Research Article YASHAYURVED OCT-DEC 2024; 3(4):11-21

YASHAYURVED – E-Journal of Holistic Health
Peer reviewed | Quarterly Journal | Open Access

Randomized Open Controlled Clinical Study to Assess the Effect of Karpoor Ghrita As A Ropan in Management of Sadhyovrana.

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ABSTRACT

Since Sadyo Vrana Chikitsadhyaya was cited, this medication's composition should only be utilized in Sadyo Vranas, or Shuddha Vrana. Techniques: 60 diagnosed sadyovrana patients were selected for this study from the hospital's Shalyatantra Department's O.P.D. and I.P.D. A clinical was carried out. Clinical trials were conducted using a computer-generated random number table. Thirty patients in the control group received silver colloid dressing, and thirty patients in the trial group received Karpoor Ghrita dressing. Following Groups Irrespective Of Sex And Religion.

Observations and results: In this clinical study it is seen that, Clinical parameters like Pain, Swelling, Burning sensation, were significantly reduced after treatment in Trial group than in Control Group and Discharge, Tenderness, Granulation and Size of wound showed equal results. After testing the effectiveness of Karpoor ghrita treatment against the Standard silver colloid Treatment, results showed that The Karpoor ghrita treatment has better results than the Standard silver colloid in Sadyovrana Patients.

Keywords: *Sadyo vrana, Wound healing, Karpoor, ghrita, Karpoor ghrita.*

INTRODUCTION

The science of life, Ayurveda, is thought to have existed since the beginning of existence. As stated in the Charak Samhita, on this earth. ‘Shalyatantra’ is branch of Ayurveda it includes

procedure of excision of different types of straw, pieces of bone, hair, nail, pus, obstructed labour, blunt and sharp instrument, kshar and agnikarma. (Su. Su. 1/7)

The ‘vrana’ nirukti is –

'व्रणगात्रविचूर्णनेवर्णयतीति।' (Su. Chi. 1/6)

‘Gatra’ means tissue (body tissue or part of body) ‘Vichurnane’ means destruction, break, rupture and discontinuity of the body tissue.

So ‘Vrana Gatra Vichurnane’ means phenomenon complex causing destruction or rupture or discoloration of tissue in a particular part of a body is termed as ‘Vrana’. Vranayati means discoloration.

In Ayurveda particularly sushruta has mentioned various types of vrana and their management, which is prime important in any surgical practice or procedure. (Su. Chi. 1/3)

Vrana has been accorded a higher status by the Sushruta Samhita. The Vrana is described in the Sutrasthan of this Samhita in Chikitsasthan. Shalyatantra makes it very evident that a surgeon must possess the fundamental ability to treat vrana.

Sadyao Vrana is mostly occurring due to accidental injury as we see in today world. The no of major and minor injuries taking place it increases surgery; the wound may be some kind of trauma or it by surgical knife. Vrana is mainly classified as Nija and Aagantuja Vrana. Aagantuja correlate with Sadyao Vrana.

WOUND is a break in the integrity of the skin or tissue often, which may be associated with disruption of the structure and function. Types of Wounds – incised wound, lacerated wound, contusion, haematoma, abrasion, punctured wound, penetrating wound, avulsion injury, crush injury, gunshot injury.

Shalyatantra is specialised branch which deals with the surgical problems which affects people's health. Vrana and process of healing is the core of the Shalyatantra. Prevalence of acute traumatic wounds in India is 10.55%.

Traumatic wound is the commonest painful condition which should be cured with less cost effect such treatment modality is highlighted in chakra dutta.

Vrana and healing are the two sides of surgical coins on which expert surgeon has to play this role very sincerely.

Management of traumatic wound generally involve Ropana followed by sterile dressing, whereas KARPOOR GHRITA fulfil the properties of vranaropan, vedanashamak, shothahara by its properties which is required for wound healing.

The goal of treating a wound is to either reduce the amount of time it takes for it to heal or to lessen infection and other undesirable effects. To better understand the phenomena of wound

healing, medical scientists have conducted several studies and tests. The treatment of wounds involves the use of analgesics, antibiotics, and antiseptics such as silver sulphadiazine, silver colloid, and povidone iodine. Hypersensitivity, allergic reactions, and other side effects are still possible with these therapy approaches. An agent that will hasten wound healing while minimizing adverse effects is being sought after. Today, there is no one medication that can be used to treat wounds that has both cleaning and healing characteristics. That is why the search is still on to find out a drug which can fulfil the optimal requirement. Studies reveal that it is difficult to achieve complete aim of wound management with single agent hence there is need to find out a single effective formulation which possesses vrana ropana property without wound infection. Also KARPOOR GHRITA can be easily available and can be used for minor wounds.

SADYO VRANA is in Shuddha state for 7 days so; if these Vranas are treated within 7 days their chances of getting infected are reduced. As Karpoor ghrita is easily available and can be prepared and required less hospital stay. Thus, due to above reason present topic was taken for study.

AIMS

Randomized Open Controlled Clinical Study To Assess The Effect Of Karpoor Ghrita As A Ropan In Management Of Sadhyovrana.

OBJECTIVES

1. To asses effect of KARPOOR GHRITA as a ropan in management of sadhyovrana.
2. To study the ropan property of Karpoor ghrita.
3. To assess improvement by signs and gradation of assessment criteria.
4. To study etiopathy of sadhyovarna in detail according to ayurveda and wound in detail according to modern text.
5. To reduce discomfort and complaints of patients.
6. To achieve outcome of study in 15 days.

MATERIALS AND METHODS

A. **Conceptual study:** Literary study of Karpoor ghrita and Vrana was done.

B. Clinical trial:

- Patient selection: From the hospital's Shalyatantra O.P.D. and I.P.D. departments, 60 Sadyo Vrana patients were chosen for the current clinical trial. These patients were chosen regardless of their socioeconomic background, age, sex, religion, level of education, and marital status. Every patient's complete medical history was gathered using a proforma that was produced. Hemograms, urine routines, B.S.L. randomization, and random patient sampling were among the routine investigations carried out. each patient's written, informed consent to participate in the study. A clinical trial was then carried out. Patient grouping: Two groups were created for the current clinical study. For the study, 30 Sadyo Vrana patients were chosen from each group. NS was used to clean the wounds in each group.Group A (Trial Group) - Vrana Karma done with Karpoor ghrita.
- Group B (Control Group) - Vrana Karma done with Silver colloid.

Inclusion Criteria - • Patient having age between 20 to 60 years. • Patient having sign and symptoms of Abrasions having size upto 6cm. will be randomly selected. Lacerated wound upto 5cm×3cm×1cm • Ghrishta vrna(Abrasions) • Kshataj vrana(laceration) • Patients having both Ghrishta vrana (Abrasion) and Kshataj vrana(Laceration)at once.

Exclusion Criteria - • Known cases of HIV, Hepatitis B, any systemic disease and any known allergy • Patients suffering from wounds like • Chhinna vrana (Excised) • Bhinna vrana (Stab injury) • Viddha vrana (punctured) • Pichichita vrana (crushed).

Withdrawal Criteria - • If patient is not willing to continue the treatment. • Patient unable to tolerate the treatment. • Any unknown adverse drug reaction of treatment on patient. Patient fails to report for follow up or irregular medication.

Drug Review

Karpoor ghrita:

Sr. no	Sanskrit Name	Botanical Name	Part Used	Proportions
1	Karpoor	Cinnamomum camphora	Resin	1 Part
2	Ghrita	-	Ghrita	1 Part

METHOD OF PREPARATION OF KARPOOR GRITA:

It is prepared as mentioned in Chakradatta samhita adhyay no. 44, shlok no. 53.

- **Materials:**
  - Upadhan dravya (Base): ghrita – 1 Part
  - Adhan dravya (main ingredient): Karpoor(Bhimsen)- 1 Part
  - A pan
- **Method:**
  - The preparation done according to reference of chakra datta Samhita.
  - Karpoor (Bhimsen) will be taken from GMP approved pharmacy.
  - Ghrita will be taken from GMP approved pharmacy.
  - Both karpoor and ghrita will taken in same proportion.
  - Mix the karpoor with ghrita in a pan.
  - Mix the contain well.
- Packaging: collect in an airtight plastic container.

Raspanchaka of dravyas used in Karpoorghrita:

1. Karpoor: Tikta, Katu, Madhur rasa, Laghu, Tikshna guna, Shita virya, Katu vipaka and Tridoshahara.
2. Ghrita: Madhur rasa, Snigdha, Guru, Shita guna, Shita virya, Madhura vipaka, Tridoshahara.

MODERN REVIEW

- **Silver colloid:**

"Silver colloid" is term used to describe tiny particles of silver suspended in a solution.

- **Properties and effects:**

Physical properties-

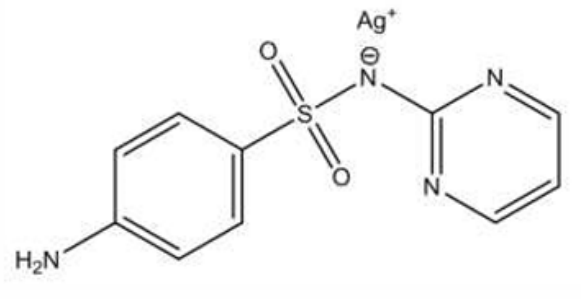
Molecular weight-107.8682

It is as antimicrobial agent

Chemical properties-

1. Soluble in water
2. Odourless
3. Flavourless
4. Non-toxic
5. No oral effects

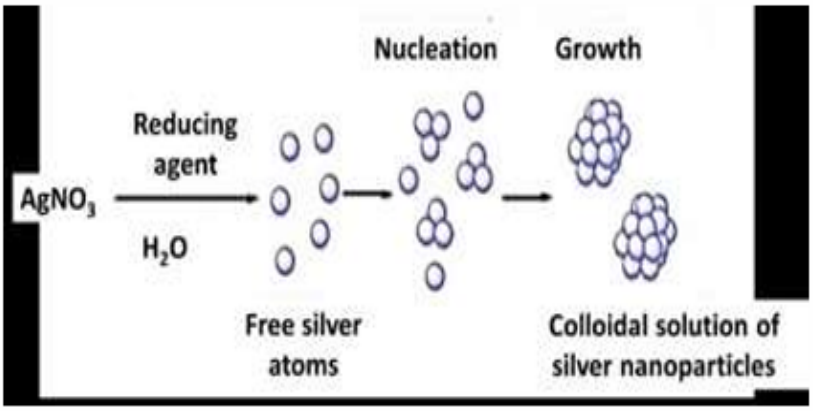
- **Structure-**



- **Benefits-**

1. Silver Colloid works by decreasing biofilm biomass
2. Helps to heal the wound faster
3. Protect the growth of bacteria in wound.
4. Silver colloid has been a known agent with good antimicrobial & healing properties & recent time has seen an upsurge in various silver base dressing supplement.
5. A variety of bacterial, viral, and fungal illnesses have been shown to be effectively treated by silver.Biologically, active ions released by silver bind & act over various bacterial cells structure & execute its potential effects by various mechanisms.
6. Apart from this, the bacterial resistance to silver preparations has been documented to be slower & less as compaired to antibiotics.

Colloidal synthesis:



Clinical End-points:

The primary end-point is seven days during which the sadyo vrana's suddha Avastha is maintained and, with appropriate wound care, clinical symptoms are totally eliminated.

Secondary End-point: The study's secondary end-point was the total number of days for Ropan.

Assessment Criteria:

Subjective Criteria:	
Pain: graded by VAS score	
0	No pain.
1	Mild pain (VAS 1 to 3)
2	Moderate pain (VAS 4 to 7)
3	Severe and continuous pain (VAS 8 to 10)
Swelling of surroundings	
0	Absent
1	Slight red, tender and hot with painful movement and without induration
2	Red, having painful movement, with more local temperature and with induration
3	Discoloration, hot, resist to touch and with more induration.
Burning sensation	
0	No burning
1	Slight, localized and sometime feeling of burning sensation
2	More localized and often burning sensation which does not disturb sleep
3	Continuous burning sensation with disturbed Sleep
Discharge	
0	No discharge / dry dressing
1	Scanty occasional discharge and Slight wet dressing
2	Often discharge and with blood on dressing
3	Profuse, continuous discharge which needs frequent dressing
Tenderness	
0	No tenderness
1	Mild tenderness to palpation without grimace
2	Moderate tenderness with grimace to palpation
3	Severe tenderness with withdrawal (jump sign)
Granulation Tissue	
0	Healthy granulation tissue
1	Presence of unhealthy granulation tissue less than 25%
2	Presence of unhealthy granulation tissue between 25-50%
3	Presence of unhealthy granulation tissue more than 50%
Objective Criteria:	
Size	
0	complete healing
1	1/4 of previous area and depth of the wound remaining

2	1/2 of previous area and depth of the wound remaining
3	>1/2 of previous area of depth of the wound remaining

OBSERVATIONS AND RESULTS

Efficacy testing of the treatment was performed using "Wilcoxon Signed Ranks test" for within the group analyses. For between the group analysis of various subjective assessment criteria, Mann Whitney – U test is applied.

Also, for objective assessment criteria, as they are not normally distributed, Wilcoxon Signed Ranks test is used for within the group analyses (i.e. before and after treatment of a group) and Mann Whitney–U test is applied for between the group analyses.

SUMMARY OF STATISTICAL DATA OF BETWEEN THE GROUP ANALYSES OF VARIOUS ASSESSMENT CRITERIA

OVERALL EFFECT OF TREATMENT

SIGN /SYMPTOM	GROUP	MEAN SCORE	MEDIAN SCORE	S.D.	S.E.	MANN WHITNEY –U TEST VALUE	P VALUE & INFERENCE
PAIN	GROUP A	2.4	2.5	0.3	0	U= 587 U' = 313	0.04338 (<0.05) Very Significant
	GROUP B	2.2	3	0.6	0.1		
SWELLING	GROUP A	2.5	3	0.2	0	U = 601.5 U' = 298.5	0.02574 (<0.05) Extremely Significant
	GROUP B	2.1	3	0.7	0.1		
BURNING SENSATION	GROUP A	2.5	3	0.3	0	U = 604 U' = 296	0.0232 (<0.05) Very Significant
	GROUP B	2.1	3	0.7	0.1		
DISCHARGE	GROUP A	2.5	3	0.3	0.1	U= 480 U' = 420	0.065994 (>0.05) Not Significant
	GROUP B	2.4	3	0.4	0.1		
TENDERNESS	GROUP A	2.9	3	0.3	0.1	U = 540 U' = 360	0.18684 (>0.05) Not Significant
	GROUP B	2.7	3	0.5	0.1		
GRANULATION	GROUP A	2.1	2	0.3	0	U = 510 U' = 390	0.37886 (>0.05) Not Significant
	GROUP B	2.1	2	0.4	0.1		
SIZE OF WOUND	GROUP A	2	2.1	0.3	0	U = 510 U' = 390	0.37886 (>0.05) Not Significant
	GROUP B	2	2.1	0.4	0.1		

While assessing overall effect of treatment, all assessment parameters were used.

DISTRIBUTION OF PATIENTS ACCORDING TO CHANGE IN OBJECTIVE PARAMETERS:

OVERALL EFFECT	GROUP A		GROUP B	
	No. Of Patients	%	No. Of Patients	%
Cured	28	93.3	24	80
Markedly improved	2	6.7	6	20
Moderately improved	0	0	0	0
Not improved (Unchanged)	0	0	0	0
TOTAL	**30**	**100**	**30**	**100**

In group A, out of 30 patients, 28 (93.33%) showed complete cure while remaining 2 (6.7%) patients showed marked improvement in objective parameters.

In group B, out of 30 patients, 24 (80%) showed complete cure while remaining 6 (20%) patients showed marked improvement in objective parameters.

patients showed marked improvement in objective parameters.

For between the group analysis Group A treatment is considered as more effective than Group B in reducing Pain, Swelling and Burning sensation at 5% level of significance while they are equally effective in Discharge, Tenderness, Granulation and size of wound.

PROBABLE MODE OF ACTION OF THE DRUG IN TRIAL GROUP-

The action of ropana may result from Vrana prasadan karma of ghrita, and it is highly helpful in promoting wound healing. Karpoor ghrita exhibits this effect because it possesses vrana ropan potential. Because "eugenol" is an analgesic, depresses the sensory nerves, and is vedana sthapana, it may decrease vedana vedana. Karpoor is somewhat antibacterial and helps to avoid doshpak of the Vrana because it includes the antiseptic compounds "cineol and terpineol."

Vrana i.e granulation of wound may be attributed to the property of Karpoor that it stimulates local vessels thus increasing vascular supply required for healing.

Cineol is a rubefacient hence, increases dermal uptake of the drug.

Karpoor belongs to the gana of sugandhi dravyas and possesses a pleasant odour since it contains “volatile oils” hence Gandha may be absent at end of treatment.

We may conclude that Vrana Karma with Karpoor ghrita has considerable effects on Sadhyo Vrana in comparison to Silver colloid because it has the Vrana ropana property, which explains disinfection and wound size. The Trial group was observed to have significant results as the Control group.

CONCLUSION

On clinical and statistical analysis it was found that *Karpoor Ghrit* has *Ropan* effect on *Sadhyo vrana* thereby accelerating the process of wound healing in comparison to Silver Colloid.

It is less cost effective, easy to apply, less time consuming and has excellent result in wound healing with zero adverse reaction.

It has an instant Analgesic and Anti-Inflammatory action thereby providing instant pain relief.

Karpoor Ghrit was found to be effective on all parameters included in the study and hence proves its *Ropan effect* in *Sadhyo vrana.*

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