THE EFFICACY STUDY OF APPLICATION OF TILA KALKA LEPA (Sesamum Indicum Linn.) AGAINST BETADINE OINTMENT IN SADYOVRANA – A RANDOMISED CONTROL OPEN TRIAL.

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Received on: 23/11/2019; Revised on: 02/12/2019; Accepted on: 06/12/2019

ABSTRACT

Structural and physiological disruption and discontinuity of a living tissue is called wound. It may be produced by a physical, chemical, thermal, microbial or immunological damage to the tissue. Healing of wound is one of the phenomena that holds a great importance since ancient times and hence has occupied a great space in our Ayurvedic texts. Sushrutacharya being a well-known surgeon has emphasized on this area of surgery which is central focus of surgery even in today’s era. Sushrutacharya has explained different types of wounds and their complete management. Sixty measures for the management of have been dealt with in detail, among which Kalka application is one such measure. This study aims at establishing this measure against contemporary management of wound. Sixty candidates fulfilling the inclusion criteria were selected. Candidates only with Sadyovrana were selected for the study. They were then randomly divided into two groups viz. Group A and Group B, each comprising of thirty candidates. Group A was taken as experimental group in which Tila (Sesamum Indicum Linn.) Kalka was applied on the wound every day. In Group B, Betadine ointment was applied on the wound every day. This treatment was carried out for seven successive days and the efficacy was then assessed based on the parameters of wound healing. After this therapy, it was observed that almost similar effect was observed in both the groups, which proves that Tila (Sesamum Indicum Linn.) Kalka application is as effective as Betadine ointment in wound healing.

Keywords: Sadyovrana, Tila (Sesamum Indicum Linn.) Kalka, Betadine ointment, Wound healing, Vrana, Vranaropana, Vedana, Akruti, Gandha, Varna, Srava.

1. INTRODUCTION

Wound healing is natural process. It is restorative response to injury of tissues. Resurfacing, reconstitution and restoration of the tensile strength of injured skin generated due to interaction of a complex cascade of cellular event is healing of wound. Wound healing is a systematic process. This process occurs in three classic phases. Inflammation phase, Proliferation phase and Maturation phase are three phases of wound healing. Inflammatory phase: Inflammatory cells debride injured tissue forming a clot during the inflammatory phase. Proliferative phase: During proliferative phase epithelialization, fibroplasia, and angiogenesis occur. Granulation tissue forms during this phase and contraction of the wound begins.
Maturation phase: Cross-linking of collagen to other collagens takes place. This tight cross-linking with protein molecules, increases the tensile strength of the scar.

As the science has advanced, newer & newer remedies are being tried out for speedy recovery of various diseases and surgical conditions but the oldest remedies are still in the race. These therapeutic measures not only accelerate the healing process but also aim at maintaining the quality and aesthetics of healing. Many scientific investigations have already been carried out to study the efficacy of such a large number of Vranaropaka Dravya that are mentioned by our Acharyas. Herbal medications involve Krimighna (disinfection), Lekhan (debridement) and Ropana (providing a moist environment to encourage the establishment for natural healing process) properties. Hence, considering the prevalence of wound and requirement of proving the efficacy of our age-old measures, Tila (Sesamum Indicum Linn.) Kalka application was chosen as the topic of study.

2. MATERIALS AND METHODS

2.1. Materials

The materials selected for the study were Tila (Sesamum Indicum Linn.) Kalka and Betadine ointment. Methods as per Ayurvedic pharmacopeia of India were adopted for physicochemical analysis. The Beeja of Tila (Sesamum Indicum Linn.) were taken and crushed to make a fine paste by adding distilled water to attain a homogenous paste like consistency. Standardization of the final product was done and it was stored in bottles. Fresh Kalka was prepared every day.

2.2. Study design

60 patients of Sadyovrana were selected as per the inclusion criteria, from Department of Shalyatantra, PMT’s Ayurveda College, Shevgaon, Maharashtra. Selection was done irrespective of age, gender, religion, caste, educational, marital and socio-economic status. The candidates were divided into 2 groups by random selection which rendered 30 candidates in each group. Group A was the experimental group which was given Tila (Sesamum Indicum Linn.) Kalka application. Group B was the control group which was given Betadine ointment application. Duration of the study was 7 days. IEC approved the study.

2.3. Method of application of Tila (Sesamum Indicum Linn.) Kalka

Standard aseptic precautions were taken into account while applying Tila (Sesamum Indicum Linn.) Kalka. Wound was cleaned with H₂O₂ and dried with sterile gauze piece. Freshly prepared Tila (Sesamum Indicum Linn.) Kalka was applied evenly over wound. Wound was covered with sterile gauze piece and bandage was applied.

2.4. Selection of Patients

2.4.1. Inclusion Criteria

- Age 20 to 70 years, both genders.
- Patients of Sadyovrana.
- Ghrishta Vrana (Abrasions).
- Kshataja Vrana (Laceration).
- Wounds due to accident and trauma.

2.4.2. Exclusion Criteria

- Age below 20 to above 70 years.
- Chhinna Vrana.
- Bhinna Vrana.
- Picchita Vrana.
- Viddha Vrana.
- Dagdha Vrana.
- Diabetic wound, Infected wound, Chronic non-healing ulcer tec.

2.4.3. Withdrawal criteria

- Patient not responding to the treatment within 7 days.
- If aggravation of symptoms is seen.
- Patient refuses to continue the treatment.

2.5. Assessment Criteria

The response of the patient to the treatment was assessed by following parameters.
2.6. Gradation of parameters

According to the severity, grading for the parameters was done.

**Vedana (based on VAS pain scale)**
- 0: Grade 0
- 1: Grade 1 to 3
- 2: Grade 4 to 7
- 3: Grade 8 to 10

**Akruti**
- 0: < 2 cm
- 1: 2-4 cm
- 2: 4-6 cm
- 3: > 6 cm

**Varna**
- 0: No Granulation of tissue
- 1: Granulation of tissue (*Ruhyaman vrana*)
- 2: Pale base of wound
- 3: Yellowish slough at base & edges

**Gandha**
- 0: No foul smell
- 1: Foul smell

**Srava**
- 0: No discharge
- 1: Bloody discharge
- 2: Serous discharge
- 3: Purulent discharge
- 4: Heavy Purulent discharge

3. RESULTS AND DISCUSSION

Descriptive data that include median and p value were calculated for all the variables in the groups. Efficacy testing of the treatment of Trial and Control Groups were performed by using Wilcoxon Signed Rank (W) test. Comparison between Trial and Control Groups was done by using Mann-Whitney U test. The frequency distribution of demographic data was done. To assess the overall effect of the therapies, net results obtained on various parameters of assessment were taken into consideration. Then it was graded in terms of percentage of relief of symptoms.

Wilcoxon Signed Rank test has been used for assessing *Vedana, Srava, Gandha* and *Srava*. It was found that P-Values for Trial Group and Control Group for both the parameters were less than 0.05. Hence, we concluded that effects observed in both the groups are significant. In the case of *Akruti*, Wilcoxon Signed Rank test was used the P-value in both the groups was greater than 0.05. This indicated that results observed in both the groups are not significant when this parameter is taken into consideration.

For comparison between trial group and control group, Mann Whitney U test was used. P-Values for all parameters were found to be greater than 0.05. Hence, we concluded that there was no significant difference found in effect observed in trial group and control group.

It was observed that the percentage of relieved patients in the Experimental group was same as that in the Control group for *Vedana, Varna, Gandha* and *Srava* symptoms. For *Akruti* and Total days required for *Vranaropana*, the percentage of relief in the Trial group was slightly higher as compared to that in the Control group. Thus, it can be concluded that the therapy given to the Trial group is equally effective as that given to the control group as far as relief is concerned.

4. CONCLUSION

- *Tila* (*Sesamum Indicum* Linn.) *Kalka* is significantly effective to reduce *Vedana, Strava, Gandha* and improve *Vrana* parameters in *Sadyovrana* patients.
- No significant effect of *Tila* (*Sesamum Indicum* Linn.) was found on *Akruti* parameter in *Sadyovrana* patients.
- *Tila* (*Sesamum Indicum* Linn.) *Kalka* and Betadine ointment were found almost equally effective to improve *Sadyovrana*.
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Cite this article as:
Mundhe VC, Joshi MS. The efficacy study of application of Tila Kalka Lepa (Sesamum Indicum Linn.) against Betadine Ointment in Sadyovrana – A Randomised Control Open Trial. International Journal of Research in Ayurveda and Medical Sciences 2020; 3 (1): 7-10.

Source of Support: Nil; Conflict of Interest: None declared.