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Research Article

A CLINICAL TRIAL ON THE EFFICACY OF *BHALLATAKADI LEPA* IN *CHARMAKEELA* W.S.R. CUTANEOUS WARTS

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ABSTRACT

Ayurveda described few diseases under the heading of *Kshudra roga. Charmakeela* is one of them and it is simple and does not cause threat to life but it has a cosmetic problem, which results in considerable distress to the patients when they are seen on face and exposed part of the skin. *Bhallatakadi lepa* has prepared for this study. Total 15 patients suffering from *Charmakeela* (Warts) were selected for study, 5 patients dropped out due to various regions and remaining 10 patients treated with *Bhallatakadilepa*. The duration of the trial was one month with a further follow up of two months. The data collected was statistically analyzed for the interpretation of results. *Bhallatakadilepa* was found not effective in reducing number of warts or size of warts. Though mild ASR's (Application site reactions), including pruritus, irritation or burning sensation, erythema, hyper and hypo-pigmentation and LSR's (Local skin reactions) including dryness or scaling, hyperpigmentation, hypo-pigmentation, irritation or burning sensation and erythema were seen in some of the patients. So the conclusion of the study is that the lack of efficacy of the trial drug may be attributed mainly to the seasonal variations in the drug collection, drug potency and drug adulteration from market places, which were practically inevitable during this research work. The research may also consider a longitudinal / prospective study in order to obtain complete analysis of the drug.

KEYWORDS: *Charmakeela*, Warts, *Kshudra Roga, Bhallatakadilepa.*

INTRODUCTION

Ayurveda considered as a science of life has contributed a lot to human kind to achieve longevity and healthy life with the help of nature. Ayurveda described few diseases under the heading of *Kshudra roga*[1], meaning that category of diseases that do not need major attention or the diseases that are simple and do not result in any complications or cause threat to life. Diseases like *Nyaccha, Vyanga, Indralupta, Tilkalak* and *Charmakeela* are not causing any noticeable discomfort but still their impact on body and mind is such that the individual suffering from such diseases falls into a state of distress.

Charmakeela[1]is one such condition, which under ordinary circumstances does not show any severe problem however, it has a cosmetic problem, which results in considerable distress to the patients when they are seen on face and exposed part of the skin.

In modern science, *Charmakeela* can be correlated with Warts[2] (Verruca vulgaris). Warts are benign proliferations of skin and mucosa caused by the human papilloma virus (HPV). Currently, more than 100 types of HPV have been identified. The primary clinical manifestations of HPV infection include common warts, genital warts, flat warts and deep palmoplantar warts (myrmecia), less common manifestations include focal epithelial hyperplasia (Heck disease), epidermodysplasia verruciformis and plantar cysts.

Therefore, the patients need to get rid of the *Charmakeela* without any disfiguration at the site of onset like discoloration or scar etc. Treatment ranges from folk remedies to sophisticated modern techniques but the important factors remain that there is no complete cure. Surgical removal contraindicated as it leads to scarring and recurrence, curettage and diathermy give results but later often accompanied by pain and scar.

Application of *Lepa* is safe and does not usually require any numbering of the area. It is a very easy procedure as it is less time consuming. *Lepa* does not lead to any cosmetic or body disfiguration. It is acceptable, available, approachable and affordable.

Hence an attempt is made here to manage the *Charmakeela* through complete removal by maintaining the integrity of the skin at the site of onset. Thus keeping this aspect in mind the external application of *Bhallatakadilepa*[3] on *Charmakeela* is selected for the management of *Charmakeela*.

MATERIAL AND METHODS

Prospective, Randomized, Controlled, Unicentric, Single blind Trial; where a total number of 15 patients with *Charmakeela* were enrolled in this study.

Selection criteria

Inclusion criteria

- Patient's age ranging from10-60 years was selected.
- Subjects with classical signs and symptoms of *Charmakeela* (common warts, filiform warts, plane warts)
- Subjects who were ready to give written informed consent.

Exclusion criteria

Tuberculosis, Facial warts, Anogenital warts, Deep palmoplantar warts, Focal epithelial hyperplasia / Heck disease, Mosaic warts, Cystic warts / Plantar epidermoid cyst, Immunocompromised or unstable patients, Immunosuppressive medications users, Previous recent participation in trial, Uncontrolled Diabetes Mellitus, Uncontrolled HTN, CKD patients, HIV, HBsAg patients, Pregnancy and Lactation, Who are not willing to give written informed consent, Those with STD's.

Withdrawal criteria

- If the subject withdraws consent for any reason
- If the subject is lost to follow-up
- If the subject fails to adhere to the protocol requirements
- If the subject's clinical condition worsens in spite of currently prescribed medications.

Assessment criteria

- **Primary outcome measures:**

Clearance

Clearance	Numerical score
Complete	**0**
Partial	**1**
No change	**2**

2. Photographic representation

Secondary outcome measures

Application site reactions (ASR's)

- Purities
- Irritation/burning sensation
- Erythema
- Hyper/Hypopigmentation

Local skin reactions (LSR's)

- Dryness/ scaling
- Hyper/Hypopigmentation
- Erythema
- Irritation/ Burning sensation

Physical examination was done for each patient to assess the number, location of the lesions, and presence of other types of warts. The nature of the disease, course, prognosis, and full information related to the therapy including the possible side effects, action, and way of application were explained to the patients. Formal consent was taken from each patient prior to their inclusion in this study; in addition, the approval of the ethical Committee of institutional ethical committee, NIA, Jaipur was also obtained.

Drug Review-*Bhalltakadi Lepa*

Ingredients

Sr.no.	Name of drug	Botanical name	Used part
1.	*Bhallataka*	*Semicarpus anacardium*	Fruit
2.	*Gajapippali*	*Scindaspsus officinale*	Fruit
3.	*Snuhi*	*Euphorbia antiquorum*	Root
4.	*Arka*	*Calotropis procera*	Root
5.	*Shunthi*	*Zingiber officinale*	Rhizome
6.	*Maricha*	*Piper nigrum*	Fruit
7.	*Pippali*	*Piper longum*	Fruit
8.	*Gunja*	*Abrus precatorius*	Fruit
9.	*Sankha*	*Turbinella rapa*	Powder
10.	*Tutha*	Copper sulphate	Powder
11.	*Kustha*	*Sassurea lappa*	Root
12.	*Saindhavlavana*	Sodium chloride	Powder
13.	*Sovarchallavana*	Unaqua sodium chloride	Powder
14.	*Samudralavana*	Sodimuris	Powder
15.	*Vida lavana*	Ammonium salt	Powder
16.	*Audbhidalavana*	Reha salt	Powder
17.	*Yavakshara*	Potassium bicarbonate	Powder
18.	*Sajjikshara*	Sodium bicarbonate	Powder
19.	*Langalika*	*Gloriosa superba*	Root

Drug preparation

Take equal quantity of above mentioned each drug and make them to powder and cooked on weak fire in iron pot. Add *Arka, Snuhi* latex four times to the total powder and mix well with the help of an iron rod or stirrer and make paste in a *Kharal* and pack in air tight glass container.

Dosage Schedule: Sufficient quantity of the prepared drug was mixed in *GulabJal* (to make it paste) at the time of application.

Method of application: Patients were instructed to apply thin layer of medicine to cover the wart area by using an applicator (tooth pick), twice in a day.

Precautions: Leave it to dry for 2-3 min.

All patients were reexamined at the end of every week for one month to evaluate the response to treatment depending on clinical and photographic assessment and to record any possible side effects.

The patients were considered as responder when there was complete disappearance of warts; however, if there was no change, the patients were considered as non-responder; if there is a decrease in the number of warts, the patients were considered as partial responder.

If complete response occurred at the end of one month or earlier, patients were followed up monthly for 2 months to detect any recurrence or persistent side effects, the follow-up was performed by monthly visit or by phone calling the patients.

Statistical Analysis

A descriptive statistics like mean and SD (standard deviation) together with analytic statistics like Chi-squared test, Fisher's exact test have been done when appropriate.

RESULTS

A total of 15 patients were included in this study but five patients were dropped out from the study due to various reasons and this study completed by 10 patients only.

This group comprised of 8 (80%) males and 2 (20%) females with a male to female ratio of 4 : 1. Ages ranged from 10 to 50 years (mean±SD = 31.6±11.31). The number of warts in each patient ranged from 1 to 30 (mean ± SD = 8.6±13.3). The duration of the lesions ranged from 1 to 24 months with a mean duration of 14.1±19.2.

Cure Rate at the End of Fourth Week

Response		***Bhallatakadilepa***	**Total**
Complete clearance	NO.	00	00
	%	00	00
Partial response	NO.	00	00
	%	00	00
No response	NO.	10	10
	%	100	100

None of the patient had shown response to treatment and was considered as treatment failure. Even the partial response (decrease in number or size or both) was also not observed.

Regarding Side Effect

Sr.No.	**ASR**	**No.**	**%**	**LSR**	**NO.**	**%**
1	Pruritus	7	70	Dryness or scaling	5	50
2	Irritation or burning sensation	6	60	Irritation or burning sensation	7	70
3	Hyperpigmentation	1	10	Hyperpigmentation	1	10
4	Hypopigmentation	2	20	Hypopigmentation	2	20

Regarding the side effects, Application site reactions (ASR's) including Pruritus (7 patients 70%), irritation or burning sensation (6 patients 60%), dyspigmentation like (hyper-1, hypopigmentation-2) side effect were recorded as ASR's.

In local skin reactions (LSR's) including dryness or scaling (5 patients, 50%), irritation or burning sensation (7 patients 70%), dyspigmentation (hyper-1, hypo-pigmentation-2) side effect were recorded as LSR's.

DISCUSSION

This study showed that the trial drug, *Bhallatakadilepa* had not shown effect against *Charmakeela*/warts, hence the trial group was considered as treatment failure.

The probable causes of treatment failure or non-efficacy of *Bhallatakadilepa* might be because of

Ayurvedic classics were written after a lot of clinical trials (Empirical) by our *Acharyas* hence it is illogical to challenge the formulation- *Bhallatakadilepa*, for its non-efficacy, as most of the ingredients like *Bhallatak, Gunjaphal, Arka* and *Snuhi Ksheer, Kshar* etc. are *Teekshna dravyas.*

So, the other factors which influence the efficacy of the drug such as Season, Time, Place of Collection, Storage, Adulteration etc. are to be taken into consideration which might have influenced the pharmacodynamics of the compound drug, imparting clinical non-efficacy.

In this research work raw drugs except *Ksheer* were purchased from the market, and the drug collection part was hence skipped from this work, to comment. *Bhallatak* was taken in purified form. In the process of Research, *Ksheer* was collected in the month of end-February, while classics advised to collect in *Sharadritu* (as per *Acharya Charaka*) and *Hemanthritu* (as per *Acharya Susruta*) which falls during October- November and December-January respectively, the seasonal variation of which might have resulted in the lack of potency of the obtained *Ksheer.*

S. No.	Important ingredients of *Bhallatakadi Lepa*	PH Value
1	*Snuhi Ksheer*	4.89
2	*Arka Ksheer*	4.81
3	*Bhallatakadi Lepa* without *Snuhi & Arka Ksheer*	7.13
4	*Bhallatakadi Lepa* with *Snuhi & Arka Ksheer*	6.54
5	Distilled water	6.97
6	Rose water	6.42

By observing the pH values; *Bhalatakadilepa's* pH is 6.54 which is weakly acidic and towards neutral. This might be the cause for non-efficacy of *Bhallatakadilepa*.

To rule out the cause for weak acidic nature of the *Lepa,* further workup was done on pH of the ingredients of *Lepa.* The ingredients of *Lepa* consist of two *Ksheer-Snuhiksheer* and *Arkaksheer* with pH 4.89 and 4.81 respectively and two *Kshara- Sarji* and *Yavakshar*. The amalgamation of these *Ksheer* and *Kshar* (acid and alkali) and the variation in collection period of the drugs, variation in *Desa* & *Kala* and probable adulteration of other ingredients might have rendered a weakly acidic nature to the final drug- *Bhallatakalepa*, the potency of which is visible through its non-efficacy.

CONLUSION

The lack of efficacy of the trial drug may be attributed mainly to the seasonal variations in the drug collection, drug potency and drug adulteration from market places, which were practically inevitable during this research work. Consideration and control of these practical disadvantages could yield the efficacy of the drug as claimed in the classics. The research may also consider a longitudinal/prospective study in order to obtain complete analysis of the drug.

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