TO STUDY THE EFFICACY OF SHARPUMKHAMOOL LEPA IN MANAGEMENT OF DUSHTAVRANA

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KEYWORDS: Sharpumkhamool, Lepa, Dushtavrana, Healing process.

**ABSTRACT**

The life of every individual starts with the healing of the wound of the cut umbilical cord. So, treatment for healing of this wound is of prime importance. While explaining the scope of Shalya Tantra. Even though healing of Vrana is a natural process of the body, the Vrana should be protected from Dosa Dushti and from various micro organisms, which may afflict the Vrana and delay the normal healing process. So, for the early and uncomplicated healing of Vrana, treatment is necessary. In healing of Vrana, local treatment is also important along with oral medications. Dushta Vrana is a long standing ulcer with profuse discharge and slough, where clearing slough and enabling drug to reach the healthy tissue is more important. Slough can be cleared by using surgical instruments or oxidizing agents where healthy granulation tissues are damaged. In recent years various efforts were made in the field of wound healing, especially as local treatments but healing remains the prime objective of the physicians. Though the herbal drugs are prescribed with high appreciation for healing purpose but it needs scientific evaluation with proper study design. Keeping all these things in view, drugs like Sharpumkha and Madhu has been selected after reviewing the literature. This study is designed to conduct an experimental as well as a clinical study thoroughly.

The study is entirely based on clinical observation and assessment of selected 60 patients attending OPD/IPD were selected randomly and subjected to clinical trial. Duration of study for 12 days administered with Madhuyukta Sharpumkhamoola lepa and Betadine ointment.

INTRODUCTION

Science is not merely a collection of facts & relationship but is more than a composite of these facts, accumulated & systematically correlated over the ages. Classics of Ayurveda has emphasized at various places to take care of wounds which occurs either as a result of vitiated Doshas or of traumatic in origin. The life of every individual starts with the healing of the wound of the cut umbilical cord. So, treatment for healing of this wound is of prime importance. While explaining the scope of Shalya Tantra.

Even though healing of Vrana is a natural process of the body, the Vrana should be protected from Dosa Dushti and from various micro organisms, which may afflict the Vrana and delay the normal healing process. So, for the early and uncomplicated healing of Vrana, treatment is necessary.

During the early part of the century, research on wound healing was largely concerned with qualitative descriptions of histological emergence & changes in the macroscopic appearance of the wound during its progression towards formation of the final and fine scar. For carrying out such a responsibility of a surgeon, thorough knowledge of all types of wounds and its management is of utmost importance.

The task of the wound healing is to increase our basic understanding about the molecular and cellular events of the repair and healing processes and to use this information as the basis for developing new therapies that can minimize the adverse consequences of wounds.

To treat a wound is to bring out the process of repair of the tissues in the manner most conducive to the present and future welfare of the patients. Such an important responsibility can’t be carried out without thorough and adequate knowledge of Vrana Shodhan & Ropana (Wound Healing) along with the modern medical doctrines. Better wound healing with minimal scar formation with least pain effectively is the prime motto of every surgeon.

The history of medical science starts with the art and skill of wound healing. Treatment of the wound is
probably the first medical problem faced by human beings. The frequency of injuries is more common than any other disease. Centuries ago, injury in the battle field due to hit by arrows was one of the common problems, along with contamination of the wound. Falling from trees, fall from heights, crushing against stone or hard materials, animal bites were the other causes for injury. The contamination of the wound due to various micro organisms delayed the process of wound healing. Bleeding and pain were and are the main complications of a wound which require immediate treatment.

Usage of various types of leaves or soil was the treatment to arrest bleeding. Quest for knowledge by ancient peoples led to many investigations and assumptions. Gradually things with better results were selected and tried with different forms. Ayurveda, more a science of life than only a medical science, gives more importance to preventive measures and complete curing of a disease with a minimum chance of recurrence.

Sushruta, the Father of Indian surgery in his book Sushruta Samhita, has explained Vrana, its complication and management in great detail. In the Vrana of Vrana Adhyaya he has explained that, If the Rakshaa Karma of Vrana is proper then the Nis`aacara”s leave the patient, in the same way as the Mrugaas (deer) run away from the jungle terrified by a lion.

For Sushruta health was not merely a freedom from disease, but a normal state of mind, body and soul. He conceived of a total management of the disease from the earliest stage of vitiation of Dosha to total recovery in which he insisted on bringing back the site of the lesion to normalcy in all respects. Thus it may well be said that Sushruta”s management was more thorough than even conceived today.

Sushruta”s classification of traumatic wounds, their prognostic evaluation and management, insistence on primary suturing in clean wounds, avoidance of sepsis etc. correspond remarkably with the modern outlook of wounds and wound management.

In healing of Vrana, local treatment is also important along with oral medications. Dushta Vrana is a long standing ulcer with profuse discharge and slough, where clearing slough and enabling drug to reach the healthy tissue is more important. Slough can be cleared by using surgical instruments or oxidizing agents where healthy granulation tissues are damaged. In recent years various efforts were made in the field of wound healing, especially as local treatments but healing remains the prime objective of the physicians.

Though the herbal drugs are prescribed with high appreciation for healing purpose but it needs scientific evaluation with proper study design. Keeping all these things in view, drugs like Sharpmukha and Madhu has been selected after reviewing the literature. This study is designed to conduct an experimental as well as a clinical study thoroughly.

The study is entirely based on clinical observation and assessment of selected 60 patients attending OPD/IPD were selected randomly and subjected to clinical trial. Duration of study will be for 12 days. They were administered with Madhuyukta Sharpmukhamoola lepa and Betadine ointment. The results are encouraging. This study has opened a new avenue for further exploration in the field.

AIMS AND OBJECTIVES

AIMS

1. Study the effect of Madhuyukta Sharpmukhamool lepa in management of Dushta vrana.
2. To decide the etiological factors both local as well as systemic responsible for the non-healing of the wound.

OBJECTIVES

1. Study the details of Dushta vrana and Sharpmukha as per Ayurvedic treatise.
2. Correlation of Dushta vrana as per modern text.
3. To collect the comprehensive data about Sharpmukha and Madhu.
4. To compile the data about Pralepa.
5. To evaluate the role of Sharpmukhamoola Lepa in the management of Dushta Vrana.
6. To compare the effect of Sharpmukhamoola Lepa with Betadine ointment.

MATERIALS AND METHODS

The descriptions of wounds show separate entity from the time of Hippocrates. The management for this problem has been varying from age to age, now with the help of new advance techniques and methods of microscopic and experimental studies to confirm pathophysiology of this subject is more appreciated.

The recipe Sharpmukhamool lepa mentioned in Bhaishjyaratnawali is selected for local application to study its effect on the healing process of Dushta Vrana. For the local management of wound, Sharpmukha and Madhu are well known drugs due to antimicrobial, antibiotic, anti inflammatory and analgesic effect. According to Ayurveda, these drugs are having the properties of Vrana Shodhana, Vrana Ropana and Shothaghna etc. The Madhu is recommended as one of the best Yogavahi drug and for the local application as a vehicle.

In the modern era, there are so many preparations available for the management of wound. Povidone Iodine is a well known drug for local application and being widely used. It is available in many forms like ointment, solution, gel, gargling, mouth wash, scrub etc. The ointment form was taken as standard control in this present study. Though the prime importance in Ayurveda has been given to wound healing, the very fact that the subject of wound healing is under study from the days of Sushruta.

There are no wonder that many research scholars in all over the world are working to know the remedies which are more effective in wound healing, but the final answer is yet awaited. Keeping all these points in mind the present clinical trial entitled —To study the efficacy of Sharpmukhamool lepa’ in management of Dushta vrana has been carried out.
A) MATERIALS
No of Patients: 30 in Each group
Selection of patients: From the hospital's O.P.D and I.P.D

**Group A (Trial group):** 30 patients with Madhuyukta Sharpumkhamool lepa.

**Group B (Control group):** 30 Patients with Betadine ointment.

Technique & Methods for - Measuring size of wound
Transparent graph paper, Magnifying lens, marker was used to get its measurements and it was measured in mm/2.

B) METHODS

**Medium of study:** English which is supplemented by Ayurvedic terminology wherever necessary in sanskrut.

Type of study: It was an open controlled Randomised study in which patients were divided randomly in two groups.

A. Trial Group
1. 30 patients were selected for Madhuyukta Sharpumkhamool lepa.
2. Madhuyukta Sharpumkhamool lepa was applied appropriately and the changes during the span of study was noted on 0, 4, 8, and 12th day.

B. CONTROL GROUP
1. 30 patients were treated with Betadine ointment.
2. Betadine was applied appropriately and the changes during the span of study was noted on 0, 4, 8 and 12th day.

**Method of preparation of Drug**
Raw materials were purchased directly from the market. The drugs were checked for the authenticity.
Madhuyukta Sharpumkhamool lepa was prepared by the standard method given in the Sharngadhar samhita.

**Drug:** Madhuyukta Sharpumkhamool lepa (Bhaishjyaratnawali), Betadine ointment.

**Dose:** As per requirements

**Equipments:** Transparent graph paper, Magnifying lens, marker

**Method:** Open method of dressing was adopted.

**Follow up:** Daily dressings were done, but for the purpose of the study findings were recorded on CRF Madhuyukta Sharpumkhamool lepa was applied appropriately and the changes during the span of study was noted on 0, 4, 8 and 12th day.

**Duration of treatment:** 12 days.

**Plan of Clinical Trial**

1) **Ethical Clearance:** Ethical clearance was sought from the ethical committee of the hospital.

2) **Consent:** An understanding of the procedure was given to the patients about the trial and a written consent was taken from the patients prior to participation in the trial.

3) **Clinical examination:** Complete general and clinical local examination of Vrana was carried out for diagnosis and assessment.

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**Criteria for selection**

**INCLUSION CRITERIA**
1. Non specific ulcers
2. Age group 12yrs to 60yrs will be included.
3. Ulcer having duration ≤6months.

**EXCLUSION CRITERIA**
1. Specific ulcer like tuberculosis, leprosy, malignant etc.
2. Bleeding disorder, Diabetes etc.
3. HIV, HGV, HBsAg.

**Investigations**
To rule out other pathology before treatment by routine as well as microscopic blood were carried out like i.e., CBC, ESR, CT, BT, RBS.

**Microscopic examination** – Other investigations like tuberculin test, pus culture etc. were done as per requirement.

**Criteria for assessment**

**Improved**
1. No pain
2. Serous discharge
3. Granulation ≥75%
4. Ulcer decreased in size

**Not Improved**
1. Pain
2. Pus discharge
3. Granulation ≤25%
4. Ulcer not decreased/or increased in size.

**Scores of clinical features**
Scoring of all signs & symptoms according to severity were given marks (0-3) as

**Pain**
0 – No pain.
1 – Occasional pain during movement only (once or twice in a day).
2 – Intermittent pain even during rest (every 2 to 3 hrly).
3 – Continuous pain & not relieved by rest.

**Discharge**
0 – No discharge.
1 – Scanty occasional discharge & little wet dressing.
2 – Often discharge & with blood on dressing.
3 – Profuse, continuous discharge which needs frequent dressing.

**Granulation**
0 – Complete granulation.
1 – More granulation (≥75%), less pus.
2 – Equal granulation (>50%) & pus.
3 – Less granulation (≤25%), more pus.

**Size**
0 – Size of the wound 0.
1 – Size of the wound>0.1mm-5 mm.
2 – Size of the wound>5.1mm-10 mm.
3 - Size of the wound > 10 mm.

**CRITERIA FOR ASSESSMENT OF OVERALL EFFECT**

- **Marked Improvement** – 76 to 100% relief in signs and symptoms along with healing of wound.
- **Moderate Improvement** – 51-75% relief in signs and symptoms along with healing of wound.
- **Mild Improvement** – 26-50% relief in signs and symptoms along with healing of wound.
- **No Improvement** – Upto 25% relief in signs and symptoms without healing of wound.

The patients were gauged individually & percentage of score reduction in the symptomatology was determined by mathematical calculations.

**OBSERVATIONS AND RESULTS**

**OBSERVATIONS**

Clinically diagnosed 60 Patients of *Dushta Vrana* were selected and assigned in two groups of 30 Patients each randomly for the study. Group A patients were treated with *Madhuyukta Sharpumkhamool lepa* for 12 days as trial group. The patients of second Group named as Group B were treated with Betadine for 12 days. All the 60 patients of this study, details of which are presented here in tabular form with brief description of each finding:

**Table 1: Distribution of 60 patients of Dushta Vrana based on Age**

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-25</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>13.33</td>
</tr>
<tr>
<td>26-40</td>
<td>20</td>
<td>22</td>
<td>42</td>
<td>70</td>
</tr>
<tr>
<td>41-60</td>
<td>6</td>
<td>4</td>
<td>10</td>
<td>16.66</td>
</tr>
</tbody>
</table>

*Age:* Out of 60 patients, maximum patients i.e. 70% were from the age group of 26-40 years, 16.66% from the age group of 41-60 years and minimum number i.e. 13.33% of the patients was from 12-25 years.

**Table 2: Distribution of 60 patients of Dushta Vrana based on Sex**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>21</td>
<td>22</td>
<td>43</td>
<td>71.66</td>
</tr>
<tr>
<td>Female</td>
<td>9</td>
<td>8</td>
<td>17</td>
<td>28.33</td>
</tr>
</tbody>
</table>

*Sex:* Out of 60 patients, maximum patients i.e. 71.66% were male and 28.33% were female.

**Table 3: Distribution of 60 patients of Dushta Vrana based on Marital status**

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>23</td>
<td>22</td>
<td>45</td>
<td>75</td>
</tr>
<tr>
<td>Unmarried</td>
<td>7</td>
<td>8</td>
<td>15</td>
<td>25</td>
</tr>
</tbody>
</table>

*Marital Status:* Out of 60 patients 75% were married and 25% were unmarried.

**Table 4: Distribution of 60 patients of Dushta Vrana based on Occupation**

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service</td>
<td>18</td>
<td>16</td>
<td>34</td>
<td>56.66</td>
</tr>
<tr>
<td>Housewife</td>
<td>5</td>
<td>4</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Education</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Farming</td>
<td>4</td>
<td>7</td>
<td>11</td>
<td>18.33</td>
</tr>
</tbody>
</table>

*Occupation:* Out of 60 patients, maximum patients i.e. 56.66% were doing job by nature of work, 18.33% were farmer, 15% were Housewife and 10% were studying.

**Table 5: Distribution of 60 patients of Dushta Vrana based on Habitat**

<table>
<thead>
<tr>
<th>Habitat</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban</td>
<td>14</td>
<td>14</td>
<td>28</td>
<td>46.66</td>
</tr>
<tr>
<td>Rural</td>
<td>16</td>
<td>16</td>
<td>32</td>
<td>53.33</td>
</tr>
</tbody>
</table>

*Habitat:* Out of 60 patients 53.33% were from rural area and 46.66% were from urban area.

**Table 6: Distribution of 60 patients of Dushta Vrana based on Socio-economic status**

<table>
<thead>
<tr>
<th>Socio-economy</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor</td>
<td>19</td>
<td>18</td>
<td>37</td>
<td>61.66</td>
</tr>
<tr>
<td>Middle</td>
<td>9</td>
<td>10</td>
<td>19</td>
<td>31.66</td>
</tr>
<tr>
<td>Rich</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>6.66</td>
</tr>
</tbody>
</table>

*Socio-economic Status:* Out of 60 patients, maximum patients i.e. 61.66% were of Poor group and 31.66% were from middle Class group and only 6.66% were Rich.

**Table 7: Distribution of 60 patients of Dushta Vrana based on Diet**

<table>
<thead>
<tr>
<th>Diet</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixed</td>
<td>24</td>
<td>23</td>
<td>47</td>
<td>78.33</td>
</tr>
<tr>
<td>Vegetarian</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>21.66</td>
</tr>
</tbody>
</table>

*Diet:* Out of 60 patients, maximum patients i.e. 78.33% were having mixed type of diet, minimum i.e. 21.66 % were having vegetarian diet.
Table 8: Distribution of 60 patients of Dushta Vrana based on Religion

<table>
<thead>
<tr>
<th>Religion</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hindu</td>
<td>30</td>
<td>29</td>
<td>59</td>
<td>98.33</td>
</tr>
<tr>
<td>Muslim</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1.66</td>
</tr>
</tbody>
</table>

Religion: Out of 60 patients, maximum patients i.e. 98.33% were Hindus and minimum i.e. 1.33% were Muslims.

Table 9: Distribution of 60 patients of Dushta Vrana based on Site of wound

<table>
<thead>
<tr>
<th>Site</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head &amp; neck</td>
<td>6</td>
<td>5</td>
<td>11</td>
<td>18.33</td>
</tr>
<tr>
<td>Upper limb</td>
<td>8</td>
<td>9</td>
<td>17</td>
<td>28.33</td>
</tr>
<tr>
<td>Lower limb</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>21.66</td>
</tr>
<tr>
<td>Middle body</td>
<td>7</td>
<td>7</td>
<td>14</td>
<td>23.33</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>8.33</td>
</tr>
</tbody>
</table>

Site of wound: Out of 60 patients, maximum patients i.e. 28.33% were having wound in upper limb, 23.33% in middle body and 21.66% were having wound at lower limb and minimum 8.33% at other area (perianal region).

Table 10: Distribution of 60 patients of Dushta Vrana based on Aetiology of wound

<table>
<thead>
<tr>
<th>Type</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nija</td>
<td>12</td>
<td>12</td>
<td>24</td>
<td>40</td>
</tr>
<tr>
<td>Agantuja</td>
<td>18</td>
<td>18</td>
<td>36</td>
<td>60</td>
</tr>
</tbody>
</table>

Aetiology of wound: Out of 60 patients, the Aetiology for Nija Vrana was 40% and also 60% for Agantuja Vrana.

Table 11: Distribution of 60 patients of Dushta Vrana based on onset

<table>
<thead>
<tr>
<th>Onset</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gradual</td>
<td>20</td>
<td>18</td>
<td>38</td>
<td>63.33</td>
</tr>
<tr>
<td>Sudden</td>
<td>10</td>
<td>12</td>
<td>22</td>
<td>36.66</td>
</tr>
</tbody>
</table>

Onset: Out of 60 patients, 63.33% had gradual onset and 36.66% had sudden onset.

Table 12: Distribution of 60 patients of Dushta Vrana based on Chronicity of wound

<table>
<thead>
<tr>
<th>Duration</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 3wks</td>
<td>8</td>
<td>7</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>&gt;3wks-1mnth</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>21.66</td>
</tr>
<tr>
<td>&gt;1mnth-2mnth</td>
<td>8</td>
<td>11</td>
<td>19</td>
<td>31.66</td>
</tr>
<tr>
<td>&gt;2mnth-3mnth</td>
<td>6</td>
<td>3</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>&gt;3mnth-6mnth</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>6.66</td>
</tr>
</tbody>
</table>

Chronicity of wound: Out of 60 patients, maximum Patients i.e. 31.66% had >1mnth-2mnth of chronicity of wound. 25% had up to 3wks and 21.66% had >3wks-1mnth as wound period. 15% had >2mnth-3mnth and 6.66% had >3mnth-6mnth the period of chronicity of wound.

Table 13: Distribution of 60 patients of Dushta Vrana based on Addiction

<table>
<thead>
<tr>
<th>Addiction</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>12</td>
<td>13</td>
<td>25</td>
<td>41.66</td>
</tr>
<tr>
<td>Tobacco</td>
<td>8</td>
<td>11</td>
<td>19</td>
<td>31.66</td>
</tr>
<tr>
<td>Smoking</td>
<td>8</td>
<td>7</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>Alcohol</td>
<td>8</td>
<td>6</td>
<td>14</td>
<td>23.33</td>
</tr>
</tbody>
</table>

Addiction: Out of 60 patients, maximum patients i.e., 41.66% were not indulged in smoking or alcohol, 31.66% in only tobacco, 25% only in smoking and minimum i.e. 23.33% were indulged both in alcohol.

Table 14: Distribution of 60 patients of Dushta Vrana based on Sleep

<table>
<thead>
<tr>
<th>Sleep</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>16</td>
<td>17</td>
<td>33</td>
<td>55</td>
</tr>
<tr>
<td>Sound</td>
<td>9</td>
<td>7</td>
<td>16</td>
<td>26.66</td>
</tr>
<tr>
<td>Disturb</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td>18.33</td>
</tr>
</tbody>
</table>

Sleep: Out of 60 patients 55% had good sleep, 26.66% had sound awake sleep and minimum 18.33% had disturb sleep.

Table 15: Distribution of 60 patients of Dushta Vrana based on Prakruti

<table>
<thead>
<tr>
<th>Prakruti</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vata-pitta</td>
<td>11</td>
<td>12</td>
<td>23</td>
<td>38.33</td>
</tr>
<tr>
<td>Vata-kapha</td>
<td>12</td>
<td>11</td>
<td>23</td>
<td>38.33</td>
</tr>
<tr>
<td>Pitta-Kapha</td>
<td>7</td>
<td>7</td>
<td>13</td>
<td>21.66</td>
</tr>
<tr>
<td>Tridoshaja</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Prakruti: Out of 60 patients majority of the patients i.e. 38.33% were belonged to Vata Pitta and Vata Kapha Prakruti
followed by 21.66% Pitta Kapha Prakruti. Here in this present study no patient was found with Tridoshaja Prakruti.

Table 16: Distribution of 60 patients of Dushta Vrana based on Agni

<table>
<thead>
<tr>
<th>Agni</th>
<th>Group A (Sharpumkha)</th>
<th>Group B (Betadine)</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manda</td>
<td>6</td>
<td>8</td>
<td>14</td>
<td>23.33</td>
</tr>
<tr>
<td>Sama</td>
<td>9</td>
<td>7</td>
<td>16</td>
<td>26.66</td>
</tr>
<tr>
<td>Vishama</td>
<td>10</td>
<td>12</td>
<td>22</td>
<td>36.66</td>
</tr>
<tr>
<td>Tilshna</td>
<td>5</td>
<td>3</td>
<td>8</td>
<td>13.33</td>
</tr>
</tbody>
</table>

*Agni*: The data of the table reveals that 36.66% were having Vishama Agni whereas 26.66% of the patients were having Sama Agni. 23.33% and 13.33% were having Manda Agni and Tilshna Agni respectively.

Table 17: Distribution of 60 patients of Dushta Vrana based on Symptoms

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group A (Sharpumkha)</th>
<th>%</th>
<th>Group B (Betadine)</th>
<th>%</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>29</td>
<td>96.66</td>
<td>29</td>
<td>96.66</td>
<td>58</td>
<td>96.66</td>
</tr>
<tr>
<td>Discharge</td>
<td>28</td>
<td>93.33</td>
<td>29</td>
<td>96.66</td>
<td>57</td>
<td>95</td>
</tr>
<tr>
<td>Granulation</td>
<td>30</td>
<td>100</td>
<td>30</td>
<td>100</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Size</td>
<td>30</td>
<td>100</td>
<td>30</td>
<td>100</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

In this present clinical study total 96.66% patient were found with pain in group A and group B. Discharge was observed 93.33% in group A and 96.66% in group B. 100% each were observed with granulation and size in both group A as well as in group B.

RESULTS

STATISTICAL ANALYSIS

All information which were based on various parameter were gathered & statistical analysis was carried out in terms of Mean (X), standard deviation (SD), standard error (SE), paired test (t’) & finally result were incorporated term of probability P’ by using Z test.

The data collected from this clinical research work and arranged for further process by subjecting to various statistical methods and presented for early comprehension. So the obtained data on the basis of observation in each group were subjected to statistical analysis in terms of paired t’ test. The t’ test used for paired observations before treatment and after treatment. The formula for that is

1) t’ Calculated = MR/SE, where MR is the mean reduction between gradation of symptoms at two time period.
2) MR = Σd/n, where d is the difference between gradation of symptoms at two time period.
3) SD of difference = Square root of (Σd2 – (Σd)2/n)/n, where n is the number of patients in one group.
4) SE of difference = SD/ √ n.

Now two hypotheses were made.
1) H0 = where symptoms before treatment and after are same i.e. test is insignificant (MR = 0).
2) H1 = where symptoms before treatment and after treatment are different i.e. test is significant (MR ≠ 0).

It was considered at level of P > 0.05 (Insignificant), P < 0.05, P<0.01 (Significant) and P < 0.001 (Highly significant). The t table at 5 %, 1 %, 0.1% is considered (n=1) DF, to carry out the results.

The obtained data on the basis of observation of two groups were subjected to statistical analysis in terms of t’ test as numbers of patients were more than 30. For comparing results in two groups, this test was done. As above, in this test also two hypotheses were made.

1) H0= where relief obtained in both groups are same i.e. test is insignificant, means Sharpumkhamool lepa’ and Betadine’ is equally effective.
   The formula used is Z calculated = (x1– x2)/SE, where x1 is the mean reduction in group A and x2 is the mean reduction in group B.
   SD of mean difference = Square root of ((n1 SD12 + n2 SD22)/(n1 + n2 -2))
   S.E. = S.D. of mean difference x (1/n1 + 1/n2)
   It was considered at level of P < 0.05 (significant), P < 0.01 (significant); to carry out the results table value of Z at 5 % level of significance is 1.96.
   **Paired t’ test:** Paired t’ test is used to work out mean reduction between first and subsequent days under study and test is significant.
   Results obtained are presented in following table. The t’ value at 5% is 2.045, 1% is 2.756 and 0.1% is 3.66.

*P < 0.05, **P < 0.01, ***P < 0.001.*

Table 18: Effect of Madhuyukta Sharpumkha lepa on 30 Patients of Dushtha Vrana

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>%</th>
<th>S.D.</th>
<th>S.E.</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.96</td>
<td>0.566</td>
<td>71.67</td>
<td>0.563</td>
<td>0.103</td>
<td>13.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge</td>
<td>1.46</td>
<td>0.53</td>
<td>70</td>
<td>0.4026</td>
<td>0.0736</td>
<td>12.229</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Granulation</td>
<td>2.5</td>
<td>1.1</td>
<td>60</td>
<td>0.62</td>
<td>0.11</td>
<td>12.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Size</td>
<td>2.3</td>
<td>0.766</td>
<td>63.89</td>
<td>0.86</td>
<td>0.157</td>
<td>9.749</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The table shows that the pain was decreased 71.67% in *Sharpumkhamool lepa* treated group which was statistically
highly significant. Discharge was reduced upto 70 % which was statistically highly significant. The granulation was improved upto 60% and statistically highly significant where as size of wound was decreased upto 63.89 % which was highly significant by statistically.

Table 19: Effect of Betadine ointment on 30 Patients of Dustha Vrana

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>%</th>
<th>S.D.</th>
<th>S.E.</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.76</td>
<td>0.733</td>
<td>60.55</td>
<td>0.587</td>
<td>0.107</td>
<td>9.315</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge</td>
<td>1.433</td>
<td>0.733</td>
<td>60</td>
<td>0.4661</td>
<td>0.085</td>
<td>8.215</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Granulation</td>
<td>2.33</td>
<td>1.233</td>
<td>48.33</td>
<td>0.61</td>
<td>0.11</td>
<td>9.91</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Size</td>
<td>2.03</td>
<td>1.033</td>
<td>48.89</td>
<td>0.718</td>
<td>0.131</td>
<td>7.36</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

In Povidone Iodine group the pain was decreased 60.55% which was statistically highly significant. Discharge was reduced upto 60 % which was statistically highly significant. The granulation was improved upto 48.33% and statistically highly significant where as size of wound was decreased upto 48.89 % which was highly significant by statistically.

Table 20: Overall result of therapy (Group wise)

<table>
<thead>
<tr>
<th>Result</th>
<th>Group A (Sharpumkha)</th>
<th>%</th>
<th>Group B (Betadine)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marked Improvement</td>
<td>10</td>
<td>33.33</td>
<td>5</td>
<td>16.66</td>
</tr>
<tr>
<td>Moderate Improvement</td>
<td>11</td>
<td>36.66</td>
<td>12</td>
<td>40</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>7</td>
<td>23.33</td>
<td>8</td>
<td>26.66</td>
</tr>
<tr>
<td>No Improvement</td>
<td>2</td>
<td>6.66</td>
<td>5</td>
<td>16.66</td>
</tr>
</tbody>
</table>

It was noticed that, 33.33% markedly improved cases were observed in treated group i.e. Madhuyukta Sharpumkhamool lepa group followed by 36.66% were moderately improved, 23.33% were mild improved whereas 6.66% remain unchanged.

In standard control group i.e. Povidone Iodine group total 16.66% each markedly improved and no improved cases were found while 40.00% were moderately improved and 26.66% were mildly improved.

DISCUSSION

The present study entitled "To Study The Efficacy of Sharpoomkhamool Lepa In Management Of Dushtavrana" was carried out to evaluate the effects of Madhuyukta Sharpumkhamool lepa on Dushta vrana. The main aim of the study was to evaluate the Sodhaka effects of Madhuyukta Sharpumkhamool lepa and so the parameters, pain, discharge, granulation and size were taken up for the study The results of the study drug were found to be significant on all parameters. 60 patients of Dushta vrana were selected and divided randomly in two groups. Group A was treated with Madhuyukta Sharpumkhamool lepa and Group B with betadine ointment. Patients of age group 12-60 years, of both sex suffering from infected wound were taken up for the study.

To assess hematological stability of the patients, blood investigations were done prior to and after treatment as per necessity. The observations recorded on various days of the study were put to statistical analysis. According to study design 60 patients of Dushta vrana were selected from the OPD and IPD of study centre and were divided randomly in both the groups. Group A termed as trial group was treated with Sharpumkhamool lepa. Group B, termed as control group was treated with Betadine ointment.

Although healing commences immediately after injury which has been well elaborated by the modern pathologist and surgeon in the light of recent research. As far as the management of wound is concerned appropriate Shodhana and Ropana of wound are required at appropriate time.

Process Of Healing

An attempt was made to understand the Ropana process in a better way from Ayurvedic point of view:

A) Phase of Shodhana: Healing always take place in Shuddha Vrana only. Shodhana in this context refers to Sroto-shodhana and irrigation of the local debris by means of Lekhana action and Laghu, Tikshna and Sara properties. This ultimately cleans the Vrana.

B) Phase of Pachana: Vrana Dushti is caused due to formation of Ama and then Khavaigunya occurs which is the result of local and general Agnimandhya. The properties like Dipana, Pachana and Vatahara action will help in regaining the Agnivardhana and maintaining the Samyaavastha.

C) Phase of Ropana: Action of Dhatu Poshana, Prinana and Balya in medication are effective to its maximum content by way of letting the wound becomes heal. To achieve the main goal of healing, it is necessary to remove the maximum local Dushtri or Debridement at the site of Vrana. By the virtue of Lekhana, Putihara, Dahahara, Kanudughana, Vrana Shodhana and Vrana Ropana properties of Sharpumkha and Madhu, the local Dhatu Dushti is ceased. The second step in the path of healing is to enhance the healing, for this purpose Madhu made easy way.

There are various type of chemical substances have been established for their properties of wound healing agents. Several herbal products and Ayurvedic traditional Yoga are mentioned and used for the management of wound. For this study, treated group is given Sharpumkha mool lepa as a trial drug which is mentioned in Bhaishajya Ratnavali and Bhavprakash in Vranashotha Roga Adhikara for the treatment of Vrana.

Discussion on general observation of patients

Age: It is seen that 70% of patients belonged to age group 26 to 40 yrs followed by 16.66% of age group 41
to 60 yrs. This factor may be due to mainly earning occupational age and external exposure also. Hence here we can see that maximum no of the patients were Young. Sex: 71.66% of patients in the study were males and rest were females. This reveals that the incidence of Dushta vrana is more in males due to external exposure and nature of work.

Occupation: Majority of the patients were labourer by occupation (56.55%) and hence the wounds were found more than any other occupation group.

Diet: 78.33% of patients followed mixed diet pattern in the study. It can be said that the non-veg diet plays a significant role in the etio-pathogenesis of Dushta vrana. It leads to Agnimandya and hence vitiation of Doshas leading to Dushta vrana.

Duration of Vrana: 31.67% and 25% of patients in the study had Vrana from 1-2 month and within 3 week respectively. This shows that the patients seek treatment early for the Vrana thereby revealing the health orientation and awareness of the patients.

Symptoms wise distribution: Most of the patients had pain, discharge and unhealthy granulation in the wound. This reveals that the Dushta vrana is always accompanied by discharge and unhealthy granulation.

Site wise distribution of patients: 28.33% and 21.66% of patients had wound on upper limbs and lower limb indicating that the Dushta vrana is more common on extremities. Reason for this factor may be that maximum patients were observed with manual natural of work.

Aetiology wise distribution of patient: 60% of the patient had Agantuja type of Vrana which reveals that Dushta vrana is mainly caused due to some foreign matter.

Also Maximum no of the patients were Hindu (98.33%) and married (75%). Though there is no direct relation with wound but the area where study has been carried out persist higher number of Hindus.

Maximum patients were found with regular sleep (55%). Maximum no of the patients were having Vata Pitta and Vata Kapha Prakruti (38.33%). However these factors were not responsible mainly for happening of wound.

Both the groups have shown highly significant result on all clinical symptomatology of wound, because trial drug and standard drugs promoted the natural healing process and checked the disease Dushta Vrana

Pain: The pain was decreased 71.67%. In Betadine group the pain was decreased 60.55% which was statistically highly significant in both groups.

Discharge: Discharge was reduced 70% in Sharpumkhamooll lepa group while in Betadine group it was reduced 60%. Both were statistically highly significant.

Granulation: The granulation was improved 60% whereas in Betadine group relief was 48.39% while it was highly significant in both groups.

Size: In Sharpumkhamooll lepa group size was decreased 63.89% and in Betadine group 48.89%. They were highly significant statistically in both groups.

Probable mode of action

Sharpumkha and Madhu is having Tikta, Kashaya and Madhu, Kashaya rasa respectively as well as both are Katu vipaka therefore it is Shothahara, Kushthaghna, jantughna, Vishaghna. Ushna guna causes Panchan of Sama dosha, thereby promoting the Samyak dhaut utpatti. Tikshana guna causes Panchana of Aama. Being Kledanashan Sharpumkha is Vranashodhak, Ropaka and Rakta stambhaka. Sharpumkha alleviates inflammation, benefits in skin diseases and posses bactericidal, wound healing, haemostatic, antidote effect. Honey possesses nutritive properties so it provides Dhatu Poshana (Nutrition) to skin and all Dhatu. Liquid honey does not spoil. Because of its high sugar concentration, it kill bacteria by plasmolysis. It has been shown Vrana Shodhana, Lekhana, Ropana and Vishaghna properties also. There for it helps to remove microbes from wounds and prepare in Shuddha Vrana. These drugs are Stambhana and Raktashodhaka also there for it checks bleeding and discharge from wounds and shows haemostatic action very well.

SUMMARY

Ayurvedic review comprises etymology and definition of Vrana. Then some synonyms and classification of Vrana were discussed. The classification was mentioned according to Sushruta Samhita, Charaka Samhita, and Ashtangahrudaya. Various etiological factors were presented. Samprapti of Vrana according to Ayurveda with its Ghatakas were defined, Shadvidha Kriyakala given by Sushruta was discussed in case of Vrana. Then Rupa, Upadrava and Chikitsa were described.

The second section includes the modern aspect of Vrana in the form of wounds. The process of wound healing and its management and types were discussed simultaneously.

The third section consists of a brief description about the selected drugs viz. Sharpumkhamoool lepa and Betadine. In this section description of ingredients of the selected drugs and their pharmacological action has also been incorporated.

Materials and method consists of broad classification of total 60 patients into age, sex, and their complaint wise. They were randomly divided into 2 groups and treated with the trial drug Sharpumkhamoool lepa and Betadine as local application for the duration of 12 days.

They were studied and their data related to effect of therapy was mentioned simultaneously in tables of observation and result.

Further chapter contains some valuable and fruitful discussion about the disease and the probable mode of action of the selected drug. Then the data obtained after the clinical trial were discussed carefully.

Lastly total study was summarized briefly and a conclusion was drawn in fifth chapter. In this research study total 60 patients were registered and treated in
two groups, among them 30 patients in Sharpumkhamool lepa group and 30 patients in Povidone iodine group. On the basis of this study the following conclusion can be drawn.

a) Maximum no. of the patients was from the age group of 26 to 40 years (70%).
b) Maximum no. of the patients was Males (71.66%).
c) Maximum no. of the patients were Hindu (98.33%).
d) Maximum no. of the patients were from poor class (61.66%) by social and economical status.
e) Maximum no. of the patients was serviceman (56.66%) by occupation.
f) Maximum no. of the patients was married (75%).
g) Maximum no. of the patients had gradual onset (63.33%).
h) Maximum no. of the patients had wounds at upper limb (28.33%).
i) Maximum no. of the patients had the wounds with pain (96.33%), discharge (95%), granulated wound bed (100%).
j) Maximum no. of the wounds was Agantuja (60%).
k) Maximum no. of the patients was having mixed diet (78.33%) and Vishamagni (36.66%).
l) Maximum no. of the patients was having good sleep (55%).

Effect of Sharpumkhamool lepa Group (Treated Group): In this group 71.67%, 70%, 60%, and 63.89% relief was obtained in pain, discharge, granulation and size respectively. The statistical data reveals that highly significant result was achieved in size, pain, discharge, and granulation.

Effect of Betadine Group (Standard Group): In this standard control group 60.55% relief was obtained in pain, 60% relief was observed in discharge. Rest of the symptoms like granulation and size were relieved upto 48-50%. The statistical data mentions that highly significant result was observed in pain, discharge, granulation and size.

Overall result of therapy (group wise): It was noticed that, 33.33% markedly improved cases were observed in treated group while Povidone iodine group total 16.66% markedly improved. 36.66% were moderately improved in trial group while 40.00% were moderately improved in control group. In trial group 23.33% were mild improved whereas 26.66% mildly improved in control group. 6.66% and 16.66% remain unchanged in trial group and control group respectively.

CONCLUSION

On the basis of clinical observations it can be concluded that the trial drug Sharpumkhamool lepa possess analgesic, anti inflammatory and anti bacterial properties. There are no unwanted effects found during the course of treatment. It is found better in the management of wounds due to its effectiveness and low cost. The present research work was aimed to find out the effective therapy for Vrana with the help of Ayurvedic and modern procedures.

After the present study, it can be concluded that Sharpumkhamool lepa (Trial drug) has shown better statistical results than Betadine (control drug). It is noted that, Sharpumkhamool lepa group - A (Trial drug) has shown better result in all symptoms of Dushtavrana than Betadine (control drug).

From the study, it can be concluded that administration of Sharpumkhamool lepa is an effective treatment modality for Dushtavrana. More detail study may be conducted in this regard to establish the efficacy of Sharpumkhamool lepa in management of Dushtavrana. Though, the results are very good, but further study on large number of patients with longer duration of therapy is need to achieve a definite conclusion.

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Cite this article as:

Source of support: Nil, Conflict of interest: None Declared