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Original Research Article

COMPARATIVE STUDY OF THE SAFETY AND EFFICACY OF VARIOUS INTRALESIONAL DRUGS IN THE TREATMENT OF CUTANEOUS WARTS

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ABSTRACT

Background: Cutaneous warts in various forms on different body sites continue to be a therapeutic challenge for doctors despite the availability of various modalities of treatment including destructive therapies and various intralesional (IL) drugs. As destructive therapy is cumbersome in nature, in this study we observed the efficacy of various intralesional drugs. The aim is to evaluate the therapeutic efficacy and safety of intralesional BCG vaccine, MMR vaccine, bleomycin and vitamin D3 in cutaneous warts.

Materials and Methods: A total of 60 patients were randomised into four groups with 15 patients in each group. Patients of group A received IL BCG vaccine, group B received IL MMR vaccine, group C received IL bleomycin and group D received IL vitamin D3. Treatment was given at 3 week intervals for a maximum of four treatments. Patients were evaluated during each visit for treatment response and post-treatment follow up was done for 3 consecutive months.

Results: A total of 60 patients with a mean age of 24.15 having 251 warts were included in this study. There were 36 males and 24 females. Complete clearance of warts was better with Bleomycin (96.3%) followed by MMR vaccine (91.2%), BCG vaccine (65.4%) and inj. vitamin D3 (63.3%). Majority of the patients reported pain on injection with all four intralesional drugs. Adverse effects were reported more frequently with BCG vaccine and included superficial ulcer formation in 86.6%, post- inflammatory pigmentary change in 33.3% and flu-like symptoms in 33.3% of patients. 26.6% of Patients treated with vitamin D3 experienced swelling at the site of injection. In the bleomycin group, hemorrhagic eschar was seen in 33.3% and post-inflammatory pigmentary changes were seen in 13.3% of patients. Pigmentary changes in 13.3% patients was the only side effect seen in the MMR group. Recurrence of lesions was seen in 13.3% of patients in the MMR group and 20% of patients in the vitamin D3 group. No recurrence was seen in patients treated with bleomycin and BCG during the 3 month follow up.

Conclusion: All four intralesional drugs used in our study have a shown good therapeutic potential, safety profiles and low relapse rate for the treatment of warts.

Keywords: BCG, MMR, bleomycin, vitamin D3.

INTRODUCTION

Human Papilloma Virus (HPV) is a double-stranded DNA virus that causes cutaneous warts, most commonly located on the skin and genitalia. Minor abrasions and infections promoted by maceration of the epithelium frequently serve as conduits for HPV to the basal keratinocytes, the primary targets for HPV infection. Viral activity likely depends on the

immune status and response of the infected individual.[1]

The most common indications for the treatment of common warts include pain, functional impairment, cosmetic reasons and the risk of malignancy. Although majority of common warts heal spontaneously within two years, elimination of warts is the most common treatment in practice because of the aforementioned reasons. However, the treatment method should not harm the normal skin or leave a scar.[2] Several therapeutic approaches have been used to treat warts with variable results.

Immunotherapy has become one of the most important therapeutic tool for the treatment of warts. Common immuno-therapeutic modalities used for the treatment of warts include contact sensitizers, imiquimod, intralesional interferon and oral drugs such as levamisole, cimetidine and zinc sulfate. Intralesional antigens such as MMR (measles, mumps, and rubella) vaccine, skin test antigens (mumps, Candida, and Trichophyton), BCG (bacillus Calmette-Guurin) vaccine, and Candida antigen were reported as successful treatment modalities in various forms of warts.[3]

We conducted a study to evaluate the efficacy and safety of various intralesional drugs- BCG vaccine, MMR vaccine, bleomycin and vitamin D3 in treatment of warts.

MATERIALS AND METHODS

This (Open labelled) randomised study was conducted between July 2019 to December 2019 in the department of DVL after obtaining approval from the institutional Ethics Committee.

Study design: 60 consecutive patients with cutaneous warts irrespective of number and duration were included in the study. Children <12yrs, pregnant and lactating women, immunocompromised individuals, patients with anogenital warts, patients with history of Raynauds disease and those with past history of treatment for warts were excluded from this study. Diagnosis was made on the basis of history and classical features on clinical examination. After taking written informed consent, patients were randomised into 4 groups of 15 each. Randomisation was done in sequence, that is 1st case- BCG, 2nd case- MMR, 3rd case- bleomycin, 4th case- vitamin D3 and the sequence was repeated.

Group A were treated with IL BCG vaccine. 0.1ml was injected into the largest wart.

Group B were treated with 0.5ml of IL MMR vaccine. MMR vaccine was available in the form of single-dose vial of freeze-dried vaccine. It was reconstituted with 0.5 ml of provided diluent (distilled water). 0.25 ml - 0.3ml of reconstituted MMR vaccine was injectedinto the wart with 30G insulin syringe.

Group C were treated with IL bleomycin. Bleomycin powder for injection (15 mg vial) was dissolved in 5 ml distilled water to prepare 3 mg/ml of stock solution and stored at 4–8°C for a maximum of 30 days. One part of the bleomycin stock solution and two parts of 2% lignocaine were mixed in an insulin syringe with a 30 G needle to obtain a final bleomycin concentration of 1 mg/ml and was injected intralesionally until blanching was observed.

Group D were treated with IL vitamin D3 (cholecalciferol 6,00,000 IU). About 0.5ml was injected into base of the wart.

Patients of all groups were reviewed at 3 week intervals for a maximum of four times and treatment was repeated if required. During each visit, the patient was evaluated for clinical improvement by clinical examination and photographs were taken. Side effects like pain, ulcer, pigmentation, eschar, fever, myalgias etc, if any, were noted. Complete clearance was considered if all the treated warts resolved completely. It was regarded as no response if there was 0 to <100% reduction in size of the lesions. Post-treatment follow up was done monthly for 3 months to assess for recurrence or side effects, if any. Results were tabulated and statistically analysed.

RESULTS

A total of 60 patients with a mean age of 24.15 having 251 warts were included in the study. There were 36 males and 24 females with a mean age of 22.28 and 26.96 respectively.

Baseline demographic and clinical data of the patients include:

Table 1

Total pts n=60	**GroupA(BCG) n=15**	**GroupB (MMR) n=15**	**Group C (Bleomycin) n= 15**	**GroupD (vitamin D3) n=15**
Mean age	22.66	23.46	25.73	24.73
Gender ratio (M:F)	1.5:1	1.14:1	2:1	1.5:1
Total no.of warts	52	57	82	60
Type of warts				
VV	38	42	66	39
Plane	1	2	0	2
Palmar	0	0	6	8
Plantar	13	13	5	11
Periungual	0	0	5	0
Site of warts				
Hand	26	27	27	32
Face	3	6	17	2
Leg	3	6	21	12
Foot	18	13	5	11
Periungual	0	0	2	0

Forearm	2	5	10	3

Group A (BCG): A total of 15 patients with 9 males and 6 females (M:F =1.5:1) aged between 12 to 36 years (mean=22.6y) had 52 warts which varied between 1 to 6 (mean 3.5 warts) in each patient. Of 52 warts, 38 were verruca vulgaris (VV), 13 were plantar warts and 1was a plane wart. 26 warts were located on the hands, 3 on the face, 3 on the legs, 18 on the feet and 2 on the forearm. Complete clearance was seen in 24 (63.16%) out of the 38 VV, 9 (69.23%) out of 13 plantar warts and 1 (100%) plane wart. On the whole, 34 (65.4%) warts showed complete clearance by the end of 12 weeks. No response to partial response was seen in 14 (36.84%) of the VV and 4 (30.7%) of the plantar warts. In total, 18 (34.6%) of the 52 warts showed no response to partial response. Pain at the injection site was complained by all patients. In some, oral analgesics for a period of 3 days was prescribed for severe pain. A flu-like illness that rapidly subsided within 3 days was observed with each injection in about 5(33.3%) patients. Superficial ulcer was noted in 13(86.6%) patients. Post inflammatory pigmentary changes were seen in 5(33.3%) patients. No recurrence of warts was observed during the3 months of follow up after completion of treatment.

Group B (MMR)

A total of 15 patients with 8 males and 7 females (M:F=1.14:1) aged between 13 to 37 years (mean=23.4y) had 57 warts. The number of warts ranged from 2 to 6 in each patient with a mean of 3.8 warts. Of the 57 warts, 42 were VV, 13 plantar warts and 2 plane warts. 27 warts were located on the hands, 6 on the face, 6 on the legs, 13 on the feet and 5 on the forearm. Complete clearance was seen in 37 (88.09%) out of the 42 VV, 13 (100%) out of the13 plantar warts and 2(100%) out of the 2 plane warts. On the whole 52 (91.22%) warts showed complete clearance by the end of 12 weeks. No response to partial response was seen in 5(11.9%) out of the 42 VV which constitute 8.77% of the 57 warts treated with MMR vaccine. Post-inflammatory pigmentary change was seen in 2(13.3%) patients. Recurrence of warts was seen in 2(13.3%) patients during the 3 months of follow up after completion of treatment.

Group C (bleomycin)

A total of 15 patients with 10 males and 5 females (M:F =2:1) aged between 13 to 54 years (mean=25.7y) had 82 warts. The number of warts ranged from 1 to11in each patient with a mean of 5.5 warts.

Of the 82 warts 66 were VV, 6 palmar, 5 periungual and 5 plantar warts. 27 were located on the hands, 17 on the face, 21 on the leg, 5 on the foot, 10 on the forearm and 2 on the perungual areas. Complete clearance was seen in 65(98.5%) out of the 66 VV, 5 (83.3%) out of the 6 palmar warts, 5(100%) out of the 5 plantar warts and 4 (80%) out of the 5 periungual warts. On the whole 79(96.3%) showed complete clearance by the end of 12 weeks. No response to partial response was seen in 3(3.6%) of the 82 warts. Hemorrhagic eschar was seen in 5(33.3%), post-inflammatory pigmentary changes were seen in 2 (13.3%) and severe pain persisting for more than 3 days in 1(6.6%) patient. Injection around the nail did not have any adverse effect on the nail.

No recurrence was observed during the 3 months of follow up after completion of treatment.

Group D (vitamin D3)

A total of 15 patients with 9 males and 6 females (M:F = 1.5:1) aged between 14 to 57 years (mean=24.7y) had 60 warts. The number of warts ranged from 1 to 10 in each patient with a mean of 4 warts. Of the 60, 39 were VV, 2 plane, 8 palmar and 11 plantar warts. 32 were located on the hands, 2 on the face, 12 on the leg,11 on the feet and 3 on the forearm. Complete clearance was seen in 31(79.5%) out of the 39 VV, 5(62.5%) out of the 8 palmar warts, 1(9.1%) out of the 11 plantar warts and 1(50%) out of the 2 plane warts. On the whole 38(63.3%) warts showed complete clearance by the end of 12 weeks.

No response to partial response was seen in 8(20.5%) out of the 39 VV, 3 (37.5%) out of the 8 palmar warts, 10 (90.9%) out of the 11 plantar warts and 1 (50%) out of the 2 plane warts. In total 22 (36.7%) warts showed no response to partial response to vitamin D3. Swelling was seen in 4 (26.6%) patients which subsided in 3 to 5 days. Recurrence was seen in 3(20%) patients during the 3 months of follow up after completion of treatment.

Z test of proportions is used to compare proportion of response in between the groups.

In our study bleomycin showed better treatment response over BCG (Z = -4.8, P= 0.00001) and vitamin D3 (Z = 5.101, P=0.000001) which was statistically significant. MMR showed better treatment response over BCG (Z=-3.30, P= 0.00096) and vitamin D3 (Z= 3.58, P= 0.00034) and this difference in treatment response is also statistically significant. Though bleomycin showed better treatment response than MMR this difference was not statistically significant (z=1.27,P= 0.204). Treatment response between BCG and vitamin D3(z=0.226,P= 0.8181) groups was also not statistically significant.

DISCUSSION

Recurrent multiple warts represent a therapeutic challenge which is frustrating for both patients and physicians. Although several therapeutic modalities have been used in the treatment of warts, a universally efficacious approach with low recurrence rate has yet to be explored.[4] In recent years, intralesional therapy has been considered as a novel treating option and has been tried with bleomycin, PPD, MMR, Candida albicans, Mycobacterium w vaccine and many more. In our study we document the clinical efficacy and safety of IL drugs like bleomycin, MMR vaccine, BCG vaccine and vitamin D3.

Bleomycin is a cytotoxic glycopeptide antibiotic isolated from a strain of bacteria Streptomyces verticillus. It has antitumor, antibacterial, and antiviral activities which may be related to its ability to bind with deoxyribonucleic acid (DNA), causing DNA strand scission and elimination of pyrimidine and purine bases. Bleomycin does not bind directly to HPV. The probable mechanism of action of bleomycin is by affecting cellular DNA synthesis; and also by controlling keratinocyte turnover, thereby affecting viral survival.[5]

Immunotherapy for warts employs the ability of the immune system to recognise certain viral antigens that induce a delayed type hypersensitivity reaction which increases the ability of the immune system to recognise and clear the human papilloma virus. Injection of the viral antigen results in peripheral blood mononuclear cell proliferation, promoting Th1cytokine responses, particularly interferon gamma and interleukins.[2,4] This results in activation of cytotoxic Tcells and natural killer cells that help to eradicate human papilloma virus infected cells. It is also proposed that antigen immunotherapy can stimulate tumour necrosis factor α and interleukin 1 release, down regulating gene transcription of human papilloma virus. It is also able to target distant warts situated away from the site of the injection and therefore helps in treating multiple warts on inaccessible sites or sites where ablative therapy is difficult.[6]

In this study group, the sex ratio and age of the patients were nearly similar and there was no significant difference between the four groups. This finding indicates that underlying factors such as age and sex have not confounded the results of the study.

BCG

In our study, 34 (65.4%) warts out of 52 treated with BCG showed complete clearance by the end of 12 weeks. In similar studies done by Jaisinghani AK and Rao AG, complete response was reported in 73.53% and 70% of patients respectively.[7,8] A study by Jagati et al,[9] showed overall complete response in 78.2% of their patients.

MMR

In our study, 52 (91.22%) warts out of 57 treated with MMR showed complete clearance by the end of 12 weeks. Similar high treatment success rate was reported in 82.4%, 81.4% and 75% of patients in studies done by Chouhan Ps et al,[10] Nofal and Nofal,[11] and Zamanian et al,[12] respectively. Study by Mohamad et al,[13] showed complete clearance in 82% of patients with plantar warts. In a study by Guneetawal,[14] only 68% of patients in the MMR group showed complete response compared to 10% in the control group given with normal saline even though patients in his study were treated at 2 week intervals for a maximum of 5 treatment sessions.

Bleomycin

In our study, 79 (96.3%) warts out of 82 treated with bleomycin showed complete clearance by the end of 12 weeks. Similar findings were found in studies done by Kumar P et al,[15] unni M et al,[5] and Sony Pet al,[16] with complete clearance seen in 95.1%, 93.1% and 96.47% of warts respectively. High treatment success rate was also seen in a study by Mehta et al,[17] in which complete clearance was seen in 84% of patients treated with bleomycin.

VITAMIN D3

In this study, 38(63.3%) warts out of 60 treated with vitamin D3 showed complete clearance by the end of 12 weeks. In a study done by Kavya M et al,[18] patients were treated every 2 weeks for a maximum of 5 treatment sessions and complete clearance was seen in 78.57% of patients. Banoth S.19, in his study also showed complete clearance in 76.92% of patients.

Table 2

Reference vaccine	Treatment schedule	Results	Study group	Recurrence
Mehta et al 2019	1mg/ml bleomycin 2 injections at 2 week interval and followed up 4weekly for 24 weeks	84% patients	In 50 patients with common warts	No
Kumar P et al 2019	1mg/ml bleomycin 2 injections at 2 week interval and followed at 4 and 12 weeks	95.16% warts	Common warts including palmoplantar and periungual warts.	recurrence in 3.27% patients
Unni M et al 2017	1u/ml bleomycin 2 injections at 4 week interval and followed at 8, 12 weeks and at 6 months.	93.1% warts	Inj bleomycin vs normal saline with 25 patients with common warts in each group.	16% patients in bleomycin group
Soni P et al 2011	2 IL injections 2 weeks apart in 1mg/ml bleomycin strength.followup to 1 year	96.5% warts	Inj bleomycin vs normal saline in 25 patients with Palmo plantar and periungual warts in each group	No recurrence of resolved wart
Hayes and O'Keefe 1986	IL bleomycin 1u/ml 3 injections at 3 week interval and final assessment at end of 3 months	76% warts		
Suneel Singh Sengar et al 2018	MMR vaccine 0.5ml/dose given at 2 week interval for a maximum of 4 sessions and followed up for 6 months	45% patients	Of 120 patients included in study 30 treated with MMR vaccine. Response seen for both injected and distant site	16.6% patients in MMR group

Guneetawal 2018	MMR vaccine 0.5ml into single large wart at 2 week interval for a maximum of 5 injections and followed for 4 months after last injection	68% patients	Of 150 patients with cutaneous warts included in study 72 treated with MMR and 50 with NS	2.7% patients given MMR vaccine
Nofal and Nofal 2010	MMR vaccine IL 0.3 ml once in 2 weeks till clearance or 5 doses maximum and followed for 6 months	80% patients with recalcitrant warts and 84.6% with multiple warts	Of 135 patients with single or multiple recalcitrant or non-recalcitrant common warts85 given MMR vaccine and 50 given NS	Norecurrence with MMR
Mohamad et al. 2013	MMR vaccine IL 0.3 ml once in 3 weeks till clearance or 3 doses maximum followed up for 6 months	82% treated warts 86.9% distant warts	Of 100 patients with plantar warts 50 given with MMR others with NS	—-
Zamanian et al 2014	MMR vaccine 0.5ml into single large wart at 2 week interval for a maximum of 3 injections and followed for 6months	75% patients	24 patients with warts treated with MMR vaccine and 22 with normal saline	No
Chouhan Ps et al 2019	MMR vaccine 0.25ml IL at 2week interval till clearance or for maximum of 5 doses and followed up for 8 weeks after last injection	82.4% of patients	110 patients with common warts	No recurrence
Jaisinghani AK 2019	0.1 ml BCG vaccine at 3 week interval for max 3 sessions or till complete clearance and followed monthly for 3 months	73.53% patients	40 patients with multiple recurrent extragenital warts assessed both treated and distant warts	No recurrence
Rao AG 2020	0.1ml BCG at 3 wk interval for max 5 injections or till complete clearance and followed up for 6 months	complete clearance in 70% patients at lesional site end of 3 months	30 patients with multiple, extensive non-genital cutaneous common warts	—-
Jagati et al. 2017	0.1 ml BCG into single large wart and evaluatedevery 2 weeks and followed for 6 months	78.2% patients	46 patients with recalcitrant warts	—
Kavya M et al 2017	0.2ml vitamin D3 2wkly for max 4 sessions or till complete clearance and followed for 6 months after last injection	78.57% patients Complete clearance	42 patients with multiple warts	2.38%
Banoth S 2019	0.2 ml vitamin D3 IL every 3 weeks for max 3 sessions and followed up for 3 months after last injection	76.9% patients Complete clearance	26 patients with common warts treated with MMR vaccine in 13 and rest with NS	No recurrence

All four intralesional drugs used in our study showed good therapeutic efficacy with variable results. VV responded best for bleomycin (98.5%) followed by MMR vaccine (88.1%), vitamin D3 (79.5%) and BCG vaccine (63.2%). Palmar warts responded best for bleomycin (83.3%) followed by vitamin D3 (62.5%). None of the patients treated with BCG and MMR vaccine had palmar warts. Plantar warts responded best for Bleomycin (100%) and MMR vaccine (100%) followed by BCG vaccine (69.2%) and only 9.1% warts responded with Vitamin D3. Plane warts showed excellent response to MMR vaccine and BCG vaccine (100%) while only50% of warts responded to vitamin D3. None of the patients treated with bleomycin had plane warts. Periungual warts showed complete clearance in 80% of warts treated with bleomycin.

In a study by Guneetawal,[14] patients treated with MMR vaccine showed complete response in 70.9% of palmoplantar warts, 68.7% of verruca vulgaris and 55.5% of plane warts. Jagati et al, in their study showed that patients treated with BCG vaccine had complete clearance in 86.66% of palmoplantar warts, 60% of common warts and 100% of periungual warts. In a study by Kavya M et al, patients treated with vitamin D3 showed complete clearance in 82.60% of palmoplantar warts and 77.77% of verruca vulgaris. Soni P et al, among his patients treated with bleomycin, complete clearance in 96.1% of palmoplantar warts and 100% of periungual warts.

Among 4 drugs compared in our study, complete clearance of warts was better with bleomycin (96.3%) followed by MMR vaccine (91.2%), BCG vaccine (65.4%) and vitamin D3(63.3%). Similarly in a study by Munnangi.[20] MMR vaccine showed a better treatment response over the BCG vaccine where complete clearance was seen in 73.3% of patients in the MMR group as against 33.3% patients in the BCG vaccine group. Also Shaldoum DR et al,[21] in his study comparing the efficacy of intralesional MMR vaccine and vitamin D3 injection, showed better results with MMR vaccine (80% of patients showed complete response) than vitamin D3 (66.7% of patients).

Adverse effects were reported more frequently with the BCG vaccine group in our study. Patients

complained of pain at injection site, ulcer formation, post-inflammatory pigmentary changes and flu-like symptoms. Similar side effects were reported in a study by Jaisinghani AK.[17] In addition, scarring, nodule/granuloma formation and BCGitis were also reported in their study. Swelling at the site of injection was seen with vitamin D3 in our study, which was also reported by Kavya M et al,[18] along with dyspigmentation. Side effects like hemorrhagic eschcar, hyperpigmentation, hypopigmentation and scaring were reported in a study by Unni M,[5] with IL bleomycin. Similar side effects were also reported in our study but scarring was not seen in any of our patients. Pain, erythema, swelling, flu-like symptoms were reported by Dhope A,[22] with IL MMR vaccine but in our study pigmentary change was the only side effect seen. Majority of the patients reported pain on injection with all four intralesional drugs which subsided eventually. None of the patients experienced any serious adverse effects during the period of treatment and during the 3 month follow up period.

Recurrence of warts was seen in 13.3% patients in the MMR group and 20% patients in the vitamin D3 group during the 3 month follow up in our study. Chauhan PS et al.10 showed no recurrence of warts in patients treated with MMR vaccine during a 2 month follow up period while Kavya M et al,[18] showed a 2.3% recurrence rate with vitamin D3 during her 6 month follow up period. In our study no recurrence was seen in bleomycin and BCG vaccine groups during the 3 month follow up period while S Kumar P et al,[15] showed recurrence in 3.27% of patients treated with bleomycin at the end of his 3 month study period and Jaisinghani AK,[7] showed no recurrence of warts in his patients treated with BCG vaccine during a 3 month follow up period.

CONCLUSION

Intralesional therapy is a safe, cost effective and non-destructive method of treating warts. All four intralesional drugs used in our study have shown a good therapeutic potential, safety profiles and low relapse rate for the treatment of warts.

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