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Comparative Antiseptic activity of Sarjarasa Malahar; when prepared with or without Tuttha: A randomized clinical trial

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Abstract
Aim: To compare the antiseptic activity of Sarjarasa Malahara prepared with or without tuttha by external application on padadari (crack heel).
Materials and Methods: 20 no. patients of padadari taken and randomly divided in 2 groups, group 1 treated with Sarjarasa Malahara prepared with tuttha and group 2 treated with sarjarasa malahara prepared without tuttha and their comparative antiseptic activity noted. Assessment criteria for the comparison - no. of cracks and length of cracks are used.
Results: In Group 1 - when Sarjaras Malahara prepared with Tuttha applied daily from the day one, gradually Cracks were reduced from mild to zero cracks, moderate to mild and severe to mild. In Group 2- when Sarjaras Malahara prepared without Tuttha, applied continuously from the day one, gradually Cracks were reduced from mild to almost no cracks, moderate to mild and severe to moderate.

Keywords: Tuttha, Sarjaras Malahara, padadari, visha, amruta, maharasa

Introduction
Tuttha 6th Maharasa Dravya, also known as copper sulfate, “blue vitriol” and “bluestone” is considered as copper sulphate in English with chemical formula CuSO4.5H2O[1]. Mythologically it is considered as vomitus of Garuda deva; after drinking amrita and halahala (toxic substance), Garuda deva vomited on the mountain of marakata (name of mountain) [1]. There after this vomitus, the combination of amrita and visha solidified and collected as Tuttha [1]. It is also called as Sasyak, Tutthanjana, Mayuraka, Tamragarbha, Shikhigreeva etc [1]. It is available in natural and manufactured artificially with the combination of copper and sulphur. The Tuttha having shikhikantha chaya (like peacock neck color), neela varna (bluish color), guru (heavy), snigdha (unctuous), mahojwala (bright) qualities, is to be considered for therapeutic purpose [1].
The properties of Tuttha as a bhasma are mentioned by Ayurvedic classic as pungent (Katu), alkali (Kshara), astringent (Kashaya), light to digest (Laghu), emetic (Vamaka), scraping (Lekhana), penetrating (Bhedana), hot (Usna) in potency, good for eyes (Chakshushya), pacifies Kapha and Pitta [2].
Ayurveda classical texts indicate to use in skin diseases, ulcer, sinus, worm infection, vitiligo, obesity, pain, asthma, hyper acidity, haemorrhoids and diseases of eyes etc [3]. Anti-microbial, useful in Diabetes mellitus, anti-obesity, strengthening, anti-inflammatory, heart disease, skin diseases, Vitiligo, Hyperacidity and as Rejuvenator [3].
Tuttha is used in various kalpas in Ayurveda, commonly in the healing kalpa like Sarjarasa malahar, Jatyadi tail, Jatyadi ghrut, Kasisadi tail etc also in Trailokyachintamani rasa, Mahajwarankush rasa, Varishoshan rasa etc that are used to treat the inflammatory conditions.
Malahar or ointments are generally easy to use, or easy to apply on body parts, easy to prepare and cost-effective, also malahar has a property like oleation, cleansing, healing, scaraping, and beutifying depends on the drugs used in the preparation [4].
so, the tuttha used in ointment i.e. sarjarasa malahar. Which is used for the further study.

Objective of the study
It is an attempt to compare the antiseptic activity of sarjarasa malahara prepared with or without tuttha used to treat the disease padadari (crack heel).

Materials and Methods

Selection of the drug

Drug required to prepare sarjarasa malahar are, Til tail (16 Parts), Ral (4 Parts), Tuttha (1 Parts), Kankshi (1 Parts).

The sample of Tuttha were collected from the local market. It was then evaluated to check whether it matched the grahya lakshanas (acceptable qualities described in classical ayurvedic texts) the assessment confirmed that the sample possessed the required characteristic's and was suitable for therapeutic use. Also, the sample of tiltail, Ral and kankshi collected from local market and identified.

(Quantitative analysis revealed that Tuttha before purification contains copper - 23.78%, Sulphur - 11.98%, Iron - 0.33% [3]. After purification of Tuttha with Lemon juice, the content of copper was 26.74%, iron was 0.76% and sulphur was 8.46%) [3].

Apparatus Required: Stainless steel vessel, spatula, cotton cloth, gas stove and cylinder.

Methods: It involves following pharmaceutical procedures:

1. In a clean stainless-steel vessel Til taila was taken and placed over mild flame.
2. Heat was given until foam starts appearing.
3. After some time required amount of Ral was added to it according to reference.
4. After some time, Ral (Sarjarasa)completely melts in oil then added kankshi at given proportion.
5. Tuttha was added at given proportion along with kankshi, and after completely melts in oil then it was filtered to another clean vessel containing water.
6. Then manthana is done till the complete achievement of Malahara like semisolid consistency.

Same procedure repeated without adding of tuttha for preparation of Sarjarasa malahara without Tuttha.

Precautions

1. Heat was kept mild throughout the process.
2. It was stirred continuously to prevent the material from burning.
3. Mixture was poured immediately after melting into the vessel containing water.

Clinical study

Source of Data: A total twenty patients, aged between 15 to 60 years were diagnosed with Padadari (crack heel). were selected for the study and divided in two group randomly, Group 1 - Treated with Sarjarasa Malahara prepared with Tuttha. & Group 2 - Treated with Sarjarasa malahara prepared without Tuttha.

Study design: A clinical study on the efficacy of sarjarasa malahar prepared with or without tuttha in the management of Padadari (crack heel) was conducted.

Inclusion and exclusion Criteria for Patients

Inclusion Criteria

1. Patients exhibiting the classical sign and symptoms of Padadari (crack heel)., Lakshana of Padadari (crack heel). such as: 1. Padayo Kurute Daari (Cracks in feet) 2. Saruja (with pain) 3. Ruksha (dryness of feet).
2. Patients aged 15 years to 60 years were included in the study.
3. Patients from both the gender were eligible for inclusion.

Exclusion Criteria

1. The patient diagnosed with systemic disorders (e.g. DM, HIV etc.) were not included.
2. The pregnant women and lactating mother were not included in the study.
3. Patient less than 15 yrs. and above 60 yrs. of age were excluded.
4. Patient with history of allergy.
5. Any infection-intervening conditions were excluded.
6. Intervention: Drug: Sarjarasa malahar prepared with or without tuttha.

Method: External application on affected area.

Time: Morning and evening Treatment.

Duration: 15 days: Follow up during treatment: After every 7 days.

Assessment criteria: Assessment and scoring were performed based on the classical sign and symptoms of padadari (crack heel). Therapeutic outcomes were assessed through both subjective and objective criteria. A comprehensive assessment was carried out based on multiple research parameters. Assessment was done 0^{th} 7^{th} & 15^{th} day during the entire study period.

Objective parameters and their Assessment criteria -

Total number of cracks observed on the hands and feet -

1. G0 - No crack
2. G1 - 1-10 crack
3. G2 - 11-20 crack
4. G3 - > 20 crack

Overall length of cracks measured in millimetre

1. G0 - Absent
2. G1 - < 10mm
3. G2 - 10-20 mm
4. G3 - > 20 mm

The overall assessment of the therapy was conducted after treatment, based on both subjective and objective parameters. The percentage of improvement was calculated and classified as follows -

1. Maximum improvement - > 75% improvement.
2. Moderate improvement - > 50% to 75% improvement.
3. Mild improvement - > 25% to 50% improvement.
4. Unsatisfactory - Negligible (≤ 25%) improvement.

Observations

In the present study, 20 patients were selected and randomly assigned to two groups, group 1 & group 2 out of these, 10 patients diagnosed with Padadari (Crack Heel) were selected for the treatment with Sarjarasa Malahara prepared with Tuttha and considered as group 1 and 10 patients treated with Sarjaras Malahara prepared without tuttha are considered as group 2. The trail was completed by all selected patients without any discontinuation.

At the onset, the vital data of all the patients of this series are being oriented. Thereafter, the therapy is described.

Crack of feet Among 10 patients of group 1- 30% had mild crack, 50% had moderate crack, and 20% had severe crack.

Measured length of cracks in the 10 patients of group 1 - 50% with superficial cracks, and 50% with severe cracks.

Crack of feet Among 10 patients of group 2 - 30% patients show mild cracks, 60% patients show moderate cracks, and 10% patients presents severe cracks.
Length of cracks Among 10 patients of group 2- superficial cracks were observed in most patients i.e. 60%. and 40% patients with severe cracks.

Results
Group 1: The count of cracks on the feet was measured in each of 10 patients as follows - 30% patients present with mild crack, 50% with moderate crack, and remaining 20% shows severe cracks.
Measured length of cracks in the 10 patients of group 1 - 50% patients present with superficial cracks; and remaining 50% shows severe cracks.
With consistant application of Sarjarasa Malahara prepared with Tuttha from the day one, the cracks showed progressive healing over time, from mild to zero cracks, moderate to mild and severe to mild.

Group 2: the number of cracks present in the 10 patients was assessed - 30% patients present with mild crack, 60% with moderate crack, and remaining 10% shows severe cracks.
Measured length of cracks in the 10 patients of group 2- most of the patients, 60% shows superficial cracks; and remaining 40% presents with severe cracks.
With consistant application of Sarjarasa Malahara prepared without Tuttha, from the day one, cracks showed progressive healing over time from mild to zero cracks, moderate to mild and severe to moderate.

Here are the results of the statistical tests
Within-Group Comparison (Before vs. After Treatment)
Group 1

Number of cracks
Paired t-test p = 0.0001
Wilcoxon p = 0.002

Length of cracks
Paired t-test p = 0.000013
Wilcoxon p = 0.002
Group 2

Number of cracks
Paired t-test p = 0.000001
Wilcoxon p = 0.002

Length of cracks
Paired t-test p = 0.00009
Wilcoxon p = 0.007

Interpretation: Both groups show a statistically significant reduction in both number and length of cracks after treatment.
Between-Group Comparison (Change from Before to After)

Reduction in Number of Cracks
Independent t-test p = 0.91
Mann-Whitney U test p = 0.65

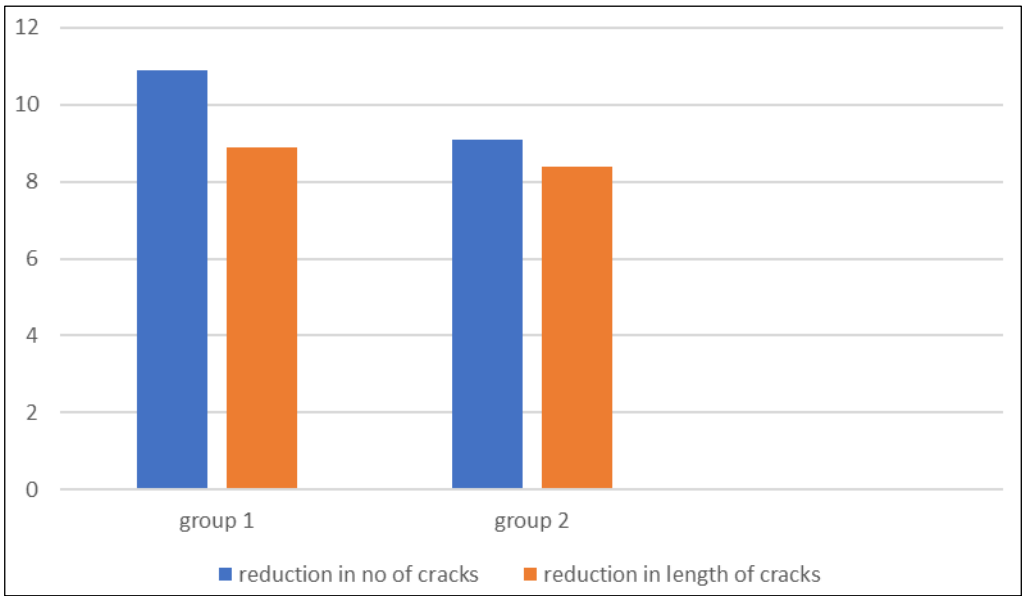
Reduction in Length of Cracks
Independent t-test p = 0.48
Mann-Whitney U test p = 0.79

Interpretation: There's no significant difference between Group 1 and Group 2 in terms of how much they improved. Both treatments seem to work similarly.

Group 1
Mean reduction in number of cracks = 10.9
Mean reduction in length of cracks = 8.9

Mean of Differences
Group 1 - Number of cracks: 10.9 & Length of cracks: 8.9
Group 2 - Number of cracks: 9.1 & Length of cracks: 8.4

Here's the bar plot showing the mean reduction in both the number and length of cracks for Group 1 and Group 2 after treatment.



Group 1: Had slightly greater mean reductions in both outcomes, The differences between groups are relatively small.

Discussion

Proposed Mode of Action of Sarjarasa Malahara Lepa in the management of Padadari (Crack Heel): According to constituents - the contents are Tilataila, Sarjarasa, kankshi, & Tuttha.

Tilataila (Sesamum Indicum) possesses Madhur (sweet), Kashaya (astringent), Tikta (bitter), Katu (pungent) tastes, it is characterised by Guru (heavy), Snigdha Guna (unctuous), Ushna Virya (hot), and is known to pacify all three doshas i.e. Tridosha shamaka it exhibits Snehana (Oleation and lubrication), Vrana Shodhana (Wound cleansing), Vedana sthapaka (Analgesic and Pain reliving), and Sandhaniya[6] (Promoting union of fissured part).

Sarjarasa (Shorea Robusta) possesses Kashaya Rasa (astringent taste), along with Ruksha (dry) and Sheeta (cold) Gunas (qualities) it exhibits Vranaropaka (Wound Healing), Sandhaniya (tissue unifying), Jantughna[6] (Anti-microbial).

Kankshi possesses kashay-amla rasa (astringent-sour taste), vishaghna (anti-poisonous), vranaghna (Wound Healing) tridoshashamak.

Tuttha possesses pungent (Katu), alkali (Kshara), astringent (Kashaya) tastes, and exhibits antimicrobial, antifungal also anti-inflammatory property.

Discussion on cracks - cracked heel, or padadari, are a common condition characterised by dryness, fissuring, and thickening of the skin, primarily on the soles and heels. The pathogenesis can be correlated with vatapradhan kshudra kushta. The healing can be attributed to the combined effects of the ingredients used, As Sarjarasa Malahara consist of Tilataila (Sesamum Indicum), Sarjarasa (Shorea Robusta), Kankshi and Tuttha (Copper Sulphate). Therapeutic action of Sarjarasa, Tilataila are Snigdha Guna (Moisturizing/Humidifying), Vranaropaka (Wound Healing), Sandhaniya (Approximation), Snehana (Lubrication) which is effectively contributed to the wound healing process. Also, it helped to soften skin, relieve pain, and restores the integrity of skin.

The Sarjarasaa malahar has wound healing or antiseptic activity when prepared with Tuttha. But many people prepare Sarjarasa malahar without adding Tuttha, because Tuttha is considered as poisonous, and ignores his anti-microbial, anti-fungal and anti-inflammatory activity, so this study is to rule out the role of tuttha in Sarjarasa malahar to treat crack heel.

Group 1 patients - The count of cracks on the feet was measured in each of 10 patients as follows - 30% patients present with mild crack, 50% with moderate crack, and remaining 20% shows severe cracks.

Measured length of cracks in the 10 patients of group 1 - 50% patients show superficial cracks; and remaining 50% shows severe cracks.

After consistant application of Sarjarasa Malahara prepared with Tuttha from the start, Cracks were reduced gradually from mild to zero cracks, moderate to mild and severe cracks converted to mild with significant result.

Group 2 patients- The count of cracks on the feet was measured in each of 10 patients - 30% patients show mild crack, 60% shows moderate crack, and remaining 10% patients show severe cracks.

Measured length of cracks in the 10 patients of group 2- most of the patient, i.e. 60% presnts superficial cracks; and reaming 40% shows severe cracks.

with consistant application of Sarjarasa Malahara prepared without Tuttha, from the day one, cracks showed progressive healing over time from mild to zero cracks, moderate to mild and severe to moderate.

Conclusion

In group 1: Sarjarasa Malahara Lepa (Sarjarasa Ointment) demonstrated significant effectiveness in decreasing both the number of cracks and length of cracks, along with reducing foot dryness.

In group 2: Sarjarasa Malahara Lepa (Sarjarasa Ointment) demonstrated less effectiveness in reducing number of cracks and length of the cracks, but showed marked improvement in addressing foot dryness.

hence, Sarjarasa Malahara (Sarjarasa Ointment) prepared with Tuttha can be considered an effective therapeutic option in the treatment of padadari, the topical application of Sarjarasa Malahara (Sarjarasa Ointment) showed statistically significant improvement in the signs and symptom of the disease. Throught out the treatment period, no side effects or adverse events were reported.

Further Scope

The other formulations like Jatyadi tail, Jatyadi ghrut, Kasisadi tail used for healing purpose contains Tuttha. By studying this preparation prepared with or without Tuttha can also evaluate the tuttha's antiseptic activity.

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