Original Research Article

“Wound healing activity of topical herbal aerosol sprays on diabetic and Varicose Ulcers: A randomized, controlled, open labelled, multicentric clinical trial”

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Background: Panchavalkala Kwatha and Jatyadi Taila are recommended for cleaning and healing of non-healing ulcers such as Diabetic Foot Ulcer (DFU) and Varicose Ulcers (VU).

Objectives: Innovative topical aerosol sprays viz. Panchavalkala Kwatha Aerosol Spray (PKS) and Jatyadi Taila (Healz) Aerosol Spray (JTS) were evaluated for healing in DFU & VU against conventional treatment.

Materials & methods: After obtaining approval from Ethics Committees & informed consent, 53 patients were randomized in two study groups. In one group, ulcer cleaning was done with PKS and then JTS was used for dressing while in other group, cleaning was done with Hydrogen peroxide and/or Hypochlorite followed by dressing with 10% Povidone iodine. Ulcer examination was done from baseline to every 7th day by Bates Jensen ulcer assessment tool, digital photographs and photographic ulcer assessment tool. Comparison of categorical variables was done using t-test.

Results: The dual action of PKS and JTS exhibited potentially comparable effect to the conventional treatment.

Conclusion: PKS and JTS were found to be effective, comfortable, hygienic and acceptable in management of chronic ulcers.

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1. Introduction

Diabetic Foot Ulcers (DFU) and Varicose Ulcers (VU) are chronic non-healing ulcers generally encountered in clinical practice. DFU has a major long-term impact on the quality of life of diabetics along with affecting their morbidity and mortality [1]. It is one of the major complications due to long standing Diabetes Mellitus with around 25% of diabetics developing DFU during their lifetime [2,3]. Individuals with DFU are at a greater risk of premature death, myocardial infarction and fatal stroke [4]. Treatment of DFU involves appropriate dressing, antibiotics, debridement and if
required arterial revascularization [5]. VU are the most common type of chronic skin ulcers, occurring due to improper functioning of venous valves [6]. Apart from proper dressings similar to other chronic ulcers, treatment of VU involves wearing of support, sclerotherapy, laser therapy and surgery [7,8]. Ensuring healing of DFU and VU at their initial stages with proper debridement, cleaning and dressing prevent them to reach to deeper tissues and avoid the possibility of amputation.

Traditional medicinal systems like Ayurveda, has elaborately described various formulations for cleaning as well as healing of chronic ulcers. Panchavalkala Kwatha and Jatyadi Taila are such preparations that have been recommended in Ayurveda for ulcer cleaning and healing respectively [9,10]. Scientific studies have established their efficacy in the management of chronic ulcers. However, due to reasons like tedious preparation methods, easy contamination chances, inconvenience of application and shorter shelf life, their usage is dificult. To overcome these challenges, innovative topical aerosol sprays of Panchavalkala Kwatha and Jatyadi Taila were prepared. This was done to facilitate targeted delivery in a hygienic way which can be hassle-free for the surgeon/physician and the patient. Though used in conventional form since many years, this was the first effort to evaluate the ulcer cleaning and healing properties of Panchavalkala Kwatha and Jatyadi Taila in the form of aerosol sprays.

2. Materials and method

2.1. Study design, sites

This Randomized, Multicentric, Open labelled, Comparative, Prospective clinical study was carried out in six study centres, viz. R A Podar Medical College (Ayu) & M. A. Podar Hospital, Mumbai; Govt. Ayurved College, Nanded; Government Ayurvedic College, Osmanabad; MAMs SS Ayurveda Mahavidyalaya & Sane Guruji Arogya Kendra, Pune; Ayurved Seva Sangh, Ayurved Sansodhan Vibhag, Nashik and S.D.M. College of Ayurveda, Udupi, India.

2.2. Ethical considerations

Ethical approvals from Institutional Ethics Committees of all study centres were taken and the study was registered with Clinical Trials Registry - India (CTRI/2017/09/009703, dated 11th September, 2017).

2.3. Enrolment of patients

Patients suffering from DFU or VU, attending outpatient department of the study centers and who agreed through written informed consent to participate in the study were included in the trial. The study was carried out and reported adhering to CONSORT statement.

2.4. Study duration and visits

The total duration of the study treatment was 3 months (90 days) or till the complete healing of ulcers, whichever was earlier. Patients were asked to visit study site for dressing on alternate days for 3 months. Patients were evaluated every 7th day for ulcer healing process by clinical examination and various assessment scales. Study visits were planned and outcomes assessed on Day –5, Day 0, Day 7, Day 14, Day 21, Day 28, Day 35, Day 42, Day 49, Day 56, Day 63, Day 70, Day 77, Day 84 and Day 91. However, assessment of Day 28, Day 63 and Day 91 were taken into consideration for statistical analysis.

2.5. Inclusion criteria

Patients of either sex in the age group of 18–70 years (both inclusive), having either DFU or VU for a duration of more than one month and an ulcer surface area of between 1 cm² to 25 cm² who voluntarily provided written informed consent and were ready to follow procedures as per the study protocol were included in the study. For DFU, patients having either Type I or Type II Diabetes mellitus (HbA1C of <8%) with non-healing single or multiple ulcers, neuropathic or mild neuro-ischaemic ulcer, classified as grade 1 or 2 on Wagener’s classification of DFU were included in the study [11]. For VU, patients having non-healing VU with or without Diabetes, (HbA1C < 8%) were considered for inclusion in the study.

2.6. Exclusion criteria

Patients with ischemic ulcers (Diagnosed Clinically and/or with Doppler), known cases of severe/chronic hepatic or renal disease, known cases of any active malignancy, having history of significant cardiovascular event <12 weeks prior to randomization, chronic alcoholics/alcohol abuse, patient’s ECG demonstrating any signs of uncontrolled arrhythmia/acute ischemia, patient’s X-ray chest showing any active lesion of tuberculosis, patients having known chronic, contagious infectious disease, such as active tuberculosis, Hepatitis B or C, or HIV, patients using any other investigational drug within 1 month prior to recruitment, known hypersensitivity to any of the ingredients used in study drug, Pregnant and Lactating females were excluded from the study.

2.7. Laboratory and radiological investigations

Investigations such as CBC, ESR, Hb%, BSL Fasting and Post-prandial, HbA1c, Liver Function Tests, Lipid Profile, Renal Profile, HIV I & II, Urine Routine and Microscopic evaluation were done. Chest X-ray PA view, ECG and Arterial Doppler of Lower limb (if required) were done.

2.8. Assessment of ulcers

Clinical examination of ulcer was done and assessed on Bates Jensen ulcer assessment tool [12]. Digital photographs were taken and ulcer was assessed on photographic ulcer assessment tool. Ulcer area was calculated using Graph paper and also through mathematical formula (for circular and elliptical wounds).

2.9. Sample size

A total of 77 patients of DFU or VU were screened, out of which 53 were recruited in the study. Of them, 47 patients completed the study. The enrolment, allocation, follow-up and analysis details are presented in the CONSORT flow diagram (Fig. 1).

2.10. Treatment groups

The recruited patients were randomized in two groups, viz. Herbal Sprays Group and Standard care group. Twenty-seven patients were allocated in Herbal Sprays group while 26 were allocated in Standard care group. Subjects were randomized using stratum/block randomization with block/stratum-size of 6 subjects each.

2.11. Details of intervention

Panchavalkala Kwatha Aerosol Spray (PKS) and Jatyadi Taila (Healiz) Aerosol Spray (JTS) were used as study interventions. These
aerosol sprays were developed by Millennium Herbal Care Ltd, Mumbai. The individual compositions are provided in Table 1. Their quality control and standardization data have been provided in supplementary file 1.

In Herbal Sprays group, ulcer cleaning was done with PKS and then JTS was used for dressing while in the Standard care group cleaning was done with Hydrogen peroxide and/or Hypochlorite solution followed by application of Povidone iodine 10% and dressing was done. Standard method of bandaging was followed in both the groups. If required debridement of ulcer was done. Diabetic patients were advised to continue their oral hypoglycemic drugs and/or insulin dose which they were taking already.

2.12. Parameters of assessment and their methods [13]

1. Assessment of Ulcer mean surface areas by graph paper - Assessment of ulcer mean surface area was done on every visit and change in the mean surface area at the end of study was compared to baseline. Ulcer area was determined by tracing the outline of the ulcer (ulcer circumference) on a transparent graph paper divided into 1 cm squares.

2. Assessments of Ulcer mean surface area by formula - Assessment of ulcer mean surface area was done on every visit and change in the mean surface area at the end of study was compared to baseline. Ulcers were categorized in 3 types according to their shapes: Circular/Elliptical/Irregular. Ulcers were traced, measured with a ruler and the standard formula for the calculation of the area of a circle ($\pi r^2$, where $r$ is the radius of the circle) and ellipse ($\pi ab$, where $a$ is the length of major axis and $b$ is the length of minor axis) were applied. For irregular shaped ulcers, 8 radii were identified, each taken approximately 45° from the next radius and results were approximated to actual values. Surface area was calculated by using formula $\left\{ (r_{12} + r_{22} + ... + r_{82})/8 \right\} \times (\pi/8)$.

3. Assessment of ulcer healing process by Bates Jensen ulcer assessment tool - [12] Evaluation of ulcer healing process by clinical examination for evaluation of depth of ulcer, undermining, ulcer edges, necrotic tissue type and amount, type and amount of exudates, appearance of skin (colour) around the ulcer, peripheral tissue edema, peripheral tissue induration, granulation of ulcer, epithelialization of ulcer was done on every visit on graded scale on Bates Jensen ulcer assessment tool and was compared with baseline.

4. Assessment of ulcer healing process by digital photographs [14].

For evaluation of ulcer healing process, digital photographs were taken on every visit for the evaluation of ulcer edges, necrotic tissue type, necrotic tissue amount, skin colour surrounding the ulcer, granulation of ulcer, epithelialization of ulcer and these were compared with baseline on graded scale.

2.13. Safety considerations

Assessment of safety of interventions was done by regularly monitoring of adverse events (both local and systemic) and assessing their causality. Initial and post treatment clinically significant changes in laboratory parameters including CBC, ESR, Hb%, Liver Function Tests (LFT), Renal Function Tests (RFT), Urine routine and microscopic examination, ECG and vitals were also done.

2.14. Statistical methods

Data describing quantitative measures were expressed as mean ± SD or SE or the mean with range. Qualitative variables were presented as counts and percentage. Comparison of variables representing categorical data was performed using t-test. All p-values were reported based on two-sided significance test and all statistical tests were interpreted at least up to 5% level of significance or 95% confidence limits.

3. Results

3.1. Demographic details

Of the total of 53 patients recruited in the study, 27 had VU and 26 had DFU. In Herbal Sprays group, there were 15 patients of VU while 12 patients had DFU. In Standard care group, there were 12 patients of VU and 14 patients with DFU. The average age of patients in Herbal Sprays group was 50.11 ± 12.70 years while in Standard care group it was 51.42 ± 10.40 years. There were 22 (81.48%) males and 5 (18.52%) females in Herbal Sprays group while there were 20 (76.92%) males and 6 (23.08%) females in Standard care group.

3.2. Comorbidities and Concomitant medications

There were 10 subjects of Diabetes Mellitus (two taking Insulin plus OHA and 8 taking only OHA) in Herbal spray group while 14 subjects had Diabetes Mellitus (3 taking Insulin plus OHA while 11 taking only OHA) in Standard care group. 4 subjects in Herbal spray group and 3 subjects in standard care group had hypertension and were taking antihypertensive drugs. 6 subjects in Herbal spray group and 5 subjects in standard care group had Ischemic Heart Disease for which they were taking medications. A total of 16 subjects in Herbal spray group and 14 subjects in standard care group had obesity as comorbidity. 6 subjects had dyslipidemia in Herbal Spray group while 7 subjects had it in standard care group and were taking lipid lowering agents (Atrovastatin Tablets). Osteoarthritis was observed in 10 subjects in herbal spray group and 9 subjects in standard care group for which they were taking either calcium supplement or analgesics (SOS). Also 5 subjects in Herbal spray group and 6 subjects in standard care group had Lumbar spondylitis.

3.3. Assessment of efficacy

3.3.1. Assessment of change in ulcer size (by graph paper)

At the end of 30 days, 10 patients in both the groups (43.47% in Herbal Sprays group and 41.67% in Standard care group) showed more than 50% reduction in ulcer size. At the end of 60 days, 18 patients (78.26%) showed more than 50% reduction in size in Herbal Sprays group while the number in Standard care group was 17 (70.83%). 21 patients (91.30%) in Herbal Sprays group and 14 subjects in standard care group showed more than 50% reduction in ulcer size at the end of 90 days (see Table 2 and Table 3).

It was observed that, in Herbal Sprays group, the mean ulcer area reduced significantly from 6.19 ± 6.03 cm² to 3.80 ± 5.25 cm² at the end of 30 days. There was a further reduction at the end of 60 days and 90 days when the ulcer size reduced to 2.51 ± 4.75 cm² and 1.59 ± 3.82 cm² respectively. In Standard care group, the mean ulcer area reduced significantly from baseline score of 6.33 ± 6.81 cm² to 2.89 ± 3.57 cm² after 30 days and further to 1.88 ± 4.15 cm² at 60 days and 1.70 ± 4.68 cm² at 90 days. On analysis between the groups, no significant difference was observed at all follow up visits (Table 2).

3.3.2. Assessment of change in ulcer size (by formula)

A total of 10 patients in each group showed more than 50% reduction in the ulcer size at the end of 30 days (43.47% in Herbal Sprays group and 41.66% in Standard care group). At the end of 60
days, the number of patients showing more than 50% reduction in ulcer size was 18 (78.26%) and 17 (70.83%) respectively. At the end of the study i.e., 90 days 21 patients (91.30%) in Herbal Sprays group and 20 patients (83.33%) in Standard care group showed more than 50% reduction in ulcer size (Table 2).

One patient at day 30 and 2 patients at day 60 showed less than 50% increase in the ulcer size while none of the patients showed any increase in ulcer size at the end of 90 days in Herbal Sprays group. None of the patients showed increase in ulcer size in Standard care group. One patient in each of the two groups showed no change in the ulcer size.

On statistical analysis, it was observed that, in Herbal Sprays group, the mean ulcer area (by formula) reduced significantly from $6.92 \pm 7.10 \text{ cm}^2$ (baseline visit) to $4.70 \pm 6.15 \text{ cm}^2$ at the end of 30 days and further to $2.98 \pm 5.22 \text{ cm}^2$ at day 60 and $2.10 \pm 4.75 \text{ cm}^2$ at day 90. In Standard care group, the mean ulcer area reduced significantly from $6.78 \pm 7.61 \text{ cm}^2$ (baseline visit) to $3.00 \pm 3.69 \text{ cm}^2$ at the end of 30 days and further to $2.16 \pm 4.58 \text{ cm}^2$ at the end of 60 days and $1.61 \pm 5.10 \text{ cm}^2$ at the end of 90 days. On analysis between the groups, no significant difference in the mean ulcer area was observed. The results in the two groups were comparable with neither of the groups showing superiority/inferiority over the other (Table 2).

### 3.3.3. Assessment of ulcer healing process on Bates Jansen ulcer assessment tool

In the Herbal Sprays group, the mean Bates Jansen Ulcer Assessment score was $30.59 \pm 7.11$ at baseline visit which reduced significantly to $23.45 \pm 8.79$, $20.48 \pm 10.24$ and $15.32 \pm 7.63$ on day 30, 60 and 90, respectively. In Standard care group, the mean score at baseline visit was $30.58 \pm 8.72$ which reduced significantly to $21.05 \pm 9.78$, $16.48 \pm 8.57$ and $14.92 \pm 7.69$ on day 30, 60 and 90, respectively. On analysis between the groups no significant difference was observed and both the groups showed comparable efficacy on ulcer reduction with neither of the group superior/inferior over the other (Table 2).

### 3.3.4. Assessment of ulcer healing process by digital photographs

In the Herbal Sprays group, the mean score of assessment of Ulcer healing process by digital photographs was $16.20 \pm 7.84$ at baseline visit which reduced significantly to $10.60 \pm 6.10$, $4.50 \pm 4.98$ and $3.00 \pm 3.24$ on day 30, 60 and 90 respectively. In Standard care group, the mean score at baseline visit was $12.50 \pm 4.18$ which reduced significantly to $7.37 \pm 4.28$, $5.63 \pm 3.70$ and $5.00 \pm 5.27$ on day 30, 60 and 90, respectively. Analysis between the groups showed comparable efficacy in both the groups with no superiority/inferiority over each other (Table 2).

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**Fig. 1.** CONSORT representation of study design.
3.3.5. Assessment of time required for healing of ulcer

Assessment of the time required for complete healing of the ulcers in the two groups showed that of the 23 patients in Herbal Sprays group, 2 (8.69%) had complete healing of their ulcers in 30 days, while 8 patients (34.78%) had complete ulcer healing after 60 days and 6 patients (26.08%) at 90 days of the study. Seven patients (30.43%) in this group continued to still have unhealed ulcer after the study completion of 90 days. In Standard care group of the 24 patients, there was complete healing of ulcer in 2 patients (8.33%) after 60 days and 6 patients (25%) at 90 days of the study. Seven patients (33.33%) in this group whose ulcer still remained unhealed after the study duration being completed.

3.3.6. Assessment of requirement of rescue medications

One patient in each group required anti-inflammatory drug as rescue medication for pain in ulcer area. Also, one patient in each of the two groups required anti-biotics for the management of ulcer infection.

3.4. Assessment of safety

None of the subjects in the study reported of any local adverse effect due to use of the intervention in either of the two groups. Also, no significant change in safety related laboratory parameters from baseline to 90 days follow up were observed in the study groups. It was observed that, these parameters remained within the normal range at both baseline and final visits.

3.4.1. Adverse events (AE)

Out of 26 patients, 6 patients reported of Adverse events. In Herbal Sprays group, there were 9 AEs (cough, constipation, low back pain, Nausea) during the trial. All the 9 AEs were unrelated to the study drugs. In Standard care group, there were 6 AEs (loose motions, knee joint pain) during the trial. All the 6 AEs were unrelated to the study drug.

3.4.2. Treatment compliance

Patients were asked in every visit about the immediate effect that they experienced post application of medicines. It was observed that patients in standard care group complained of mild burning sensation and irritation. No treatment was required and the symptoms subsided on its own while those in Herbal Sprays group reported that the application was comfortable without any burning or irritation.

4. Discussion

DFU and VU are common chronic ulcer conditions found in clinical practice having varied pathophysiology. Management of these conditions require regular cleaning, creating healthy tissue.

### Table 1
Composition of herbal aerosol sprays.

| Ingredients (Common Names) | Botanical Names | Quantity |
|---------------------------|----------------|----------|
| PKS                       |                 |          |
| Each 100 ml contains water Extract of: |                 |
| Parisa                    | Thespesia populnea | 5.00%    |
| Udumbera                  | Ficus glomerata  | 5.00%    |
| Plaksa                    | Ficus lacor      | 5.00%    |
| Asvattra                  | Ficus religiosa  | 5.00%    |
| Nyagrodha                 | Ficus bengalensis| 5.00%    |
| Purified Water            | QS              |          |
| JTS                       |                 |          |
| Each gm prepared from:    |                 |
| 1. Jatyadi Tails prepared from |             |
| a. Chameli                | Jasmim grandiflorum | 69.50%   |
| b. Neem                    | Azadirachta indica |          |
| c. Patol                  | Trichosanthes dioica |       |
| d. Karanj                 | Pongamia glabra  |          |
| e. Yashimadhu             | Glycyrrhiza glabra |       |
| f. Haridra                | Curcuma longa    |          |
| g. Dararudhra             | Berberis aristata|          |
| h. Kutki                  | Picrorhiza kurrooa|         |
| i. Manjistha              | Rubia cordifolia |          |
| j. Padmesh                | Prunus cerasoides|          |
| k. Lodhra                 | Symplcocos racemosa|       |
| l. Haritaki               | Terminalia chebula|         |
| m. Nitgler                | Nymphae alba    |          |
| n. Taitiya                | Copper sulfate   |          |
| o. Sariva                 | Hemidesmus indicus|        |
| p. Mom                    | Wax             |          |
| 2. Chandan Oil            | Santalum album  | 0.25%    |
| 3. Kumari Oil             | Aloe barbadensis| 0.25%    |
| Propellant Base           |                 | 30.00%   |

### Table 2
Change in ulcer area (square cm) (Mean ± SD).

| Method of Assessment | Baseline       | Day 28       | Day 63       | Day 91       |
|----------------------|----------------|--------------|--------------|--------------|
| Graph paper          | 6.19 ± 6.03    | 3.80 ± 5.25a | 2.51 ± 4.75a | 1.59 ± 3.82a |
| Herbal Sprays group  |               |              |              |              |
| (n = 23)             | 6.33 ± 6.81    | 2.89 ± 3.57a | 1.88 ± 4.15a | 1.70 ± 4.68a |
| Standard care group  |               |              |              |              |
| (n = 24)             | 6.92 ± 7.10    | 4.70 ± 6.15a | 2.98 ± 5.22a | 2.10 ± 4.75a |
| Formula              |               |              |              |              |
| Herbal Sprays group  |               |              |              |              |
| (n = 23)             | 6.78 ± 7.61    | 3.00 ± 3.69a | 2.16 ± 4.58a | 1.61 ± 5.10a |
| Standard care group  |               |              |              |              |
| (n = 24)             | 30.59 ± 7.11   | 23.45 ± 8.79a| 20.48 ± 10.24a| 15.32 ± 7.63a|
| Bates-Jansen Ulcer Assessment tool |           |              |              |              |
| Herbal Sprays group  |               |              |              |              |
| (n = 23)             | 30.58 ± 8.72   | 21.05 ± 9.78a| 16.48 ± 8.57a| 14.92 ± 7.69a|
| Standard care group  |               |              |              |              |
| (n = 24)             | 16.20 ± 7.84   | 10.60 ± 6.10a| 4.50 ± 4.98a | 3.00 ± 3.24a |
| Digital Photographs  |               |              |              |              |
| Herbal Sprays group  |               |              |              |              |
| (n = 23)             | 12.50 ± 4.18   | 7.37 ± 4.28a | 5.63 ± 3.70a | 5.00 ± 5.27a |

*p < 0.05, considered significant compared to baseline values.*
and thus facilitate healing. Conventional management involves the use of antiseptic, anti-microbial and healing compounds which have proven efficacy. Traditional methods of wound cleaning and healing involves the use of herbal decoctions and oils. These decoctions and oils have difficulty in usage, have shorter shelf life, may not be essentially sterile and thus have limitations of use. The present study on PKS and JTS in the form of sprays provides an opportunity for the use of traditional formulations in the most hygienic manner with precision of use at the target and ease of use both by the treating medical personal and the patient.

The study provides a spectrum of measurement methods for assessment of the wound healing process. These methods not only provide accuracy but are also reliable, validated and feasible for application in routine clinical practice as well as research studies. Tools like the Bates Jansen wound Assessment tool (BWAT), digital photographs assessment, graph paper assessment and assessment of change in ulcer size by formula were used in the study to ensure consistency in outcome measurement and provide detailed quantitative and qualitative assessment of the wound healing process in cases of DU and VU.

The BWAT provides reliable, objective data for assessing pressure injury healing progress by assessing the depth of ulcer, undermining, ulcer edges, necrotic tissue type and amount, type and amount of exudates, appearance of skin (colour) around the ulcer, peripheral tissue edema, peripheral tissue induration, granulation of ulcer and epithelialization of ulcer [15]. Digital photography is a non-invasive, simple, objective, reproducible and practical imaging modality for wound healing assessment. A series of digital images taken at regular intervals carries the most informative wound healing indexes, colour and dimension, that may help clinicians to evaluate the effectiveness of a treatment regimen, to relieve patient discomfort, to globally assess the healing kinetics and to quantitatively compare different therapies [16].

Chronic ulcers may vary shape and size and therefore accurate measurement of their area is paramount for assessing progress. In the present study, assessment of change in ulcer size was done by graph paper which is a rapid method, inexpensive requiring minimal training and provides uniformity in measurement of ulcer size in both regular and irregular shaped ulcers. Assessment of change in ulcer size by formula is a mathematical method for wounds which are of regular shapes. Both the methods were used in the study to minimize measurement errors.

It was observed that the dual action of PKS and JTS have potentially comparable effect to the standard care for wound healing. Assessment of Ulcer Healing Process showed comparable efficacy in both the groups with no superiority/inferiority over each other. Time required for healing of ulcer was found to be better in Herbal Sprays group compared to Standard Care group.

The dual combination of PKS and JTS are based on safe and natural ingredients, which have been in human use for centuries. The overall efficacy of PKS and JTS are attributed to the polyherbal compositions of these formulations, which include Neem (Azadirachta indica), Haridra (Curcuma longa), Karanj (Pongamia glabra), Damaruhrida (Berberis aristata) amongst others. Apart from having anti-microbial property these ingredients have potential and powerful anti-inflammatory, anti-oxidant, analgesic and wound healing properties. In Ayurveda practice Jatyadi Taila is used as Shothahara (anti-inflammatory), Vedanashapaka (helpful in pain management) and Vrana Ropaka (Wound healing). Jatyadi Oil is a time tested Classical Ayurvedic Formulation used for the effective management of wound, ulcers, burns and various other skin disorders. Scientific studies on Jatyadi Oil have reported wound healing and anti-microbial properties [17,18]. Tuttha i.e. copper sulphate a component of Jatyadi tel has been reported to induce vascular endothelial growth factor (VEGF) expression in the wound [19]. Antimicrobial properties of Tuttha have also shows good minimum inhibitory concentration (MIC) effect on Pseudomonas aeruginosa, Staphylococcus aureus [19]. Panchavalkala is a combination of five herbs having properties not only of cleansing but also healing of wounds. Panchavalkala is found to have anti-inflammatory and antimicrobial properties [20].

These potent formulations were converted into an easy-to-use, sterile, novel aerosol spray form. Assessment of ease and comfort of application was reported to be higher by the subjects using PKS and JTS sprays. The application of PKS and JTS was reported to be more hygienic as compared to conventional method by the subjects. More detailed insights can be gathered by converting traditionally used potent formulations in such novel delivery forms in further studies. The present study was conducted on two separate chronic ulcer conditions viz DFU and VU. While wound-healing activity could be elicited from the outcomes of the study targeted single ulcer type study would provide better inferences.

5. Conclusion

The present study concludes that the dual action of Panchavalakka Kwatha spray (PKS) and Jatyadi Taila (Healz) Aerosol spray (JTS) have potentially comparable effect to the currently used conventional wound healing treatment. The exact mode of action of these sprays with respect to their anti-microbial action and wound healing potential needs to be further evaluated.

Declaration of competing interest

One of the co-authors (NK) is an ex-employee of the company. The Authors declare no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jaim.2022.100594.

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