

ORIGINAL RESEARCH

Comparative Efficacy and Safety of Intralesional MMR Vaccine versus Vitamin D3 for Multiple Warts: A Prospective Study**¹Dr. Shabir Ahmed, ²Dr. Fayaz Ahmed, ³Dr. Ummer Yaseen**¹Associate Professor, ²Senior Resident, ³Assistant Professor, Department of Dermatology, Govt. Medical College, Anantnag, Jammu and Kashmir, India**Corresponding Author**

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Abstract

Background: Warts pose a considerable challenge in dermatology, necessitating effective therapeutic interventions. This prospective study aims to compare the efficacy and safety of intralesional administration of the measles, mumps, and rubella (MMR) vaccine with intralesional vitamin D3 in patients with multiple warts.

Methods: Conducted at the Department of Dermatology, Government Medical College, Anantnag, this prospective study involved patients attending the Dermatology OPD with clinically diagnosed cutaneous warts, either multiple or single, based on predefined inclusion and exclusion criteria. A total of 200 patients were randomly selected, with 100 patients allocated to each group. Patients clinically diagnosed with cutaneous warts were divided into two groups: Group A received intralesional MMR, and Group B received intralesional vitamin D3.

Results: In Group A, 43 cases (86%) exhibited a complete treatment response, 4 cases (8%) showed a partial response, and 3 cases (6%) had no response to treatment. Similarly, in Group B, 39 cases (78%) demonstrated a complete treatment response, 6 cases (12%) showed a partial response, and 5 cases (10%) had no response. The comparison between the two groups yielded a non-significant p-value of 0.578. Regarding distant wart clearance, Group A displayed a complete response in 39 cases (78%), while Group B showed a comparable response in 35 cases (70%). Partial response was observed in 14% of cases in Group A and 16% in Group B. Additionally, no response was recorded in 8% of cases in Group A and 14% in Group B. Both groups were comparable with respect to the clearance of distant warts with a non-significant p-value of 0.576. Furthermore, our findings affirm the favorable tolerability and safety profiles of both intralesional MMR vaccine and vitamin D3 immunotherapy, with no occurrences of serious adverse events documented.

Conclusion: The study demonstrates that both treatments exhibit similar effectiveness and safety profiles, with MMR showing slightly better response rates. No serious adverse events were reported with either treatment.

Keywords: Warts, dermatology, measles mumps and rubella vaccine, MMR vaccine, vitamin D3, intralesional administration

Introduction

Cutaneous warts, caused by the human papillomavirus (HPV), are a common dermatological condition affecting individuals across diverse demographics worldwide.^{1,2} While numerous treatment modalities exist, including topical agents, cryotherapy, and surgical excision, the quest for an optimal therapeutic approach continues due to varying efficacy rates and adverse effects associated with current interventions. The prevalence of warts in school-age children is estimated to be in the range of 22%-33%, exhibiting a progressive decline with advancing age.^{3,4} Notably, the incidence of warts is observed to be higher in girls compared to boys, with peak rates recorded at 13 years and 14.5 years, respectively.⁵ Insightful studies conducted by Bruggink et al and Van Der Werf have demonstrated that approximately half of primary school children affected by warts experience spontaneous resolution of individual lesions within a one-year timeframe.^{3,6,7} Despite the self-limiting nature of warts in a significant proportion of cases, a notable subset of children with large, symptomatic, or visually conspicuous warts actively seeks medical intervention. This inclination towards seeking treatment is often motivated by factors such as social stigmatization, pain, and irritation, which can significantly impact the psychosocial well-being of affected individuals. Consequently, understanding the prevalence trends and associated factors influencing the decision to seek treatment is crucial for developing targeted and effective management strategies tailored to the unique needs of this pediatric population.

In recent years, intralesional therapy has garnered attention as a promising alternative for the management of cutaneous warts. Among the agents under investigation, Measles-Mumps-Rubella (MMR) vaccine, Bacillus Calmette-Guérin (BCG), and Vitamin D3 have emerged as potential candidates, each having distinct mechanisms of action and purported benefits. Over the past two decades, immunotherapy has emerged as a viable treatment approach for multiple, recurrent, and stubborn warts. The measles-mumps-rubella (MMR) vaccine, known to stimulate a Th1 immune response and trigger the production of various cytokines, initiates a delayed hypersensitivity reaction against MMR viral antigens and potentially against wart-causing viruses.⁸ This process activates cytotoxic T cells and natural killer cells to eliminate HPV-infected cells, with the use of three antigens enhancing the immune response and preventing recurrence. Similarly, vitamin D3 exhibits antiviral effects through the induction of antimicrobial peptides and promotion of epidermal cell differentiation, ultimately leading to wart clearance.⁹ Placebo-controlled studies have consistently demonstrated the superiority of intralesional immunogen injections over placebo, facilitating direct comparison between different immunogens for wart treatment in children.^{10,11} This paper aims to critically evaluate and compare the efficacy and safety profiles of intralesional MMR and Vitamin D3 in the treatment of cutaneous warts. By scrutinizing existing literature, we seek to provide clinicians and researchers with comprehensive insights into the comparative effectiveness of these interventions, facilitating informed decision-making in clinical practice.

Methods

The present prospective comparative study was conducted at the Department of Dermatology, Government Medical College, Ananatnag. The methodology involved the selection of patients attending the Dermatology OPD with clinically diagnosed cutaneous warts, whether multiple or single, based on predefined inclusion and exclusion criteria. A total of 200 patients were randomly selected, with 100 patients allocated to each group. In terms of the procedure, patients clinically diagnosed with cutaneous warts were grouped into two groups: Group A received intralesional MMR, and Group B received intralesional vitamin D3. The study adopted a hospital-based comparative design, aiming to assess the efficacy and safety of different treatment modalities for cutaneous warts. Inclusion criteria encompassed patients of both genders aged 12 years and above, presenting with clinically diagnosed cutaneous warts of

varying sizes, durations, and sites (excluding mucosal warts). Exclusion criteria were defined to exclude patients who had received any modality of treatment within the previous month, individuals with mucosal warts (genital, oral), pregnant or lactating females, patients on immunosuppressants, individuals with active infections or malignancies, patients unwilling to participate, and those with a history of hypersensitivity reactions. Prior to participation, written and informed consent was obtained from all patients, ensuring their understanding and agreement to take part in the study. This rigorous approach to patient enrollment and consent aimed to uphold ethical principles and safeguard patient rights throughout the research process. During the study, patient histories were meticulously recorded, including demographic details such as name, age, gender, address, contact number, marital status, and occupation. Additionally, disease history, encompassing the age of onset of lesions, duration of lesions, and any associated symptoms, was documented. Comprehensive treatment history, past medical/surgical history, personal history, and family history were also diligently documented. Subsequently, selected patients underwent thorough examinations to assess the type, number, and location of cutaneous warts.

All patients were subjected to baseline investigations, including testing for VDRL, HIV, and Hepatitis B & C. Each group received respective intralesional injections at 2-week intervals for up to 6 sessions or until complete clearance. Vitamin D3 (0.2 ml, 15 mg/ml) was injected to the base of warts after injecting with lignocaine (0.2 ml, 20 mg/ml). The injections were repeated 2 weeks apart for a maximum of 6 sessions or until complete clearance, whichever was earlier. A maximum of 2 warts were treated per session and patients were followed up for 3 months after the last injection. Dose in MMR was 0.5 ml reconstituted vaccine in largest parent wart 2 weekly for maximum of 6 sessions.

Results

Assessment of treatment outcomes involved various parameters, including global assessment scores, dermoscopy, and clinical photographs. Efficacy was evaluated based on grades of clinical improvement using the Visual Analogue Scale (VAS), with complete clearance, partial response, or no response noted. Safety was assessed by global evaluation, categorizing adverse events as excellent, good, fair, or severe based on their severity and management requirements. Throughout the study, clinical photographs were consistently taken by the same photographer under standardized conditions to ensure accuracy and reliability of the assessments.

Statistical Methods

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Statistical software SPSS (version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data. Data was expressed as Mean \pm SD. Kolmogorov-Smirnov test was applied to test the normality of data. Student's independent t-test was employed for comparison of continuous variables. Chi-square test or Fisher's exact test, whichever appropriate, was applied for comparison of categorical variables. A P-value of less than 0.05 was considered statistically significant.



Results

In this section, the results of the study will be described:

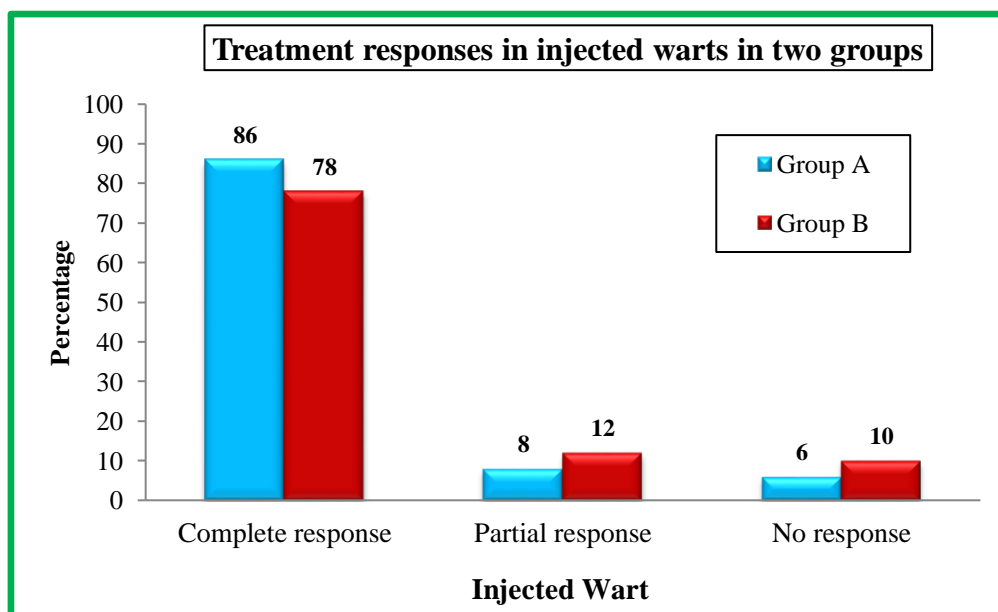
Parameter	Group A	Group B	P-value
Age (Years)	23.7±4.17	25.1±3.94	0.176
Male	29 (58%)	34 (68%)	0.301
Female	21 (42%)	16 (32%)	
Number of warts	6.7±3.15	6.5±2.84	0.739
Duration (Months)	7.6±3.4	8.1±4.3	0.521

Group A (MMR); Group B (Intralesional vitamin D3)

Table 1 presents the demographic and clinical characteristics of patients allocated into two groups, Group A and Group B. The comparison includes parameters such as age, gender distribution, number of warts, and duration of the condition. In Group A, the mean age was 23.7 years (± 4.17), with 58% males and 42% females, while in Group B, the mean age was 25.1 years (± 3.94), with 68% males and 32% females. The difference in age and gender between the groups was not statistically significant. The average number of warts in Group A was 6.7 (± 3.15), and in Group B, it was 6.5 (± 2.84), with no significant difference observed ($p=0.739$). Similarly, the duration of the condition in months was 7.6 (± 3.4) in Group A and 8.1 (± 4.3) in Group B, with no statistically significant difference noted ($p=0.521$).

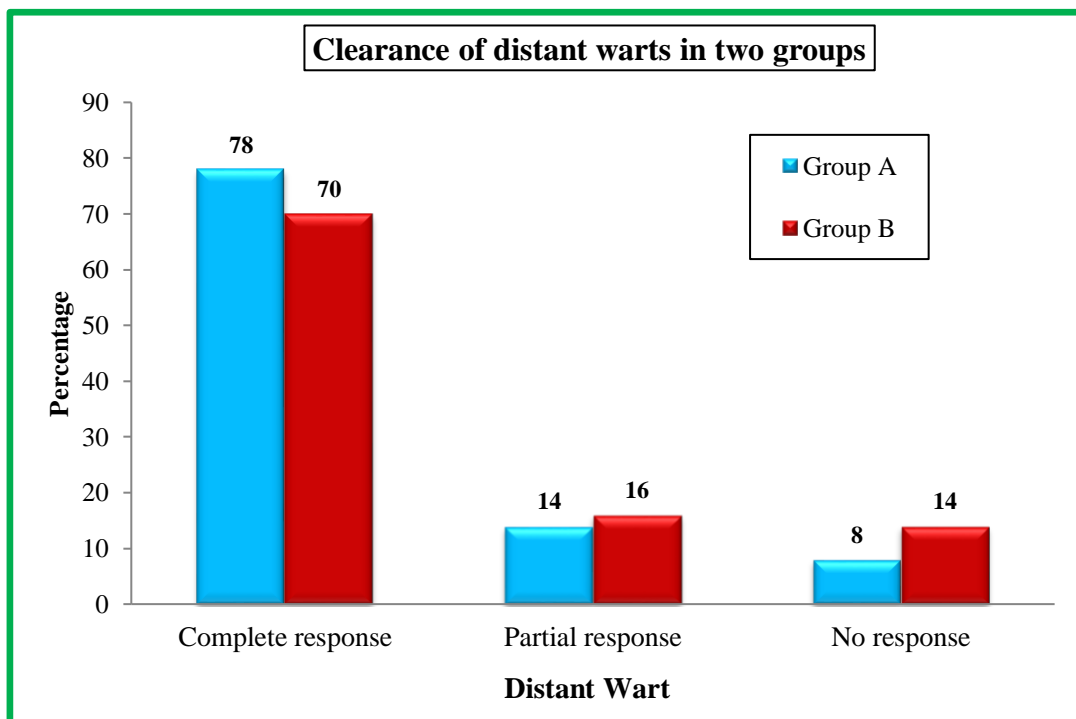
Injected Wart	Group A		Group B		P-value
	No.	%age	No.	%age	
Complete response	43	86	39	78	0.578
Partial response	4	8	6	12	
No response	3	6	5	10	
Total	50	100	50	100	

Group A and Group B were analyzed for complete, partial, and no response to treatment. In Group A, 43 cases (86%) showed a complete response, 4 cases (8%) displayed a partial response, and 3 cases (6%) showed no response. In Group B, 39 cases (78%) exhibited a complete response, 6 cases (12%) showed a partial response, and 5 cases (10%) showed no response. The P-value for the comparison between the two groups was 0.578.



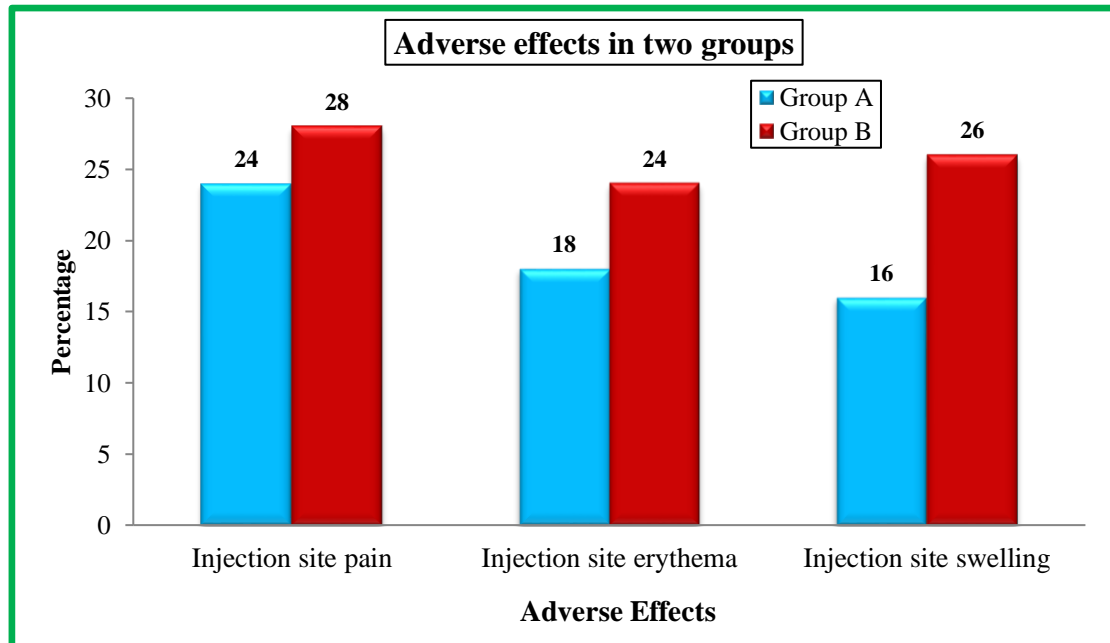
Distant Wart	Group A		Group B		P-value
	No.	%age	No.	%age	
Complete response	39	78	35	70	0.576
Partial response	7	14	8	16	
No response	4	8	7	14	
Total	50	100	50	100	

Table 3 presents a comparison of distant wart clearance between two groups. Group A exhibited complete response in 39 cases (78%), while Group B showed a similar response in 35 cases (70%), with a non-significant p-value of 0.576. Partial response was observed in 7 cases (14%) in Group A and 8 cases (16%) in Group B. Additionally, no response was recorded in 4 cases (8%) in Group A and 7 cases (14%) in Group B.



Adverse effects	Group A		Group B		P-value
	No.	%age	No.	%age	
Injection site pain	12	24	14	28	0.648
Injection site erythema	9	18	12	24	0.461
Injection site swelling	8	16	13	26	0.219

Table 4 presents the comparison of adverse effects between two groups. Group A and Group B were assessed for the occurrence of injection site pain, erythema, and swelling. In Group A, 12 individuals (24%) reported injection site pain, while in Group B, the number was 14 (28%), with no significant difference observed ($p = 0.648$). Similarly, for injection site erythema, Group A had 9 cases (18%) compared to 12 cases (24%) in Group B, with a non-significant p-value of 0.461. Injection site swelling was reported in 8 individuals (16%) in Group A and 13 individuals (26%) in Group B, showing no significant difference ($p = 0.219$).



Discussion

The management of warts poses a significant challenge for clinicians due to the suboptimal response observed with currently available therapies. Despite their use, none of these treatments can guarantee a 100% efficacy rate. Consequently, the quest for novel and efficacious therapeutic alternatives remains an ongoing and elusive endeavor. This persistent need for improved solutions underscores one of the most frustrating aspects of dermatological practice. In this context, intralesional vitamin D3 has emerged as a promising new avenue for addressing cutaneous warts. Concurrently, the application of the measles, mumps, and rubella (MMR) vaccine for this purpose has become an established modality. However, comprehensive comparative data regarding the efficacy of either the MMR vaccine or vitamin D3 as immunotherapy specifically for cutaneous warts has remain limited, highlighting the need for further investigation in this domain. To address this gap in knowledge, the present study undertook a comparison of the efficacy and safety of intralesional injections of MMR vaccine versus intralesional injections of vitamin D3 in patients with multiple warts. The comparative analysis between the two groups revealed no statistically significant differences in key parameters, including age, gender distribution, number of warts (Group A: 6.7 ± 3.15 , Group B: 6.5 ± 2.84 , $p=0.739$), and duration of the condition (Group A: 7.6 ± 3.4 months, Group B: 8.1 ± 4.3 months, $p=0.521$). The consistent age distribution, gender balance, frequency of warts, and comparable duration of the condition suggest a robust randomization process, reinforcing the scientific rigor of the study and minimizing the likelihood of skewed results favoring one group over the other.

In our comparative analysis of treatment responses in injected warts between Group A (MMR utilization) and Group B (Intralesional vitamin D3), we observed notable outcomes. In Group A, comprising MMR utilization, 43 cases (86%) demonstrated a complete response, 4 cases (8%) exhibited a partial response, and 3 cases (6%) showed no response. Conversely, in Group B, involving Intralesional vitamin D3, 39 cases (78%) displayed a complete response, 6 cases (12%) showed a partial response, and 5 cases (10%) exhibited no response. The P-value for the inter-group comparison was 0.578, indicating no statistically significant difference in treatment responses between the two groups. This finding aligns with the study conducted by Mohta et al, where injected warts in both groups A and B showed similar patterns of response.¹²In their study, Group A exhibited complete clearance in 87.8% of patients, partial clearance in 6.1%, and no response in 6.1%, while in Group B, 77.4% displayed complete clearance, 16.1%

showed partial clearance, and 6.5% had no clearance.¹² The absence of a statistically significant difference in responses between the two groups mirrors our own results. Furthermore, our study's outcomes resonate with that of Nofal et al, who reported complete cure in 81.4% of patients with MMR utilization compared to 27.5% in the placebo group.¹³ Similar results were reported by Mohamad et al, Gamil et al and Zamanian et al, showing complete clearance in 82%, 81% and 75% of patients, respectively, with MMR.¹⁴⁻¹⁶ While our results were slightly better than Agrawal et al, who reported a complete response in 60% of patients with injected warts.¹⁷ These collective findings underscore the comparable efficacy of MMR utilization in Group A and Intralesional vitamin D3 in Group B, emphasizing their potential as effective treatment modalities for injected warts.

The comparison of distant wart clearance between Group A (utilizing MMR) and Group B (utilizing Intralesional Vitamin D3) in our study revealed noteworthy findings. Group A exhibited a complete response in 39 cases (78%), while Group B showed a similar response in 35 cases (70%), with a non-significant p-value of 0.576. Partial response was observed in 7 cases (14%) in Group A and 8 cases (16%) in Group B. Additionally, no response was recorded in 4 cases (8%) in Group A and 7 cases (14%) in Group B. These outcomes are in line with several previous studies that have compared the response of intralesional vitamin D3 against MMR vaccine and other immunotherapies like PPD, candida antigen. For example, Mohta et al reported a complete response in distant warts for 75.7% of patients in Group A and 64.5% of patients in Group B, with no statistically significant difference observed between the two groups.¹² Furthermore, in a separate study focusing on the pediatric population, Mohta et al compared the effects of MMR vaccine to intralesional Vitamin D3 and found distant warts cleared in 23 (76.7%) patients in Group A compared to 20 (66.6%) patients in Group B.¹⁸ Consistent with our findings, both studies reported comparable differences in distant wart clearance between Group A and Group B, indicating no significant disparity. Chauhan et al reported an impressive complete distant wart resolution rate of 82.4% with MMR, further supporting the efficacy of MMR vaccination in distant wart clearance.¹⁹ Agrawal et al also reported favorable outcomes, with complete clearance observed in 69.5% of patients with distant warts due to MMR.¹⁷ Similarly, Mahajan et al evaluated the effect of MMR vaccine in the pediatric age group and reported a complete clearance rate of 58.7%, slightly lower than our observed rate of 78%.²⁰ Our study revealed a response rate of 70% with intralesional vitamin D3, mirroring the initial inquiry by Aktaş et al, who documented complete clearance in 80% of their patients.²¹ Nonetheless, their methodology diverged from ours, employing a higher dosage and administering injections to up to five warts per patient. In a separate comparison, Singh et al juxtaposed Vitamin D3 with PPD tuberculin, noting a complete response in 72.5% of participants in the former group, a figure closely aligned with our observed rate of 70%.²² In another comparative saline-controlled study, Kareem et al compared vitamin D3 with candida antigen, where 70% of patients showed an excellent response with vitamin D3.²³ Subsequent studies by Kavya et al and Raghukumar et al reported complete clearance rates of 78.57% and 90%, respectively, further supporting the efficacy of vitamin D3 in wart clearance.^{24,25} In parallel with our study design, Shaldoum et al conducted a comparative analysis of intralesional MMR injection and vitamin D3 injection, revealing equal effectiveness in both interventions.²⁶ The consistency in outcomes across these studies suggests a robust response to MMR vaccination in distant wart clearance, despite variances in patient demographics and study methodologies. Although our study did not identify a statistically significant difference in distant wart clearance between Group A (MMR utilization) and Group B (Intralesional Vitamin D3), the clinical implications suggest a higher response rate with MMR, underlining its potential as a more effective intervention for distant wart clearance. The uniformity of findings, coupled with the prevalence of MMR vaccination in India, helps mitigate confounding factors and enhances the reliability of our results. Our findings suggest

that both intralesional MMR vaccine and vitamin D3, utilized as immunogens for wart treatment, are well-tolerated and safe, with no incidence of serious adverse events noted. Although comparable between the two groups, post-treatment occurrences of injection site pain, erythema, and swelling were more frequently reported by patients subjected to vitamin D3 treatment. Notwithstanding, it is imperative to acknowledge the study's limitations, including a brief follow-up period, a modest sample size, the absence of immunologic assessments, and the lack of a placebo-control group.

Conclusion

Our study was designed to conduct a comparative assessment of the efficacy and safety profiles of intralesional administration of the MMR vaccine against intralesional vitamin D3 in patients afflicted with multiple warts. Both study cohorts exhibited comparability across crucial parameters, including age, gender distribution, number of warts, and duration of the condition, indicative of a robust randomization process. The comparative analysis of treatment responses revealed analogous outcomes between the two groups, consistent with earlier investigations, thereby corroborating the efficacy of both MMR vaccination and intralesional vitamin D3 in wart management. While statistical significance was not detected in the rates of both injected and distant wart clearance, the clinical ramifications hint at a marginally superior response rate associated with MMR, suggesting its potential as a more efficacious intervention for distant wart resolution. Furthermore, our findings affirm the favorable tolerability and safety profiles of both intralesional MMR vaccine and vitamin D3 immunotherapy, with no occurrences of serious adverse events documented.

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