JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

"A COMPARATIVE STUDY ON EFFICACY OF *SIKTHAKADI GHRIT* AND SILVER SULFADIAZINE CREAM IN *DURDAGDHA* (SECOND DEGREE BURN WOUND) IN WISTAR ALBINO RATS" : A Study Protocol

Dr Sagar [1] ,Dr Rajender Singh [2], Dr Manjusha [3], Dr Anamika[4]

1 PG Scholar , Department of Shalya Tantra , Insstitute for Ayurved Studies & Research – Faculty Of Ayurveda SKAU Kurukshetra , Haryana , India.

2 Professor , Department of Shalya Tantra , Insstitute for Ayurved Studies & Research – Faculty Of Ayurveda SKAU Kurukshetra , Haryana , India.

3 M.Pharma , Ph.D , Professor of Institute of Pharmaceutical Science , Kurukshetra University , Kurukshetra, Haryana , India.

4 Associate Professor, Department of Shalya Tantra , Insstitute for Ayurved Studies & Research – Faculty Of Ayurveda SKAU Kurukshetra , Haryana , India.

ABSTRACT

Ayurveda, a traditional Indian medical system dating back over 3,000 years, focuses on promoting health through a holistic balance of mind, body, and spirit. Unlike modern medicine, which often treats diseases, *Ayurveda* will emphasize prevention andbalancetomaintainoverallwell-being.Thebranchof*Shalyatantra*willspecialize in surgical techniques, addressing physical and emotional distress. *Acharya Sushruta*, a key figure in *Ayurveda*, described for types of burn called *Dagdh*[1]Among them, where the skin color gets distorted in excessive quantity and it appears burnt like, it is called '*Plushta*'. Where the burn causes severe blisters and the pain like *Chosh*(sucking pain), *Dah, Raga* (redness), *Pak* (purpura) and pain are intense and the one who gets relief for a longer time is called *'Durdagdha'*. Where the ulcer is not low and its color is similar to palm fruit and is well organized (uniform) and the above mentioned, it is called '*Samayagdagdha*' which is accompanied by burning symptoms of skin, flesh and tip. Pieces of burnt meat were seen hanging in *'AtiDagdha'* Dislocation or disintegration of body parts or joints occurs, the ends, nerves, joints, bones, etc. In the future, formulations like *SikhtakadiGhrit*will be used forburn wound healing . This will allow for efficient testing on animals to validate its effectiveness, with hopes of advancing burnwound healing therapies and preparing for eventual human trials.

Keywords:*SikthakadiGhrit,Dagdh*

INTRODUCTION

In Ayurveda, burn injuries are considered a type of traumatic injury that can disrupt the balance of the *Doshas* (*Vata, Pitta, and Kapha*) and lead to various complications if not managed properly.

Sushruta, the father of surgery precisely realized the importance ofknowledge ofwounds, ulcersand theirmanagement inthe field ofsurgery.The word*Dagdha* is been derived from *"Dhatyasmaiti"* meaning Burn. India is blessed with a great heritage of traditional knowledge on medicine. Ayurveda being the most ancient and still successfully practiced sciences, many years back, ancient *Acharyas* have mentioned much easily available and clinically useful topical herbal applications.[2]*AgnidagdhaVrana* is a type of

wound.[3]Ayurvedic texts provide guidelines for the treatment of burn injuries, focusing on soothing the affected tissues, promoting healing, and preventing infections. *Vrana* is one of them which is being managed by human being from starting of civilization. *Sadyovrana* is an entity we commonly come across; it is associated with a lot of pain and caused due to external trauma.

Burn depth is classified into one of three types based on how deeply into the epidermis or dermis the injury might extend.

- Superficial burns (First Degree) involve only the epidermis and are warm, painful, red, soft and blanch when touched. Usually, there is no blistering. A typical example is a sunburn.
- Partial thickness burns (Second Degree) extend through the epidermis and into the dermis. The depth into the dermis can vary (superficial or deep dermis). These burns are typically very painful, red, blistered, moist, soft and blanch when touched. Examples include burns from hot surfaces, hot liquids or flame.
- Full-thickness burns (Third Degree) extend through both the epidermis and dermis and into the subcutaneous fat or deeper. These burns have little or no pain, can be white, brown, or charred and feel firm and leathery to palpation with no blanching. These occur from a flame, hot liquids, or superheated gasses.

NEED OF THE STUDY

Burn injury can lead to considerable amount of agony and disability among the victims.Post healing, the most common problem is scarring and contractures, so the process of wound healing and the final outcome of this process all depends on the way it is being managed throughout the stages of wound healing.[4]
Acharya Sushruta gives realistic acquaintance about surgery and its procedures, methods and line of treatment which were written many years ago & also functional in modern era. To validate it more precisely formulation is taken on animal study.
Experimental research will be conducted before a clinical investigation to evaluate the effectiveness of this formulation in treating wounds.
It is a need of an hour to find out a rotational and optimal healing compound for the wound management in a better way, hence it is important to find out comparative efficacy that possesses both *Shodhan*and *Ropan*(cleaning and healing) properties in *SikthakadiGhrit*in management of *Agnidagdha*as an herbal formulation foundation to increase its viability, ease of local application, and ease of use in upcoming human clinical trials
Animals are quite biologically similar to humans; in fact, mice and rats have morphological, physiological, and genetic similarities to humans. This is just one of many reasons why using animals in biomedical research is essential.`

AIM

To provide an alternative better herbal formulation in treatment of*Agnidagdha* wound.

OBJECTIVE

1. To study the effect of *'SikthakadiGhrit*' in minimizing infections in*Agnidagdha* wound in Wistar albino rats.
2. To study efficacy of the*SikthakadiGhrit*' in healing of *Agnidagdha* wound in Wistar albino rats.

RESEARCH QUESTION

Is there any difference between efficacy of *SikthakadiGhrit* and Silver sulfadiazine in management of *Agnidagdha* wound in single gender albino rats?

CASE STUDY

This study, titled"A COMPARATIVE STUDY ON EFFICACY OF *SIKTHAKADI GHRIT* AND SILVER SULFADIAZINE CREAM IN *DURDAGDHA* (SECOND DEGREE BURN WOUND) IN WISTAR ALBINO RATS" will aim to compare the effectiveness of *SIKTHAKADI GHRIT* withSilver Sulfadiazine creamin *Durdagdha* (second degree burn wound) in wistar albino rats**".** The primary goal will be to assess burn healing wound.

StudyType:Thiswillbeanexperimentalpre-clinicalstudy. Study type: Interventional
MethodofAllocationConcealment:NotApplicable Site of Study:
Kurukshetra , Haryana

Levelofstudy: IPD& OPDLevel
Masking:NotApplicable,opentrial Control:
Controlled
Samplingmethod:Simplerandom Timing: Prospective
No.Ofgroup:two Sample Size: 18
PrimaryPurpose:Treatment Study Duration: 15 days
Endpoint:EfficacyandSafety Experimental Source:

- Animals:Thestudy willinvolveWistar strainalbino rats ofasinglegender.
- Weight:Therats willweighapproximately 250±20 grams.
- Age:The animalswill bebetween6-12months old.
- Procurement: The rats will be procured from a CPCSEA-registered facility (Regn.No. 562/GO/Re/s/02/CPCSEA).
- Feeding:TheratswillbefedwithaspecificdietobtainedfromA certifiedsupplier.

MATERIALS

1. Albino Wistar rats, surgical gloves, burn rod, mask, kidney tray, syringe with needle, anesthesia agent, *SikthakadiGhrit*, Silver sulfadiazine cream & any other material required.
2. Total 18 rats will be divided into following groups and received the following treatment:

Group	Total no. of rats	Treatment	Duration
I (Vehicle control)	6	Without Medication	15 days
II (Standard Group)	6	Silver sulfadiazine cream	15 days
III(Test Group)	6	*SikthakadiGhrit*	15 days

PROCEDURE ON EXPERIMENTAL STUDY

INCLUSIONCRITERIA:

- Thestudy will includealbino rats ofasinglegender.
- Theselected ratswill weighbetween 180-250 grams.
- Theagerangeforinclusionwillbe6to12months. EXCLUSION CRITERIA:
- Ratsyounger than6 monthsor olderthan 12months willbe excluded.
- Unhealthyordiseasedratswill notbeconsideredforthe study.
- Ratsweighinglessthan180gramsormorethan250gramswillalsobeexcluded. CRITERIA FOR WITHDRAWAL:
- Any rats that develop acute illness or complications during the study will be noted, treated

accordingly, and withdrawn from the experiment.

The study will commence after receiving approval from the Institutional Animal Ethical Committee (No. IAEC2/Desp No 58/DT 3.01.14). All procedures will follow the CPCSEA guidelines for the care and use of animals in experimental research. The rats will be housed in clean polypropylene cages, maintained under controlled conditions with a temperature range of 23-25°C, relative humidity of 50-60%, and a natural light-dark cycle. They will be provided with food and water as per the guidelines.

• **ACCLIMATIZATION** Rats will be only used after 15-day acclimatization period (12:12 hours, light: dark cycle) to the laboratory environment. They will be housed under the standard nutritional and environmental conditions of light, temperature and humidity. They will be given the feed provided by standard laboratory. Post experimental study, the rats will be returned to the animal house after rehabilitation

PRE-OPERATIVE PREPARATION

❖ Weight of the rats will be duly noted.

❖ Body hair will be removed from the surgical site and surgical scrub alternating between a disinfectant and alcohol will be carried out.

INDUCTION OF ANESTHESIA

❖ General Anesthesia with the help of Injection Ketamine in the dose of 20mg/kg.

❖ Dose of Anesthesia will be ensured by absence of deep peddle reflexes of rat.

SURGICALPROCEDURE:

❖ The area of the wound will be created on the gluteal portion of the rat and will be outlined on the back of the animals with permanent marker. A full thickness of the burn wound of circular area 2x2cm will be created. Rods are usually made up of brass, aluminum, or stainless-steel rod may be used. The material of rod influences how rapidly heat is conducted from rod to skin, and subsequently the depth of burn. Metal rod with high thermal conductivity would cause a deeper level of burn compared to metal rod with lower thermal conductivity, when exposed to skin for same duration. Using a metal rod with low thermal conductivity would allow greater control over depth of burn infliction

❖ In the first group, no medication will be applied.

❖ To Second group, Silver sulfadiazine cream will be applied topically

❖ To Third group, *SikthakadiGhrit* will be applied topically.

❖ Drugs will be applied from the day of burn wound to 15 days.

❖ Then, the animals will be kept in separate cages on normal diet.

POST-OPERATIVE MANAGEMENT

Rats will be frequently checked every 10-15 mins during recovery from anesthesia. Food and water intake will be observed and also analgesic will be administered if needed.

CRITERIA OF ASSESSMENT

The wound contraction rate will be assessed by tracing the wound on alternate days.

Wound contraction (%) = Initial wound area- Analyzed area/Initial area × 100

HISTOLOGICAL ASSESSMENT:

It will be done on two rats from each group.

Skin biopsies will be collected from rats on 16th day and fixed in formaline solution (10% w/v).

OBSERVATION AND RESULT:

The observation and results will be analyzed and presented in accordance with the respective and applicable statistical tests.

SUMMARY AND CONCLUSION:

The work will be summarized and the result will be concluded after the above-mentioned study with the help of statistical data.

DEPARTMENTAL COLLABORATION

• Department of *Shalya Tantra* of Institute for Ayurved Studies & Research Faculty of Ayurved, Kurukshetra,
• Research and Innovation Department, Shri Krishna Ayush university, Kurukshetra
• Small Animal facility, Kurukshetra University, Kurukshetra–136118 (HARYANA) (562/GO/Re/S/02/CPCSEA)
• If required, Co-operation of the other departments of Institute for Ayurved Studies & Research, Faculty of Ayurved, Kurukshetra, will be taken with due permission from concerned authority.

DECLARATION:

- **Time schedule:** This study will be completed within stipulated time limit.
- **IAEC:** approval of IAEC will be taken before starting the preclinical trials.
- **Ethics committee:** Approval of IEC will be taken before starting the Pre clinical trial.

DISCUSSION

Thisstudywillevaluateandcomparethe Burn wound-healingefficacyof*Sikthakadighrit* andSilver sulfadiazine cream in second degree Burn wounds in Wistar albino rats, utilizing both Ayurvedic and modern approaches.

TreatmentGroups

Thethreetreatment groups will include:

1. ControlGroup (A):No treatment.
2. Silver sulfadiazine cream(B):Standardgroup
3. *SikthakadiGhrit*(C): Test group

STATISTICALANALYSIS

The results are expressed as mean ± SEM. Comparison between the groups will be made by analysis of variance (ANOVA), followed by Student's t test as per suitability.

Ayurvedic Insights

SikthakadiGhrit is known to heal a burn. Bee wax one of its ingredientprevent a painful inflammation that comes with an infection.

CONCLUSION

This study will combine Ayurvedic and modern medicine to assess Burn wound healing, potentially offering a holistic approach to wound management.

References

[1] Dutta. Kaviraja. Ambika, “Sushruta Samhita of Maharsi Sushruta Part 1 edited with,” *Ayurveda Tattva Sandipika Hindi commentary Sutrasthans,* pp. Chapter -12/16 Page no 53.

[2] https://www.wjpls.org/download/article/75022022/1646028897.

[3] https://www.researchgate.net/publication/361585392.

[4] https://pubmed.ncbi.nlm.nih.gov/34362607.