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EVALUATION OF COMPARATIVE EFFICACY OF INTRALESIONAL *APAMARGA KSHARODAK* VERSUS INTRALESIONAL CIDOFOVIR IN THE MANAGEMENT OF *CHARMAKEELA* (WARTS)

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ABSTRACT

Background: *Charmakeela* is an ancient term denoting a nail-like or skin attachment, recognized since antiquity for its cosmetic significance. It's classified as a minor ailment (kshudraroga) by *Acharya Sushrutha*, with its pathology attributed to an imbalance of *vyana vata* and *kapha* affecting the skin, resulting in the formation of a firm, nail-like protrusion termed *Charmakeela*. Its characteristics vary depending on the dominant *dosha*: dry and painful for *Vata* dominance, dark-colored for *Pitta* dominance, and oily with nodules for *Kapha* dominance. This condition shares similarities with warts based on classical indications and symptoms. In modern understanding, warts, typically caused by Human Papillomavirus (HPV), are a common dermatological issue. *Sushrutha* discusses *Charmakeela* within the framework of *Kshar Karma*, a therapeutic procedure utilizing caustic alkaline substances. *Kshara*, renowned for its cleansing and antibacterial properties, aids in the healing process. *Ksharodak*, a solution containing alkalis, is recognized as a beneficial therapy for *Charmakeela* (warts). **Aim:** Evaluation of comparative efficacy of Intralesional *Apamarga Ksharodak* versus Intralesional Cidofovir in the management of *Charmakeela* (Warts). **Materials:** Numerous sources on *Ayurveda* abound,

including ancient texts like the *Samhitas*, online materials, scholarly articles, and published books. **Methodology**: After analyzing the drugs, 60 eligible individuals will be selected and split into two groups of 30 each. Group A will receive a single dose of Intralesional Cidofovir, while Group B will receive a single dose of Intralesional *Apamarga Ksharodak*. Assessments will occur on the second, fourth, and sixth days post-intervention, followed by follow-ups on the eighth and fourteenth days. **Results:** The findings from assessing both subjective and objective characteristics will yield outcomes. **Conclusion:** The study's findings will be drawn from statistical analysis conducted on the gathered data.

Trial registration: CTRI/2023/01/048654 Date of registration: 02/01/2023 Registration URL: https://ctri.nic.in/Clinicaltrials/rmaindet.php?trialid=77201&EncHid=80774.27870&modid=1&compid=19

KEYWORDS: *Sushrutha Samhitha;* Ksharodak; Human Papilloma Virus; *kshanana; Charmakeela; Warts.*

INTRODUCTION

The *Sanskrit* words "*Ayur*" (life) and "Veda," which form the name "*Ayurveda*," is used to describe the medicinal system, which has its true origins in India (Science of knowledge).[1] In the term "*Charmakeelatheethi*," any object resembling a nail or adhering to the skin is referred to as a "*charmakeela.*".[2] According to *Ayurveda*, this ailment resembles *Charmakeela*. Its pathophysiology is attributed to an imbalance of *Vata* and *Kapha* over the skin, leading to the development of a hard nail-like structure akin to *Charmakeela*.[3-6] Depending on which *dosha* is dominant, they exhibit various traits. *Ruksha* and *ruja* are the characteristics of a *Vata*-dominant *Charmakila* (Warts), *krishna varna* is the characteristic of a *Pitta*-dominant *Charmakila* (Warts), and *twacha varna*, *snigdha*, and *granthi* are the characteristics of a *Kapha*-dominant *Charmakeela* (Warts).[7]

Warts, also known as verrucae, are common and harmless viral infections affecting the skin and mucous membranes, caused by the Human Papillomavirus (HPV). The most common means of transmission is direct contact, however autoinoculation is conceivable.[8] The most prevalent method of transmission for warts, direct contact is the most common way for HPV to spread Although self-inoculation is an option for harmless viral infections affecting the skin and nearby mucous membranes.[9] Warts frequently develop on the face, hands, feet, legs, and external genitalia. Mucous membranes come in a variety of forms, including

common, flat, plantar, anogenital, cervical, laryngeal, and others. Warts are benign epidermal proliferations that are often small, hard, rough growths that are color-matched to the surrounding skin. Other than when on the sole, where they may be uncomfortable, they normally do not exhibit any symptoms. There are many different types of warts, such as flat, mosaic, periungual, plantar and more. The form and location of these warts on the skin varies.[10] Non-genital warts are categorised morphologically into five kinds in the study: common, flat, palmoplantar (found 1 cm which is limited to the soles and palms), filiform/digitate warts and mosaic (many tiny popular wart which joined into one centimetre plaques). palmoplantar (twenty %), Common (forty two %), flat (eighteen %), and filiform/digitate (four %), mosaic (six %), were the other foot types. Warts were the most morphologically diverse non-genital warts.[11]

Multiple recurring warts typically demand more costly and time-consuming treatments. Observation, which is also a component of therapy, should always be included. Within 24 months, almost two-thirds of warts spontaneously vanish. The biggest downside is that the wart has a potential of becoming larger and spreading to other locations. Usually, initial treatment involves topical medications. Salicylic acid is commonly used as a first-choice treatment for common warts. It's accessible for home use without a prescription. This treatment resolves warts in around 50% to 70% of patients. Other treatment options include retinoic acid, cryotherapy, podophyllin, interferon, topical 5-fluorouracil, and imiquimod.[12]

In the *Sushruta Samhitha Sutra Samhita*, *Sushruta* essentially lists four treatment methods as *chikitsopakarma* for *Asrha* (piles): *bheshaja* (medication), *ksharakarmas* (alkali preparation), *agnikarmas* (cauterisation), and *Shastrakarmas* (surgery). He places particular emphasis on *ksharakarma*, which is also effective for treating *kadar* and *Charmakeela*. Two varieties of preparation of *ksharas* exist: *paniya kshara* intended for use of internal and *prathisaraneeya kshara* intended for outward use. *Prathisaraneeya kshara* comes in three variants: *Mrudu* (gentle action), *Madhyam* (moderate action), and *Tikshna* (potent action).[13] Within this research, we are going to use *Aparmag Ksharodak* intralesional at the base of *Charmakeela* this can be a another treatment option for *ayurvedic* modility.

Objectives

1. To study the efficacy of Intralesional *Apamarga Ksharodak* on the subjective and objective parameters of *Charmakeela* (Warts).

2. To investigate the effectiveness of intralesional cidofovir on the *Charmakeela* (Warts) subjective and objective measures.
3. To evaluate the effectiveness of intralesional cidofovir and intralesional *apamarga ksharodak* on the subjective and objective *Charmakeela* (Warts) criteria.

Case definition

Charmakeela patients exhibiting clinical characteristics based on *dosha* dominance. For warts, the primary characteristics associated with *Vata dosha* are dryness and pain; those linked with *Pitta dosha* are dark coloration; and those related to *Kapha dosha* are oily texture, smooth skin, and nodular formations. Small, fleshy, grainy lumps that are rough to the touch and sprinkling with black pinpoints—small, occluded blood vessels—are described in modern medicine. Routine hemograms, BT & CT scans, ESR tests, HIV, HbsAg, HPV serology, and RBS tests will be used to confirm the existence of *charmakeela*.

Research Question

Whether Intralesional *Apamarga Ksharoadak* is equal, more efficacious than Intralesional Cidofovir for the management of *Charmakeela* (Warts)?

Null Hypothesis (H_0)

Intralesional *Apamarga ksharoadak*is not efficacious as Intralesional Cidofovir for the management of *Charmakeela* (Warts).

Alternative Hypothesis

(H_1): Intralesional *Apamargaksharoadak*is equally efficacious as Intralesional Cidofovir in the management of *Charmakeela* (Warts).

(H_2): Intralesional *Apamargaksharoadak*is more efficacious than Intralesional Cidofovir in the management of *Charmakeela* (Warts).

MATERIALS AND METHODS

A parallel-design, randomised control study with a 1:1 allocation ratio between the two groups. The following formula was used to determine the sample size of 60 people, with 30 in each of the trial and control groups: n1=kn.2, n2=(za2/=zb) 2x2 (1=1k/) (m.E-mC-d)2. The computerised table method of random sampling will be used as the sampling approach. The MGACH AND RC in Wardha, Maharashtra, India, would be the site of the study. The research is anticipated to last from January 2023 to August 2024, or one and a half years. The

reference number for the approval obtained from the Institutional Ethical Committee (IEC) is MGACHRC/IEC/Aug-2022/567. The CTRI/2023/01/048654 registration number for the study is attached to it. Prior to the trial commencing, informed consent will be obtained. The study protocol's Gantt chart may be seen in [Table-1]. Trial registration: CTRI/2023/01/048654, Date of registration: 02/01/2023 RegistrationURL: https://ctri.nic.in/Clinicaltrials/rmaindet.php?trialid=77201&EncHid=80774.27870&modid=1&compid=19

Table 1: Gantt Chart (Quarterly based).

Steps	Q1	Q2	Q3	Q4	Q5	Q6
Enrolment of patients	■					
Drug collection and preparation		■				
Data collection			■			
Writing thesis parts up to methods				■	■	
Data analysis				■	■	
Writing rest of thesis						■
Submission						■

Inclusion criteria

- The patient gives written, informed permission in accordance with the Helsinki Declaration.
- The age range of 17 to 70.
- Patients exhibiting painless, tiny, rough, and hard growths that resemble skin warts.
- Patients without regard to their gender, line of work, or financial situation.

Exclusion criteria

1. Diabetes Mellitus that requires insulin and is not well regulated, Uncontrolled Hypertension, Tuberculosis, Carcinoma, Endocrine Disorders and Kidney or hepatic disorder.
2. Sites of warts – sensitive places like: genitals, eye lids, lips, etc.
3. History of anticoagulants and haemophilla.
4. Pregnant and lactating females.
5. Substantial abnormalities in hematological.

Drug collection/authentication, as well as drug production details

The raw materials will be sourced from local markets, while the pharmaceuticals will undergo recognition and validation by the *Dravyaguna*, Department of MGACH & RC, Salod (H), Wardha.

Primary results

The primary goal is to investigate the effectiveness of Intralesional *Apamarga Ksharodak* on subjective and objective criteria in the treatment of *Charmakeela* (Warts). Intralesional *Apamarga Ksharoadak* may reduce size, discomfort, and produce shade off the lesion as a primary consequence.

Secondary outcomes

Enrollment and intervention schedule: Intralesional *Apamarga ksharodak* will be given one time and follow up will be done on day 2^{nd}, 4^{th}, 6^{th} days and Revisit will be done on 8^{th} & 14^{th} days.

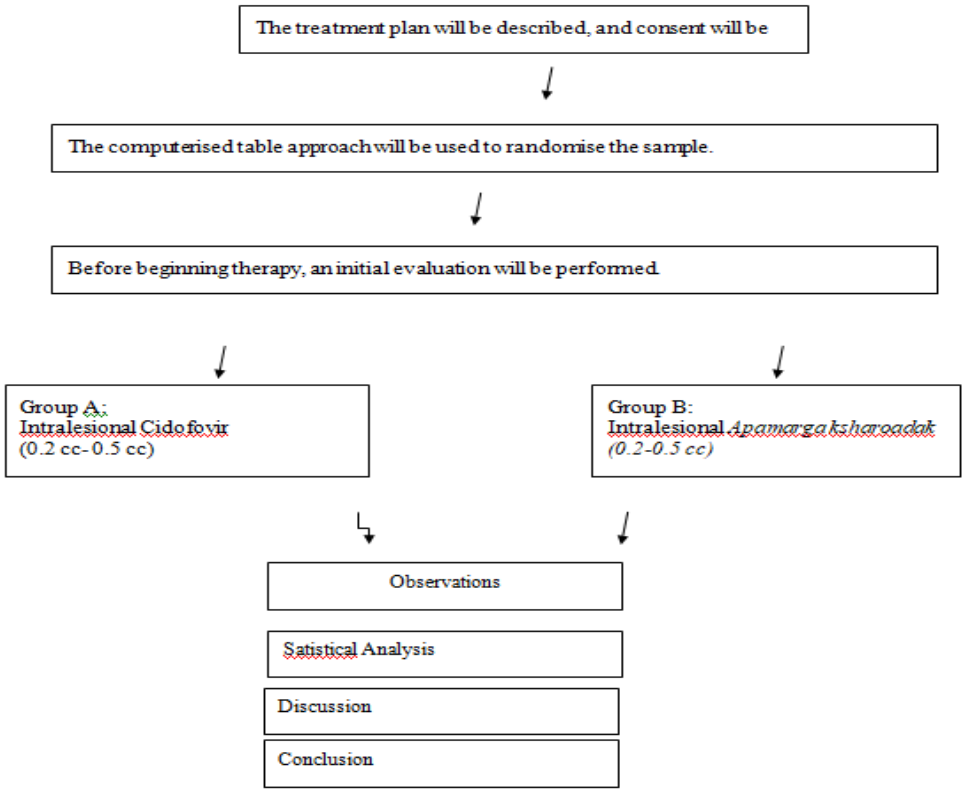
Implementation

At least 30 patients will be included in each of the two groups. [Table-2].

Table 2: Grouping and posology.

Group	Sample size	Intervention	Duration	Follow up	Revisit
Control Group A	30	Intralesional Cidofovir (0.2 cc- 0.5 cc)	7 Days	2^{nd}, 4^{th}, 6^{th} day	8^{th}, 14^{th} Day
Study Group B	30	Intralesional *Apamarga ksharoadak (0.2-0.5 cc)*	7 Days	2^{nd}, 4^{th}, 6^{th} day	8^{th}, 14^{th} Day

Study Plan



Assessment criteria[14]

Objective Parameters:

- Size of lesion
- Pain

Subjective Parameters:

- Discharge
- Burning sensation

Gradation of Symptoms

Objective Parameters

- Size of Lesion: Regression-reduction in size of lesion theory is used. The lesion was measured by vernier caliper.
- Pain: Pain is examined by the VAS Scale.

Subjective Parameters

- Burning sensation: It is graded using a system such as G0- No Burning. G1- Localised and occasionally scorching sensation G2- Moderate, with a burning sensation at times. G3-More localised and often burning; G4-Continuous burning.
- Tenderness: Dr. Frank Painter's grading for tenderness.

Data administration

The data will be coded by the principal investigator.

Assent or consent: Before beginning the research, the subject will be asked to provide written consent. Each patient's confidentiality will be preserved during the research.

Policy on Dissemination

The dissemination of information will occur through publication in scientific journals. Guidelines regarding who qualifies as an author and any deliberate involvement of professional writers will be clearly outlined.

Materials for informed consent

Participants will be provided a permission form and other necessary papers along with all of the information model.

ANALYSIS STATISTICAL

We are using SPSS for statistical analysis. To determine the significance of observations, we will employ the Mann-Whitney U test, the Wilcoxon signed-rank test, and the Student's t-test. These tests will evaluate both objective parameters such as stone size, location, and presence of blood in urine, as well as subjective parameters like pain and discomfort. We have set the significance level at 95%.

DISSCUSION

Warts are benign skin growths that have been a problem for humans since the dawn of time. Several treatment procedures have been used to treat them. Breaking the *samprapti* and preventing its recurrence are the fundamental goals of *Ayurvedic* treatment. *Lekhana karma, kshara karma,* and *agnikarma* make up the main management of *Charmakeela* in *Ayurveda*. These techniques could eradicate viral colonies and stop recurrence.[1] As per our traditional text, *kshara* acts by digesting inflamed tissues to reduce the size of the lesion. Its warming and penetrating nature enables it to dissolve blockages caused by imbalances of *kapha* and

vata. Application assists in healing wounds with significant pus accumulation. It aids in cleansing and repairing wounds, while also stopping itching and bleeding by stabilizing and drying the wound and absorbing excess moisture.[15] As a result, we shall attempt to assess the efficacy of Intralesional *Apamarga Ksharodak* in patients for the treatment of *Charmakeela* (Warts).

Ethical considerations

This study will commence upon receiving approval from the Institutional Ethics Committee (IEC) of Mahatma Gandhi *Ayurveda* College Hospital and Research Centre, Salod (Hirapur), Wardha. Subsequently, it will be registered prospectively with the Clinical Trial Registry of India (CTRI), as per government regulations.

Competing interests

No conflicts of interest were declared.

Data availability statement

No data are associated with this article.

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