



A PRE-POST STUDY TO EVALUATE THE ANTIMICROBIAL EFFICACY OF TUTTHAKADI MALAHARA IN DUSHTAVRANA (NON-HEALING ULCER)

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ABSTRACT:

Background: Chronic ulcers or non-healing ulcers are defined as ulcers that are unresponsive to initial therapy or that persist despite appropriate care and do not proceed towards healing in a defined time period with an underlying etiology. Major cause for delayed healing of an ulcer is infection by micro-organisms. The flora of non-healing ulcers is usually polymicrobial. Bacteria in an infected wound produce inflammatory mediators that delays phases of healing. Due to increasing antibiotic resistance there is wide scope for exploring Ayurvedic formulations which are cost effective with *vrana shodhana* (cleansing of wound bed) and *ropana* (healing) property. **Aim** - To evaluate the antimicrobial effect of *Tutthakadi malahara* in non-healing ulcer by assessing the microbial load, discharge type and amount and severity of pain. **Materials and methods:** This is a pre and post clinical trial with 26 participants in a single group selected on the basis of inclusion and exclusion criteria. Topical application of *Tutthakadi malahara* once daily for a period of 28 days followed by assessment of microbial load in pus culture, discharge and pain. Assessment was done on 0th, 7th, 14th, 21st and 28th day for subjective parameters (Pain in non-healing ulcer assessed on 0th, 7th, 14th, 21st and 28th day) and objective parameters (Microbial load in pus culture and Discharge type and amount, assessed on 0th, 7th, 14th, 21st and 28th day). **Results:** Both subjective and objective parameters were statistically significant with P value < 0.001. **Conclusion:** On analysing the results, it can be concluded that *Tutthakadi malahara* can be used effectively in *dushtavrana* (non-healing ulcer) to reduce microbial load, discharge and pain.

Keywords: *Dushtavrana*, *Tutthakadi malahara*, Non healing ulcer

INTRODUCTION

An ulcer is a discontinuity of the surface epithelium or molecular death of the surface epithelium.[1] If the normal healing process is interrupted, an ulcer can become chronic in nature. As per Indian epidemiological data, the prevalence of chronic non-healing ulcers was reported to be 4.5 per 1000 population [2]. It is estimated that almost 10% of the population would develop a chronic wound in the course of a lifetime with wound related mortality rate of 2.5% [3]. Infection of an ulcer with a large number of bacteria delays the healing process.[4] The clinical signs and symptoms of infectious ulcer includes increasing pain, increase in wound exudate, presence of slough or nonviable tissue at wound base and unpleasant odour.

Acharya Susruta has mentioned detailed management of *Vrana*. *Lepa* is one of the major procedures in *Vrana Chikitsa* while describing the *Shashtirupakrama*. *Lepa* act as both *Sodhana* and *Ropana*[5] . The process of *shodhana* aims at keeping the wound bed free from microbial load, reduces exudation and removes foul odour.[6]

Although there are various formulations to treat non healing ulcer there is recent emergence of herbomineral dressing due to its wide antibacterial spectrum. The contents of *Tutthakadi Malahara* as per *Rasatarangini* 21st *Taranga- Upadhathwadi vijaniya* are *Tuttha* (Copper sulphate), *Tankana* (Borax), *Khatika* (Calcium carbonate), *Kaparda bhasma* (Cyprae moneta), *Rala choorna* (resin of *Shorea robusta*) and *goghrita* (cowghee). This formulation have the property of *vrana shodhana*, *pooya nissarana* (eliminates pus) and *vividha vrana*

nashana (wide use in management of different type of wound).[7] The present study with *Tutthakadi malahara* is proposed with an economically feasible, cost effective, easily available ingredients and conservative treatment for non-healing ulcer.

AIM

The aim of this study was to evaluate the effect of topical application of *Tutthakadi Malahara* in reducing the symptoms of non-healing ulcer.

OBJECTIVE

To evaluate the antimicrobial effect of topical application of *Tutthakadi Malahara* in non-healing ulcer by assessing microbial load, discharge and pain.

MATERIALS AND METHODS

Diagnosis was made on the basis of clinical examination and by pus culture and sensitivity. Patients were monitored regularly, and observations were recorded before, during and till the end of study period.

Study Setting

OPD and IPD, Dept. of Salyatantra, Govt. Ayurveda College, Trivandrum. The study was conducted for a period of 1.5 years from 01/04/2023 to 31/08/2024.

Study Design:

Interventional pre and post study in a single group. The consort flow diagram of the study is provided in chart 1.

Study Population

Participants between the age of 30-70 years irrespective of gender with non-healing ulcer attending the OPD and IPD of Salyatantra Department, Government Ayurveda College, Thiruvananthapuram.

Sampling method: Consecutive sampling

Sample Size: 26

Trial Drug Details:

Name of the trial drug: *Tutthakadi Malahara* [7]

Ingredients of the *yoga* (*Tuttha, Tankana, Kapardika Bhasma, Khatika, Rala and Goghrita*) were collected from a GMP certified shop and the genuinity or authenticity of drugs were ensured. Preparation and storage of drug was done in a clean and safe condition.

Preparation Of *Tutthakadi Malahara*

Goghrita 2 *tola* (24 g) was melted and to it *Rala churna*- 1/8 *tola* (1.5g) was added until it became a uniform mixture. Then powdered *Shodhitha* (purified) *Tuttha*-1\8 *tola* (1.5g), *Khatika*-1 *tola* (12g), *kapardika Bhasma* (1 *tola*) and purified *tankana* (1 *tola*) were added and triturated. Then water was added and rubbed several times till the water was clear, the resultant mixture was *Tutthakadi Malahara*. It was stored in an airtight glass container containing sterile water and water was changed every day.

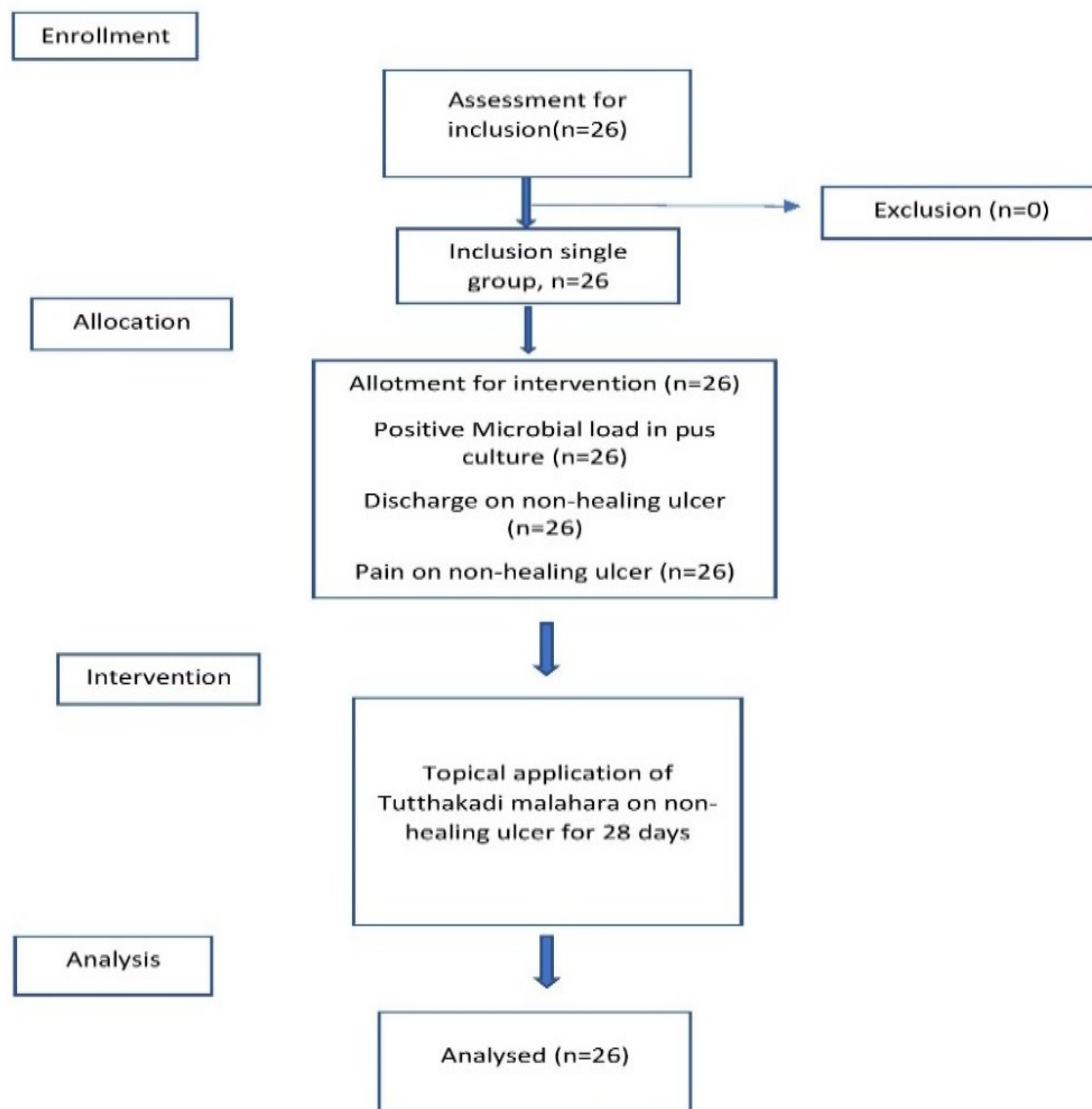


Chart 1: Recruitment of patients

Selection Criteria:

Inclusion criteria:

- Non healing ulcer with microbial load in pus culture, discharge and pain.
- Participants irrespective of gender within the age limit of 30-70 years

Exclusion criteria:

- Known cases of HIV, Hepatitis B or other sexually transmitted infections.
- Known cases of Tuberculosis, Leprosy, bleeding disorders
- Uncontrolled diabetes mellitus.
- Gangrenous ulcer
- Malignant ulcer
- Trophic ulcer

Intervention:

Participants with non-healing ulcer was subjected to topical application of *Tutthakadi Malahara* once daily for a maximum period of 28 days. The swab test for microbial load were done on 0th ,7th ,14th ,21st and 28th day after cleaning the ulcer with distilled water. After swab test ulcer was dressed with *Tutthakadi malahara*. Similarly severity of pain, discharge type and quantity were assessed on 0th,7th ,14th ,21st and 28th day.

Treatment Period: 28 days.

After the intervention period participants were given standard treatment for healing of the ulcer and further follow up was not done.

Assessment Criteria [8]

Clinical assessments based on subjective and objective parameters were made on 0th day, 7th day,14th day,21st day and 28th day. Swab test for

pus culture and sensitivity was taken on 0th,7th,14th,21st and 28th day.

The outcome measures assessed were microbial load in pus culture, discharge and pain.

Subjective Parameter:Table 1. Pain

VRS		
No pain	No complaint of pain	0
Mild pain	Bearable pain requires no treatment	1
Moderate pain	Pain bearable upto some extend	2
Severe pain	Unbearable pain (disturbed sleep)	3

Objective Parameters:

Table 2. Pus culture- microbial grading

MICROBIAL GRADING	EXPLANATION
0	ABSENT
1	MILD
2	MODERATE
3	SEVERE

2.Discharge

Table 3. Amount of discharge

0	No discharge
1	Mild-If <i>vrana</i> wets 1 sterile pad of 4x4cm size
2	Moderate-If <i>vrana</i> wets 2 sterile pads of 4x4cm size.
3	Profuse discharge-If <i>vrana</i> wets more than 2 sterile pads

Table 4. Type of discharge

0	Serous drainage: clear or light yellowish
1	Sanguinous drainage: bright red
2	Serosanguinous drainage: pink
3	Purulent drainage: thick and yellow or pale green

Data Analysis

The data related to various assessments of both subjective and objective parameters, before and at the end of treatment of 26 participants were taken for statistical analysis. The result of treatment was analysed through Wilcoxon Signed Rank Test for subjective parameter like pain and objective parameters like microbial loading, discharge type and amount, to interpret the significant changes.

OBSERVATIONS & RESULTS

In this study group, based on Wilcoxon Signed Rank test, the subjective parameter like pain and objective parameters like microbial grading, discharge type and amount showed a significant improvement after treatment.

Microbial load on Day 0 and Day 7, were relatively high with means of 2.69 and 2.73, respectively. By Day 14, the mean decreased to 2.07. A more significant drop was observed by Day 21, with a mean of 1.58. By Day 28, the microbial load further diminished to a mean of 0.81, with yielding p-values of less than 0.001 indicating a substantial decrease in microbial presence over the 28-day period.

The mean discharge amount grade was consistent at 2.38 on Day 0 and Day 7. However, as the days progressed, a noticeable decrease in both mean and median values occurred, with the mean falling to

0.96 reflecting a shift towards lower amount of discharge grades as time progressed. The comparison between Day 0 and Day 7 yields a Z-score of 0 with a p-value of 1, indicated no statistically significant change between these two time points. Significant reductions in discharge amount were observed when Day 0 is compared with Day 14, Day 21, and Day 28, where the Z-scores are substantial (exceeding 3.7) and p-values were less than 0.001, indicating statistically significant decreases in discharge amount over time.

The mean discharge type rating started high at 2.81 on Day 0 with a low standard deviation (SD) of 0.40, reflecting a relatively consistent initial condition across the sample. Over time, both the mean and median values decreased, reaching the lowest values of 0.83 and 0 (median) by Day 28, with an increased SD of 0.99, indicating greater variability in discharge types as the days progressed. The comparison between Day 0 and Day 7 showed a Z-score of 1 with a p-value of 0.317, indicating no significant change in discharge types over this period. However, significant decreases in discharge type ratings were noted in comparisons from Day 0 to Day 14, Day 21, and Day 28, with Z-scores exceeding 3.7 and p-values less than 0.001 in each case with a notable shift from purulent to serous discharge.

The mean pain score is relatively high at 2.43 on 0th Day. As the days progressed, there was a noticeable decrease in both the mean and median pain scores, reaching 0.81 and 1 respectively by Day 28. This trend indicated a significant decrease in pain levels over the 28-day study period. 1. MICROBIAL LOAD – GRADING

Table 5. Descriptive Statistics of Microbial Load Measurements

Variable	Mean	SD	Median	IQR
Day0	2.69	0.47	3	2-3
Day7	2.73	0.45	3	2-3
Day14	2.07	0.62	2	2-2
Day21	1.58	0.75	1	1-2
Day28	0.81	1.27	0	0-2

Table 6: Wilcoxon Signed-Rank Test Results for Microbial Load Measurements

Comparison	Z-score	P-value
Day0 vs Day7	0.58	0.564
Day0 vs Day14	3.77	<0.001
Day0 vs Day21	4.07	<0.001
Day0 vs Day28	4.16	<0.001

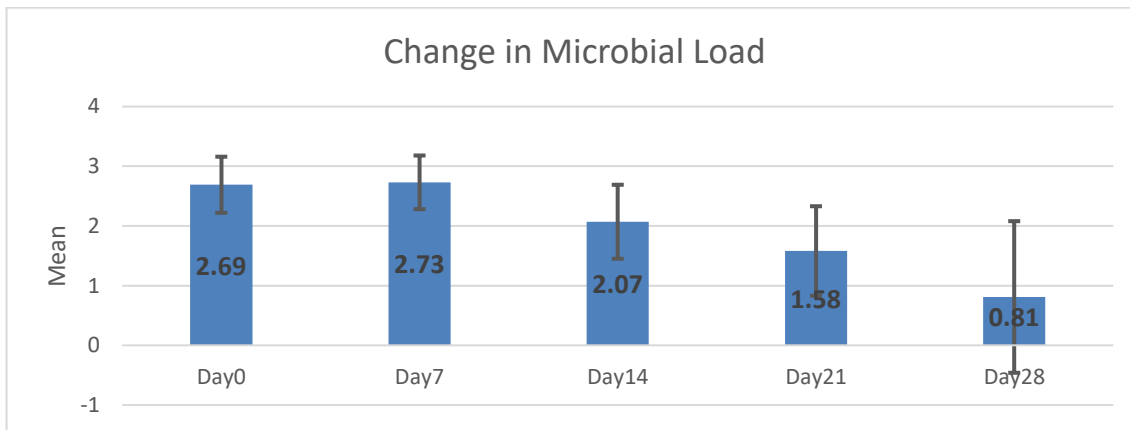


Figure 1: Mean reduction on Microbial load

2-DISCHARGE AMOUNT GRADING

Table 7. Descriptive Statistics of Discharge amount grade by day

Variable	Mean	SD	Median	IQR
Day0	2.38	0.75	3	02-03
Day7	2.38	0.8	3	02-03
Day14	1.62	0.7	2	01-02
Day21	1.23	0.71	1	01-02
Day28	0.96	0.77	1	0-2

Table 8: Wilcoxon Signed-Rank Test Results for Discharge amount grade by day

Comparison	Z-score	P-value
Day0 vs Day7	0	1
Day0 vs Day14	3.726	<0.001
Day0 vs Day21	4.609	<0.001
Day0 vs Day28	4.554	<0.001

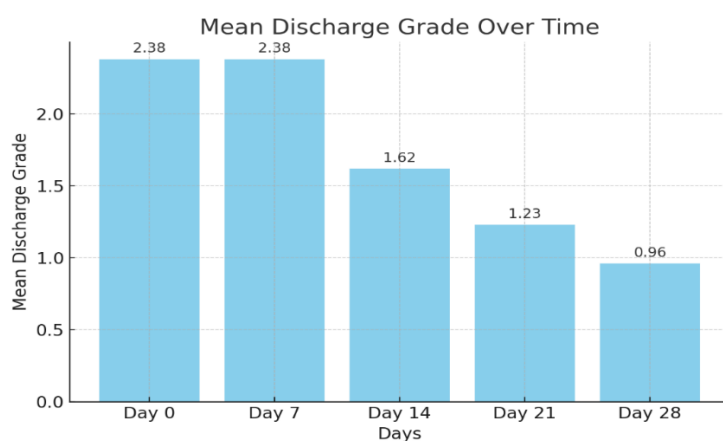


Figure 2: Mean reduction on Discharge amount

3. DISCHARGE TYPE GRADING

Table 9. Descriptive Statistics of Discharge Type by Day

Variable	Mean	SD	Median	IQR
Day0	2.81	0.40	3	3-3
Day7	2.77	0.51	3	3-3
Day14	1.84	0.90	2	2-2
Day21	1.36	0.95	2	0-2
Day28	0.83	0.99	0	0-2

Table 10. Wilcoxon Signed-Rank Test Results for Discharge type

Comparison	Z-score	P-value
Day0 vs Day7	1	0.317
Day0 vs Day14	3.726	<0.001
Day0 vs Day21	4.609	<0.001
Day0 vs Day28	4.554	<0.001

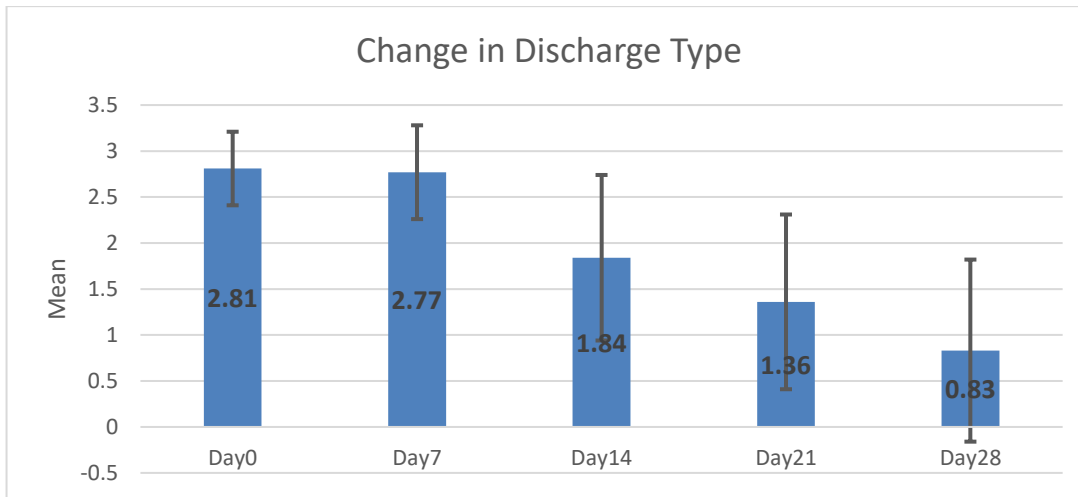


Figure 3: Mean reduction on change in discharge type

4-PAIN GRADING

Table 11. Descriptive Statistics of Pain Measurements by Day

Variable	Mean	SD	Median	IQR
Day0	2.43	0.64	2.5	2-3
Day7	2.23	0.71	2	2-3
Day14	1.92	0.84	2	1-3
Day21	1.35	0.94	1	1-2
Day28	0.81	0.89	1	0-1

Table 12. Wilcoxon Signed-Rank Test Results for Pain Measurements by Day

Comparison	Z-score	P-value
Day0 vs Day7	2.24	0.025
Day0 vs Day14	3.3	0.001
Day0 vs Day21	4.29	<0.001
Day0 vs Day28	4.48	<0.001

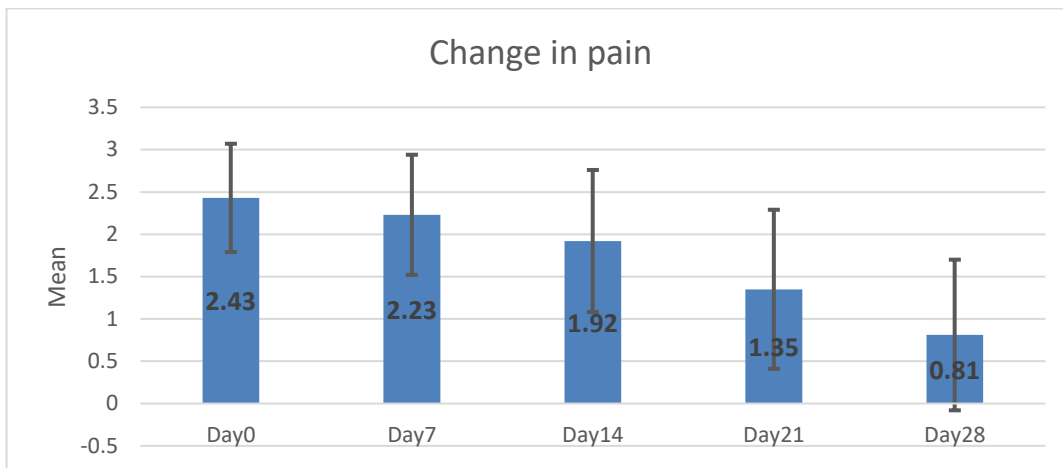


Figure 4: Mean reduction on Pain

DISCUSSION

Discussion on sociodemographic data

As per the study males constitute a significant majority at 76.92%, This is because compared to females, males due to the nature of work like strenuous activities, long standing, alcohol or smoking habits, improper wound care, inadequate rest are likely to develop chronic ulcer. The age distribution focuses on four age ranges: 30-40, 40-50, and 50-60,60-70 years. The majority of the group falls into the 60–70-years age range, accounting for 46.15%. This data signifies healing is slow as the age advances. Most participants suffer from varicose ulcers, making up 84.62% of cases. Among leg ulcers, varicose ulcer is seen more in general population, same is reflected in the study sample.

Discussion based on clinical response

The study was mainly aimed to evaluate the antimicrobial effect of *Tutthakadi malahara* in reducing the microbial load, pain and discharge in 26 participants for a treatment period of 28 days. The subjective parameter like the pain got reduced significantly after treatment. Among 26

participants, 13 participants had severe pain,11 participants had moderate severity of pain and 2 participants had mild pain before treatment, 12 patients had no pain at the end of study period,8 participants had mild pain and 5 participants had moderate pain and 1 participant had severe pain. Out of the 26 participants with microbial load, the micro- organism present before study was absent after treatment in 18 participants.18 participants had severe microbial grading, 8 participants had moderate microbial grading before the treatment which reduced to severe microbial grading in 5 participants and moderate microbial grading in 3 participants. Among 26 participants,18 patients had significant reduction in the amount of discharge and 8 patients had no discharge at the end of study period. Among 21 participants with purulent discharge and 5 participants had serosanguinous discharge before the treatment on 0th day, at the end of study period 10 participants had serous discharge,7 participants had serosanguinous discharge, 1 participant had sanguinous discharge and 8 participants had no discharge in the sterile pad used for dressing. Initially after application of

malahara the consistency of thin purulent discharge were changed to thick purulent discharge on 7th day later the consistency changed during the study period. Microbial loading in pus culture, discharge type and amount, pain was statistically significant with $P < 0.0001$. The present study was aimed at evaluating the antimicrobial effect of *Tutthakadi malahara* in non-healing ulcer. The statistical interpretation of effect of clinical study based on different outcome variables, were tabulated and graphically plotted. The qualitative data analyzed statistically by Wilcoxon's signed rank test which showed statistically and clinically highly significance. On analysis of the results, it can be concluded that *Tutthakadi malahara* is effective in reducing the microbial load, discharge and pain in non-healing ulcer which is also cost-effective, safe, and easy to implement in clinical practice.

LIMITATIONS OF THE STUDY

- No follow up was done after study period as standard treatment for the healing was advised after completion of study period.
- The current study was limited to the antimicrobial effect, but we have additionally observed a healing effect for the intervention which was not assessed hence future studies can be planned on the same with a control group.

Probable mode of action of the drug

The drugs included in *Tutthakadi malahara* are *Tuttha*, *Tankana*, *Kapardika Bhasma*, *Khatika* and *Rala choorna*. *Tuttha* possess *Katu* (pungent), *Kashaya* (astringent) *rasa* (taste), *ushna virya* (hot in potency), *katu vipaka*. *Katu rasa* has

Vrana Shodhana, *Kushthaghna* (alleviates skin disorders), *Krimighna* (antimicrobial) and *Lekhana Karma* (scrapping effect). *Kashaya rasa* has *Vrana Shodhaka*, *Vrana Ropaka* and *Kleda Shoshaghna Karma* (dries out excess moisture). *Tuttha* is *Kaphapittaghna* (pacifies kapha and pitta dosha), it has *lekhana*, *krimighna* and *vrana shodhana* property which results in reduction of *srava* (exudate) and antimicrobial action. It is suggested that copper nanoparticles release their ions by creating electrochemical potential onto the cell membrane of bacteria that leads to the disruption of the bacterial cell due to oxidative stress.[9] *Tankana* possess *Katu rasa*, *Tikshna* (penetrating), *ruksha guna* (creates dryness), *ushna virya*, *katu vipaka* and has *kaphavishleshaka* property which results in decreasing *srava*. *Tankana* comes under *kshara varga* (alkali), *Ksharakarma* (application of caustic alkali) is one of the best treatment modalities for *Dushtavrana* described by *Acharya Sushruta*. *Vrana* with *Utsanna* (Protruded) *Katinamamsa* (hard in consistency), *Chirothita* (long standing) *Dushoddhya* (purifactory therapies are contraindicated) and *Kandu* (associated with itching) should be treated by *Ksharakarma*. Due to its *Ushna Teekshna*, *Chedana*, *Bhedana*, *Dharana*, *Lekhana* properties, it helps in wound debridement and makes the ulcer bed clean and free from microbes. It also possesses *vatasamana* (pacifies vata) property which result in reduction of pain and is *vrana nashana* which aids in better wound healing. *Kapardika Bhasma* possess *Katu*, *tiktha rasa*, *ruksha*, *Tikshna guna*, *ushna veerya* and *katu vipaka*. It has *kaphapittaghna*,

lekhana, sravahara property which results in reduction of discharge and is *Vatasamaka* which results in reduction of pain. Modern studies also show significant antimicrobial, antiseptic, anti-inflammatory and wound healing effect of *Kapardika. Khatika* exhibits sweet and bitter tastes, oily properties, and cooling potency, and possesses properties that mitigate *pitta*, purify blood, promote wound healing, and reduce discharge and pain. Similarly, modern wound dressings utilize calcium carbonate, which has been shown to exhibit hemostatic, hygroscopic, and antibacterial properties. Its hemostatic action and rapid fluid absorption facilitate reduced discharge from wounds. *Rala* possess *Kashaya rasa, ruksha guna, ushna veerya, katu vipaka*, it has got *kaphapittahara, vranashodhana, ropana, raktadoshahara* (removes toxins in blood) and *krimighna* properties. Modern research work shows the oleoresin of *Shorea robusta* possess analgesic and stronger and broader spectrum of antimicrobial action which aids in faster wound healing.[10][11][12] *GoGhrita* (cow ghee) possess *Madhura rasa* (sweet taste), *snigdha guna* (unctuous), *seetaveerya* (cold in potency), *Madhura vipaka* .It is *tvachya* (good for skin), *Vatapittasamana* and *vishahara* (removes toxin) which results in *vedanaprasamana* (pacifies pain) and *kriminashana* (antimicrobial). Hence the study demonstrated the antimicrobial, anti-inflammatory and analgesic properties of the drug, proving its role in the management of non-healing ulcer.

CONCLUSION

The trial drug was found to be effective in reducing the microbial load, discharge and pain in non-healing ulcer. No adverse events of the drug were noted during the course of treatment. Hence it can be concluded that *Tutthakadi malahara* is effective in the management of non-healing ulcer with delayed healing due to heavy microbial load.

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