A Comparative Clinical Study of jalaukavcharan and Shodhana Ropana Lepa in Dushta Vrana

*Dr. Kalpana Verma, **Dr. B. Swapna

*Assistant Professor, Deptt. of Shalya Tantra, Institute of Ayush Medical Sciences, Lucknow,
**Assistant Professor, Deptt. of Shalya Tantra, National Institute of Ayurveda, Jaipur

ABSTRACT

A wound which refuses to heal or heals very slowly in spite of best efforts is known as Dushta Vrana. Advance technologies and medicare system are still unsatisfactory in the process of healing and bringing down the aggravated clinical problems of an ulcer. Aacharya Sushruta has given the prime position to “Wound, i.e. Vrana”. To achieve good approximation, early healing and acceptable scar, without complications Acharya Sushruta has elaborately explained Shashti Upakrama. Among them Raktamokshana & Vrana Shodhana and Ropana are there. However Sushruta has specifically indicated Raktamokshina in Dushta Vrana treatment and Acharya Sharangdhara explained Shodhana Ropana Lepa in the management of Dushta Vrana. So the present study is planned to evaluate the efficacy of Shodhana Ropana Lepa over leech therapy as leech therapy was taken as controlled comparator. For the present study 30 patients fulfilling the inclusive criteria were selected. The patients were classified into two groups, Group A and Group B, each containing 15 patients. ‘Group A’ was taken as control comparator group on which Jalaukavacharana was done and ‘Group B’ was taken as experimental group in which application of Shodhana Ropana Lepa was done. The treatment was accessed with observations and results for a period of eight weeks. After this therapy, significant result was observed. It was observed that the results achieved in both groups are effective and stable during follow up period.

Keywords: Dushta Vrana, Shodhana Ropana Lepa, Jalaukavacharana

Address of Correspondence:
Dr. Kalpana Verma
Assistant Professor,
Dept. of Shalya Tantra,
Institute of Ayush Medical Sciences, Lucknow.
Email ID: kalpanaverma637@gmail.com
Contact No: 9549812650

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Introduction:
The knowledge of wound is known since antiquity. From Vedic age to modern era, man has been suffering from various ailments. Although much advancement had taken place in modern medicine to solve the problem, still they are unable to find proper solution to the utmost satisfaction [1]. With reference to the history of evolution warfare among groups and animals denotes human
suffering leading to emergency medicines for warrior. Thus treatment of wound is primitive than that of other emergencies. Since ages the new evolution in wound and its management is going on in each era.

Ayurveda the age old and holistic system of medicine offers various tools for management of Dushta Vrana. In Ayurveda Acharya Sushruta, pioneer surgeon, have mentioned various types of wound and its management. Dushta Vrana is an unsolved problem faced by health care professionals in India and abroad. A clean wound in normal body heals earlier with minimum scar as compared to contaminated wound. Therefore in present concept all efforts are directed to keep the wound clean during various stages of wound healing. Such healing process is called Shodhana and Ropana.

Aims and Objectives:
The main aim of the study is to evaluate and compare the efficacy of Jalaukavacharana and to assess the wound healing property of Shodhana Ropana Lepa in the management of the Dushta Vrana.

Materials and methods:

Grouping of the patients: For the interventions to be administered, total 30 subjects with the classical signs and symptoms of Dushta Vrana were selected randomly from O.P.D, Department of Shalya Tantra, NIA, Jaipur, ages ranging from 15-70 yrs., irrespective of sex, religion and socioeconomic status and were divided into two groups, A and B with 15 subjects in each group. The study was clearly explained to the subjects and their signed, written informed consent was taken before starting the trial. Routine blood investigations (Hb gm%, TLC, DLC, BT, CT, ESR, RBS, HIV & HBsAg.) were done to every patient before starting the trial.

In Group A, Jalaukavacharana and in Group B, application of Shodhana Ropana Lepa was done. Total time frame of the study was 12 weeks, with trial period for 8 weeks and a follow up for 4 weeks.

The protocol was approved by the Institutional Ethics committee at National Institute of Ayurveda, Jaipur and the ethical approval letter’s ref. number is F10 (5)/EC/2014/7217, dated: 7/11/2014.

Selection criteria:

- Inclusion criteria:
  - Age 15 - 70 years
  - Patients having clinical features of Dushta Vrana will be included
  - Those ready to give written informed consent

- Exclusion criteria:
  - Malignancy
  - Tubercular ulcers
  - Syphilitic ulcers
  - Soft sores
  - Actinomycosis, Meleney’s ulcers
  - Immunocompromised or unstable patients
  - HIV, immune deficiency syndrome
  - Immunosuppressive medications users
  - Who are not willing to give written informed consent
  - Previous participation in trial

Assessment criteria:
Effect of therapy was evaluated before, during & after the course of treatment by using parameters as stated below with standard grading.

a) Primary Outcome Measures:
  - Circumference of the wound (Length, Width & Depth)
  - Exudate quantity
  - Pain (VAS scale)
  - Odour
  - Granulation Tissue

b) Secondary Outcome Measures:
  - Patient satisfaction
  - Recurrence

Subjects were assessed for above said variables, were recorded and stored in specific case record proforma.
Privacy and confidentiality of the patients was maintained. The collected data was subjected to statistical analysis by using Stat Graph Pad 3 software (Trial version), Wilcoxon matched-pairs signed ranks test, One Way ANOVA test, Chi-Square test, Mann-Whitney tests were used to bringout the level of significance i.e. P value.

Photographs were taken before starting the trial, during and on 8th week follow up or after complete healing of the wound, whichever is the earlier.

Observations:
This study shows that maximum no. of patients were between the age group 61-70 Years (50%), 86.66% of patients were males, maximum number i.e.96.66% of patients were from Hindu religion, 26.67% was from Business class and Labourer, maximum number of patients (27) i.e. 90% were married, maximum number of patients was under middle income group i.e.60%, 3 (10%) patients had a family history of relevant condition and the remaining 27 (90%) patients had no relevant family history, that maximum patients were practiced to mixed diet (60%), majority of patients i.e. 60% were Smokers followed by alcoholics 23.33%, maximum number of patients, 12 (40%) were with non healing ulcer from 6-12 months, Maximum patients were found from Sedentary life style with a rate of 46.67%, majority of patients (70%) were of Pittaja Pradhan Deha Prakriti,26 (86.67%) patients had ulcers on their lower limbs, maximum patients were found with Serosanguineous discharge with a rate of (36.67%), maximum number, 10 (33.33%) patients were of venous ulcer.

Results:
Effect of therapy in individual parameters:

Exudate:
★ In Group A the mean score before treatment was 1.67 which lowered down to 0.27 after treatment, with SD±0.6172 giving a relief of 83.83% and the value of P<0.0001 which is statistically highly significant.
★ In Group B the mean score before treatment was 1.53 which lowered down to 0.33 after treatment, with SD±0.4140 giving a relief of 78.43% and p value is

Odour
★ In Group A the mean score before treatment was 0.4 which lowered down to 0.067 after treatment, with SD±0.4880 giving a relief of 83.25% and is statistically significant with P<0.05
★ In Group B the mean score before treatment was 0.4 which lowered down to 0.27 after treatment, with SD±0.3519 giving a relief of 32.5% and is statistically Non significant with P>0.05

Granulation tissue:
★ In Group A the mean score before treatment was 2.07 which lowered down to 0.47 after treatment, with SD±0.7368 giving a relief of 77.29% and is statistically highly significant with P<0.0001
★ In Group B the mean score before treatment was 2.6 which lowered down to 0.47 after treatment, with SD±0.8338 giving a relief of 81.92% and is statistically highly significant with P<0.0001

Pain:
★ In Group A the mean score before treatment was 6.46, with SEM±0.59 which lowered down to 0.46 after treatment, with SEM±0.29 giving a relief of 92.72% and is statistically highly significant with P<0.0001
★ In Group B the mean score before treatment was 3.86, with SEM±0.91 which lowered down to 0.06 after treatment, with SEM±0.06 giving a relief of 98.29% and is statistically highly significant with P<0.0001

Circumference of wound:
★ In Group A the mean score before treatment was 28.60, with SEM±12.71 which lowered down to 3.05 after treatment, with SEM±1.94 giving a relief of 89.33% and is statistically nonsignificant with P>0.05
★ In Group B the mean score before treatment was 25.90, with SEM±14.71 which lowered down 10.07 after treatment, with SEM±9.49 giving a relief of
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- 61.11% and is statistically non significant with P>0.05

Internal comparison:

**Table No I: Intergroup Comparison of Group A & Group B for exudate, odour and granulation: (Mann-Whitney Test)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>(AT) Mean</th>
<th>SD±</th>
<th>SE±</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exudate</td>
<td>A</td>
<td>0.27</td>
<td>0.6172</td>
<td>0.1594</td>
<td>&gt;0.05 (0.4678)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.33</td>
<td>0.4140</td>
<td>0.1069</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odour</td>
<td>A</td>
<td>0.067</td>
<td>0.4880</td>
<td>0.1260</td>
<td>&gt;0.05 (0.0789)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.27</td>
<td>0.3519</td>
<td>0.0908</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granulation</td>
<td>A</td>
<td>0.47</td>
<td>0.7368</td>
<td>0.1902</td>
<td>&gt;0.05 (0.4893)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.47</td>
<td>0.8338</td>
<td>0.2153</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(HS: Highly Significant  S: Significant  NS: Non Significant)

**Table No. II: Intergroup Comparison of Group A & Group B for pain and circumference: (Mann-Whitney Test)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A Mean± SEM</th>
<th>Group B Mean± SEM</th>
<th>P Value</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>6± 0.577</td>
<td>3.8± 0.921</td>
<td>&gt;0.05 (0.0693)</td>
<td>NS</td>
</tr>
<tr>
<td>Circumference</td>
<td>25.54± 11.53</td>
<td>15.82± 6.325</td>
<td>&gt;0.05 (0.4665)</td>
<td>NS</td>
</tr>
</tbody>
</table>

( HS: Highly Significant  S: Significant  NS: Non Significant)

On comparing the p value of individual parameters among the groups ...

1) **Exudate:** The value of P >0.05, is statistically non significant which shows that there is no statistical difference in the efficacy of both treatments on exudate.

2) **Frequency of Odour:** The P value is >0.05, is statistically non significant which shows that there is no statistical difference in the efficacy of both treatments on odour.

3) **Granulation:** The P value is >0.05, is statistically non significant which shows that there is no statistical difference in the efficacy of both treatments on granulation.

4) **Pain:** The P value is >0.05, is statistically non significant which shows that there is no statistical difference in the efficacy of both treatments on pain.

5) **Circumference:** The P value is >0.05, is statistically non significant which shows that there is no statistical difference in the efficacy of both treatments on circumference.

**Table No. III: Percentage Difference in Individual Variables of Group A and Group B after treatment**

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameter</th>
<th>Group A %</th>
<th>Group B %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Exudate</td>
<td>83.83%</td>
<td>78.43%</td>
</tr>
<tr>
<td>2.</td>
<td>Odour</td>
<td>83.25%</td>
<td>32.5%</td>
</tr>
</tbody>
</table>

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Granulation</td>
<td>77.29%</td>
</tr>
<tr>
<td>4.</td>
<td>Pain</td>
<td>92.72%</td>
</tr>
<tr>
<td>5.</td>
<td>Circumference</td>
<td>89.33%</td>
</tr>
</tbody>
</table>

**Graph No.1 Percentage Difference in Individual Variable of Group – A and Group – B**

**Table No. IV: Post procedure complications in 30 Patients**

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group A</th>
<th>Group B</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>%</td>
<td>Count</td>
</tr>
<tr>
<td>Pain</td>
<td>03</td>
<td>20%</td>
<td>06</td>
</tr>
<tr>
<td>Bleeding</td>
<td>05</td>
<td>33.33%</td>
<td>00</td>
</tr>
<tr>
<td>Burning Sensation</td>
<td>03</td>
<td>20%</td>
<td>07</td>
</tr>
<tr>
<td>Infection</td>
<td>00</td>
<td>00%</td>
<td>03</td>
</tr>
</tbody>
</table>

**Graph No.2 Satisfactory Score of Group A and Group B given by patients**

**Recurrence:** The patients who got cured completely didn’t have a recurrence after a follow up for one month after the trial.

**Table No. V: Total effect of therapy in 30 patients**

<table>
<thead>
<tr>
<th>Treatment response</th>
<th>Group A</th>
<th></th>
<th>Group B</th>
<th></th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Complete relief</td>
<td>06</td>
<td>40.00%</td>
<td>07</td>
<td>46.66%</td>
<td>13</td>
<td>43.33%</td>
</tr>
<tr>
<td>Marked relief</td>
<td>05</td>
<td>33.33%</td>
<td>04</td>
<td>26.66%</td>
<td>09</td>
<td>30.00%</td>
</tr>
<tr>
<td>Moderate relief</td>
<td>00</td>
<td>00</td>
<td>01</td>
<td>6.66%</td>
<td>01</td>
<td>3.33%</td>
</tr>
<tr>
<td>Mild relief</td>
<td>04</td>
<td>26.27%</td>
<td>03</td>
<td>20%</td>
<td>07</td>
<td>23.33%</td>
</tr>
<tr>
<td>No relief</td>
<td>00</td>
<td>00</td>
<td>00</td>
<td>00</td>
<td>00</td>
<td>00</td>
</tr>
</tbody>
</table>

**Graph No.3: Total effect of therapy in 30 patients**

**Discussion:**

The overall effect of the interventions in their respective groups i.e. among 15 subjects of Group A, 6 subjects got cured completely (100%), 5 subjects got marked relief (>75%), 4 subjects got mild relief (25%-50%) and whereas among 15 subjects of Group B, 7 subjects got cured completely, 4 got marked relief, one subject got moderate relief (51%-75%) and 3 subjects got mild relief.

The patients who got treated with Jalaukavcharan had yielded better outcome with more percentage of relief in exudate, odour, granulation and circumference of the wound with highly significant p values in each parameter as compared to the patients who underwent treatment with Shodhana Ropana Lepa.

At the end, by assessing the P value and percentage of relief in different variables of both the groups, Group A & Group B, after treating them with their respective interventions, it was observed that both the treatment procedures had shown better result in wound healing where in circumference of wound decreased tremendously with Jalaukavcharana in a period of eight weeks trial, which confers that the rate of healing is faster with leech therapy as compared to Shodhana Ropana Lepa.

**Summary and Conclusion:**

The overall effect of the interventions in their respective groups i.e. among 15 subjects of Group A, 6 subjects got cured completely (100%), 5 subjects got marked relief (>75%), 4 subjects got mild relief (25%-50%) and whereas among 15 subjects of Group B, 7 subjects got cured completely, 4 got marked relief, one subject got moderate relief (51%-75%) and 3 subjects got mild relief. Though, both the treatment procedures had shown better result in wound healing where in circumference of wound decreased tremendously with Jalaukavcharana in a period of eight weeks trial, which concludes that the rate of healing is faster with leech therapy as compared to Shodhana Ropana Lepa.
Fig. 1: Method of Preparation of Shodhana Ropana Lepa

NIMB KALKA  MIXTURE OF DANTI, TRIVRIT  WITH MADHU  MARDHANA
SANDHAV, TIL

SHODHANA ROPANA LEPA

Fig 2: Images showing efficacy of Shodhana Ropana Lepa before and after treatment

1. Before Treatment  2. During Treatment  3. After Treatment

Fig 3: Images showing efficacy of Leech Therapy before and after treatment

1. Before Treatment  2. During Treatment  3. After Treatment

References


सारांश:

ब्रण जो सामान्य उपक्रमों द्वारा रोपित न हो एवं चिरकालिक हो और उत्तम उपक्रमों द्वारा रोपित न हो रहा हो ऐसा ब्रण, दुष्ट ब्रण की श्रेणी में आता है। आचार्य गोपाल ने ब्रण के उपाय को प्रश्न रखा। उत्तम उपक्रमों द्वारा रोपित नहीं रहा हो ऐसा ब्रण, दुष्ट ब्रण की श्रेणी में आता है। आचार्य सुभूति ने ब्रण को प्राचीन रूप से द्वारा रोपित नहीं रहा हो ऐसा ब्रण, दुष्ट ब्रण की श्रेणी में आता है। आचार्य ने ब्रण को प्राचीन रूप से द्वारा रोपित नहीं रहा हो ऐसा ब्रण, दुष्ट ब्रण की श्रेणी में आता है।