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Case Study

EFFECT OF TOPICAL APPLICATION OF *APAMARGADI GHRITA* FOR *UTSADANA* - GRANULATION TISSUE FORMATION IN *DUSHTA VRANAM*

Athira Soman[1]*, P.Benedict[2], Sreelekha M.P[3]

*[1]PG Scholar, [2]Former Professor and HOD, [3]Assistant Professor, Department of Shalyatantra, Govt. Ayurveda College, Trivandrum, Kerala, India.

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ABSTRACT

Non-healing ulcers are defined as spontaneous or traumatic lesions, mainly in lower extremities that persist despite appropriate treatment and do not proceed towards healing in a defined time period. Wound healing is a very dynamic and complex process. It is divided into 5 stages in which granulation tissue formation, angiogenesis and synthesis of collagen occurs in the proliferative phase. On the basis of clinical features, non-healing ulcers can be considered as *Dushtavrana* in Ayurveda. Different types of *Vrana* and sixty types of treatment modalities are well explained in Susrutha Samhitha. *Utsadana karma* is indicated in non-healing ulcers with poor granulation tissue. It is the procedure by which the deep floor of the wound is elevated using drugs which promote growth of new tissues. *Utsadana* of *Vrana* can be correlated with the proliferation of new tissues in the wound healing process. The conservative and surgical management for non-healing ulcers mainly includes debridement, skin grafting and wound dressings. Even though these treatment methods help in healing the ulcer, the rate of recurrence is more due to the formation of unhealthy granulation tissue. Also it leads to complications like infection, sensory deficits, scarring and bleeding. Susruthacharya mentioned the drugs for *Utsadana* in *Misrakadhyaya*, they are *Apamarga, Aswagandha, Suvarchala, Talapatri* and drugs of *Kakolyadi gana*. Dalhana in his commentary mentioned Ghrita preparation of these drugs for topical application. *Rasayana*, *Brimhana* and *Balya* properties of these drugs will help in the formation of healthy granulation tissue. In the present case study a 30yr old male patient visited the OPD with non healing ulcer was selected for *Utsadana karma*. Daily dressing was done with *Apamargadi ghrita*. The study was done for a period of 30 days The dimensions and attributes of the ulcer was systematically measured on 1st, 8th, 15th, 30th day and the result was assessed. The result shows that topical application of *Apamargadi ghrita* is effective in *Utsadana*- granulation tissue formation of *Dushta vrana*.

INTRODUCTION

Ulcer is a break in the continuity of the covering epithelium either in skin or mucus membrane due to molecular death[1]. Non healing ulcers are those that have failed to progress through a timely sequence of repair without restoring anatomic and functional results. It is a major health problem worldwide and have great impact on personal, professional, and social levels. Its prevalence in the world ranges from 1.9% to13.1% of the total population.

In non-healing ulcers, the floor is covered with pale granulation tissue, base is considerably indurated and so is the edge and surrounding skin[2]. Granulation tissue consists of new connective tissue with microscopic blood vessels that form on the surface of a wound during the healing process. In general, non healing ulcers show characters like high level of proteases, elevated inflammatory markers, low growth factor activity, and reduced cellular activity. From the ancient period, wound healing has been the centre problem in surgical practice. The basic principles of wound management are debridement, dressings, nutritional supports, glycemic control and adjuvant

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therapies. Conventional treatment complications include infection, sensory deficits, scarring and bleeding. The major drawback of mechanical debridement includes potential disruption of newly formed tissue.

In the chapter *Dvivraniya chikitsa*, Susrutha has described *Shashtirupakrama* for *Vrana*.[3] *Utsadana* is one among them. It is indicated in *Sushka*, *Alpamamsa* and *Gambeera vrana*.[4] Here the term *Shuska*, *Alpamamsa* can be considered as ulcers having no granulation or unhealthy granulation tissue and the term *Gambeera vrana* as deep seated wound. *Utsadana* karma is beneficial to elevate the wound floor with new healthy tissues by topical application of various drugs. *Ghrita* formulation of drugs with *Utsadana* property will be beneficial to promote healthy granulation thereby accelerate wound healing promoting *Vrana utsadana* to accelerate wound healing.

Susruthacharya mentioned the drugs for *Utsadana* in *Misrakadhyaya* which includes *Apamarga*, *Aswagandha, Talapatri, Suvarchala* and *Kakolyadi gana*[5]. So in the present study, *Utsadana karma* with topical application of *Apamargadi ghrita* in non-healing ulcer will be done.

Scope of the Study

Dushta vrana or non-healing ulcers are those that do not heal in an orderly set of stages and in a predictable amount of time. Chronic ulcer affects about 10% of the total population. It can be considered as one of the leading health problems in our society due to its increased rate of recurrence and non-healing nature.

Almost all the patients approaching for treatment of chronic ulcers are labourers and poor patients who are malnourished and don't take proper care. Non-healing ulcers are the one that fails to heal in the expected time for an ulcer of that type which is usually less than 3 weeks. These have significant impact on health and quality of life of the patients and their families causing pain, loss of function, depression, anxiety, embarrassment, social isolation, financial burden, prolonged hospital stays and chronic morbidity.

In modern management surgical procedures like skin grafting is done in non-healing ulcers having unhealthy granulation tissue. But it may lead to complications like infection at the donor or recipient site, increased or decreased sensation at the recipient site, graft tissue contraction, scarring and bleeding. The complexity of the procedures and huge expenses are main drawbacks in the modern management of ulcer.

Acharya Sushrutha has explained sixty treatment modalities for wound healing. *Utsadana karma* is one among them which helps in the formation of healthy granulation and thereby elevation of the floor of the wound. It is mainly indicated in *Shushka, Alpamamsa* and *Gambeera vrana. Rasayana, Brihmana* and *Balya* properties of *Utsadana* drugs will tone up the granulation tissue and promote wound healing.

So the present work has been undertaken to assess the effect of topical application of *Apamargadi ghrita* in the *Utsadana* of *Dushta vranam.*

Case Report

A 30 yr old male patient, shop keeper by occupation came to the OPD with complaints of pain and pus discharge from a non healing ulcer over the right ankle. The patient had a history of RTA 5 yrs ago due to which he got injured at the right lower limb. On the basis of detailed history and clinical examination the patient was diagnosed as *Dushta vrana*.

Past History

Underwent skin grafting for about 3 times but he got only temporary relief

General Examination

General condition	Fair
Built	Moderate
Height	6'5''
Weight	68kg
Bp	120/80mmHg
Pulse rate	72/min
Respiratory rate	16/min
Pallor	absent

Clinical Examinations

Examination of ulcer

Mode of onset: Ulcer developed from an RTA 5 years ago

Duration: Chronic ulcer

Pain: Painful with inflammatory changes

Discharge: Purulent discharge

Associated disease: Nil

Inspection

Size: 8.7 X 7 X 0.2

Shape: Irregularly oval

Number: 1

Position: Medial aspect of Right ankle

Edge: Sloping edge

Floor: Washed leather floor, slough present

Surrounding area: Blackish discolouration present and the skin was wrinkled

Base – Ulcer rest on muscle

Discharge – Purulent

Bleeding - Absent

Palpation

Tenderness: Present

Slight induration is felt

Relation with deeper structures: Muscle

Examination of the Lymph Nodes

Regional lymph nodes are enlarged and tender.

Investigations done

CBC, FBS, PPBS, LFT, RFT – Within normal limits

CRP Quantitative - within normal limits

Methodology

- *Apamargadi Ghritam* is prepared as per classical references by adding *Kalka* made of *Apamarga*, *Aswagandha, Talapatri* and *Suvarchala* and *Dravadravya* taken is *Kakolyadi gana kashaya*.
- The *Ghrita* was taken according to the size of the wound and applied over the wound. Then dressed with a sterile pad daily.
- The ulcer was washed with *Thriphala kashaya* as a pre operative procedure. After that the *Apamargadi ghritha* is applied over the wound and dressed with sterile pad. The dressing was repeated daily for a period of 30 days. The dimensions and attributes of the ulcer were systematically measured on 1st, 8th, 15th, 30th day.

Materials Required

- *Thriphala kashaya*
- Kidney tray
- Scissors
- Sponge holding forceps
- Sterile gloves
- Sterile cotton pad
- Sterile cotton swab
- Gauze
- Adhesive plaster
- *Apamargadi ghrita*
- Spatula

For Internal Use

Guggulutiktakam kashayam- 90ml bd before food

Kaishora guggulu 1bd with *Kashayam*

Guggulu panchapala choornam- 5gm twice daily with honey.

For External Use

Kshalanam with *Triphala kashayam*

Daily dressing with *Apamargadi ghrita*

Ingredients of *Apamargadi ghrita*

Drugs	***Rasa***	***Guna***	***Virya***	***Vipaka***	***Karma***
Apamarga (*Achyranthus aspera*)	*Tikta, Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Dipana, Pachana, Ruchya, Vatakaphara, Medohara, Mutrala*
Asvagandha (*Withania somnifera*)	*Tikta, Kashaya*	*Laghu*	*Ushna*	*Madhura*	*Vatakapha haram, Balya, Rasayana, Vajikarana*
Talapatri (*Curculigo orchiodes*)	*Madhura, Tiktha*	*Guru, Snigdha*	*Ushna*	*Madhura*	*Vatapitha hara*
Vidharikandha (*Ipomea paniculata*)	*Madhura*	*Guru, Snigdha*	*Seeta*	*Madhura*	*Shukrala, Rasayana*
Mudgaparni (*Vigna trilobata*)	*Madhura, Tiktha*	*Laghu, Ruksha*	*Seeta*	*Madhura*	*Pitha hara, Shukrala, Kapha haram, Rasayana, Visagna*
Mashaparni (*Terammus labialis*)	*Tiktha, Madhuram*	*Laghu, Ruksha*	*Seeta*	*Madhura*	*Vatapithahara, Grahi, Balyam, Vrshyam, Shukrala*
Shatavari (*Asperagus racemosus*)	*Madhura, Tikta*	*Guru, Snigdha*	*Seetha*	*Madhura*	*Shukrala, Balya, Hrdya, Pithahara, Kaphavatahara*
Chinnaruha (*Tinospora cordifolia*)	*Tiktha, Kashaya*	*Laghu*	Ushna	*Madhura*	*Tridhoshashamaka, Sangrahi, Balya, Deepana, Rasayana Raktashodaka*
Karkadaka Sringi (*Pistacia chinensis*)	*Kashaya, Tiktha*	*Guru*	*Ushna*	*Katu*	*Kaphavata hara*
Tugakshiri (*Curcuma augustifolia*)	*Madhura*	*Laghu, Snigdha*	*Seeta*	*Madhura*	*Vatapitha shaman*
Padmaka (*Prunus Cerasoides*)	*Kashaya, Tiktha*	*Laghu*	*Seeta*	*Katu*	*Ruchyam, Vatala, Garbhastapana*
Varahikanda	*Madhura,*	*Laghu, Snigdha*	*Ushna*	*Katu*	*Kapha vata hara*

(*Dioscorea bulbifera*)	*Katu*				
Mridvika (*Vitis vinifera*)	*Madhura*	*Guru, Snigdha*	*Sitam*	*Madhura*	*Vatapithahara*
Jivanti (*Leptadenia reticulate*)	*Madhura, Kashaya*	*Laghu, Snigdha*	*Sitam*	*Madhura*	*Rasayan, Balya, Caksusya, Grahi, Vrsya, Brhmana, Stanyajanana, Visagna*
Madhuka (*Glycyrrhiza glabra*)	*Madhuram*	*Guru, Snigdha*	*Sitam*	*Madhura*	*Pitha hara*
Prapoundarika (*Nelumbo nucifera*)	*Kashaya, Madhura*	*Laghu, Snigdha*	*Sitam*	*Madhura*	*Kaphapitha haram*
Suvarchala (*Cleome viscosa*)	*Katu*	*Tikshna, Ruksha Vishtambi*	*Ushna*	*Madhura*	*Kaphavata haram*

Preparation of the Formulation

1. All the ingredients are taken of pharmacopoeial quality
2. *Murchita ghrita* is prepared and taken in a vessel and heat it mildly, then add Kalka *Dravya* made of *Apamarga, Aswagandha, Talapatri* and *Suvarchala* and, stir thoroughly while adding *Dravadravya Kakolyadi gana kashaya* in the specified ratio.
3. Heat for 3 hours with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allowed to stand for overnight. start the heating next day and observe the boiling mixture for subsidence of froth (*Phena santhi*) and constantly check the Kalka for the sign of *Varti* breaking down into pieces on attending to form a *Varti* (*Khara paka lakshana*).

Preparation of *Apamargadi ghrita*

Apamargadi ghrita

Poorva Karma

4. Patient made to lie comfortably.
5. Ulcer and its surrounding area exposed and cleaned using *Triphala kashaya.*

Pradhana karma

1. On a sterile pad, *Apamargadi ghrita* was taken using a spatula according to the size of the wound
2. The sterile pad with *Apamargadi ghrita* is placed over the ulcer and dressing will be done by using gauze roll keeping the pad in position.

Paschat karma

Condition of the patient will be assessed after the procedure for any adverse reactions

Assessment of the Study

The dimensions and attributes of the ulcer were systematically measured on 1st, 8th, 15th and on 30th day.

- The period of assessment was 30 days. The patient advised for review after 1 month to check the granulation tissue formation.
- The duration of the treatment procedure was 1 month.

Efficacy of the treatment is assessed by objective parameters mainly based on the clinical observations by grading method.

1. Size of the wound
2. Scoring system for granulation tissue formation.
3. Percentage of epithelialization.

Scoring system for granulation tissue formation

Score	Granulation tissue formation
1	No/minimal granulation tissue
2	Low granulation tissue
3	Moderate granulation tissue
4	Extensive granulation tissue
5	Very extensive granulation tissue

Epithelialization

Assessment	Score
100% wound covered, surface intact	1
75% to <100% wound covered &/epithelial tissue extends >0.5cm into wound bed	2
50% to <75% wound covered &/epithelial tissue extends to <0.5cm into wound bed	3
25% to <50% wound covered	4
<25% wound covered	5

OBSERVATION AND RESULT

Periodic Changes in the Non-Healing Ulcer by the Treatment in the Present Study

	1st day	8th day	15th day	30th day
Length	8.7cm	7cm	6cm	2.2cm
Width	7cm	6.5cm	5.5cm	3.5cm
Depth	0.2cm	0.2cm	0.1cm	0cm
Granulation Tissue Score	2	3	4	5
Epithelialization tissue score	5	4	3	2

Assessment of the Ulcer During the Treatment Period

1st Day **8th Day** **15th Day** **30th Day**

DISCUSSION

In the present study the assessment criteria's were the size of the wound, granulation tissue formation and epithelialization

Size of the Wound

Size of the wound was assessed by measuring the length, breadth and depth of the ulcer.

Length is measured from top to bottom of the ulcer, breadth is measured from side to side of the wound and depth is measured by inserting a q-tip to the deepest part of the ulcer.

Here the length of the ulcer at the start of the study was 8.7 which was reduced to 7cm at the 8th day of treatment. After 15 days of treatment length further decrease to 6cm. After 30 days of treatment the length decrease even more to 2.2cm.

While considering the width, at the start of the study the value was 7cm, after 7 days of treatment it was reduced to 6.5cm, at the 15th day of treatment it was further reduced to 5.5cm. After 30 days of treatment it was further reduced to 3.5cm.

Considering the depth of the ulcer at the start of the study it was 0.2cm, after 7 days of treatment there was no considerable change but at the 15th day it was reduced to 0.1cm and after 30 days of treatment there was a complete decrease (0cm) in the depth of the ulcer.

Granulation Tissue Formation and Epithelialization

It was assessed by the scoring system mentioned earlier. At the start of the study the granulation tissue score was 2 (low granulation tissue) which was further increased to 3 (moderate granulation tissue) after 7 days of treatment, after 15 days of treatment it was further increased to 4 (extensive granulation tissue) and during the 30th day it was raised to 5 (very extensive granulation tissue).

Epithelialization

It was also assessed by scoring system, at the start of the study the epithelialization score was 5 (<25% wound covered) which was reduced to 4 (25%

to <50% wound covered) after 7 days of treatment. At the 15th day of treatment the score was 3 (25% to <50% wound covered) and after complete treatment the score was 2 (75% to <100% wound covered &/ epithelial tissue extends>0.5cm into wound bed).

Thus the *Apamargadi ghrita,* which is used in the present study, has been found to have a significant effect on increasing granulation tissue formation and also decreasing the size of the wound. This may be due to:

- Most of the drugs involved in the study is having *Vatapitha hara, Sandhaneeya, Rasayana, Brahmana* and *Balya* properties that will help in the formation of healthy granulation tissue.
- Most of the drugs are having *Madhura, Tikta, Katu, Kashaya rasam.*
  - *Madhura rasam* promotes profound strength of *Dathus*, improves complexion, promote healing. It is *Guru, Snigdha*, pacifies *Pitta* and *Vata* and it is anti- toxic.
  - *Tikta rasa* cures worms, toxicity, skin ailments.
  - *Katu rasa* cures *Udarda* (urticarial), skin ailments, it is *Vranavasadana* (abrasive to hypergranulation in ulcers).
  - *Kashaya rasa* purifies blood, extract or squeezes abscess, promotes *Ropana* and it is *Ati twak prasadanam* (great skin tonic).
  - The presence of Aqueous and ethanol extract of *Achyranthus Aspera* (*Apamarga*) which is one of the main ingredient increases the fibroblast cell count, epithelial cells and synthesis of extracellular matrix including collagen synthesis which is responsible for granulation tissue formation.[6]
- And also with the use of 5% methanol extract of *Achyranthes Aspera* there is well organized epidermal layer, increased no of fibrocytes, remarkable degree of neovascularization and epithelisation. There is an enhanced rate of wound contraction and a drastic reduction in healing time, which might be due to enhanced epithelisation which can be directly measured in terms of days for complete closure of wound.[7]
- The active components of *Curculigo orchioides* (*Talapatri*) that have been reported are flavones, glycosides, steroides, saponins, triterpinoides and other secondary metabolites are found to have effects on pathogenic strains of gram positive bacteria (S.aureus and Staphylococcus epidermidis) and gram negative bacteria (E.coli, Pseudomonas aeruginosa).[8]
- The methanolic extract of *C.orchiodes* increases the rate of angiogenesis and improves antioxidant enzymes status that eventually leads to faster wound healing.[9]
- Betaine/polyhexanide, one of the chemical constituents of *Apamarga* is a combination of two medications that helps soften encrusted wounds, prevent wound infections and promote the healing of chronic or infected wounds that don't heal.[10]
- The chemical compounds of *Tinospora cordifolia* have found to have properties like antioxidant, antimicrobial, antibacterial and antifungal activities.[11]
- Achyranthine helps in wound contraction, elevation of various antioxidant enzymes like SOD, catalase, vitamin C and pro-healing and biochemical parameters like hydroxyproline and protein content.
- Saponins present in the study drug has been found to accelerate neovascularization and increase vascular endothelial growth factor and interleukin (IL)- 1beta which is one of the inflammatory cytokines known to induce the accumulation of macrophages at the wound sites and accelerate wound healing
- Ecdysterone exhibits more obvious granulation tissue formation, proliferation of epithelial cells, endothelial cells and fibroblasts

From all these inferences it is clear that the ingredients of *Apamargadi ghrita* have a significant role in increasing the fibroblast cell count, epithelial cells and synthesis of extracellular matrix including collagen synthesis which is responsible for granulation tissue formation.

The catalase, vitamin C and pro-healing and biochemical parameters like hydroxyproline and protein content which are enhanced by the ingredients of *Apamargadi ghrita* provide strength and integrity to the wound tissues and in turn it provides *Dathu pushti* of the affected tissues, leads to *Utharothara dathu pushti* and finally results in the faster wound healing.

Ghrita

- *Ghrita* which is one of the major component is also having *Vatapittahara, Kapha Vridhikara, Deepana, Vayasthapana* and *Rakshogna* properties.
- Useful for those suffering from emaciation as a result of injury to chest, *Parisarpa*, injury from weapons and fire. It contains beta-carotene and vitamin E which are anti oxidants.
- The qualities of *Ghrita* as a substance for use, was established in the *Upanishad* and Susrutha Samhitha period.
- Bhavaprakasha mentioned *Ghrita* as *Yogavahi Rasayana* - an agent capable of acquiring and imparting the entire quality of drug added to it.

CONCLUSION

The present study was undertaken with an objective to evaluate the effect of topical application of *Apamargadi ghrita* in the *Utsadana* – granulation tissue

formation of *Dushta vrana* which is assessed by the size of the ulcer, scoring system for granulation tissue formation and percentage of epithelialization.

The findings from the above case study suggest that *Apamargadi ghrita* demonstrates superior effectiveness compared to current treatment modalities like skin grafting, hyperbaric oxygen therapy, negative pressure wound therapy (NPWT), Low-Level Laser Therapy (LLLT) etc

- Topical application with *Apamargadi ghrita* is less expensive compared to above treatments. Faster wound healing, lower recurrence rate and increased patient satisfaction are just a few of the outcomes that were noticed and provide convincing proof that *Apamargadi ghrita* may be useful in treating this difficult medical condition. The main ingredients of *Apamargadi ghrita* increases the fibroblast cell count, epithelial cells and synthesis of extracellular matrix including collagen synthesis which is responsible for granulation tissue formation (*Utsadana*).
- They were also found to contribute in the formation of well organized epidermal layer, increased number of fibrocytes, remarkable degree of neovascularization and epithelialization. Thus there will be an enhanced rate of wound contraction and a drastic reduction in healing time.
- Thus the present study is found to be effective in the *Utsadana* (granulation tissue formation) of *Dushta vranam*.

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***Address for correspondence**
Dr. Athira Soman
PG Scholar,
Department of Shalyatantra,
Govt. Ayurveda College,
Trivandrum.
Email:
athirasoman1993@gmail.com
Ph: 82814 83414