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A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFECT OF JATHY-ADI GHRITA WITH POVIDONE IODINE OINTMENT IN DUSHTAVRANA

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ABSTRACT

Dushtavrana is a commonly encountered problem faced in surgical practice. The presence of Dushtavrana worsens the condition of the patient with different complications which may become fatal and life-threatening. Good wound healing with minimal scar formation and pain is the prime motto of every surgeon. Many formulations have been in use for centuries. One of these is a polyherbal drug, Jathyadi Ghrita. The present study compares the effect of Jathyadi Ghrita and Povidone Iodine ointment on relief in signs and symptoms of Dushtavrana. Clinically diagnosed 34 Dushtavrana patients were divided into groups A and B. Group A (Trial group) managed with Jathyadi Ghrita. Group B (the control group) was managed using the Povidone Iodine ointment application. The study duration was 28 days in both groups, with 17 participants in each group. Assessment was done on 0th, 7th,14th,21st and 28th day. The data obtained was statistically analysed and interpreted. The assessment was done on the 0th,7th,14th,21st and 28th day. The collected data were subjected to statistical analysis using appropriate statistical methods. Frequency and percentages were calculated for qualitative variables, while mean and SD were calculated for quantitative variables. Nonparametric methods were employed to analyse the data. The Wilcoxon signed-rank test was used to assess the significant effect before and after treatment within each group. The Mann Whitney U test was used to compare two groups based on before and after treatment values. P value less than 0.05 is statistically significant. All analyses were carried out with the help of the software SPSS 23.0. Statistically significant changes were noted in pain and itching sensation by management with Jathyadi Ghrita in Dushtavrana compared to Povidone Iodine ointment. Considering all observations, statistical analysis was done, and conclusions were drawn. The study results statistically reveal that *Jathyadi Ghrita* shows better results than Povidone Iodine ointment in managing pain, itching sensation, burning sensation, ulcer size, and discharge. Thus, the null hypothesis is rejected, and the alternate hypothesis is accepted.

Keywords: *Dushtavrana*, *Jathyadi Ghrita*, Povidone Iodine ointment

INTRODUCTION

Ayurveda is a time-tested health system with a vast scope of trials to prove certain principles and the therapeutic effects of medicines. To make Ayurveda more acceptable globally, it is necessary to prove certain principles and the therapeutic effects of medicines. *Sushruta*, an accomplished surgeon in his era, was much ahead of his time in elaborating and practising the beautiful concept of *Vrana Ropana*.

According to Acharya Sushruta, Dushtavrana is a persistent ulcer that can appear in any part of the body and is caused by either the doshas or any trauma¹. An ulcer is a break in the continuity of the covering epithelium, skin, or mucous membrane². The ulcer that fails to heal after two weeks is said to be non-healing. Non-healing ulcers affect nearly 6 million people worldwide³. Wound healing is a normal biological response to any tissue injury. It is a complex process that involves cells, cellular products and extracellular components that act together to restore the structural and functional integrity of the tissue. After injury, healing is a natural phenomenon and continues sequentially till the formation of a healthy scar. In the present day, all efforts are made to keep wounds clean during various stages of healing.

Usually, nature takes complete care during healing. But when the infection is massive, the surface area of the wound is enormous, and the slough or necrotic tissue is too much, this auto-cleansing mechanism becomes inadequate. *Acharya Sushruta* has indicated how these impediments can be removed, thus paving the way for uninterrupted healing. This process is called *Vrana Shodhana*, and later, healing can be accelerated by the method described under *Vrana Ropana*. The content of *Jathyadi Ghrita* has *Shodhana*, *Ropana*, *Raktha Shodhana*, *Krimighna*, *Kandughna* and *Shothahara* properties, which are

necessary for healing wounds. Its contents also have antiseptic, antimicrobial, and antibacterial properties; this property is widely used in clinical practice. *Jathyadi Ghritha* is a traditional preparation recommended for the *Shodhana* and *Ropana* of *Vrana*. The *Shodhana* and *Ropana* medications used in *Jathyadi Ghritha* have been proven to be particularly successful in reducing pain, discharge, and oedema of the surrounding tissues, as well as acting as a debriding agent, removing slough and necrotic material from the wound, and promoting healing.

In India, the prevalence of non-healing ulcers is approximately 4.5/1000 in the population⁴. Non-healing ulcers are those wounds that do not heal by two weeks; these significantly impact the health and quality of life of the patients and their families. Since ancient times, wound healing has been the central problem in surgical practice. Treating a wound aims to shorten the time required for healing or minimise the undesired consequences. Many investigations and experiments have been carried out in medical science to understand the phenomenon of wound healing. Local applications with antiseptics like Povidone Iodine are used to treat wounds. These treatment modalities still have their own limitations and side effects. Attention is directed to discovering an agent that will accelerate wound healing with fewer side effects. Modern-day treatment of wounds does not consist of a single drug offering the properties of cleaning and healing wounds with the same drug. The search for a drug that can fulfil the optimal requirement is ongoing.

Jathyadi Ghrita is one such medicine mentioned in Ayurveda classics that has both Vrana Shodhana and Ropana effects. It can be used in Marmasritha Vrana (wound present over vital points), Sukshma Nadivrana (ulcer with a narrow sinus), Kledivrana (wound with excessive secretion), Gambhira Vrana (deepseated wound), and Saruja Vrana (painful wound)⁶. Wound healing is a natural and critical process for the body. It is the biggest challenge for every surgeon to successfully heal a wound in the present era. Ayurveda is an ancient science of herbal medicine and surgery that provides various wound-healing treatments. There is a need to find a rational and optimal healing compound for wound management in a better way. Acharya Sushruta has described the management of Vrana in Sushruta Samhita. In Ashtangahridaya Uttarastana Vranaprathisheda adhyaya, Jathyadi Ghrita is mentioned as having both Vrana Shodhana and Ropana property⁷. Susruta Samhita Sutra Sthana, Vranasrava Vijnaneeya Adhyaya, and Dushtavrana are mentioned. Shastiupakrama for Vrana is told in Chikitsa Sthana Dwivrananeeyam Adhyaya, where Shodhana and Ropana chikitsa for Vrana are also mentioned. Many studies have been conducted regarding Vrana Ropana in a clinical study of Manjishtadi Ghrita in Vrana Ropana 8. It was concluded that Manjishtadi Ghrita possesses high efficacy in Vrana Ropana without producing any adverse effects in a study to evaluate the impact Of Saptacchada Kshara Pratisarana and Jatyadi Gritha in Dushtavrana 9. The effect of Saptacchada kshara and Jatyadi Gritha was found to be better in managing Dushtavrana than Povidone Iodine. Another study on Karpooradi Ghritha in The Management of Vrana concludes that Karpooradi Ghrita effectively manages *Dushtavrana* ¹⁰.

AIM OF STUDY OBJECTIVES

- To study the efficacy of *Jathyadi Ghrita* and its role in managing *Dushtavrana*.
- To study the efficacy of Povidone Iodine ointment and its role in managing *Dushtavrana*.
- To compare the effect of *Jathyadi Ghrita* and Povidone Iodine in managing *Dushtavrana*.
- To assess the effect of *Jathyadi Ghritha* and Povidone iodine and compare the healing impact of Povidone Iodine Ointment and *Jathyadi Ghrita* in the management of *Dushtavrana*.

MATERIALS AND METHODS

A Randomized Controlled Trial with participants satisfying the diagnostic criteria and inclusion criteria of Dushtavrana of age 20 years to 70 years who attended OP and IP Department of Salyatantra, Sree Narayana Institute of Ayurvedic Studies and Research Hospital, Pangode, Puthur, Kollam were selected divided into two groups using the lottery method,17 participants in each group, with a total sample size of 34. Samples were selected from the sampling frame following inclusion and exclusion criteria and after clinical examination and laboratory investigations. The 17 subjects chosen for trial Group A were treated with Jathyadi Ghrita. The 17 subjects selected for control Group B were treated with Povidone Iodine ointment. The study duration was 28 days; the assessment was done on the 0th,7th, 14th, 21st and 28th days.

Diagnostic criteria

(Classical signs and symptoms of *Dushtavrana*)

- 1. Discolouration of surrounding tissue
- 2. Discharge
- 3. Foul smell
- 4. Pain
- 5. Oedema
- 6. Itching

Subject inclusion criteria

- 1. Non-healing ulcers with slough, discolouration, and discharge last over two weeks.
- 2. Wound size not more than 5cm x 5cm x 1cm.
- 3. Patients were selected irrespective of sex and religion.
- 4. Patients were selected from the age group of 20 to 70 years.

Subject exclusion criteria

- 1. Uncontrolled diabetes mellitus.
- 2. Patients with any systemic disorders like HIV or tuberculosis.
- 3. Arterial ulcers, pressure ulcers, malignant ulcers.
- 4. Patients with osteomyelitis.

PROCEDURE

Materials required: *Jathyadi ghrita*, Povidone Iodine ointment 10%, sterile cotton swabs, pads, gauze, normal saline, sterile gloves, and bandage cloth.

GROUP A: Wound dressing with *Jathyadi Ghrita*

GROUP B: Wound dressing with Povidone Iodine ointment!

The patient was made to sit comfortably, and the wound was cleaned with normal saline and dried well with sterile gauze. *Jathyadi Ghrita* was applied in

Group A, and Povidone Iodine was applied in Group B, bandaged with a sterile pad and gauze.

Dressing was done daily for 28 days.

Assessment and follow-up

Assessment was done on the 0^{th} day, 7^{th} day, 14^{th} , 21^{st} and 28^{th} day.

Outcome measures

SUBJECTIVE PARAMETERS	OBJECTIVE PARAMETERS
Pain	Size of ulcer
Burning sensation	Discharge
Itching	

Group A - Jathyadi Ghrita



Fig I Dressing Set



Fig 2 :Jathyadi Ghrita



Fig 3 : Before Treatment 0" Day



Fig 4: After Treatment 28th Day

OBSERVATION AND ANALYSIS

A total of 34 subjects fulfilling the inclusion criteria were randomly selected for the study. They were divided into two groups, Group A and Group B, with 17 participants in each group. Data related to Age, Sex, Religion, Socio-Economic Status, Education, and Addiction of 34 participants were collected and observed.

The collected data were subjected to statistical analysis using appropriate statistical methods. Frequency and percentages were calculated for qualitative variables, while mean and SD were calculated for quantitative variables. Since the data was not distributed normally, non-parametric methods were employed to analyse the data. The Wilcoxon signed-rank test was

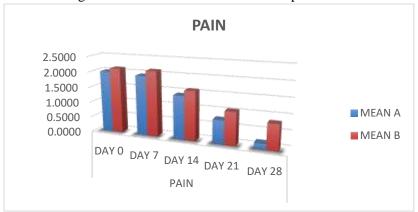
used to assess the significant effect before and after treatment within each group. The Mann Whitney U test was used to compare two groups based on before and after treatment values. p value less than 0.05 was statistically significant. All analyses were carried out with the help of the software SPSS 23.0.

Effect of treatment on study parameters

The effect of treatment on each group was evaluated by the Wilcoxon signed rank test, and both groups were compared with the Mann—Whitney U test.

1. Effect on Pain

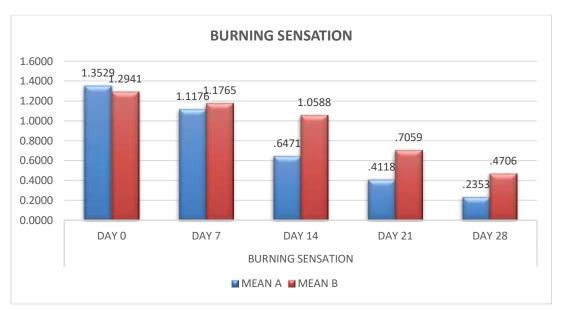
Mann Whitney U test showed a significant difference in pain level in Group A and Group B on the 28th day as the p<0.05. So, Group A showed a significant reduction in pain levels.



GRAPH 1: Diagrammatic representation of comparison of pain in both groups

2. Effect on Burning sensation.

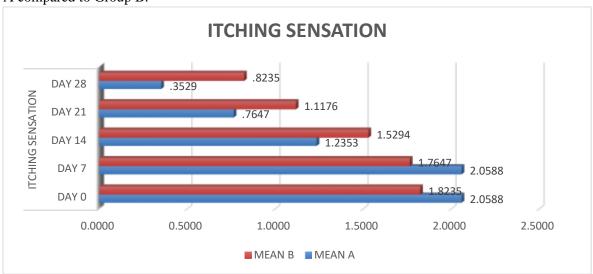
The Mann-Whitney U test showed decreased burning sensation in Groups A and B. The mean values on day 0 of both groups were 1.3529 and 1.2941, reduced to 0.2353 and 0.4706, respectively. Even though it was not statistically significant, there was a faster reduction in burning sensation in Group A than in Group B.



Graph 2: Diagrammatic representation of comparison on a burning sensation in both groups

3. Effect on itching sensation.

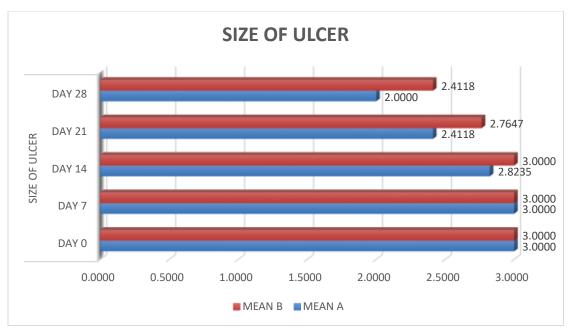
The Mann Whitney U test showed a decrease in itching sensation in both Groups A & B. After the treatment on the 28th day, itching sensation in Groups A and B differed significantly with p<0.05. So, there was better relief in Group A compared to Group B.



Graph 3: Diagrammatic representation of comparison on itching sensation in both groups

4. Effect on size of ulcer.

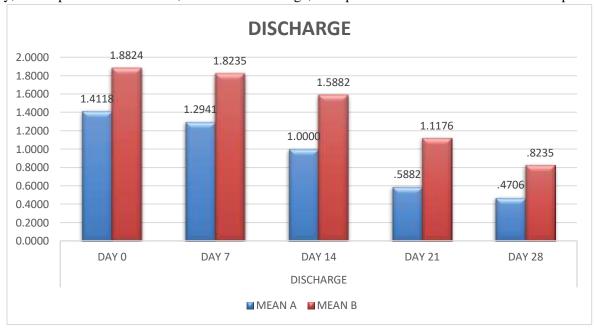
The Mann-Whitney U test showed that the size of the ulcer decreased in both Group A and Group B. In Group A, the change in size of the ulcer from day 7 to the 14th day was 3 to .2.8235, but no change was observed in Group B during the same time period. So, in terms of reducing the size of the ulcer, Group A showed a better result than Group B.



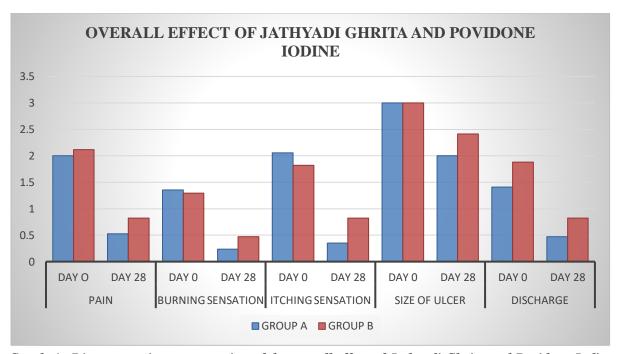
Graph 4: Diagrammatic representation of a comparison of the size of ulcers in both groups

5. Effect of discharge

The Mann-Whitney U test showed that Group A and Group B differed significantly in discharge level during the 14th day, with a p-value of 0.042. So, in terms of discharge, Group A showed a better result than Group B.



Graph 5: Diagrammatic representation of a comparison of discharge in both group



Graph 6: Diagrammatic representation of the overall effect of Jathyadi Ghrita and Povidone Iodine

DISCUSSION

Wound healing is when damaged tissue is restored to its normal state as closely as possible. The problem of wound healing has been dealt with at various levels by humanity ever since the advent of humanity. An ideal dressing material should not only accelerate wound healing but also reduce the loss of protein, electrolytes and fluid from the wound and help to minimise pain and infection. The plethora of wound care products in the market has resulted in practitioners using a combination of products, which may make the treatment very expensive ¹¹.

Wound healing is completed in three phases: Inflammation, proliferation, and remodelling. Granulation, collagen maturation and scar formation are other phases of wound healing that run concurrently but are independent of each other ¹².

Ropana is always associated with shodhana because a wound cannot be healed without Shuddha. An attempt was made to explore the shodhana and ropana properties of the trial drug. Vrana ropana involves shodhana followed by ropana; two stages happen practically, i.e., subsiding local shotha by removal of local dhatu dushti, followed by initiation of ropana

process, i.e., contraction and covering of wound by epithelial layers.

Probable mode of action based on *Rasa* of *Jathyadi Ghrita*

The main ingredients of *Jathyadi Ghrita* are *Katu Rasa*, *Tiktha Rasa*, and *Kashaya Rasa*.

When we critically study the *Guna karmas* of *Katu Rasa* as mentioned in our classics, we end up with the term *Vrana Avasadayati* in the *Charaka Sutra* and *Ashtanga Samgraha Sutra Sthana*^{13.} Also, the properties like *Mamsa Lekhana, Shodhana, and Chedhana* mentioned in the context of *Katu Rasa* imply that they do the *Chedana* and *Lekhana* of *Dushta Mamsa* (unhealthy tissue) formed at the site of *Vrana*, thus doing the *Shodhana* of *Vrana*¹⁴.

Tiktha Rasa does the Shoshana of Kapha, Puyasrava, and Kleda. The Twak mamsa sthirikarana property mentioned for Tikhta Rasa helps strengthen tissues. It has Lekhana Guna; thus, it plays a significant role in Vrana Shodhana by keeping the wound area clean. The Krimighna property of Tiktha Rasa prevents the growth of microbes and, therefore, provides a shield against infection ¹⁵.

Kashaya rasa fastens the process of contraction by its Sandhaniya karma. Ropana karma helps form

healthy granulation tissue, thus facilitating the wound-healing process ¹⁶.

Effect on pain: Groups A and B differ significantly in pain level on the 28th day of treatment. Statistical and clinical data of both groups show that Group A had speedy pain relief compared to Group B.

The Ayurvedic pharmacodynamics of Haridra reveals that it possesses Katu, Tiktha, Ruksha, and Ushna properties and has Kapha pittahara action. Haridra also possesses four medicinal properties, including Dahahara, Rujahara, Varnya, and Vishodana action. Vedanasthapana property may be due to Ushna Virya's presence in Jati, Patola, Haridra, Daruharidra, Manjishta, Karanja and Tuttha. Lekhana's property of Tuttha and Abhava may have helped remove slough and other unwanted tissues, which reduced infection, improved circulation, and reduced pain ¹¹⁷. Madhuka, Sariva, and Go Ghrita have Vata Shamaka properties, which may also reduce pain. Due to Madhura Rasa, Madhura Vipaka and Sheetha Virya, Madhuka has Pitta and Vata Shamana property 18. The overall effect reduces infection and removes slough and unwanted tissues, thus reducing pain.

Effects on Burning sensation: In Group A, the burning sensation significantly changed from the 0th to the 7th day. Thereafter, it reduced progressively; by the 28th day, significant relief was found.

In Group B, there was no significant reduction in burning sensation from the 0th to the 7th day. However, when comparing both groups, there was no significant difference in a burning sensation. So, there is an observed faster reduction in burning sensation in Group A than in Group B.

In nonhealing ulcers, due to poor local circulation, there is hypoxia to the nerve, resulting in a burning sensation. *Jathyadi Ghrita* removed slough and other unhealthy tissues from the ulcer with the *Lekhana* action of *Tutta and the Vrana Shodhana action of Darvi. Jati* may have also helped reduce the burning sensation. *Ushna veerya* of *Jati*, *Patola*, *Haridra*, *Daruharidra*, *Manjishta*, *Karanja and Tuttha* remove *Srotorodha* and improve circulation. All these actions, which will enhance local circulation, may have

reduced hypoxia, resulting in relief from the burning sensation.

Effects on Itching sensation: In Group A and Group B, there is a significant change in itching sensation during the 14th day, which is progressive. While comparing both groups, Group A had considerable relief in its itching sensation compared to Group B. Itching may occur due to the presence of infective organisms, slough, and other exudates. Charaka and Sushrutha Acharya have mentioned that Karanja has Kandugna action. Bhavamishra has specifically mentioned Karanja in Kushta and Krimi. It contains Karanjin and Pongamin constituents, which have antibacterial properties. As per Bhavamishra, Nimba has Krimi-kushtagna action as it pacifies vitiated Kapha and Pitta¹⁹. Nimba, Katuki, and Nakthahwa are in Jathyadi Ghrita and have Kandughna property. Also, the Jantughna and Kushtaghna properties of various ingredients, Abhaya, Siktha, Nisha and Jati, might have contributed to the effect. Curcumin in Haridra has anti-inflammatory, antiseptic, antibacterial and antimicrobial properties; salicylic acid in Jati has antibacterial, antifungal, and anti-inflammatory properties ²⁰. Collecting fluids in tissue can cause mechanical stress that may exacerbate itching sensation ²¹. Shothahara properties of Patola, Katuka, Darvi, Jati and Sariva might have helped to reduce the peripheral tissue oedema and itching sensation.

Effect on size of ulcer: Statistical data and clinical data of both groups show that Group A had a speedy reduction in size as compared to Group B

The ingredients of *Jathyadi Ghrita include Tiktha*, *Kashaya Rasa*, *Laghu*, *and Ruksha Gunas*. These *Rasa* and *Guna* possess properties like *Vrana Ropana*, *Twak Mamsa Sthireekarana* (Strengthening the tissue)²², promotion of collagen synthesis by fibroblasts, and neo angiogenesis, which increases the amount of granulation tissue, speeding up the regeneration process. Also, *Ushna Veerya* drugs probably stimulate the proliferation of healthy granulation tissue.

Jathyadi Ghrita does the Snehana of tissue and provides adequate nourishment. Preparation with a ghee base facilitates enhanced drug penetration for early

wound healing, giving nutrition to the tissue. *Rakta prasadak dravya*, like *Manjishta* and *Sariva*, enhances the *Raktadhatu*, which helps in improving tissue perfusion and strengthening local venous structure ²³. *Charakacharya* mentioned that *Madhuka* is a good *Rakthaprasadaka* and *Raktha shodaka* drug. Studies conducted on modern scientific parameters proved Yasthimadhu's skin-regenerating activity.

Katuka in the Jathyadi Ghrita improves reepithelialization, neovascularisation, and migration of endothelial cells, dermal myofibroblasts and fibroblasts into the wound bed ¹⁴². Recent studies proved that Tuttha (CuSO4) promotes angiogenic responses in vitro, in vivo wound models, thus helping in rapid filling of wound area with granulation tissue, which in turn helps in closure of wound area Beeswax has the qualities like Mridu (soft), Snigdha (unctuous) and having the properties Vranashodhana (cleansing the wound), Vranaropana (healing the wound). All these effects reduced wound size from day 21 to 28.

Effects on discharge: Group A and Group B differ significantly in discharge level during the 14th day. So, regarding discharge, Group A has shown a better result than Group B.

The decrease in the quantity of discharge is due to the *Shodhana* effect of *Jathyadhi Ghrita*, *which contains Jati*, *Daruharidra*, *and Tuttha*, *which have Kashaya* (astringent), *Tiktha Rasa*, *Lekhana* (scraping), *and Kleda Shoshana* (drying of exudates) properties. A recent animal study proved that Beeswax is effective in reducing wound exudates.

CONCLUSION

The following conclusions were drawn based on the conceptual analysis and observation made in the clinical study to evaluate Jathyadi Ghritha's effect with Povidone Iodine in *Dusthavrana*.

The Maximum number of affected participants is in the 60-70 age group, with a predominance of male participants. Socioeconomic status is more common among middle-class individuals, and most of the participants follow a non-vegetarian diet.

Based on the observation and results obtained from both groups' statistical data and clinical data, it can be concluded that *Jathaydi Ghrita* significantly affects pain and itching sensations compared to Povidone Iodine. There is a faster reduction in a burning sensation in the *Jathyadi Ghrita* group than in the Povidone Iodine group.

The Jathyadi Ghrita group had a better reduction in size than Povidone iodine, and a reduction in wound size was observed from days 21 to 28. Regarding discharge, Jathyadi Ghrita has shown better results than Povidone Iodine due to the properties of its ingredients, which are the Shodhana and Kleda Shoshana.

Based on the above facts, the null hypothesis can be rejected, and the alternative hypothesis that there is a significant difference between Jathyadi Ghrita and Povidone Iodine in the management of Dushtavrana is accepted. *Jathyadi Ghrita* has a substantial effect on *Dushtavrana*.

This treatment with *Jathyadi Ghrita* is safe for continuous use and can be used as a medicine that accelerates wound healing.

Modern-day wound treatment does not comprise a single drug offering both the properties of cleaning and healing a wound. *Jathyadi Ghrita* is one such medicine mentioned in Ayurveda classics, which has both *Vrana Shodhana* and *Ropana* effects. Thus, with the observation and results obtained in this study, *Jathyadi Ghrita* can be considered a drug that can fulfil the optimal requirement.

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