A Randomised Clinical Trial of Mother Tincture (External) with Centesimal Potency and LM Potency of "*Thuja Occidentalis*" in the Case of Warts

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Abstract: <u>Background</u>: The human papilloma virus (HPV), which comes in over 100 different varieties, causes warts. HPV is most likely transmitted to the skin by minor trauma. Using public baths, working around poultry, and being immune compromised are all risk factors. Warts are harmless in immunocompetent individuals, and they disappear within months or years due to natural immunity. Objectives: To compare the role of Thuja occidentalis Mother Tincture (External) with Centesimal Potency and LM potency in cases of warts by comparing pre by using CWart assessment tool. Study Design: Randomized, Comparative, Interventional Study. Methods: 110 cases of warts were randomly allocated to the two treatment groups. In Group A (n=55 cases) homoeopathic medicine predefined medicine Thuja Occidentalis was selected on the basis of their totality and given in Centesimalpotency with external application. In Group B (n=55 cases) homoeopathic predefined medicine Thuja Occidentalis LM potency was selected. Intervention: A total 110 (55=Thuja Occidentalis M. T with centesimal Potency, and 55 =Thuja Occidentalis L. M.) cases, after screening, were randomized to receive either Thuja Occidentalis MT external with centesimal or LM once/twice daily for 90 days. Outcome Measurement: Assessment at baseline and reassessment after 3months was done using cwarts assessment tool as the homoeopathic medicine in centesimal scale was given twice a day to the patient on the daily basis while LM potency was prescribed as perguidelines of organon. Results: Cutaneous warts was found more common in the middle age group, males as comparison to females; among more in reported more in Middle socio-economic status people. Common warts was the commonest clinical type. In group A, 17 cases (30.90 %) showed marked improvement while 12 cases (21.81%) showed moderate improvement, 5 cases (9.09%) showed mild improvement 12 cases had stat quo (21.81%) while 1 case had non - significant In group B, 12 cases (21.81%) showed marked improvement, 23 cases (41.81%) showed moderate improvement, 10 cases (18.18 %) showed mild improvement followed by 7 cases (12.72 %) had status quofollowed by (0%) of non - significant improvement An Independent t - test was conducted to compare the effect of two approach in Group A and Group B. There is statistically no significant difference in the scores of group A (M=1.53, SD=1.069) and Group B (M=1.16, SD=1.085) conditions; where t (cal) = 0.129, p = .241. These results suggest that there is no significant difference is seen in preidentified Homoeopathic medicine Thuja Occidentalis incentesimal potency with external application and LM potency in the management of cases of warts. Hence Null Hypothesis is accepted. Conclusion: Both centesimal and LM potencies of Thuja Occidentalis have been found to be effective in the treatment of warts.

Keywords: Warts, Centesimal potency, External Application, LM potency, Thuja Occidentalis

1. Introduction

Verruca or warts are harmless, tiny, circumscribed, hard or popular elevations or growths of the skin and mucosa that occur in a number of shapes and sizes depending on the location, morphological structures, and etiology. They typically appear on the skin as tiny, rough, hard growths that resemble blisters^[1]

Warts may appear at any age and are most commonly seen on the hands of children and young adults. It's usually the size of a pinhead, rounded, rough or smooth, long and slightly elevated, and pink, yellow grey, or brown in colour. It may be a single item or a group of items.

The most common types of warts are common warts (verruca Vulgaris), filiform warts (digitate warts), flat warts (verrucae Plana), Plantar warts, genital warts (condylomata acuminata), oral and laryngeal papilloma, and epidermodysplasia verruciformis. The first four forms of

warts are almost always caused by HPV types 1, 2, 3, 4, 7. The most common causes of genital warts are HPV types 6, 11, 16, $18^{[2]}$

The action of medicine in fluid form is receptive to gans through olfaction and inhalation through the mouth. However, medicinal solutions can affect the rest of the body's skin, which is covered in skin surface, particularly if the inunction is combined with aninternal solution" External application of their own medicine as well as simultaneous internal administration are recommended in the treatment of fig wartsfor a complete cure. 8 Since it functions on the totality and individuality, homoeopathy has a holistic method. As a result, wart diagnosis should be based on homoeopathic concepts, the totality of symptoms, and miasmatic understandings. ^[3]

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2. Aim and Objective

2.1 Aim

To assess the role of *Thuja occidentalis* Mother Tincture (external) with Centesimal Potency and LM potency in cases of warts.

2.2 Objectives

- 1) To study type and features of warts by using diagnostic assessment of tool C Wart assessment tool.
- 2) To compare the role of *Thuja occidentalis* Mother Tincture (External) with Centesimal Potency and LM potency in cases of warts by comparing pre and post treatment number of warts.

3. Materials and Methodology

3.1 Study Setting

The study was conducted at O. P. D/I. P. D. of Dr. Girendra Pal Homoeopathic Hospital & Research Centre Saipura, Sanganer Jaipur (Rajasthan).

3.2 Study Duration

The study will be undertaken for a period of 12 months out of which cases will be registered in first nine month so that minimum 6 visits/ observations can be obtained from the last case.

3.3 Sample size

 110 ± 10 cases (keeping 10% dropout); 55 ± 5 for each group. To see the effects of two treatments in cases of wart in two groups i. e Group A and Group B, the mean difference in the effort of Group A and Group B is 0.6. By taking the standard effect size i. e 0.6 at 80% power, the size of the samples will be 50. The 10% dropout will be assumed in the given samples. On adding the 10% dropouts, the sample size will be 55 in each group of the study.

3.4 Inclusion / Exclusion Criteria

Inclusion Criteria

- Diagnosed Cases of Warts Will Be Included
- Patients Of all Age Group (also included 5 15years of age child), Both Sexes.
- Parental consent form
- Patient consent form

Exclusion Criteria

- Discontinuation of treatment in between and cases without proper follow up will be excluded from the study.
- Patients who require emergency medical conditions will be excluded from Study
- Pregnant females and females who are lactating will be excluded.
- Cases who refuse to give their consent for the study

3.5 Drop Outs

When Patient discontinues the treatment during the course of study and required Emergency treatment during the study.

3.6 Interventions

Group A: 55 Cases – Mother Tincture (External) with centesimal potency

Potency: Medicine was prescribed in 30c, 200c along with mother tincture (external) as per the prescribing totality, susceptibility of patient and intensity of symptoms.

Dosage and Repetition: As per the Hahnemannian guidelines in 5th edition of Organon of Medicine. Change of medicine and/or dosage was on Homoeopathic principles after observing change triggered after first prescription (statusquo/improvement/deterioration).

Group B: - 55 cases - Thuja Occidentalis LM Potency were prescribed.

Dispensing of intervention: Medicines were dispensed in globule form (size60) from dispensing unit of Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital and research centre, Jaipur (Rajasthan)

3.7 Medicinal Criteria46

Mental -

- 1) The body especially the limbs are made up of Glass and would break easily
- 2) Music is unbearable

Physical General

- 3) Bad effects of vaccination
- 4) Sweat only on the uncovered parts or all over excepting the head, especially at night when he sleeps
- 5) Suppressed gonorrhea causing particular rheumatism, prostatitis, impotency, condylomata tumors and cyst.
- 6) Desire for salt, cold food, and drinks

Particulars

- 7) Dirty brownish color of the skin, brownish white mottled spots on the skin
- 8) Warts on any part of the body with little stalk called Figwarts, tubular warts, flat warts, black senile warts even condylomata may be seen.
- 9) Eruptions burn violently after scratching.
- 10) Eruptions only on covered parts.
- 11) Cauliflower like growth of warts on the skin.
- 12) Large granulations like warts on one eye.
- 13) Large growth like polypi and condylomata on ears

Out of 13 symptoms of medicine 7 symptoms should be found in patient for inclusion.

3.8 Study Design

Interventional comparative parallel arm clinical trial

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3.9 Selection of Tool

- Detailed case taking Performa especially designed for the study.
- Formation of ms xl for data collection
- Patient information sheet –Appendix III, V
- Patient consent form Appendix IV, VI
- Individualized homeopathic medicines
- Scale C Warts
- C –wart scale
- Random number table

3.10 Data Collection

- 1) Data was collected after proper follow ups and maintained in soft and hard copy. A complete history, examination and required investigation were done.
- 2) Case taking proforma: A special case taking Performa was designed for the study with the approval of guide.
- Case taking: Detailed case taking for every screened case was done on especially designed case taking proforma, based on homoeopathic principles.
- 4) Diagnostic criteria: Clinical examination and relevant investigation were carried out to establish the diagnosis.
- 5) Follow ups: All the cases were reviewed at the interval of 7 15 days and data was recorded for minimum 6 follow ups.
- 6) Record: Centralized data was recorded in approved master chart in proper excel format.
- 7) Auxiliary measures: Patients were advised to maintain proper hygiene and avoid wearing of wet clothes. Body should be properly wiped after bathing and all clothing should be properly dried in sunlight. No medicated creams or ointments to be used during the period of study. All other treatments for the same infection is to be avoided.

3.11 Data Analysis

Data will be analysed as per the baseline score of the demography of the samples. Also according to the scores obtained from the C Warts scoring method, following formula will be applied after calculating before and after scores.

Percentage= <u>Score at Baseline – Score at the end x 100</u> Score at Baseline

Following parameters would be fixed according to the type of the response obtained after the treatment – Marked Improvement= 75% - 100% Moderate Improvement= 50% - 75% Mild Improvement= 25% - 50% Non significant= <25% Status quo= 0%

3.12 Statistical Techniques

Before treatment - [mean± SEm] After treatment - [mean± SEm] Data will be analysed by using SPSS software and Excel. The statistical technique to be used will be -'Independent t - test' and 'Paired t - test'.

- Independent t test will be used to compare two treatment groups.
- Paired t test will be used to assess the before and after scores in each patient.

Observation and Results

Warts was found more common in the middle age group, among more in reported more in Middle socioeconomic status people. Common Warts was the commonest clinical type. Out of 110 cases had marked improvement, group A 17 cases (30.90%) showed marked improvement while 12 cases (21.81%) showed moderate improvement, 5 cases (9.09) showed mild improvement 12cases (21.81%) showed stat quo. In group B, 12 cases (21.81%) showed marked improvement, 23 cases (41.81%) showed moderate improvement, 10 cases (18.18%) showed mild improvement followed by 7 cases (12.72%) had status quo.

Paired T - test:



 \bar{x} = Standard error of the mean difference Sd= Standard Diffusion

n= sample size

3.13 Consent & Confidentiality

- 1) Patient Information Sheet: was given to each & every patient where they were Sensitized about the study. (Appendix III).
- 2) Consent form: Informed consent was obtained from every recruited patient Including adequacy of the information being provided to the subjects and Confidentiality of identity was maintained. (Appendix -III).
- 3) All the evaluation forms, reports and other records related to the study were kept confidential.

3.14 Ethical Clearance

Yes, ethical has verified the methodology

Observation and Results

Warts was found more common in the middle age group, males as comparison to females; among more in reported more in Middle socioeconomic status people. Common warts was the commonest clinical type. In group A, 17 cases (30.90 %) showed marked improvement while 12 cases (21.81%) showed moderate improvement, 5 cases (9.09%) showed mild improvement 12 cases had stat quo (21.81%) while 1 case had non - significant In group B, 12 cases (21.81%) showed marked improvement, 23 cases (41.81%) showed moderate improvement, 10 cases (18.18%) showed mild improvement followed by 7 cases (12.72%) had status quo followed by (0%) of non - significant improvement.

An Independent t - test was conducted to compare the effect of two approach in Group A and Group B. There is

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statistically no significant difference in the scores of group A (M=1.53, SD=1.069) and Group B (M=1.16, SD=1.085) conditions; where t (cal) = 0.129, p =.241. These results suggest that there is no significant difference is seen in preidentified Homoeopathic medicine Thuja Occidentalis incentesimal potency with external application and LM potency in the management of cases of warts. Hence Null Hypothesis is accepted.

4. Discussion & Conclusion

From the study various epidemiology, clinical and therapeutic observations have been made.110 cases have been studied with their types, manifestation, complication, associated conditions etc. various epidemiology, clinical and therapeutic observations have been made.99cases were studied with their manifestation, associated conditions etc. Homoeopathic medicine *Thuja occidentalis* were prescribed after detailed case taking and case processing

From the results of this study, the conclusion can be drawn that individuals suffering from Tinea corporis showed effective improvement by homoeopathic medicine selected via both approaches. Medicines are effective not only in the case of Warts, but also in their quality of life.

This study findings helps in recognizing homoeopathic medicine in different potencies as effective treatment modality which will help clinical practitioners in choosing better treatment modality. After conducting this study, It is recommended that randomized controlled trial of *Thuja occidentalis* with different potency in larger sample size and with longer study duration will help.

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Group A,	Before	After	Group	Before	After
N=55	Treatment	Treatment	B, N=55	Treatment	Treatment
Mean	2.73	1.53	Mean	2.69	1.16
S. D	1.521	1.069	S. D	1.426	1.085
SEM	0.205	.144	SEM	.192	.146
t - value	6.789		t - value	11.357	
Df	54		df	54	

In Group A, Paired sample t - test result, to assess the effect of Thuja Occidentalis CH potency post treatment (M = 1.53, S. D. = 1.069), compared to pretreatment (M = 2.73, S. D. = 1.521) by number of warts in cases were improved by Thuja Occidentalis CH potency, difference of mean=1.200, t ($_{55}$) = 6.789, P=0.000. Number of warts reduced after taking Thuja Occidentalis

In Group B, Paired sample t - test result, to assess the effect of Thuja Occidentalis LM potency post treatment of (M = 1.16, S. D. =1.085) compared to pre treatment (M =2.69, S. D. =1.426) by number of wart in cases were improved byThuja Occidentalis LM potency, difference of mean =1.527, t ($_{55}$) = 11.357, P =0.001

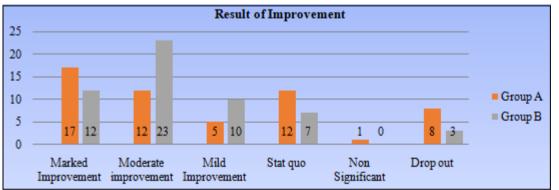


Figure: Graphical comparative representation of 110 cases of Warts according to "Status of Patients" in Group A and Group B

Out of 110 cases group A - 17 cases showed Marked improvement (30.90%), 12 cases showed Moderate Improvement (21.81%) 5 cases showed Mild Improvement (9.09%), 12 cases showed stat quo (21.81%) while 1 case is non - significant (1.81%). In Group B maximum cases of warts are located on face i.e.13 (23.63%), i. e. . cases11 on Neck (20%), 6cases (10.90%) on Hands, 5 cases on Leg (9.09%), 4 cases on Finger (7.27%), 3 cases each (3.63%) eyelids & back, whereas 1 cases each of (1.81%) of lips, forehead Feet and forearm.

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