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Research Article

A study to compare the safety and efficacy of intralesional MMR with intralesional vitamin D in the treatment of warts

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Abstract: ***Introduction:*** A wart is a benign epidermal proliferation of skin and mucosa caused by Human papilloma virus. There are various therapeutic options in the treatment of warts, but none of them is entirely effective in all patients. To overcome these limitations, immunotherapy is an ideal alternative which is being widely practiced over the last few years in the treatment of warts. **Objectives:** The present study was aimed to compare the safety and efficacy of intralesional MMR with intralesional vitamin D in the treatment of warts. **Material and Methods**: A total of 150 patients presenting with single or multiple warts attending the OPD were included in the study. They are randomly divided into three groups, with 50 patients each. Group M was treated with intralesional MMR vaccine, Group V with intralesional vitamin D and Group C with intralesional normal saline. The treatment response was evaluated by the decrease in size and number of warts and photographic comparison at each visit, recorded and analysed. Results: During the final follow up, after 3 months of the 3rd dose complete clearance of warts was observed in 82% of the patients in Group M, compared to 68% of patients in Group V and 2% of patients in Group C. Pain at the injection site was significantly higher in Group V compared to Group M and Group C. Recurrence was noted in 14% of the patients in group V compared to 6% of the patients in group M. **Conclusion**: Intralesional MMR demonstrated significantly higher frequency of complete response, lower rate of pain at injection site and lower rate of recurrence compared to intralesional vitamin D3 in the treatment of patients with warts.

Keywords: Warts Intralesional therapy MMR vaccine Vitamin D Safety Efficacy

INTRODUCTION

A wart is a benign epidermal proliferation of skin and mucosa caused by Human papilloma virus. Since the early Greek and roman era, it has been a frustration to both the patients and medical professionals[1,2].They have significant impact on the patient's quality of life by causing embarrassment, dismay of negative appraisal by others and vexation due to recurrence. There are multiple therapeutic options in the treatment of warts. Commonly employed treatment modality is the local destruction of warts which includes topical keratolytics, electrocoagulation, cryotherapy or laser therapy [3,4,5,6]. But none of these aforementioned treatment approaches is considered gold standard and they can be painful, time consuming, expensive, associated with risk of scarring and are not suitable for the treatment of multiple and refractory warts. Hence to overcome these limitations, immunotherapy is being used extensively in the treatment of the warts. It acts by strengthening the cell mediated immunity for the resolution of warts [7].

Various intralesional and topical agents are used as immunotherapeutic agents in the treatment of warts such as Imiquimod, MMR vaccine, Mycobacterium w vaccine, Bacillus Calmette Guérin vaccine, Candida antigen and Trichophyton skin antigens[8,9,10,11,12].In the recent trials intralesional vitamin D has been emerged as another promising option in the treatment of cutaneous warts[13].This study was aimed to compare the safety and efficacy of intralesional MMR and intralesional vitamin D in the treatment of patients with warts.

MATERIALS AND METHODS

Study design: Prospective comparative study

Study period: The study is conducted for a period of 1 year from July 2024 to June 2025**.**

Study sample: 150

Study area: Department of DVL, Government General Hospital, Kurnool, Andhra Pradesh.

Source of data: Patients presenting with single or multiple warts attending OPD of Department of DVL were enrolled.

Inclusion criteria:

- The patients who were clinically diagnosed with single or multiple warts.
- The patients who are not taking any systemic or topical treatment for warts for the last four weeks.
- Patients of either sex belonging to all the age groups.

Exclusion criteria:

- Patient who do not provide informed consent.
- Patient with past history of allergy to MMR vaccine and vitamin D3.
- Patient with acute febrile illness or any bacterial infection.
- Patient with immunosuppression or HIV infection.
- Pregnant or lactating women.
- Patient with history of asthma, allergic skin disorders or convulsions.
- Patient who are not willing for the procedure.

Procedure

Patients who fulfilled the selection criteria were briefed about the nature of the study and written informed consent was obtained. The patients were interviewed for demographic features like age, sex and detailed history was taken comprising of the past history of warts, previous treatments, recurrence and duration of warts, medical history including systemic diseases, drug history including the use of corticosteroid or other immunosuppressive drugs.

Clinical data including site, size, number, distribution, presence, and absence of distant warts was obtained. Patients were randomly divided into 3 groups as group C, group M and group V.

The selected patients were treated as below

Group M: Patients in this group were treated with 0.5 mL intralesional MMR vaccine.

Group V: Patients in this group were treated with 0.5 mL intralesional vitamin D3 600000 IU/mL).

Group C: Patients in this group were treated with 0.5 mL intralesional normal saline.

All the patients received the drugs into single wart or largest wart in case of multiple lesions at two weeks intervals for a maximum of 3 doses.

Outcome parameters

The response of the treatment will be evaluated by the decrease in size of warts, decrease in the number of warts and photographic comparison at each visit. Photography of the lesion before the first treatment session, two weeks after the last dose, and six months after the last dose was taken.

Complete response: The response was considered complete if there was complete clearance of wart.

Partial response: The response was considered partial response if there is regression of wart by 50 - 99% and/or reduction in the number of warts.

No response: It was considered to be non-responsive if there is regression of wart by 0 - 49% and/or no reduction in the number of warts.

RESULTS

Table 1: Comparison of treatment response among various groups in study population

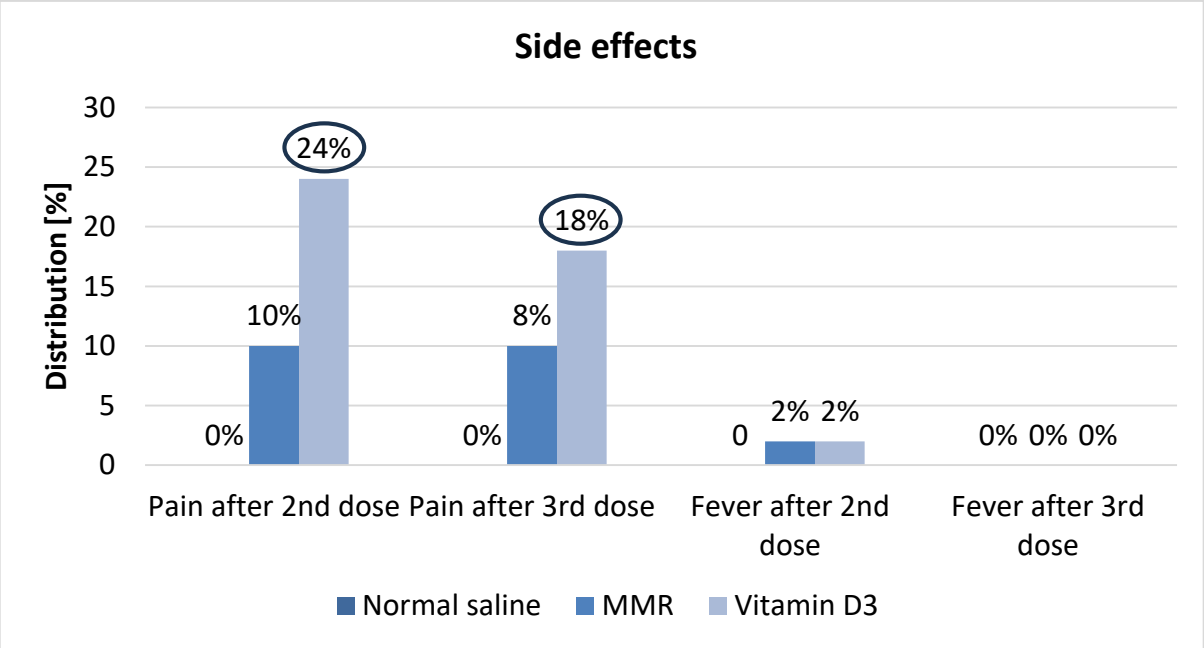
Interval	Treatment response	Group M (n=50)		Group V (n=50)		Group C (n=50)		P value
		No.	%	No.	%	No.	%	
Two weeks after the 1st dose	CR	18	36	12	24	0	0	<0.001
	PR	26	52	24	48	4	8	
	NR	6	12	14	28	46	92	
Two weeks after the 2nd dose	CR	28	56	18	36	0	0	<0.001
	PR	16	32	19	38	4	8	
	NR	6	12	13	26	46	92	
Two weeks after the 3rd dose	CR	39	78	33	66	0	0	<0.001
	PR	5	10	5	10	45	90	
	NR	6	12	12	24	5	10	
Three months after the 3rd dose	CR	41	82	34	68	1	2	<0.001
	PR	3	6	4	8	7	14	
	NR	6	12	12	24	42	84	

The treatment response in group M, group D and group C is shown (Table 1). The complete response in group M after the first dose was 36% compared to 24% in group V and 0% in group C ($p<0.001$). Similarly, after second dose, the complete response in group M was 56% compared to 36% in group V and 0% in group C ($p<0.001$). Two weeks after the third dose, complete response in group M was 78% compared to 66% in group V and 0% in group C ($p<0.001$). Three months after

the third dose, complete response in group M after the second dose was 82% compared to 68% in group V and 2% in group C(Table 2).

Table 2: Comparison of side effects among various groups in study population

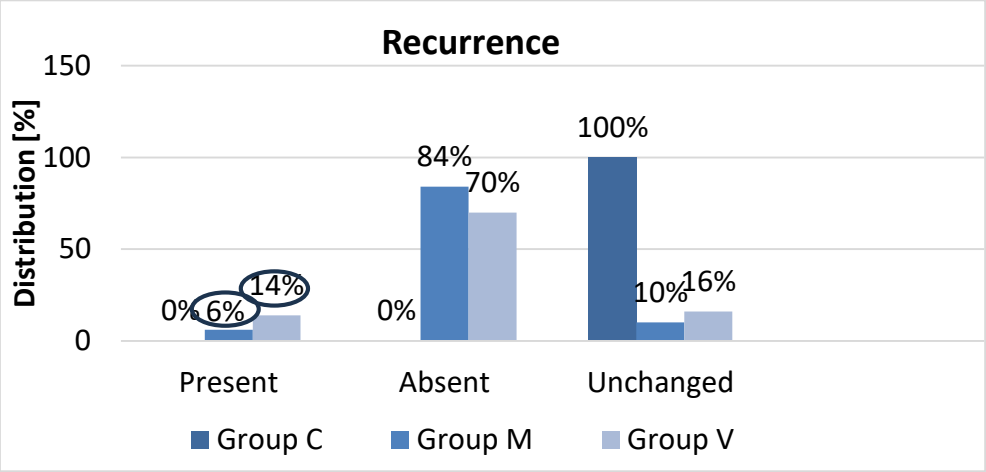
Side effects	Group M (n=50)		Group V (n=50)		Group C (n=50)		P value
	No.	%	No.	%	No.	%	
Pain after 2nd dose	5	10	12	24	0	0	0.001
Pain after 3rd dose	4	8	9	18	0	0	0.003
Fever after 2nd dose	1	2	1	2	0	0	1.000
Fever after 3rd dose	0	0	0	0	0	0	-



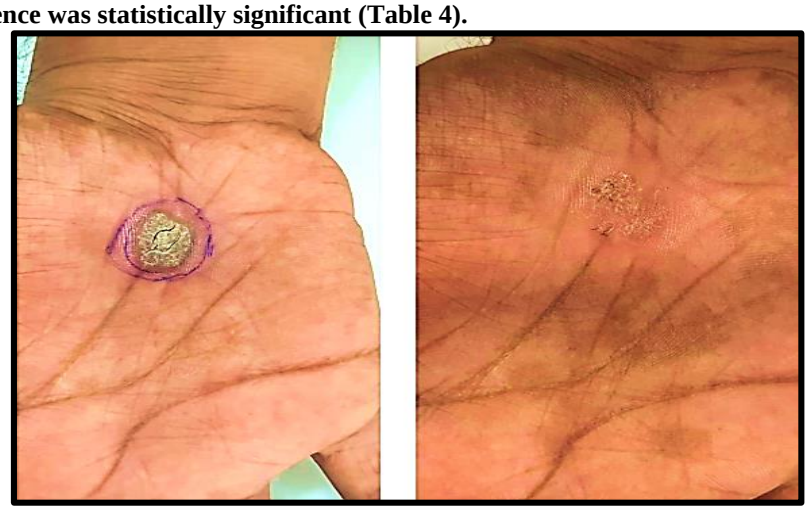
In this study, pain after the second dose was noted in 24%, 10%, and 0% of the patients in group V, group M and group C and the same after third dose was noted in 18%, 8%, and 0% of the patients respectively and this difference was statistically significant (p=0.001 and 0.003 respectively). Fever after the second dose was noted in 2% of the patients in group M and V and 0% of the patients in group C but the difference was statistically not significant (p=1.000). However, none of the patients in all the groups did have a fever after the third dose (Table 3).

Table 3: Comparison of recurrence among various groups in study population

Recurrence	Group M (n=50)		Group V (n=50)		Group C (n=50)	
	No.	%	No.	%	No.	%
Present	3	6	7	14	0	0
Absent	42	84	35	70	0	0
Unchanged	5	10	8	16	50	100
Total	50	100	50	100	50	100

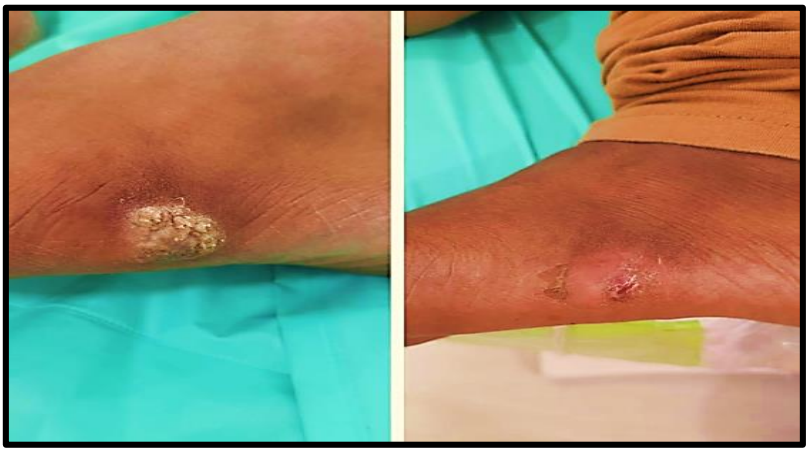


In the present study, recurrence was noted in 14% of the patients in group V compared to 6% of the patients in group M. This difference was statistically significant (Table 4).



Before **After**

INTRALESIONAL MMR VACCINE



BEFORE **AFTER**

INTRALESIONAL VITAMIN D3

DISCUSSION

Human papilloma virus is an epitheliotropic, non-enveloped and small double stranded DNA virus with icosahedral symmetry belonging to Papilloma viridae family [14]. The different strains among HPV are divided into low risk and high-risk types. The strains which primarily infects squamous epithelium, both the keratinized and non-keratinized, leading to the formation cutaneous, genital, oral and laryngeal warts are grouped

under low risk whereas high risk strains are oncogenic in nature. There is a myriad of therapeutic options for warts but no single treatment is entirely effective in all patients.

The type of treatment depends upon the site of involvement and combination of different treatment modalities are required for an inclusive approach. Most commonly employed procedure is the conventional destructive method which includes chemical cautery, cryotherapy, electrocautery, surgical excision and laser ablation which are expensive and are associated with significant adverse effects and the response will be restricted to the targeted lesion. To overcome these limitations, immunotherapy is a promising alternative that is being practiced extensively which acts by stimulating host cell mediated immunity thereby acting against virus and virus infected cells. It has added advantage of clearance both the local and the distant warts. Various immunotherapeutic agents include MMR vaccine, Tuberculin PPD, Mycobacterium w vaccine and Candia antigen.MMR vaccine acts stimulating Th1 immune response that upregulates various cytokines such as interleukins 2, 4, 5 and TNF - alpha.

This process initiates a delayed hypersensitivity reaction against both MMR viral antigens and potentially against wart-causing viruses, which further activates cytotoxic T cells and natural killer cells to eradicate human papillomavirus (HPV)-infected cells [15]. The use of three antigens boosts the immune response due to the adjuvant effects of different antigens on one another. This accelerated immune response is credited with clearing warts both at injected and distant sites and is also thought also to prevent recurrence [16,17]. Intralesional vitamin D is another novel, safer and effective technique used in the treatment of warts. The antiviral effects can be explained by vitamin D mediated induction of cathelicidin, human beta defensin 2 and release of reactive oxygen species. It also activates toll like receptors that induces antimicrobial peptide formation and regulates epidermal proliferation and differentiation [18,19]. In the present study, based on the treatment modalities used, the patients were divided into three groups of 50 each as Group C (intralesional normal saline), Group M (0.5 mL intralesional MMR vaccine) and Group V (0.5 mL intralesional vitamin D3 - 60000 IU/mL).In terms of sex distribution, slightly more than half of the patients in group C (58%) and group V (54%) were males, while in group M, a slightly more number of patients were females (56%). The male to female ratio in group C, group M, and group V was 1.38:1, 1:1.27, 1.17:1 respectively. These findings suggest that the overall frequency of warts was high among males, and this observation was consistent with studies reported by Sudhakar Rao KM. et al[20] and Gopal V. et [21] al. It can be attributed to the reason that men participate more in outdoor activities and also because of increasing tendency of cosmetic concern in them [22] Despite overall male preponderance, the gender difference across the three groups was statistically comparable (p=0.393).

Table 4: Comparison of treatment efficacy between various intralesional therapeutic agents in the treatment of warts

Study	Therapeutic agent	No. of patients	Maximum no. of sessions	Type of response			
PRESENT STUDY				CR	PR	NR	
	MMR vaccine	50	3	82%	6%	12%	
	Vitamin D	50	3	68%	8%	24%	
	Normal Saline	50	3	2%	14%	84%	
JAIN ET AL [2025]				CR	PR	NR	
	MMR vaccine	20	4	75%	20%	5%	
	Vitamin D	20	4	60%	20%	20%	
	PPD	20	4	65%	20%	15%	
MOHTA ET AL [2020]				CR	PR	NR	
	MMR Vaccine	30	3	86.7%	6.7%	6.6%	
	Vitamin D	30	3	76.7%	10%	13.3%	
SHALDOUM ET AL [2022]				CR	PR	MIN R	NR
	MMR vaccine	30	6	80%	6.7%	6.7%	6.7%
	Vitamin D	30	6	66.7%	6.7%	20%	6.7%
SALLAM, ET AL [2025]				CR	PR	NR	
	MMR vaccine	56	4	80.4%	14.3%	5.4%	
	Vitamin D	56	4	66.1%	7.1%	26.8%	
AKTAŞ ET AL [2015]	Vitamin D	20	2	80%	5%	15%	
RAGHU KUMAR ET AL [2017]	Vitamin D	60	4	90%	6.66%	3.33%	

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In the present study, during the final follow up that is, after 3 months of third dose, among the patients who were treated with 0.5ml of intralesional MMR vaccine, complete response was noted in majority of the patients [82%] and partial response in 6% of the patients while 12% of the patients did not show response to the treatment. It is in line with the results reported by Jain et al[23] [75%], Mohta et al[16] [86.7%], Shaldoum et al[24] [80%] and Sallam et al[25] [80.4%] in which the group of patients treated with intralesional MMR vaccine has shown maximum therapeutic response in the form of complete clearance. Among the patients treated with 0.5ml of intralesional vitamin D complete response was seen in 68% of the cases, partial response was evident in 8% of the patients and 24% of the cases did not show response to the treatment. In a study conducted by Aktas et al [26], complete response was seen in 80% of the patients which is in accordance with the present study. Raghukumar et al [27] study results show 90% of complete clearance of warts in patients treated with vitamin D. This comparatively higher therapeutic response can be due to the multiple intralesional injections given into each single wart for a maximum of 5 warts for a total of 4 sessions with a longer follow up period of 6 months. Jain et al [23] reported a study in which complete response was observed in 60% of cases treated with vitamin D which is lower compared to the present study due to lower cumulative dose of the intralesional injections [0.2ml given for a maximum of 4 doses].

In the present study, pain after the last dose was seen in 8% of the cases in MMR treated group, whereas vitamin D treated group showed 18% of the patients and 0% in the NS treated group. This difference was statistically significant with p value of 0.003. Jain et al reported pain as one of the adverse effects in MMR and Vitamin D treated groups with values of 5% and 10% respectively which is lower compared to the present study. It can be due to the administration of anaesthetic agent prior to the immunotherapeutic agent. In a study reported by Mohat et al, among children presented with warts, 26.7% and 30% of patients treated with intralesional MMR and vitamin D respectively, complained of pain which may be due comparatively less tolerance to pain in children with respect to adult. Nofal et al reported 100% of patients with pain as most common adverse effect, but it was mild, tolerable and did not extend beyond the time of injection. In a study conducted by Raghukumar et al, 100% of patients reported pain which is more compared to the current study which can be secondary to the multiple number of injections given into each wart individually per session.

Table 5: Comparison of frequency of pain secondary to intralesional immunotherapeutic agents

STUDY		**FLU LIKE SYMPTOMS**		
		MMR	VIT D	NS
PRESENT STUDY	AFTER 2ND DOSE	2%	2%	0%
	AFTER 3RD DOSE	0%	0%	0%
MOHAMAD ET AL [2013]		MMR		NS
		4%		0%
SHAH ET AL [2016]		MMR		
		4%		
KAVYA ET AL [2017]			VIT D	
			0%	
LATIF ET AL [2021]			VIT D	
			0%	

Table 6: Comparison of frequency of flu-like symptoms secondary to intralesional immunotherapeutic agents

STUDY	PAIN		
PRESENT STUDY	MMR	VIT D	NS
	8%	18%	0%
JAIN ET AL [2025]	MMR	VIT D	PPD
	5%	10%	20%
MOHTA ET AL [2020]	MMR	VIT D	
	26.7%	30%	
NOFAL ET AL [2014]	MMR		
	100%		
RAGHUKUMAR ET AL [2017]		VIT D	
		100%	

The second adverse effect noted in our study is flu-like symptoms seen in both the groups treated with intralesional MMR and vitamin D after the 2nd dose in each 2% of the patients respectively. The difference was not statistically significant p=1.000. After third dose of injections none of the patients had the similar complaints.

Shah et al [28] and Mohamad et al [29] reported flu like symptoms in group treated with MMR in 4% of the patients. In the studies reported by Kavya et al[30] and Latif et al[31] none of the patients had reported flu-like symptoms.

Table 7: Comparison of recurrence rate in various groups treated with intralesional immunotherapeutic agents

STUDY	RECURRENCE		
PRESENT STUDY	MMR	VIT D	NS
	6%	14%	0%
MOHTA ET AL [2020]	MMR	VIT D	
	0%	6.6%	
SALLAM ET AL [2024]	MMR	VIT D	
	3.6%	5.4%	
SHALDOUM ET AL [2020]	MMR	VIT D	
	0%	0%	
BABU ET AL [2022]	MMR	VIT D	
	0%	0%	
JOSHI ET AL [2023]	MMR	VIT D	
	16%	14%	

In the present study, recurrence was noted in 14% of the patients with intralesional vitamin D group compared to 6% of the patients in MMR group. The difference was statistically significant p<0.001. In a study conducted by Mohta et al, recurrence was noted in 0% and 6.6% of the cases treated with MMR and vitamin D injections respectively. Sallam et al observed that the recurrence rates were 3.6% and 5.4% in groups treated with MMR and vitamin D respectively. In all the above-mentioned studies recurrence rate was higher in group of patients treated with intralesional vitamin D compared to MMR vaccine. No recurrence was observed in studies reported by Shaldoum et al and Babu et al [32] Joshi et al [33] reported 16% and 14% of the recurrence rates noted in MMR and vitamin D treated groups which is higher compared to the present study.

CONCLUSION

The present study showed that, both intralesional MMR vaccine and intralesional vitamin D3 are highly efficacious and safe in the treatment of warts. Further treatment with intralesional MMR vaccine was associated with significantly higher frequency of complete response, lower rate of pain at injection site, reduction in number of warts, and lower rate of recurrence which makes it highly beneficial and efficacious and seems to be more efficacious than intralesional vitamin D3 in the treatment of patients with warts.

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