Efficacy and Safety of Diphenylcyclopropenone in the Treatment of Multiple Warts - A Prospective Study at a Tertiary Care Hospital, Mumbai

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ABSTRACT

BACKGROUND

Diphenylcyclopropenone (DPCP) produces type IV hypersensitivity reaction, immune response being directed against a complex of contact agent hapten bound to proteins of viral origin that enhance wart regression. We wanted to evaluate the efficacy and safety of DPCP in multiple warts along with the various factors affecting DPCP response.

METHODS

A prospective study with 49 patients older than 5 years with 5 or more warts in any area (except genital) was conducted. Patients were sensitized with 2 % DPCP solution and examined after 48 hours. Sensitization was graded as mild, moderate, severe or no sensitization. Patients with mild / moderate sensitization were further applied DPCP; patients with severe sensitization were included after subsidence of reaction and patients with no sensitization were excluded. After sensitization, weekly applications were made on warts. Concentration causing mild reaction was selected as optimal and was applied till lesion clearance. Follow up was for 3 months for recurrences. Response was graded as complete, partial and no response.

RESULTS

Males outnumbered females. Mean age was 23 years. Mean duration was 12 months. Recurrent and resistant warts were seen in 15 and 6 patients respectively. Mean number of warts was 15.6. 49 patients were tested for sensitization, 1 failed sensitization and 48 were continued with weekly DPCP. 2 developed distant eczematisation and 4 were lost to follow up. Out of 42, complete clearance was seen in 35 (83.3 %), partial in 3 (7.14 %) and no response in 4 (9.52 %). Local eczematisation, lymphadenopathy, hyperpigmentation were the side effects. Response was better with increasing age. Warts less than 6 months had 100 % response. There was no statistically significant difference between site and type of warts and response to DPCP, recurrent and untreated warts in terms of response and response to sensitization and final response.

CONCLUSIONS

DPCP is an excellent option for multiple / resistant warts with good safety profile.

KEYWORDS

Diphenylcyclopropenone, Multiple Warts, Safety, Efficacy, Various Factors Affecting Response

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BACKGROUND

Warts are a benign proliferation of the skin resulting from infection with human papilloma virus (HPV). Non genital warts are highly prevalent, seen in 7 % to 10 % of the population.[1] Various clinical manifestations are present, some resulting in pain or dysfunction. Extensive warts cause physical embarrassment and psychological distress to the patients as well as therapeutic challenge for the treating dermatologist. Currently available treatments[1] include cryotherapy, laser[2,3] imiquimod.[4] electro surgery, cimetidine.[5] chemical cautery,[1] 5-fluorouracil, bleomycin,[6] interferons,[1] photodynamic therapy, immunotherapy and retinoids. Although various therapeutic modalities are available, no single therapy has been found to be efficacious or cosmetically acceptable especially for multiple warts.

Topical immunotherapy is defined as the induction and periodic elicitation of allergic contact dermatitis (ACD) by applying a potent contact allergen.[7] The mechanism of action with contact sensitizers is proposed to be a type IV hypersensitivity reaction. The immune response is purported to be directed against a complex of contact agent hapten bound to protein of viral or human origin that enhances wart regression.[1] DPCP which is used commonly in alopecia areata was found to be efficacious in warts.[8]

DPCP is the standard sensitizer used for topical immunotherapy, is non-mutagenic and is available in acetone solution.[9] DPCP is non-mutagenic in the Ames assay at concentrations of 50 and 100µg/ml^{-1}.[10] A recent study[11] suggests that the response to DPCP evolves from an inflammatory peak on day 3 to a more regulated immune response after 14 days. DPCP has been reported to have a high response rate, absence of scarring and painless application[12,13] and simultaneous treatment of multiple lesions.

We wanted to determine the efficacy, tolerability, and safety of Diphenylcyclopropenone (DPCP) in treatment of patients with multiple warts (more than 5). We also wanted to study the various factors affecting response to DPCP.

METHODS

A prospective study was conducted at the Department of dermatology of a tertiary care hospital with patients older than 5 years with 5 or more warts located in any area except genital and perianal region. Pregnant and lactating mothers, immunocompromised individuals, patients receiving any systemic or topical therapy for warts within 4 weeks prior to enrolment were excluded from the study. Sample size $byn = Z^2 1\text{-}\alpha/_2\, p\,(1\text{-}p)/d^2$ with an anticipated success was calculated rate of 85 % and absolute precision as of 10. Forty-nine patients satisfying the above criteria were recruited in the study from June 2013 to May 2014. The protocol was approved by the ethical committee of our hospital.

Each enrolled patient was first sensitized with cotton stick and 2 % DPCP solution was applied on an area of 2x2cm on the back of the patient. The DPCP solution was prepared by reconstituting 98 % pure powder form DPCP dissolved in various concentrations (2 %, 1 %, 0.5 %, 0.2 %, 0.1 % and 0.01 %) of DPCP were prepared as per Table 1. The DPCP had a shelf life of 6 months and stored in amber coloured bottles.

Patients were instructed to avoid direct sun exposure of the applied area and not to wash the area for 48 hours after the application. Patients were clinically examined 48 hours after sensitization. Sensitization was graded as mild (minimal erythema), moderate (moderate erythema with pruritus), severe (severe eczema with vesicles / bulla and pruritus) or no sensitization.

Patients having mild and moderate sensitization were selected for further immediate application of DPCP. Patients having severe sensitization were included after the reaction subsided. Patients having no sensitization were excluded from this study.

After sensitization, further weekly applications were made on the warts. The starting concentration was 0.01 % for facial warts and 0.2 % for warts in other areas. Concentration was gradually increased in a step wise manner up to 2 % or till a mild eczematous reaction was noted at the site of application. The concentration at which a mild reaction developed was selected as the optimal concentration and was applied till all the lesions cleared. Patients who developed severe reactions were treated symptomatically with steroids and antihistamines. These reactions generally took 1 week to subside. Subsequently, the concentration of DPCP was lowered to the concentration slightly lower than the applied concentration. Patients who developed distant severe eczematisation at any concentration were withdrawn from the study.

Therapy was continued till complete resolution of warts was achieved or till a maximum of 10 applications. In case a patient showed partial response after 10 applications, two more applications were done. All patients were followed up at least 3 months to record any recurrences. Patients having serious side effects during sensitization or at any point of application were excluded from the study. Overall response was graded as complete response (all warts disappeared), partial response (decrease in size and number of warts) and no response (none or few warts disappeared).

Data was analysed by using Microsoft Excel and Statistical Package for Social Sciences (SPSS) version 17. Descriptive statistics such as frequencies, percentages, range and mean were used to represent the data. chi-square test as a test of association was used at 5 % level of significance.

RESULTS

Out of 49 patients recruited, 37 (76 %) were males and 12 (24 %) were females. Age of patients ranged from 5 to 60 years with a mean of 23 years. Most (67.3 %) patients were adults, 7 (14.3 %) patients were children (upto12 yrs.) and 9 (18.4 %) patients were adolescents (13-18yrs). Duration of warts varied from 2 to 50 months, with a mean of 12 months. Majority of the patients 61.2 % had symptoms for 6 months to 1 year. While 16.3 % of patients had warts for less than 6 months' duration, 22.5 % had warts for more

than 1 yr. Nearly half (42.9 %) the patients had taken previous treatment in which recurrences were seen in 15 and resistant warts seen in 6 patients. The rest (57.1 %) were treatment naive.

Weight of DPCP Powder	Volume (Acetone)	Percentile
2 gm	100 ml	2 %
1 gm	100 ml	1 %
500 mg	100 ml	0.5 %
200 mg	100 ml	0.2 %
100 mg	100 ml	0.1 %
10 mg	100 ml	0.01 %

Table 1. Formulation of DPCP

	Verruca Vulgaris	Verruca Plana	Filiform Warts	Plantar Warts	Palmar Warts
Scalp	1+1†	-	-	-	-
Face	2+1††	6	2	-	-
Extremities	14+1†+1††+3‡+5§+4¶	-	-	-	-
Palms	-	-	-	-	7+5§
Soles	-	-	-	4+4¶	-
Periungual	3‡	-	-	-	-

Table 2. Correlating Site and Type of Warts (N = 49)

†1 Patient had verruca vulgaris on scalp and extremities, †† 1 patient had verruca vulgaris on extremities and face,
‡3 patients had warts in periungual region and extremities, §4 patients had verruca vulgaris on extremities with palmar warts, 1 patient had palmoplantar warts, 3 patients had verruca vulgaris on extremities with plantar warts, 1 patient had palmoplantar warts.

Type of Warts	Complete Responders	Mean No. of Applications Required (Range)	Max. Concentration at which Response was Elicited	Concentration Range
Palmar warts (N = 10)	9	6.5 (3 - 10)	2 %	0.2 - 2 %
Plantar warts (N = 8)	6	7 (3 - 10)	2 %	0.2 - 2 %
Verruca vulgaris(N = 24)	19	7 (1 - 10)	2 %	0.2 - 2 %
Filiform warts (N = 2)	2	6 (5 - 7)	0.5 %	0.01 - 0.5 %
Verruca plana (N = 6)	5	4.4 (1 - 8)	0.5 %	0.01 - 0.5 %

Table 3. Response to DPCP According to Type of Warts in Complete Responders (N = 35)

	Characteristic	Complete Response (total = 35)	Partial / No Response (total=7)	P Value (*Yates' Correction)
Age group	Up to 12 yrs. (7)	3 (42.9 %)	4 (57.1 %)	0.009*
	13-18 yrs. (7)	7 (100 %)	0	
	More than 18 yrs. (28)	25 (89.3 %)	3 (10.7 %)	
Previous treatment	Yes (18)	16 (88.9 %)	2 (11.1 %)	0.403
	No (24)	19 (79.2 %)	5 (20.8 %)	
Duration of warts	Lea than 6 months (7)	7 (100 %)	0	0.416*
	6 months to 1 year (26)	20 (77 %)	6 (33 %)	
	More than 1 year (9)	8(88.9 %)	1 (11.1 %)	
Response to sensitization	Mild (14)	11 (78.6 %)	3 (21.4 %)	0.568*
	Moderate (21)	17 (81 %)	4 (19 %)	
	Severe (7)	7 (100 %)	0	

Table 4. Success Rate of DPCP According to Various Factors (N = 42)

Verruca vulgaris (59 %) was the most common type of wart followed by palmar warts (24.5 %), plantar warts (16.3 %), verruca plana (12.2 %) and filiform warts (4.1 %).

Extremities (other than palms, soles and periungual) (53 % patients) were the most common sites involved (53 % patients), followed by palms (24.5 %), face (22.4 % patients). Other sites of involvement were soles (16.3 %), periungual (6.1 %) and scalp (4.1 %). Correlation between site and type of warts is shown in Table 2. Number of warts varied between 5 to 79, with a mean of 15.6 warts. Nearly half the patients (49 %) were in the 5 to 10 wart group, while 15 (30.6 %) patients were in the 11 to 20 group, 5 (10.2 %) were in the 21-30 wart group and 5 (10.2 %)had more than 30 warts.

Author and Reference	No. of Patient	Wart Type	No. of Treatments	% of DPCP	% Cure	% Side Effects
Orecchia (1988)[15]	44	Face, Hand, Plantar	3 - 10	0.2 - 2.0	45	25
Rampen (1996)[13]	111	Hand, Plantar	8	0.001 - 3.0	60	4.3
Buckley (1999)[16]	48	Hand, Plantar	1 - 22	0.01 - 6.0	88	56
Upitis (2002)[12]	154	Palmoplantar	1	0.01 - 4.0	88	37
Aghaei (2006)[24]	6	Facial	8 - 10	0.001-1.0	66.6 (complete), others-partial	Unknown
Choi (2013)[17]	27	Periungual		0.1 – 2.0	85	17 (itch)
Yuvraj (2014)[18]	38	Palmoplantar, periungual, face	7.4 (median)	0.001 - 2.0	68.96 (facial) 78.57 (hand, foot warts)	60.52
Suh (2014)[25]	170	Hand, foot, face	2 - 24	0.0001 - 2 %	82.9	21.1
Park (2018)[14]	43	Multiple periungual and plantar warts	22.0 ± 24.7 (mean)	1×10^{-4} % to 1 %	75.6	
Present study	42	Palmoplantar, facial, glabrous, periungual, scalp	0 - 12	0.012 %	83.3 (complete), 7.14(partial)	45.5

Table 5. Comparison of Previous Studies for DPCP in Warts

Figure 1. Extensive Warts in a Child with Complete Excellent Response

Figure 2. Facial Warts in a Female with Complete Subsidence

Out of 49 patients tested for sensitization, 15 patients (30.6 %) had mild reaction, 23 patients (46.9 %) had moderate reaction and 10 patients (20.4 %) had severe reactions. A 24-year-old patient with verruca vulgaris on the

extremities failed sensitization and was excluded from the study. Forty-eight patients were recruited in the study. During treatment, 3 patients were lost to follow up, 1 patient voluntarily discontinued due to vesiculation and 2 patients were withdrawn from the study as they developed severe eczematisation. So, 42 patients were included in the final analysis. Out of 42 patients remaining, 35 patients (83.3 %) had complete response, 3 (7.14 %) patients had partial response and 4 (9.52 %) patients did not have response.

Response to DPCP according to type of warts in complete responders (35 patients) is shown in Table 3. All warts except verruca plana and filiform warts required 2 % DPCP for complete response. Number of applications varied from 1 to 10 in complete responders. One patient had complete response after sensitization, not requiring further applications. DPCP concentration at which response was seen varied from 0.2 % - 2 % in palmar warts, plantar warts and verruca vulgaris, 0.01 - 0.5 % in verruca plana and filiform warts. Number of applications ranged from 1 to 12 among all patients. In patients with partial response after 10 applications, two additional applications were administered. Among patients who had complete response, the mean number of applications required for response was 6.38.

Determination of various factors affecting response to DPCP is shown in Table 4. There was statistically significant association between the age group of patients and response to DPCP (P = 0.006). So, older the patient, better the response. There was no significant difference in success rates between resistant and untreated warts i.e. even patients with resistant / recurrent warts responded well to DPCP. The response to DPCP did not depend on the grade of sensitization, duration or location of warts. Among the type of warts, verruca vulgaris had 79 % (19 / 24 patients) complete response, filiform warts had complete (2 / 2) response, Palmar warts, verruca plana and plantar warts had 90 % (9 / 10) response, 83.3 % (5 / 6) response, 75 % (6 / 8) response respectively. The most common complication was eczematisation which occurred in 16.6 % of patients, seen at 0.5 - 2 % concentration. Other side effects were crusting (2.4 %), vesiculation (11.9 %), transient post inflammatory hyperpigmentation (9.5 %) and lymphadenopathy. Side effects were seen at a concentration range of 0.2 - 2 %. Two patients were withdrawn from the study due to extensive eczematisation. All the patients who showed clearance were followed up for 3 months. Only 1 patient had recurrence during the 3 month follow up period.

DISCUSSION

Out of the 42 patients analysed, 35 patients (83.3 %) had complete response, 3 patients (7.14 %) had partial response and 4 patients (9.52 %) did not have any response. Our study had 83.3 % complete response and 7.14 % partial response comparable to previous studies (Table 5). In a recent study done by Park et al.[14] the DPCP group showed response of 75.6 % which was partially less, because concentration of DPCP was less. In previous studies, response with DPCP varied in different studies.[12,13,15,16,17,18,19,20,21]

In our study complete response was seen in 83. 3 %. Among the type of warts, verruca vulgaris had 79 % (19 / 24 patients) complete response, filiform warts had complete (2 /2) response. Palmar warts, verruca plana and plantar warts had 90 % (9 / 10) response, 83.3 % (5 / 6) response, 75 % (6 / 8) response respectively. DPCP concentration at which response was seen varied from 0.2 % - 2 % in palmar warts, plantar warts and verruca vulgaris, 0.01 - 0.5 % in verruca plana and filiform warts. One patient had 79 warts, involving almost the entire scalp and also extremities. But with 8 applications of DPCP he showed dramatic complete response, proving efficacy of DPCP in treating extensive warts compared to conventional therapy.

When the age was compared with the response, p value was 0.006, so there was statistically significant difference between the age group of patients and response to DPCP. So, with increase in age, response was better which differs from some studies.[22-25]

All patients who had warts for less than 6 months had 100 % complete response. This was comparable with the studies done by Choi et al.[17] and Yuvraj et al.[18] where they found similar response. They reported that success rates decreased as the disease duration increased. However, in our study 88.8 % (8 / 9) had complete response even when the warts were of more than 1-year duration.

In the study by Park et al.[14] sensitizations were done on the wart with 0.1 % and gradually increased 3 times. Almost half of them failed sensitization. Both the sensitized group and failed group showed similar response. In our study sensitization was done with 2 %. Only one patient failed sensitization. Initial sensitization to DPCP did not have role in clinical response which was similar to our study i.e. irrespective of whether the sensitization was mild, moderate or severe, the response of warts to DPCP did not vary.

Partial Responders

Among the partial responders, all 3 patients were children, 1 patient had more than 90 % response but complete improvement was not seen. The other 2 patients had 60 % improvement.

Non Responders

Among the non-responders, one patient was a 30 yr. old male with verruca vulgaris on extremities and plantar warts since 18 months, he had mild reaction on sensitization but after 10 applications, patient did not show any response. Second patient was 6-year-old male child with 14 warts on extremities present since 12 months; this patient had moderate reaction on sensitization but did not show improvement on further application. Third and fourth patients were also healthy males with palmar and facial warts respectively.

Number of applications varied from 1 to 12 applications. One patient had complete response after sensitization not requiring further DPCP applications and no warts recurred in 3 months follow up. 3 patients had partial response after 10 applications, so applications were continued up to 12 without complete reduction. One limitation of our study was

limited number of applications. In various studies[12,16] application of DPCP was continued for many weeks. But we limited applications for better patient compliance. Among patients who had complete response, the mean number of applications required for response was 6.38, range varied from 1 to 10 applications. Plantar warts and verruca vulgaris required more number of mean applications compared to other warts.

Side Effects

Side effects were seen in 42.8 % of patients, with local eczematisation (16.6 %) being most common, followed by vesiculation (11.9 %), post inflammatory hyperpigmentation (9.5 %) though it was transient in maximum number of patients. Other side effects included crusting (2.4 %), vesiculation with lymphadenopathy (2.4 %). 2 patients had distant eczematisation for which they were treated with oral steroids, antihistamines and were stopped from further applications. 1 patient developed widespread severe eczematisation, even after applying lowest concentration of DPCP for first time on the affected area and another patient developed after second application with 0.2 % DPCP. Side effects in our study was comparable with various studies, in a study done by Naylor[21] recorded 49 % side effects, Buckley et al.[16] recorded 56 % side effects, Yuvraj et al.[18] recorded 60 % side effects, Upitis et al.[12] recorded 37 % side effects. Other studies[13,15] recorded fewer side effects which disappeared with topical steroids. But side effects were easily treatable, transient most of the times.

Recurrence

All patients who had complete response were further followed up for 3 months, only 1 patient among 35 patients (2.9 %), had recurrence of warts. In study done by Choi et al.[17] recurrence of warts was seen in 1 patient (1 / 23patients) after 6 months. Comparative study on the sustained efficacy of DPCP with cryotherapy in warts was done by Myeung et al.[23] where they found that sustained rate of clearance with DPCP was 97.8, 93.3 and 93.3 % but with cryotherapy it was 97.4, 84.2 and 76.3 % at 3 months, 6 months and 12 months follow up respectively.

Our study had a few limitations. The sample size was small. We also limited the number of applications to ensure compliance. In the real world setting, DPCP requires multiple applications and hence, patient compliance maybe an issue. Also treatment is required to be done under supervision.

CONCLUSIONS

DPCP had excellent response in maximum patients with multiple warts with 2 % concentration being required in maximum number of patients for complete response. The advantages of DPCP were its utility in resistant warts, ease of treatment especially in children (painless application) and mild cutaneous and treatable side effects.

So, DPCP is a promising, and effective treatment option in patients with multiple warts especially recalcitrant warts with good safety profile.

Limitations

Our study had a few limitations. The sample size was small. We also limited the number of applications to ensure compliance. In the real world setting, DPCP requires multiple applications and hence, patient compliance maybe an issue. Also treatment required has to be done under supervision.

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