

A RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF YAVADI KALKA AND TILADI KALKA AFTER JALOUKAVACHARANA IN THE MANAGEMENT OF DUSHTAVRANA WITH SPECIAL REFERENCE TO NON-HEALING TRAUMATIC ULCER

Priyanka Biradar¹, Prasadshakti G Gannur², A M Madni³

¹Final year PG scholar, Department of PG studies in Shalyatantra, BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur.

²Professor & HOD Department of PG studies in Shalyatantra, BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur.

³Associate Professor, Department of PG studies in Shalyatantra, BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur.

Corresponding Author: pb28121996@gmail.com

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ABSTRACT

Background: Among the nonhealing ulcers, traumatic nonhealing ulcers are one of a variety, and they are categorized in *Dusthavrana* in our classics. In Ayurveda, regarding *Dusthavrana* in etiological factors, pathogenesis and different treatment modalities are elaboratively explained. **Objectives:** In this study efficacy of *Yavadi Kalka* and *Tiladi Kalka* application after *Jaloukavacharana* was conducted in *Dusthavrana* (Non healing traumatic ulcer). **Materials and Methods:** This study was conducted at BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur. 40 cases of *Dusthavrana* (nonhealing traumatic ulcer) were selected from the OPD and IPD of BLDEA's AVS Ayurveda Mahavidyalaya Vijayapur and randomly assigned into two Groups namely Group-A and Group-B with 20 patients in each group. Subjects under Group-A were treated with *Yavadi Kalka* after *Jaloukavacharana* while subjects under Group-B were treated with *Tiladi Kalka* after *Jaloukavacharana*. **Results:** Assessment of Severity of Pain, Itching, Burning sensation, Discharge, Tenderness, Size of Ulcer, Foul smell and Floor of the ulcer in Group-A showed 85%,95%,100%,80%, 95%,85%,95% & 100%, improvement respectively and in Group-B 86%,

100%, 84%, 100%, 100%, 95% 100% & 100% improvement respectively. On assessing the overall effect of the treatment Yavadi Kalka after Jaloukavacharana showed good result with 96.57% relief while that of Tiladi Kalka after Jaloukavacharana showed with 91% relief. **Conclusion:** On comparing the results of Group-A and Group-B, Group A has shown significant effect than group-B in above said parameters.

Key words: Dushta vrana; Yavadi Kalka, Tiladi Kalka, Jaloukavacharana, Vrana Shodhana, Vrana Ropana, non-healing traumatic ulcer.

INTRODUCTION

Shalya Tantra is one among the eight branches of *Ayurveda* in which surgical and parasurgical techniques are described for management of various diseases. *Vrana* means destruction of tissues which results into break in the continuity of the skin. *Dushta vrana* is characterized by vitiation of *Mamsa*, *Meda dhatu* and *Doshas* gets aggravated by external injury which results into *Durgandha yukta puya srava* (pus), *Vedana* (pain), *Ushnata* (temperature), *Shopa* (inflammation), *Kandu* (itching), *Raga* (redness), and also oozing of *Durgandha yukta rakta* with no tendency to heal^[1]. Wound is a break in the integrity of the skin or tissue often which may be associated with disruption of the structure and function. Management of chronic non healing ulcers have always been a difficult proposition in the evolution of medical practice. The worldwide prevalence of wounds is believed to be 1% of the world population.

In contrast, an Indian perspective of the hospital-based study shows leprosy (40%), diabetes (23%), venous disease (11%), and trauma (13%) were among the essential causes of lower extremity wounds. In that study, 13% of wounds were not directly linked to any known cause^[2]. Healing of ulcers is a naturally complex process. Still, healing gets affected by infection, tissue injury, contamination, absence of rest, etc.^[3], which worsens the patient's condition and may even become fatal. Treatment of ulcers ranges from the application of simple antimicrobials to complex plastic surgery. This includes irrigation, hyperbaric oxygenation, vacuum-assisted closure, electrostimulation, and Maggot therapy techniques^[4]. All these results are not always satisfactory, and these cannot be employed as a regular management protocol as many such techniques are expensive, and the organisms are developing resistant strains. Despite

the advances that have been made, the management of chronic wounds is still a challenge for surgeons. *Acharya Sushruta* has scientifically classified *Vrana* and has elaborated detailed treatment of *Dusthavrana* in *Vrana chikitsa adhyaya* by mentioning *Shashti upakramas*. These principles of management are valid even today. Application of *Kalka* is one of the *Upakrama*^[5]. *Sushruta* mentioned application of *Yavadi Kalka* and *Tiladi Kalka* as *Vrana shodhana* and *Vrana ropana* in *Dusthavrana*. The ingredients of *Yavadi Kalka* are *Yava*, *Nimba patra*, *Madhu* & *Ghrita*. In *Tiladi Kalka* instead of *Yava*, *Tila* has used^[6]. Chronic ulcers are difficult to heal. Simple procedures like application of *Kalka* on ulcer can be a holistic, reliable, and cost-effective management of non-healing ulcers.

Materials and Methods:

Selection of patients: Subjects having signs and symptoms along with pragmatic diagnostic features of *Dusthavrana* were selected irrespective of sex, religion, occupation, habitat from the Outpatient department and Inpatient department of *Shalyatantra* of BLDEA's AVS AMV Hospital and RC, Vijayapur. The registered subjects were randomly allocated into two groups by flipping a coin randomization. This study was approved by the Institutional Ethical Committee Reference letter no- 293/E-2022-23 dated 20/07/2022 before starting the clinical trial; the study was also registered in the Clinical Trial Register of India with registration number CTRI/2022/10/046884, written on 28 October 2022.

Diagnostic criteria: The diagnosis was made based on clinical features like *Atee samvrutta*, *Atee vedana*, *Atee ushna*, *Utsadana*, *Deergha kaleen*, *Dushtarakta*

srava, Raga, Paaka, Vividha varna and Vividha srava.

Inclusion criteria: Subjects of age group from 16-70 years of both genders having diagnostic features of *Dusthavrana* within the size of 10sq.cm² and subjects fit for *Jaloukavacharana* were included in the trial.

Exclusion criteria: Subjects having bleeding disorders, size more than 10sq.cm², known cases of malignancy, tuberculosis, human immunodeficiency virus, venereal diseases and hepatitis-B positive cases, hypertension, diabetes mellitus, and cardiac disorders were excluded from the study.

Laboratory investigations: Hemoglobin, random blood sugar, clotting time, bleeding time, HIV, HCV, HBsAg, and urine routine were done before treatment.

Materials: Among 40 registered subjects, group A (n=20) was treated with *Yavadi Kalka* and *Jaloukavacharana*, and group B (n=20) was treated with *Tiladi Kalka* and *Jaloukavacharana*. *Pathya* and *Apathy* were advised to subjects of both groups.

Preparation of trial drug [7]: The raw drugs *Yava*, *Tila*, *Madhu*, and *Ghritha* procured from the local market, *Nimba patra*, were collected from the college herbal garden. All were authenticated from Dept. of *Dravya Guna* BLDEA's AVS AMVH & RC Vijayapur. *Yavadi Kalka* was prepared from BLDEA's AVS AMV Hospital & RC, Vijayapur pharmacy. *Nimba Patras* were pounded with *Madhu* and *Ghritha* in *Khalwa Yantra*. After the paste get formed, the powder of *Yava* has added and mixed well.

Preparation of Tiladi Kalka: *Tila* and *Nimba Patras* were pounded with *Madhu* and *Ghritha* in *Khalwa yantra* until *Kalka* formed. The ingredients of *Kalkas* are shown in Table 2 & Fig 1. *Kalka* was prepared as per classical references.

Methodology

All the subjects were randomly allotted into two groups by the coin flipping randomization method.

- Group- A (Trial group)
- Group B (Control group)

Both the group subjects were treated with the single sitting of *Jaloukavacharana* (Fig 2) on 1st day of the study. After one day gap, in subjects of group A, the

wound washed with Normal Saline, then *Yavadi Kalka* application with thickness of *Arda mahisha charma* [8] for 28days was done. Along with that, subjects were also advised to take *Pathya ahara vihara* as prescribed below.

In patients of group-B, after *Jaloukavacharana*, same as in group-A, after 1day gap wound was washed with NS, then *Tiladi Kalka* was applied for 28days. Along with that, subjects were also advised to take *Pathya ahara vihara* as prescribed below.

The gradation adopted for the assessment of results is depicted in Table 4. Subjects were assessed on every 7th day for 1month and follow up was done after 1month completion of the treatment to observe reoccurrence and any untoward effects of the treatment. SPSS software was used for statistical analysis. Unpaired 't' test used for intra group statistical analysis of result. The ANOVA test was used for intergroup comparison.

Observations: The maximum 60% of subjects belonged to 36-53 years age, 57.5% subjects were males, 80% of subjects were from rural, 52.5% were having mixed diet, 47.5% subjects were of *Vata pitta Prakruti*, 37.5% of subjects were having ulcer in foot, 37.5 % of subjects were having irregular shape of ulcer, 50% of subjects had ulcer of duration 1-2months, 100% of subjects were having sloping edge.

Results: The assessment was made on the basis of relief in pain, itching, burning sensation, discharge, tenderness, size of the ulcer, foul smell, and floor of the ulcer.

The both group- A (*Yavadi Kalka*) and group-B (*Tiladi Kalka*) statistically highly significant results were observed in all the parameters (p<0.0001) as shown in [Table 5 and 6] (Fig 3 & 4).

On comparison between the results of the groups by applying ANOVA test significant difference was observed in reducing pain (P=0.01), burning sensation (P<0.0001), mean size of ulcer (P=0.02), discharge (P=0.03), floor of the ulcer (P=0.03) after comparison of treatment between both groups. Both the groups have same effect on parameters like itching, tenderness and foul smell.

DISCUSSION

When *shuddhavrana* gets vitiated by *Tridoshas* by not following over *Pathya ahara and vihara*, unhygienic condition of the wound, not treating wound properly and earlier becomes *Dusthavrana*. It has turned to chronicity needs special treatment for its healing. In the context of *Saadhya asaadhya*, Sushruta has explained the importance of treatment to the ulcer. Without treatment in proper time, curable wound can convert into *Yaapya*, *Yaapya* to *Asaadhya* and *Asaadhya* may kill the patient. In the context of treatment of ulcer Sushruta described *Shasti upakramas* in *Chikitsa sthana* among those *Kalka* and *Raktamokshana* are having their role in both *Shodhana & Ropana chikitsa* for *Dusthavrana*. The study showed that maximum subjects belong to 36-53 years (it may be because they will be more dynamic and exposed themselves to different tasks under stress), higher incidence in males may be due to the factor that males are more prone to trauma, As the *Prakruthi* and habitat of patients are *Vata Pradhana* and taking *Vata* aggravating *Ahara* may delays wound healing.

Patients treated with *Yavadi Kalka* have shown significant results in pain, burning sensation, discharge, size of ulcer and floor of the ulcer. *Yavadi Kalka* has good results because it is *Vatahara* due to *Guru, Mridu, Picchila guna, Madhura, Kashaya rasa, Katu vipaka, Sheeta virya* which helps in reducing pain. *Madhura, Tikta, Kashaya rasa, Sheeta virya* of drugs helps in *Pitta shaman* and *Dahaprashamana* (reduces burning sensation). Infection was subsided by the *krimighna & Vishaghna* properties of the *Go- Ghrita* of the compound drug, it does the *Prenana, Dhatu- vardhana, Poshana* by *Madhura rasa & Sheeta virya* that helps in contraction of the wound size by promoting fibrosis & epithelialization (Helps in concise size of ulcer). it has *Kashaya, Tikta rasa* and *Vishada, Snigdha, Guru guna, Pitta-kapha hara, Stambhana karma* was done by *Shoshana guna* along with *Kledahara, Raktastambhana* and *Chhedhana* activity followed by *Krimighna* which led to prevention of discharge and secretions. *Kashaya rasa* due to their *Sandhana karma*, helps in wound closure by

tissue binding action, *Madhura rasa* helps in *Dhatu Poshana* (tissue regeneration). *Yava* has good results because *Madhura, Kashaya rasa & Sheeta virya*. For this study, both Group A & B are treated with *Jaloukavacharana* followed by *Kalka* application.

Probable mode of action of *Jaloukavacharana*: - Leech saliva contains Hirudin, Fibrin, Hirustatin, Bdelins, Hyaluronidase, Tryptase inhibitor, Eglins, Factor- X an inhibitor, Carboxypeptidase A- inhibitor, Histamine and Acetylcholine. Bdelin B-3 is found to have anti-inflammatory action at the wound site. Hyaluronidase is found to have antimicrobial property over the tissues. Carboxy peptidase A- inhibitors increase the blood flow at the wound site. Histamin and Acetylcholine like substances present in saliva of *Jalouka* are found to act as Vasodilatation on the smaller vessels over the site of application. All the properties like anti-inflammatory, antimicrobial, vasodilatation increase blood flow and are very much helpful to heal a wound. All these properties are present in the saliva of leech which helps in proper nourishment, oxygen supply and removing the toxic substances from the site of wound.

Probable mode of action of *Kalkas*:

These *Kalkas* are mentioned in Sushruta samhita for the treatment of *Vrana*. The *Tikta, Kashaya rasa, Katu vipaka & Sheeta virya* of *Yava* helps in controlling inflammatory phase of wound healing. It also helps in proliferatory phase due to the *Kashaya rasa* which helps in wound contraction, *Madhura rasa* in tissue generation & *Sheeta virya* by *Stambhana* property. In remodeling phase due to *Madhura rasa & Sheeta virya* of *Yava* provides wound strengthening & tissue granulation. *Balya & Poshana karma* of *Madhura rasa* helped in promotion of healing by *Dhatu- vardhaka* leading healthy & desired scar formation. Barley contains zinc, phosphate, Vitamin-A, thiamine, potassium, selenium and iron are aids in skin healing & wound restoration. Barley beta-glucan accelerates wound healing by favoring migration versus proliferation human dermal fibroblast. In *Yavadi kalka* majority of drugs have *Madhura rasa, Sheeta virya, Guru, Picchila, Ruksha guna*.

Tiladi Kalka has predominance of *Madhura, Kashaya, Katu and Tikta rasa, Madhura vipaka, Guru, Snigdha, Sukshma guna*. *Tila* has *Madhura, Katu, Tikta, Kashaya rasa, Ushna veerya* and *Madhura vipaka*. Seasmol a chemical present in *Tila* has a phenol ring & acts as an anti-inflammatory drug.

Nimba patra- Neem contains many active ingredients such as nimbidin, nimbin & nimbidol with anti-inflammatory, anti-bacterial, anti-fungal & anti-viral properties that may help it accelerating the wound healing process. In addition, neem contains an excellent amount of amino acids, vitamin and mineral that is very important in wound healing processes in proliferation phase.

Go Ghrita-has soothing property. It forms a thin film over them and that allows early epithelization of wound. It also protects wound from invasion of any microbe. Phytosterols, the chief components of ghee are known to be good emulsifiers, the property of which was assumed to facilitate penetration of drug into the tissue. Tannins and anthraquinones are known anti-oxidant and blood purifiers with anti-inflammatory actions. As the oxidation process hampers the wound healing, anti-oxidant protect the tissue from the oxidative damage. Tannins also reduce the secretions where as palmitine and berberines both have bactericidal action and glycosides have anti-infective activity which combated the infection and thus prevented infections in the wound. Tannins, anthraquinones, berberines and phytosterols all are anti-inflammatory and thus prevented the prolongation of the initial phase and reduces the pain as well as tenderness, redness, swelling like features, which led to progress of the wound towards healing. Tannins and phytosterols promoted the healing process by wound contraction with increased capillaries formation and fibroblast proliferation, followed by enhanced rate of epithelialization. Glycosides accelerated the healing process and reduced the scarring, as the proposed mechanism of action involves the regeneration of skin through stimulation of stem cells that allows healing without substantial scar formation. Ascorbic acid is an important requirement for collagen connec-

tive tissue synthesis which leads to wound contraction and scar maturation by cross linking of collagen fibres. Vitamin- A is essential for epithelialization which lessens the pigmentation and improves the condition of scar. The inflammatory effects of barley are very useful to improve the surrounding skin tone. Topical application of barley treats infection. It works as natural exfoliator and also controls production of secretions.

Madhu is a very good *Vrana shodhaka* due to its *Sukshmata Prabhava* it enters very small pores around the wound site and does not allow any infections to enter the site. When cleansed it also does de-sloughing of the wound by *Lekhana* property. *Madhura rasa* gives nutrition to the tissue, which helps in granulation tissue formation. Honey is hygroscopic in nature, with a pH of 3.2- 4.5. It prevents colonization and bacterial growth in tissues due to this acidic nature. Most micro-organisms do not grow in pure honey because of its low water activity of 0.6. Honey also has antibacterial properties. The presence of hydrogen peroxide and a high osmotic pressure also contribute to the antibacterial effect of honey. Honey is a hyper osmolar medium, preventing bacterial growth. Because of its high viscosity it forms a physical barrier and the presence of the enzyme catalyzes gives honey antioxidant properties.

So in nut shell these *Kalkas* enhances the speed of process of healing by promoting epithelialization, reducing inflammation by eliminating *Tikshna guna* of *Pitta* and relieving pain, reducing wound contraction, by keeping the edges soft by reducing *Rukshata* of *Vayu*, it reduces the risk of secondary infection and *Kapha* is counteracted by *Madhu*. *Madhu* is believed to act by pacifying the three vitiated *Doshas*.

Madhura rasa gives nutrition to the tissue, which helps in granulation tissue formation, while *Kashaya rasa* provides *Lekhana* that helps in de slough, preparing the wound for healing. So these excellent properties of *Kalkas* help to heal the wound by virtue of its *Shodhana, Ropana* and *Sandhana* actions.

Pathya-Apathya in ahara and vihara

Pathya: Jeerna shaalyodana, Jangala mamsa, Tanduliyaka, jivanti, Sunishannak, Vastuk, Bal-mulak, var-

tak, Patola, Karvellak, Dadima, Amlaki, Saindav, Mudga rasa, saktu, vilepi, Kulmasha, shrit jala, Nicha nakha and roma, suchi, shukla vastra, dhoopa with sarshapa, nimba leaves, lavana and ghee.

Apathya: Navadhanya, Masha, Tila, Kalaya, Kulatta, Nishpava, Haritaki, Amla, Lavana, Katu rasa Pradhana Dravyas, Guda pishta vikruti, Vallura, Shushka shaka, Aja, Avi, Aanupa, Oudaka, mamsa, Shitodaka, Krushara, Dadhi, Dugdha, Takra, Should avoid chankramana, asana, streenaam darshana, sambhashana, vaata, aatapa sevana, rajo, dhooma, irshya, bhaya, shoka, ratri jagarana, Vishama aasana, shayana, upavas, vaag, vyayama.

CONCLUSION

Yavadi Kalka showed effective results than *Tiladi Kalka* after *Jaloukavacharana* in both groups in the management of *Dusthavrana* (Non healing traumatic ulcer).

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| No | Subjective | Objective |
|----|------------------------|--------------------|
| 1 | Vedana-Pain | Akruti-Size |
| 2 | Kandu-Itching | Srava-Discharge |
| 3 | Daha-Burning sensation | Tenderness |
| 4 | Gandha-Foul smell | Floor of the ulcer |

| Dug | Botanical name | Part used | Quantity |
|--------|----------------------|-----------|----------|
| Yava | Hordeum Vulgare Linn | Fruit | 1 part |
| Tila | Sesamum Indicum Linn | Fruit | 1 part |
| Nimba | Azadirachta Indica | Leaves | 1 part |
| Ghrita | Ghrita | | 2 parts |
| Madhu | Madhu | | 2 parts |

| | | |
|--|------------|-----------------------------------|
| Enrollment – Assessed for eligibility = 45 | | |
| Excluded (n=04) | | |
| Not meet the inclusion criteria (n=03) | | |
| Declined to participate (n=01) | | |
| Randomized (n= 41) | | |
| Group A (n=20) | Allocation | Group B (n=21) |
| Loss to follow up (n=0) | Follow up | Loss to follow up (n=1) |
| Did not complete the intervention | | Did not complete the intervention |
| Analyzed (n=20) | Analysis | Analyzed (n=20) |

| Grade | None (0) | Mild (1) | Moderate (2) | Severe (3) | Highly severe (4) |
|--------------------|-----------------------|---|---|---|--|
| Pain | VAS 0 | VAS 1-3 | VAS 4-6 | VAS 7-10 | |
| Itching | No | Occasional itching | Regular itching without disturbing sleep | Persistent itching which disturbs sleep | |
| Burning sensation | No | Occasional episode of localized burning sensation | Continuous burning sensation without disturbing sleep | Continuous burning sensation which disturbs sleep | |
| Size of ulcer | No lesion | Between 0-3sq.cm ² | Between 3-6sq.cm ² | Between 6-10sq.cm ² | |
| Tender ness | No | Patient says the area is tender | Patient winces due to pain | Patient winces & withdraws the affected part | Patient doesn't allow touching the affected part |
| Foul smell | No odor | Odor is evident at close proximity to the patient. | Odor is evident upon entering the room with dressing removed. | Odor is evident upon entering the room/ 6-10 feet from the patient with intact dressing | |
| Discharge | Absent | Serous | Sero-purulent | Purulent | |
| Floor of the ulcer | Normal skin with scar | Healthy granulated tissues but still wound is not formed scar | Partially covered with slough | Fully covered with slough and purulent discharge | |

Table V: Effect of therapy in group-A (Yavadi Kalka after Jaloukavacharana)

| Parameters | | Mean | SD | SE | t-value | df | p-value |
|--------------------|----|------|------|-------|---------|----|-----------------|
| Pain | BT | 2.55 | 0.51 | 0.11 | 21.8 | 19 | <0.0001 (HS) |
| | AT | 0.25 | 0.44 | 0.04 | | | |
| Itching | BT | 2.10 | 0.64 | 0.14 | 15.1 | 19 | <0.0001 (HS) |
| | AT | 0.05 | 0.22 | 0.05 | | | |
| Burning Sensation | BT | 1.70 | 0.86 | 0.19 | 8.79 | 19 | <0.0001 (HS) |
| | AT | 0.00 | 0.00 | 0.00 | | | |
| Size | BT | 2.20 | 0.76 | 0.17 | 13.2 | 19 | <0.0001 (HS) |
| | AT | 0.30 | 0.47 | 0.12 | | | |
| Discharge | BT | 2.10 | 0.78 | 0.18 | 12.07 | 19 | <0.0001 (HS) |
| | AT | 0.05 | 0.22 | 0.22 | | | |
| Tenderness | BT | 2.75 | 0.44 | 0.099 | 23.1 | 19 | <0.0001 (HS) |
| | AT | 0.15 | 0.36 | 0.081 | | | |
| Foul smell | BT | 2.30 | 0.66 | 0.145 | 15.15 | 19 | <0.0001 (HS) |
| | AT | 0.25 | 0.44 | 0.099 | | | |
| Floor of the ulcer | BT | 1.65 | 0.81 | 0.182 | 8.72 | 19 | <0.0001 (HS) |
| | AT | 0.05 | 0.22 | 0.050 | | | |

Table VI: Effect of therapy in group-B (Tiladi Kalka after Jaloukavacharana)

| Parameters | | Mean | SD | SE | t-value | Df | p-value |
|--------------------|----|------|------|------|---------|----|-----------------|
| Pain | BT | 2.65 | 0.48 | 0.10 | 10.2 | 19 | <0.0001 (HS) |
| | AT | 0.65 | 0.47 | 0.12 | | | |
| Itching | BT | 1.90 | 0.64 | 0.14 | 13.3 | 19 | <0.0001 (HS) |
| | AT | 0.00 | 0.00 | 0.00 | | | |
| Burning Sensation | BT | 1.60 | 0.75 | 0.16 | 7.95 | 19 | <0.0001 (HS) |
| | AT | 0.60 | 0.50 | 0.11 | | | |
| Size | BT | 2.10 | 0.64 | 0.14 | 10.5 | 19 | <0.0001 (HS) |
| | AT | 0.70 | 0.57 | 0.12 | | | |
| Discharge | BT | 2.30 | 0.65 | 0.15 | 12.32 | 19 | <0.0001 (HS) |
| | AT | 0.30 | 0.47 | 0.11 | | | |
| Tenderness | BT | 2.40 | 0.59 | 0.13 | 16.4 | 19 | <0.0001 (HS) |
| | AT | 0.25 | 0.44 | 0.09 | | | |
| Foul smell | BT | 2.65 | 0.48 | 0.10 | 18.0 | 19 | <0.0001 (HS) |
| | AT | 0.35 | 0.48 | 0.10 | | | |
| Floor of the ulcer | BT | 2.15 | 0.74 | 0.16 | 14.09 | 19 | <0.0001 (HS) |
| | AT | 0.30 | 0.47 | 0.10 | | | |

Fig-1: Drugs for the preparation of Kalkas



Fig -2: Procedure of Jaloukavacharana



Fig-3: Images of Group-A BT & AT



Fig 4: Images of Group-B BT & AT

