

## **An analytical pilot study to assess the therapeutic efficacy of intralesional purified protein derivative (PPD) and measles, mumps, rubella (MMR) vaccine in cutaneous warts in a rural population.**

Dr. Sutar A. A.,<sup>1</sup> MBBS, Dr. Gund G. V.,<sup>2</sup> MD, DNB, Dr. Khadamkar K. S.,<sup>3</sup> MD

Dr. Indurkar V. A.<sup>4</sup> DNB

<sup>1</sup>Post graduate resident, <sup>2,3</sup>Assistant professor, <sup>4</sup>Professor and Head,

Department of Dermatology, Venereology and Leprosy, Dr. Vithalrao Vikhe Patil Foundation's Medical College and Hospital, Ahmednagar - 414111 Maharashtra, India

### **ABSTRACT**

**Introduction:** Multiple cutaneous warts represent a therapeutic challenge. Management is difficult due to the painful procedures, risk of disfigurement from scars, and recurrence of lesions with standard therapy. Intralesional antigen immunotherapy has shown promising efficacy in treating multiple cutaneous warts. This study was aimed to assess and compare the efficacy of intralesional Purified Protein Derivative (PPD) and Measles, Mumps, Rubella (MMR) Vaccine in cutaneous warts.

**Materials and Methods:** After obtaining written informed consent, 20 patients were evenly divided into two groups: Group A received PPD and Group B received MMR. Intralesional injections were administered fortnightly until clearance or for a maximum of 4 sessions, with 2-week intervals between each session. The improvement was assessed by comparing wart sizes before initiating the treatment and after administering the immunotherapy, using photographs and counting the number of warts. Patients with complete resolution were monitored for recurrence for three months post-treatment.

**Observations and Results:** Fifty percent from Group A and 80% from Group B showed a complete response in target warts. Thirty percent from Group A and 60% from Group B demonstrated complete clearance of both target and distant warts. In patients from both groups who showed complete resolution, recurrence of distant warts was observed in 50% of Group A and 20% of Group B.

**Conclusion:** Intralesional MMR vaccine therapy outperformed the PPD regimen, showing superior outcomes in clearing both target and distant warts, requiring fewer sessions for complete clearance, and resulting in less recurrence.

**KEY WORDS:** Immunotherapy, Purified protein derivative, Measles Mumps Rubella Vaccine, Verruca vulgaris

### **INTRODUCTION**

#### **BACKGROUND**

Cutaneous warts, represent a major skin problem in dermatology out patient department. The causative agent for verruca vulgaris is human papillomavirus (HPV), a double-stranded DNA virus that infects both keratinized and non-keratinized squamous epithelia.<sup>1,2,3,4</sup>

Their impact spans from benign lesions to inva-

sive tumours. There are varied presentations of HPV infection, such as cutaneous (nongenital) warts, epidermodysplasia verruciformis, laryngeal warts, anogenital warts, digital squamous cell carcinoma, high grade intraepithelial neoplasia and cervical carcinoma.<sup>5</sup> Nongenital cutaneous warts may manifest as common warts (verrucae vulgaris), flat warts (verruca plana), plantar warts, filiform warts. HPV 1, 2, 4, 7, 27

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**Correspondence:** Dr. Indurkar V. A., Department of Dermatology, Venereology and Leprosy, OPD no. 106, OPD Building, Dr. Vithalrao Vikhe Patil Foundation's Medical College and Hospital, Ahmednagar - 414111 Maharashtra, India. Tel. 8857991251 - Email: drvishalindurkar@gmail.com

and 57 causes common warts. Plantar warts are primarily caused by HPV types 1, 2, 4, 27 and 57 while types 3, 10 and 28 generally lead to flat warts.<sup>6,7,8,9</sup> These warts can manifest as large, tender, itchy and painful lesions, prompting patients to seek treatment.<sup>3</sup>

There are various treatment modalities that have been attempted, including cryotherapy with liquid nitrogen, 5-fluorouracil, cantharidin, intralesional bleomycin, electrodesiccation, laser ablation, surgical excision, and different formulations of salicylic acid, among others.<sup>7,10,11,12</sup>

But immunotherapy is gaining traction, particularly in treating stubborn cutaneous and genital warts. Various antigens, including Trichophyton, Candida, Mycobacterium welchii, Bacillus Calmette-Guerin, Purified protein derivative (PPD), and Measles, mumps and rubella (MMR), have shown varying degrees of effectiveness in clinical outcomes.<sup>13,14</sup>

Many studies have evaluated the efficacy of PPD and MMR vaccines, but very few have directly compared their efficacy. Therefore, this study aimed to compare the efficacy of intralesional PPD and MMR vaccines in treating cutaneous warts.

## MATERIAL AND METHODS

After obtaining ethical approval from the Institutional Ethical Committee, an analytical pilot study was conducted for a duration of 6 months (November 2022 to April 2023) at a rural-based tertiary care hospital. Following written informed consent, 20 clinically diagnosed cases of cutaneous warts (number of warts more than one in number), aged between 10 and 50 years, were included in the study. Patients who refused consent, pregnant or lactating females and im-

munocompromised patients were excluded from the study.

These 20 patients were randomly assigned into one of the two groups. Detailed demographic, medical history and cutaneous examination of the lesions was done.

The Group A received intralesional injection of 0.1 to 0.3 ml of PPD (Akray Tuberculin diluted Tuberculin PPD 5TU/0.1 ml ) and Group B received an intralesional injection of 0.1 to 0.3 ml of the MMR (TRESIVAC PFS Measles, Mumps and Rubella Vaccine Live I.P.) vaccine in mother wart.

In each group, the treatment was repeated every 2 weeks, until clearance or maximum of four sessions. The degree of improvement was assessed by decrease in size and number of warts (Target & Distant) and clinical resolution by photographic comparison of lesion on pretreatment and subsequent follow up visits. They were instructed to avoid using any alternative treatment methods during the study period.

Patients who showed complete resolution of lesions were followed up monthly for consecutive 3 months for assessing any recurrence.

### Operational definition to evaluate response:

- 1. Complete improvement:** 100% resolution of all target warts and distant warts, or target warts or distant warts, along with the normalization of dermatoglyphics in the case of palmo-plantar warts.
- 1. Partial improvement:** 50–99% resolution in both target warts and distant warts, or in either target warts or distant warts.
- 1. No response:** less than 50% resolution of both target and distant warts, or of either target warts or distant warts.

The patients who did not achieve complete res-

olution of warts even after a maximum of four sessions were managed with other treatment modalities.

**STATISTICAL ANALYSIS**

Data analysis was conducted utilizing SPSS (Statistical Program for Social Science Version 19; SPSS Inc., Chicago, IL, USA). Quantitative variables were represented by mean, standard deviation, and range, while qualitative variables were represented by number and percentage. Chi-square test was employed for comparing qualitative variables among groups. Unpaired t-test was utilized to compare quantitative variables for parametric and nonparametric data, respectively. Spearman correlation test was used to assess the ranking of various variables against each other. A significance level of  $p \leq 0.05$  was considered as statistically significant.

**OBSERVATION AND RESULTS**

All 20 enrolled patients successfully completed the study without any dropouts. Mean age of patients from group A was  $25.2 \pm 10.6$  and group B was  $25.5 \pm 9.2$ . There were 7(70%) males, 3(30%) females in group A and 6(60%) males, 4(40%) females in group B. The distribution of the number of warts among patients is detailed in Table 1, revealing that most patients in both Group A and Group B had 5 to 10 warts. According to Table 2, majority of the patients had warts for 4 to 6 months. The study groups showed no statistically significant differences regarding age, gender, number of warts and duration of warts ( $p > 0.05$ ).

When examining the treatment outcomes, complete improvement in target warts was observed in 5 cases (50%) from Group A and 8 cases

(80%) from Group B. For distant warts, complete improvement was seen in 3 cases (30%) from Group A and 6 cases (60%) from Group B, as noted in Table 3. (Fig. 1 - 8)

**Table 1** Distribution of number of warts.

Sr. No.	Number of warts	Group A (PPD treated) N (%)	Group B (MMR treated) N (%)	Total N
1	<5	3 (30 %)	4 (40 %)	7
2	5 to 10	5 (50 %)	5 (50 %)	10
3	>10	2 (20 %)	1 (10%)	3
Mean $\pm$ SD		6.7 $\pm$ 3.1	6.2 $\pm$ 2.9	-
Total: N(%)		10 (100 %)	10 (100 %)	20

**Table 2** Distribution of wart duration.

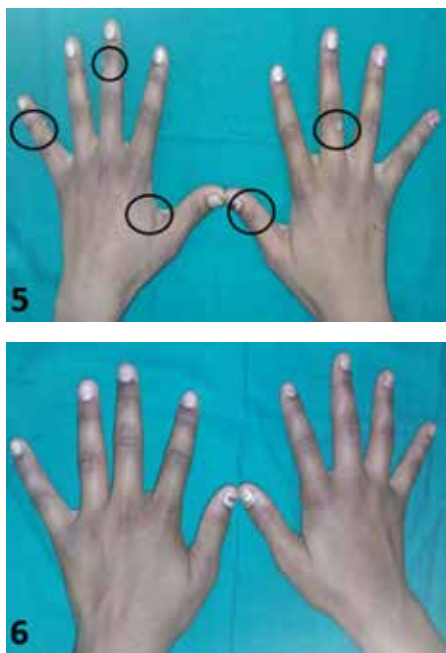
Sr. No.	Duration (Months)	Group A (PPD treated) N (%)	Group B (MMR treated) N (%)	Total N
1	1 to 3	2 (20 %)	0 (0 %)	2
2	4 to 6	6 (60 %)	8 (80 %)	14
3	7 to 9	2 (20 %)	2 (20 %)	4
Mean $\pm$ SD		4.9 $\pm$ 2.1	5.6 $\pm$ 1.3	-
Total:N(%)		10 (100 %)	10 (100 %)	20



**Fig 1, 2** Baseline and complete clearance of common warts after four session of PPD



**Fig 3, 4** Baseline and no response of common warts after four session of PPD



**Fig 5, 6** Baseline and complete clearance of common warts with a single session of MMR vaccine



**Fig 7, 8** Baseline and complete clearance of common warts with two sessions of MMR vaccine

The number of treatment sessions required varied significantly between the groups. All patients in Group A needed more than 2 sessions, while in Group B, 9 patients (90%) required 1 or 2 sessions (1 session in 50% and 2 sessions in 40%). Complete resolution was achieved in 3 cases (30%) from Group A and in 6 cases (60%) from Group B, as shown in Table 4.

Interestingly, there were no recurrences of target warts in either group. However, for distant warts, recurrences were noted in 5 cases (50%) from

**Table 3:** Distribution of therapeutic response.

Sr. No.	Therapeutic response	Group A (PPD treated) N (%)	Group B (MMR treated) N (%)	Total N	Chi square	P value
<b>In target warts</b>						
1	a. No response	0 (0 %)	0 (0 %)	0	1	>0.05 (Not significant)
	b. Partial improvement	5 (50 %)	2 (20 %)	7		
	c. Complete improvement	5 (50 %)	8 (80 %)	13		
<b>In distant warts</b>						
2	a. No response	4 (40 %)	1 (10 %)	5	2.8	0.246 (Not Significant)
	b. Partial improvement	3 (30 %)	3 (30 %)	6		
	Complete improvement	3 (30 %)	6 (60 %)	9		
<b>Total:N(%)</b>		<b>10 (100 %)</b>	<b>10 (100 %)</b>	<b>20</b>	-	-

**Table 4** Distribution of efficacy.

Sr. No.	Efficacy variable	Group A (PPD treated) N (%)	Group B (MMR treated) N (%)	Total N	Chi square	P value
1	<b>Number of sessions required</b>					
	≤ 2	0 (0 %)	9 (90 %)	<b>9</b>	0.0001	<0.05 (Significant)
	>2	10 (100 %)	1 (10 %)	<b>11</b>		
2	<b>Complete resolution</b>					
	a. Occurred	3 (30 %)	6 (60 %)	<b>9</b>	1.81	0.177 (Not Significant)
	b. Not occurred	7 (70 %)	4 (40 %)	<b>11</b>		
<b>Total: N(%)</b>		<b>10 (100 %)</b>	<b>10 (100 %)</b>	<b>20</b>	-	-

**Table 5** Distribution of recurrence.

Sr. No.	Recurrence	Group A (PPD treated) N (%)	Group B (MMR treated) N (%)	Total N	Chi square	P value
1	<b>In target warts</b>					
	a. No	10 (100 %)	10 (100 %)	<b>20</b>	1	>0.05 (Not Significant)
	b. Yes	0 (0 %)	0 (0 %)	<b>0</b>		
2	<b>In distant warts</b>					
	a. No	5 (50 %)	8 (80 %)	<b>13</b>	1.978	0.159 (Not Significant)
	b. Yes	5 (50 %)	2 (20 %)	<b>7</b>		
<b>Total: N(%)</b>		<b>10 (100 %)</b>	<b>10 (100 %)</b>	<b>20</b>	-	-

Group A and 2 cases (20%) from Group B, as detailed in Table 5.

No statistically significant correlation was found on comparing type of treatment with therapeutic response, complete resolution of warts and recurrence. Whereas, statistically significant correlation found between number of sessions required & type of treatment ( $p < 0.05$ ).

The most commonly reported adverse effect was pain at the injection site, which resolved on its own within 1-2 hours without any treatment.

## DISCUSSION

Cutaneous warts are frustrating to patients due to their persistence and high recurrence rates. The available treatment options, such as chemical cauterization, surgical excision, electro cautery, laser ablation, cryosurgery, photodynamic therapy and laser treatment, can be painful, adding

discomfort and distress to patients, especially in children. Also, these interventions can result in scarring and disfigurement, which are cosmetically undesirable, particularly for warts located on visible areas like the hands or face.

On the contrary, these adverse effects can be avoided by immunotherapeutic agents. These agents offer the potential benefit of eliminating both treated and untreated distant warts without leaving scars.<sup>15</sup> This study specifically compares the efficacy of PPD and MMR vaccine among these agents.

Intralesional immunotherapy using interferons, viral/bacterial antigens, vaccines, or proinflammatory cytokines stimulates the ability of the immune system to recognize viral, bacterial or fungal antigens inducing a delayed-type hypersensitivity reaction not only to the antigen but also against the HPV, which further increases

the ability of the immune system to recognize and clear HPV. Intralesional immunotherapy has been associated with the release of various cytokines, including IL-2, IL-4, IL-5, IL-8, INF- $\gamma$ , and TNF- $\alpha$ , which stimulate a robust immune response against HPV. The antigen injection promotes the proliferation of peripheral blood mononuclear cells, enhancing Th1 cytokine responses that activate cytotoxic T cells and natural killer cells to eradicate HPV-infected cells. Consequently, this stimulated immune response can potentially destroy both target and distant warts on the body.<sup>15,16,17,18</sup>

The HPV infects basal cells of the epidermis, enters a latent phase of slow replication. As the epidermis grows, HPV induces hyperplasia and hyperkeratosis, causing warts to grow larger and spread, becoming more resistant to treatment over time.<sup>19</sup> Therefore, early treatment of warts is essential to prevent worsening and the development of treatment resistance. Wart recurrence after the treatment may indicate potential deficiencies in cell-mediated immunity against

HPV, including insufficient memory T cell production, inadequate lymphocyte clonal expansion, impaired T cell migration to infection sites, and weakened effector response mechanisms.<sup>20</sup> Understanding these immune factors is critical for improving long-term treatment outcomes and preventing wart recurrence.

The effectiveness of MMR and PPD vaccines in treating warts has been extensively examined, revealing significant variability across studies (Table 6).<sup>21,22,23</sup> Our study findings underscored a distinct advantage for MMR over PPD in achieving higher complete response rates, particularly in target lesions. This aligns with prior study by Rutnin *et al.*,<sup>21</sup> and Shaheen *et al.*,<sup>22</sup> where MMR consistently demonstrated superior efficacy compared to PPD. However Bhalala *et al.*,<sup>23</sup> study showed lower response rates for both vaccines. This emphasizes the need for standardized protocols to accurately assess and compare vaccine efficacy across different patient cohorts and study designs.

On comparing the effectiveness of individual

**Table 6** Comparison with previous studies done on MMR and PPD.

Study	Immunotherapy	Sample size	Mean age	Dose(ml)	Max no of sessions	Complete response wart
Rutnin <i>et al.</i> , <sup>21</sup>	MMR	20	37.7 $\pm$ 13.8	0.3	5	90.0% in index lesion; 81.3% in distant lesions
	PPD	20	42.8 $\pm$ 16.6	20 iu/mL	5	80.0% in index lesion; 54.6% in distant lesions
Shaheen <i>et al.</i> , <sup>22</sup>	PPD	10	23 $\pm$ 12	0.1-0.3mL	3	60% in target and distant
	MMR	10	18 $\pm$ 10	0.1-0.3mL	3	80% in target;40% in distant
	Normal saline(control)	10	26 $\pm$ 12	0.3mL	3	0%
Bhalala <i>et al.</i> , <sup>23</sup>	PPD	35	21.62	0.1mL	3.85	51.85%
	MMR	35	23.24	0.1mL	3.71	56%
	Normal saline(control)	35	23.61	0.1mL	-	0%
<b>Present study</b>	<b>PPD</b>	<b>10</b>	<b>25.2 <math>\pm</math> 10.6</b>	<b>0.1 – 0.3mL</b>	<b>3.8 <math>\pm</math> 0.42</b>	<b>30%</b>
	<b>MMR</b>	<b>10</b>	<b>25.2 <math>\pm</math> 9.2</b>	<b>0.1 – 0.3mL</b>	<b>1.6 <math>\pm</math> 0.69</b>	<b>60%</b>

**Table 7** Comparison between studies done on individual immunotherapy drugs.

Study	Immuno-therapy	Sample size	Mean Age	Dose(ml)	Max no of sessions	Complete response wart
Kerure <i>et al.</i> , <sup>24</sup>	PPD	89	24 (12-52)	0.1	4	94.4
Amirmia <i>et al.</i> , <sup>25</sup>	PPD	35	21.14 (8-32)	0.1-0.3	6	77.1
Munnangi <i>et al.</i> , <sup>26</sup>	MMR or BCG	30 (15 each)	21.96 (12-40)	MMR: 0.3 BCG: 0.1	5	MMR: 73.3 BCG: 33.3
Agrawal <i>et al.</i> , <sup>27</sup>	MMR	30	25 (10-45)	0.3	3	60
Zamanian <i>et al.</i> , <sup>28</sup>	MMR	24	18.9 (7-31)	0.3	3	92
Surani <i>et al.</i> , <sup>29</sup>	MMR	94	28.22±10.98	0.3	3	40.42%
Nofal <i>et al.</i> , <sup>15</sup>	MMR	85	32.4 ± 9.3	0.1	5	81.4%
<b>Present study</b>	<b>PPD, MMR</b>	<b>20 (10 each)</b>	<b>25.2 ± 10.6 (PPD group); 25.5 ± 9.2 (MMR group)</b>	<b>0.1-0.3</b>	<b>PPD:3.8 ± 0.42 MMR:1.6 ± 0.69</b>	<b>PPD:30% MMR:60%</b>

MMR and PPD vaccines (Table 7)<sup>15,24,25,26,27,28,29</sup> both PPD and MMR vaccines show promising results in the treatment of warts, but their effectiveness can vary significantly. PPD generally demonstrates high effectiveness, while MMR's efficacy is variable.

Present study, along with studies by Rutnin *et al.*,<sup>21</sup> and Bhalala *et al.*,<sup>23</sup> noticed that MMR typically requires fewer treatment sessions than PPD to achieve wart clearance. This suggests that MMR may offer a more efficient treatment option, reducing the treatment burden for patients and potentially improving treatment adherence and outcomes.

Our study observed lower recurrence rates of distant warts in patients treated with MMR compared to PPD, consistent with observations by Mahajan *et al.*,<sup>30</sup> and Bhalala *et al.*,<sup>23</sup> This suggests a potential advantage of MMR in providing durable protection against recurrent warts, possibly due to its sustained cell-mediated immunity. Patients showing no recurrence for three months may have acquired long-term immunity against HPV but to confirm this necessitates longer fol-

low-up periods.

The most commonly observed adverse effect in our study was mild, self-resolving injection-related pain. This aligns with findings from Zamanian *et al.*,<sup>28</sup> Nofal *et al.*,<sup>15</sup> who also reported high rates of injection site pain among MMR recipients. Flu-like symptoms were less common, with varying incidence across studies. Shaheen *et al.*,<sup>22</sup> identified additional effects such as erythema, swelling, and vasovagal attacks. Overall, MMR vaccination is generally well-tolerated, with most adverse effects being mild and transient. Continuous monitoring of these effects is essential to ensure patient safety in MMR wart treatment.

## CONCLUSION

To conclude, MMR vaccine shows promising effectiveness, particularly in target lesions, while response rates for distant warts remain variable. Future research should prioritize larger and more diverse population studies. And exploration of varied injection volumes, simultaneous treatment of multiple warts, and increased session

frequencies could potentially enhance treatment responses.

### Recommendations by the study

Though MMR is more effective as compared to PPD, it's crucial to note that PPD is a more cost-effective option in resource-poor settings.

### LIMITATIONS

This study was done with a small sample size. There is no long-term follow-up available.

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**Conflict of Interest:** none

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