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CLINICAL EVALUATION OF TILASTAKA LEPA IN DUSHTA VRANA

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ABSTRACT

Back ground: -In day-to-day surgical practice we are facing problems in treating Dushta Vrana i.e. non healing chronic ulcer effectively in spite of making use of modern therapeutics.

Objectives:- Clinical Evaluation of Tilastaka Lepa application in the management of dushta Vrana.

Methods: -20 diagnosed case of Dushta Vrana are selected for study and recorded through the proforma designed for single group of observational study.

Results: -Tilastaka Lepa initially acts as a debriding agent removing slough and necrotic tissues. It reduces pain, burning sensation, itching, decreases discharge, oedema and helps in gradual improvement in floor & granulation tissue .Probably due to the above properties it hastens the wound healing process which helps in reduction of wound size.

Conclusion: -Tilastaka Lepa reduces the symptoms of Dushta Vrana by its Shodhana and Ropana properties. Time taken for Sodhana of Dushta Vrana is approximately one to one and half week and time taken for Ropana is approximately 4 -6 weeks.

INTRODUCTION

Shalya Tantra is one of the eight branches of Ayurveda in which surgical and parasurgical techniques are described for management of various diseases. Vrana (wound) is seen as debilitating and scaring disorder usually seen affecting the human being at any age. Management of chronic non healing wounds are always been a difficult proposition in the evolution of medical practice. Worldwide prevalence of wounds is believed to be 1% of world population [1], whereas an Indian perspective of hospital based study shows leprosy (40%), diabetes (23%), venous disease (11%), and trauma (13%) were among important causes of lower extremity wounds. In that study, 13% of wounds were not directly linked toany known cause.[2] Healing of ulcer is a natural complex process but healing gets affected by infection, amount of tissue injury, contamination, absence of rest etc.[3] and this worsens the condition of patient, may even become fatal. Treatment of ulcers ranges from application of simple antimicrobials to complex plastic surgery. This includes irrigation, hyperbaric oxygenation, vacuum assisted closure, electro stimulation, maggot therapy techniques [4] etc. With all these results are not always being satisfactory and these cannot be employed as a regular management protocol as many of such technique are expensive and the organisms too developing resistant strains. In spite of the advances that have been made, the management of chronic wounds are still a challenge for the clinician. Acharya Susruta has scientifically classified Vrana and described its management under Shastiupakramas [5]. These principles of management are valid even today. Application of Kalka is one of the upakramas.[6]. Chakradatta mentioned application Tilastaka Lepa for vrana shodhanaand the ingredients are tila, nimba, haridra, daruharidra, trivit, lavana grita, yastimadhu.[7] 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. Hence this is an effort to find a simple and effective treatment for chronic ulcers.

OBJECTIVE OF STUDY

- A detailed review of literature on Dushta Vrana (ulcers) and its management.
- To evaluate the effect of Tilastaka Lepa on wound healing.

MATERIALS & METHODS

Source of data?It is an open clinical study with pretest and posttest design in which 20 patients suffering from Dushta Vrana are selected from IPD and OPD of S.D.M College of Ayurveda Hospital Udupi.

Methods Of Collection Of Data–

20 patients suffering from dushta vrana are selected and subjected for clinical trials. Data was collected based on a detailed proforma designed for the study.

METHODS

Ulcers are cleaned with distilled water and a freshly prepared Tilastaka Lepa applied on ulcers in a thickness of 0.5cm and kept till it started drying. Lepa was removed and cleaned again with distilled water followed by regular dressing with Jatyadi Taila twice daily i.e. morning and evening. Patients are treated with Tab. Triphala Guggulu (450mg) and Tab. Gandhak Rasayana(250mg) one b.d along with 40 ml of Asanadi Kwatha as internal medication. Results are assessed by a comparative study of features before and after treatment with a proforma designed for the study.

- Duration of treatment - Treatment was carried out till ulcer healed or for a maximum duration of 15 days.
- Follow up study - After completion of the treatment patients were followed up at every week for a period of two months.

INCLUSION CRITERIA :

Patients having features of Dushta Vrana having chronicity more than 21 days are selected for the study.

EXCLUSION CRITERIA:

- Patients suffering from gangrene
- Patients with systemic features of sepsis.
- Patients suffering from specific ulcers like malignant ulcers, tubercular ulcers, leprotic ulcers.
- Patients with multiple systemic disorders.
- Burns.

ASSESSMENT CRITERIA

Investigations.-

1. Blood:
- Hemoglobin Percentage.
- Total Leukocyte Count.
- Differential Count.
- Erythrocyte Sedimentation Rate.
- Random blood sugar

2. Urine: - Albumin. sugar and microscopic.
3. Wound Swab Culture and Sensitivity test. (If necessary).
4. X-ray of wound site. (If necessary)

Grading of parameters for assessment of Dushta Vrana

Subjective criteria

1) Vedana(Pain)

All 19 patients had pain before the treatment. More than 30% had severe pain. The mean score was 2.26 before treatment & after the completion of lepa for 15 days it was reduced to 1.78 and follow up for 2 months it was reduced to 0.42. In majority of cases pain was completely reduced after the follow up period. The severity of vedana and daha are mainly due to pravruddha vata and pitta dosas. Tilastaka lepa palliates the vitiated vata and pitta and the drug like nimba, haridra, daruharidra, yastimadhu, grita, saindhva were having vedanahara, shothahara property. Pain being one among the five inflammatory signs, reduction in the pain implies diminution of inflammation. In vata-pittaja dusta vrana, pain was more just after the application of lepa but after half an hour it got subsided. This may be due to some of the drugs used in lepa are having teekshna and usna gunas.

2) Daha(Burning sensation)

All 19 patients had burning sensation before the treatment. More than 25% had severe burning sensation. The mean score was 2.05 before treatment & after the completion of lepa for 15 days it was reduced to 1.63 and follow up for 2 months it was reduced to 0.21. Among the type of dustha vrana significant reduction of burning sensation was observed in tridoshaja and vata- pittaj vrana, as some of the ingredients used in lepa like nimba,daruharidra, yastimadhu, grita were having pitta samana property. In vata-pittaja dusta vrana, burning sensation was more just after the application of lepa but after a period of half an hour it got subsided. This may be due to some of the drugs used in lepa are having teekshna and usna gunas.

3) Itching(Kandu)

Among 19 patients 16 were complained of kandu before the treatment. More than 15% had severe itching including surrounding area. The mean score was 1.52. Before treatment and after the completion of lepa for 15 days it was reduced to 1.15 and after follow up for 2 months it was reduced to 0.21. In majority of cases kandu was completely reduced in 4th-5th week of follow up. In vata- kaphaj vrana significant reduction of kandu found. Among 19 patients 2 patients developed more itching around the ulcer after4th week of follow up. Both these patients were diabetic and found to have a raised blood sugar level during the follow up. High blood glucose level hinders the wound healing and sugar laden tissues are more prone for infections.

4) Gandha (Smell)

All 19 patients had smell before the treatment. More than 60% had severe foul smell from wound. The mean score was 2.42 before treatment & after the completion of lepa for 15 days it was reduced to 2.00 and follow up for 2 months it was reduced to 0.26. In vata-kaphaj vrana and tridoshaj vrana significant reduction of smell found. The drug of Tilastaka lepa like nimba, trivit, haridra, daruharidra having putihara, krmihara property. This helps to reduce gandha of dushta vrana. Among 19 patients 2 patients developed more foul smell from wound after 4th week of follow up. Both these patients were diabetic and poor control of diabetes, improper wound care may be the reason. High blood glucose level hinders the wound healing and sugar laden tissues are more prone for infections

Objective criteria

1) Size of the ulcer :

Out of 19 patients, ulcer was almost healed completely in 14 patients. Before treatment the mean score was 4.78(length) & 4.13(width). After the treatment mean was reduced to 0.68(length) & 0.61(width). It is observed that all types of ulcer with chronicity less than one year and dimensions less than 6cm heal rapidly (5th -6th week of follow up). Probably the ingredients of Tilastaka lepa are having anti-inflammatory property; it reduces oedema, debrides necrotic tissues by which it fastens the wound healing process which automatically results in reduction of wound size. This suggests that Tilastaka lepa has helped to normalize the vitiated local doshas in wound which helped in the shodhana and ropana of vrana. In 2 patients ulcer size got increased during follow up. Both these patients were diabetic and poor control of diabetes, improper wound care, unhygienic condition may be the reason.

2) Tenderness:

Before treatment all the patients were having tenderness. The mean was 2.42 before treatment which was reduced to 0.1.94 after the application of lepa for 15 days, which was reduced to 0.57 after 2 month follow up period of treatment. In majority of cases tenderness was completely reduced in 6th -7th week of follow up period. It is statistically highly significant hence suggests that the treatment helps to reduce the signs of inflammation.

3) Discharge

Before treatment all patients were having discharge. Significant reduction of discharge was observed after 7day of Tilastaka lepa application. The mean was 2.78 before treatment which was reduced to 2.21 after the completion of lepa for 15 days. After 2 month follow up period it was 0.42, 'p' value is statistically highly significant. In some of the patients discharge was more severe. In majority of cases discharge was completely reduced after 2week of follow up period. In 2 patients discharge from wound got increased after the follow up. Both these patients were diabetic and poor control of diabetes, improper wound care, unhygienic condition may be the reason. High blood glucose level hinders the wound healing and sugar laden tissues are more prone for infections

4) Discolouration

Before treatment all the patients were having discolouration around the ulcer with the mean of 1.89 which was reduced to 1.73 after lepa application for 15 days the treatment. It was 0.47 after follow up period for 2 months .The result is statistically highly significant. This means that intervention helps to control the inflammatory process in ulcers. Cause for discolouration at and around wound site was mainly because of vascular pathology i.e. in case of TAO, the ischemic condition leads to blackish discolouration and inflammatory changes induced congestion gives reddish discolouration. In case of varicose ulcers where incompetence of venous valves causes stasis of blood, which leads to chronic venous hypertension and alters microcirculation by this RBC'Ss diffuse in to tissue planes where deposit of haemosiderin takes place as result of lysis of RBC"s. This deposited haemosiderin gives blackish pigmentation to affected part. Tilastaka lepa reduces the discolouration of wound site by its raktashodhaka property. Probably it reduces congestion in case of inflammatory discolouration and in case of venous ulcers disturbed microcirculation improves by reliving the pressure as lepa reduces oedema.

5) Floor & granulation tissue: -

Before treatment all 19 patients were having irregular floor, slough & unhealthy granulation tissue. The mean was 2.94 before treatment which was reduced to 2.57 after 15 days of Tilastaka lepa application .It was 0.36 after the follow up period for 2months. In majority of cases granulation tissue is seen in 1st-2ndweek after starting the

treatment. This means that the intervention is conducive to the growth of granulation tissue that helps to bring up a healthy floor for the speedy healing of ulcers. In 2 patients slough from wound got increased after the follow up. Both these patients were diabetic and poor control of diabetes, improper wound care may be the reason.
Adjuvant therapy- Triphala Guggulu (450mg)1tid, Gandhak Rasayana (250mg)1tid, Asanadi Quatha 40ml bd and dressing with Jatayadi Taila daily was continued in follow up periods. So local application might normalize the doshas and dhaatus in that particular region. For nourishing dosha & dhaatu, internal as well as local interventions are needed.

Results :- STATISTICAL ANALYSIS

Out of 20 patients 1 patient had developed severe burning sensation and pain after application of Tilastaka lepa hence Lepa was removed immediately and patient was withdrawn from this study. Observations were made in 19 patients BT & AT and compared using paired't' test The effect of treatment is analyzed in each among the subjective and

objective criteria :

1.PAIN

The statistical analysis revealed that the mean score of pain was 2.26 before the treatment which was reduced to 0.42 after the treatment & this change is statistically highly significant ($p<0.001$)

2.ITCHING (KANDU)

The statistical analysis revealed that the mean score of Itching (Kandu) was 1.52 before the treatment which was reduced to 0.21 after the treatment & this change is statistically highly significant ($p<0.001$)

3.SMELL (GANDHA)

The statistical analysis revealed that the mean score of Smell (gandha) was 2.42 before the treatment which was reduced to 0.26 after the treatment & this change is statistically highly significant ($p<0.001$)

4.BURNING SENSATION

The statistical analysis revealed that the mean score of Burning sensation was 2.05 before the treatment which was reduced to 0.0.2 after the treatment & this change is statistically highly significant ($p<0.001$).

5.DISCHARGE

The statistical analysis revealed that the mean score of discharge from ulcer was 2.78 before the treatment which was reduced to 0.42 after the treatment & this change is statistically highly significant ($p<0.001$).

6.DISCOLORATION

The statistical analysis revealed that the mean score of was 1.89 before the treatment which was reduced to 0.47 after the treatment & this change is statistically highly significant ($p<0.001$).

7.Tenderness

The statistical analysis revealed that the mean score of was 2.42 before the treatment which was reduced to 0.57 after the treatment & this change is statistically highly significant ($p<0.001$)

8.Floor

The statistical analysis revealed that the mean score of floor was 2.94 before the treatment which was reduced to 0.36 after the treatment & this change is statistically highly significant ($p<0.001$).

9.DIMENSION OF ULCER(mean value of l&b)

The statistical analysis revealed that the mean score of size of ulcer was 8.94 before the treatment which was reduced to 1.37 after the treatment & this change is statistically highly significant ($p<0.001$).

CONCLUSION

In this study 20 patients of dusta vrana were treated with Tilastaka Lepa application. On the basis of observation and result of the study following conclusions can be drawn:

Most of the patients suffering with Dushta Vrana were belonging to lower socioeconomic group and common site affected is lower limb. This study had revealed that local shodhana with oral medication has significant role in the healing of Dushta Vrana. Tilastaka Lepa followed by oral medications helps to reduce the symptoms of dushta vrana like discharge, pain, burning, itching substantially.70% of the ulcers healed completely within the span of 2 months follow up after the lepa application. Two patients with diabetic ulcer developed infection in follow up period due to improper wound care and poor blood sugar control. One patient shows intolerance to Tilastaka Lepa so treatment was discontinued.

SCOPE FOR FURTHER STUDY:

The study is carried out in a small sample size of 20 subjects. Patients having different types of ulcers such as Arterial, Venous, necrotizing fasciitis etc. was selected in this study. Further study may be conducted with a large sample size and to a particular type of Ulcer. Further research work is required to evaluate the antibacterial effect of the tilastaka lepa by conducting MIC (minimum inhibitory concentration) studies. Biochemical analysis of collagen synthesis in healing wound may be executed to study the effect of tilastaka on collagen synthesis.The future study of these drug combinations can be studied by dispensing them in various forms such as kashaya, sarpi etc.

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