



EFFICACY OF INTRALESIONAL BCG IN RECALCITRANT WARTS – A STUDY AT TERTIARY CARE CENTRE

Dermatology

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ABSTRACT

Background: Warts are benign cutaneous and mucosal epithelial proliferations caused by Human papilloma viruses (HPV).[1]Several therapeutic approaches have been used in treating warts like topical medication such as salicylic acid, trichloroacetic acid, podophyllin, podophyllotoxin, glutaraldehyde, formalin, imiquimod,5-fluorouracil and ablative procedures and surgical excision. This study is designed to determine the efficacy of intralesional immunotherapeutic agent BCG vaccine in clearing warts. **Materials and Methods:** The study group comprised of 20 cases of multiple recalcitrant cutaneous warts. Ethical clearance was sought and informed consent was obtained from all patients. The wart with longer duration and largest size was selected for this procedure. 0.1ml of BCG vaccine was injected intralesionally into the wart and was repeated every 3 weeks till complete clearance of the warts or for a maximum of 9 weeks. **Results:** After completion of 3 sittings at an interval of 3 weeks we observed the complete response in common warts, palmar warts and plantar warts was 64.5%, 58% and 40% respectively. **Conclusion:** Our study showed that intralesional BCG injection was safe and efficacious in the treatment of multiple recalcitrant cutaneous warts.

KEYWORDS

BCG, Common warts, Intralesional injection, palmoplantar warts.

INTRODUCTION:

Warts are benign cutaneous and mucosal epithelial proliferations caused by Human papilloma viruses (HPV). More than 100 HPV types have been recognised.^[1]The common warts are caused by HPV types 1, 2, 4, 27 and 57. HPV infection occurs through inoculation of virus into the viable epidermis through defects in the epithelium. They infect different areas of skin and mucous membranes. Warts can appear at any age. In few patients, warts may spontaneously regress, whereas others show persistence and progression with spread to other body sites, leading to physical and emotional stress. Several therapeutic approaches like electrosurgery, cryotherapy, keratolytics, vaccines have been used in treating warts, but resistance and recurrences to these therapies has been reported. Bacille - Calmette-Guérin (BCG), a live vaccine, known for its prophylactic effects against tuberculosis is also been used in the treatment of malignant melanoma, transitional cell carcinoma of the bladder, alopecia areata, recurrent oral aphthosis. In the recent times it has been showing promising efficacy in the management of recalcitrant warts.^[2]

Role Of Bcg In Recalcitrant Warts:

The mode of action of BCG is based on the stimulation of macrophages, natural killer cells and B lymphocytes that might help in the resolution of viral warts. Specifically BCG induced polymorphonuclear leukocytes directly induce monocyte chemotaxis and indirectly regulate T cell chemotaxis against HPV. The delayed hypersensitivity response against the antigen is the key to clinical response against warts. It increases the serum levels of IL-12 and decreases the level of IL-4.^[3]

AIMS AND OBJECTIVES:

1. To determine the efficacy of BCG vaccine for the treatment of multiple cutaneous warts.
2. To identify the common side effects associated with BCG immunotherapy of warts

MATERIALS AND METHODS:

Study Population:

Adults of age between 18-65 years in both sexes attending DVL outpatient department.

Sample Size:

Patients were categorized into two groups (group A-cases and group B-controls) of 20 patients in each group.

Study Design:

Hospital based interventional comparative study.

Study Duration:

January 2022 to July 2022.

Inclusion Criteria:

- 1) Patients with common, palmar and plantar warts.
- 2) Patients of age group 18-65 years
- 3) Patients who were willing to undergo the procedure after acquiring informed and written consent.

Exclusion Criteria:

- 1) Pregnancy and lactation.
- 2) Patients with systemic illness
- 3) Immunosuppressed patients.
- 4) Patients with past history of tuberculosis.
- 5) Patients who were not willing to undergo the procedure

METHODOLOGY:

After obtaining institutional ethical committee approval and application of inclusion and exclusion criteria willing participants were taken up after getting a written informed consent from them. Detailed history including name, age, sex, address, occupation, marital status, onset of skin lesions, evolution and duration of disease, distribution, treatment history were recorded. Detailed cutaneous examination with respect to size and number of warts was done. Written, informed consent was obtained from the patients in their own language for participation in the study and also for clinical photographs. Serial photographs were taken initially and at every follow up. Patients were categorized into two groups (groups A and B) of 20 each. Alternate patients were included in groups A and B which were treated with intralesional BCG and normal saline respectively. The target wart is injected using a built in needle insulin syringe intralesionally with 0.1 ml BCG. Antibiotics and anti-inflammatory agents were prescribed to prevent secondary infection and pain after injection. This therapy is repeated every 3 weeks till complete

clearance of the warts or for a maximum of four treatments without response. Evaluation of results were done based on visual inspection and by comparison of serial photography. Treatment response was assessed based on the following parameters such as reduction in number and clearance of warts. The statistical analyses were performed using SPSS trial version 20 software and was expressed as absolute numbers with percentage for describing the frequency of the parameters in case and control groups. The unpaired 't' test was used to compare means between the case and control groups for normally distributed and non-normally distributed data, respectively. Fisher's exact test was used to find the statistical difference between the proportions. $P < 0.05$ was considered statistically significant difference.

RESULTS:

A total of two hundred and forty warts (240) were present in 40 patients which were included in the present study. There were 26 males and 14 females whose mean age was 27.35 years and 29.05 years, respectively. Group A and group B patients were having 130 and 110 warts,

respectively [Table 1]. The baseline parameters (age, sex, distribution of warts) between the two groups were statistically comparable, and no significant statistical difference was observed. A total of 130 warts

Table 2: Reduction in Number of Warts at Each Visit

Type of wart	Group A IL BCG								Group B CONTROL							
	Visit 1		Visit 2		Visit 3		Visit 4		Visit 1		Visit 2		Visit 3		Visit 4	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Common	77	59.2	65	55	60	57.1	27	51.9	52	47.3	52	47.3	52	47.3	45	40.9
Palmar	40	30.8	40	34	35	33	17	32.6	34	30.9	34	30.9	34	30.9	33	30.0
Plantar	13	10.0	13	11	10	9.5	8	15.3	16	21.8	16	21.8	16	21.8	16	21.8
Total	130	100.0	118	100	105	100.0	52	100.0	110	100.0	110	100.0	110	100.0	103	100.0

Table 3: Mean and Standard Deviation

Groups	Mean	SD	P Value
Group A	30.11	23.74	0.0001 ($P < 0.01$)
Group B	26.67	18.59	

DISCUSSION:

Warts can extremely affect patient's quality of life. It causes embarrassment and frustration. It is known for its persistence and recurrence. Most of them are resistant even after repeated treatment with various physical modalities^[4] This study was undertaken with the aim to evaluate efficacy of intralesional BCG in the management of recalcitrant warts. We determined the efficacy of intralesional BCG in the treatment of common, palmar and plantar warts which were difficult to treat with other modalities. Sharquie et al^[5] observed that complete response was achieved in 40% at the end of the treatment with IL BCG. The response was distributed among different types of warts with 63.3% for common warts, 23.3% for plane warts and 13.3% for plantar warts. Our study showed complete response in of common warts 64.5% while the response in palmar warts was 58% and plantar warts was 40%.

Kenawi et al^[6] compared the efficacy of IL 5-FU and IL BCG in warts. They included 60 patients in their study with different types of warts. Injection 5-FU in a mixture of lignocaine with epinephrine was injected into the base of the wart every two weeks till complete clearance was achieved. IL BCG 0.1 ml was given in a single large wart every three weeks till complete clearance was obtained. In their study they revealed that the presence of greater number of warts were more burden to the treating physician and the problem can be overcome by BCG vaccine. BCG therapy had the advantage of injecting into a single wart and it can act on distant warts also by inducing immunological response. At the end of study Kenawi showed 63.9% complete response with IL 5-FU and found 40% complete response in IL BCG. But in our study the response of intralesional BCG was significantly higher than other study.

Kenawi et al^[6] observed pain, malaise, fever, lymphadenitis, necrosis and ulceration in their study. In our study the side effects such as ulceration, lymphadenitis were not noticed.

CONCLUSION:

This study is being presented to highlight the efficacy of intralesional BCG in recalcitrant warts. BCG therapy requires less equipment and lesser expertise. Easy pain management and shorter pain period is an advantage of BCG compared to other modalities. We conclude that intralesional BCG injection is safe and efficacious in multiple

were treated with intralesional BCG. The response in common warts was 64.5%, while the response in palmar warts was 58% and plantar warts was 40 % at visit 4. After 3 Weeks Reduction in number of warts at each visit is shown in Table 2. Warts regressed with a slight hyperpigmentation that gradually faded during the follow-up of 1 year. Of the 110 warts treated with normal saline (group), only 10% showed disappearance of the lesion within 9 weeks. The difference in the resolution rate at the end of 12 weeks was statistically significant ($P = 0.001$) between groups A and B. Most patients in group A experienced moderate pain during injection that was of short duration and was overcome by oral analgesics. None of the patients experienced any reactions during injections.

Table 1: Distribution of Warts in Study Group and Control Group

Groups	Common wart	Palmar	Plantar	Total
Group A IL BCG				
No of pts	12	5	3	20
No of lesions	77	40	13	130
Group B Control				
No of pts	10	5	4	20
No of lesions	52	34	16	110

recalcitrant cutaneous warts.

Declarations:

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Conflict of interest: None declared.

Ethical committee approval: This study is registered with Institutional ethical committee.

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