion base for maximal cytotoxic effect. Serial photographic documentation was conducted before and after treatment to objectively evaluate clinical response. Patients were reviewed at 4-week intervals over a minimum follow-up period of 24 weeks post-therapy to monitor lesion resolution and any recurrence. Clinical improvement was assessed by reduction. The primary outcome was defined by complete or near-complete clearance of lesions, while secondary outcomes included patient tolerance and recurrence rate. Data were systematically entered in Microsoft Excel and analyzed using SPSS statistical software to derive meaningful inferences regarding treatment efficacy and safety

RESULTS

Mean age of the patients was 39.5 years. Mean duration of disease was 11.5 months. Mean number of warts at baseline, 4 weeks, 8 weeks, 12 weeks, 16 weeks, 20 weeks and 24 weeks was 7.85, 6.99, 4.45, 2.36, 1.85, 1.75 and 1.69 respectively. Mean percentage improvement in terms of number of warts was 78.47 percent. Mean percentage improvement in terms of size warts was 82.36 percent. Pain, erythema, swelling and ulceration was seen in 20 percent, 15 percent, 20 percent and 30 percent of the patients respectively.

Table 1: Lesion count

Time interval	Mean	p-value
Baseline	7.85	0.000 (Significant)
4 weeks	6.99	
8 weeks	4.45	
12 weeks	2.36	
16 weeks	1.85	
20 weeks	1.75	
24 weeks	1.69	

Table 2: Percentage improvement

Percentage improvement	Value
Mean	81.34
SD	26.14

DISCUSSION

The mean age of the enrolled patients was 39.5 years, reflecting that anogenital warts primarily affect individuals in the sexually active age group. The mean duration of the disease prior to intervention was 11.5 months, indicating chronicity and the potential psychosocial burden of untreated warts. The baseline mean number of warts was 7.85, which progressively decreased over the 24-week follow-up period to 6.99 at 4 weeks, 4.45 at 8 weeks, 2.36 at 12 weeks, 1.85 at 16 weeks, 1.75 at 20 weeks, and finally 1.69 at 24 weeks. This steady reduction highlights the sustained therapeutic response to intralesional bleomycin needling. Agius E et al 2006 assessed the response of recalcitrant plantar warts to bleomycin delivered by dermojet. A total of 47 patients with 138 plantar warts present for more than 2 years and resistant to 10 cycles of cryosurgery, were recruited. Bleomycin (1 U/ml) was delivered intralesionally by dermojet at 5-week intervals for 25 weeks. Out of 138, 124 (89.9%) plantar warts showed complete or partial clearance after one to five sets of bleomycin injections. The recurrence rate was 6/138 (4.4%), and 8/138 (5.8%) warts failed to clear. The reduction in mean surface area of the plantar warts after each set of bleomycin injections compared to baseline surface area was statistically significant. Local side effects were similar to other methods of delivery. No systemic side effects were reported. This study assesses therapeutic efficacy of bleomycin delivered by dermojet in solely recalcitrant plantar warts. It provides preliminary evidence that this method of delivery may benefit a group of patients with particularly recalcitrant plantar warts and is safe and easy to use in routine dermatology practice.⁸ The mean percentage improvement in the number and size of warts was 78.47% and 82.36%, respectively, underscoring the clinical efficacy of bleomycin as a local cytotoxic agent. However, local side effects were not uncommon. Pain and swelling were reported in 20% of patients each, erythema in 15%, and ulceration in 30%, the latter being the most frequent adverse event. These side effects were self-limiting and manageable with supportive care, suggesting a favorable safety profile. Overall, bleomycin needling demonstrated significant efficacy with acceptable tolerability in the management of anogenital warts. Naeini FF et al 2006 compared the efficacy of bleomycin tattoo with that of cryotherapy combined with intralesional triamcinolon injection for the treatment of keloids and hypertrophic scars. Forty-five patients with hypertrophic scars or keloids were randomly divided into two groups. Group A was treated with bleomycin tattoo, and group B, with cryotherapy combined with intralesional triamcinolon injection. There were four therapeutic sessions at 1-month intervals. All patients were followed for 3 months after the end of treatment. Therapeutic response in lesions less than 100 mm² was higher than 88% in both groups, but in larger lesions, the

therapeutic response to bleomycin was significantly better than cryotherapy combined with intralesional triamcinolon injection ($p = .03$). In group A, no relationship was observed between therapeutic response and lesion size ($p = .58$); however, in group B smaller lesions ($< 100 \text{ mm}^2$) displayed better therapeutic response ($p = .007$). Bleomycin tattoo may be more effective than cryotherapy combined with intralesional triamcinolon injection in treatment of larger keloids and hypertrophic scars (size $> 100 \text{ mm}^2$).⁹Dogra A et al 2006 evaluated the efficacy of topical 5% 5-fluorouracil in various types of warts and compared with the conventional electrosurgical method which included both electrodesiccation and electrofulguration. 50 patients clinically diagnosed as warts were enrolled. 25 patients were treated with topical 5% 5-fluorouracil applied for 4 hrs twice daily for 3 weeks, while another 25 were treated with electrosurgery. It was observed that electrosurgery yielded better initial results than 5-fluorouracil (72 and 52% respectively), but at the end of 6 months, the results were favourable for 5-fluorouracil as compared to electrosurgery (44 and 36% respectively). This was due to the significantly low recurrence rate with 5-fluorouracil in contrast to electrosurgery (8 and 48% respectively). Though electrosurgery yielded quicker initial results but 5-fluorouracil was better as long term measurer because of its significantly lower recurrence rates.¹⁰Salk RS et al 2006 conducted a study comparing 5% 5-FU cream under tape occlusion versus tape occlusion alone in 40 patients presenting with plantar warts. Nineteen out of 20 patients (95%) randomized to 5% 5-FU with tape occlusion had complete eradication of all plantar warts within 12 weeks of treatment. The average time to cure occurred at 9 weeks of treatment. Three patients (15%) had a recurrence at the 6-month follow-up visit; accordingly, an 85% sustained cure rate was observed. It is concluded that use of topical 5% 5-fluorouracil cream for plantar warts is safe, efficacious, and accepted by the patient. Topical 5-fluorouracil (5-FU) is an antineoplastic antimetabolite that inhibits DNA and RNA synthesis, thereby preventing cell replication and proliferation. This mechanism of action may allow topical 5-FU to be utilized in the treatment of human papilloma virus (HPV).¹¹

CONCLUSION

Intralesional bleomycin proved to be a highly effective treatment modality for anogenital warts, showing substantial reduction in both size and number of lesions. Its favorable efficacy, coupled with manageable side effects, supports its role as a valuable therapeutic option in resistant or recurrent cases.

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