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Review Article

A Randomized Controlled Trial to study the effect of *Manjistha ghrita* in the management of post operative anorectal wounds.

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Abstract

In India post operative anorectal wound remains a major problem following surgical procedures for common benign anorectal illness such as anal fissure, hemorrhoids, and fistula in ano. About 20-25% of surgeries land up into consequences such as delayed or non healing wounds leading to significant morbidity [6,8]. Symptoms of persistent pain, infection, abscess development, anal stricture, and even fecal incontinence, extending recovery time and lowering of quality of life due to poor wound healing. [5,6,8]. As the wound is in constant contact with fecal matter and water, there are very high chances of infection, and failure of modern wound care can be seen. Wound healing consists of three phases: inflammation, proliferation and remodeling. Any interruption in these phases will cause wounds to heal slowly or not at all, as seen in chronic granulation tissue, discharge and delayed epithelialization. And these conditions worsens the wound and such unhealed wounds raise healthcare expenses and increase chances of infection [5,6].

In ayurvedic literature *Manjistha* (*Rubia cordifolia*) is known for its anti-inflammatory, antioxidant, and antibacterial properties. Which helps in granulation and healing of tissue [1,3,7]. *Ghrita* being *shita virya* and having rich content of fatty acids, phospholipids and fat soluble vitamins (A, D, E and K) will provide moist and

unctuous environment, minimize irritation and improve tissue regeneration. [2,4]. By combining both the drugs and using this formulation in post operative anorectal wounds can give promising results in wound healing. As the rate of morbidity and infection in post operative anorectal wounds are more there is a need to find adjuvant treatment methods that can speed up tissue healing, reduce inflammation and enhance postoperative outcomes. Hence, the current study is undertaken to investigate the efficacy of local application of *manjistha ghrita* in post operative anorectal wounds.

Aim and Objectives :

Aim: To evaluate the clinical efficacy of *manjistha ghrita* in management of postoperative anorectal wounds.

Objectives:

- To evaluate the effect of topical application of *manjistha ghrita* on post operative anorectal wound healing.
- To assess the wound healing by clinical parameters.
- To compare clinical parameters like strava (discharge), shula (pain) and varna(color of wound), before and after treatment.

- To evaluate the safety and acceptability of intervention.

Methodology :

Manjistha roots (*Rubia cordifolia*) will be purchased from authentic stores, for which authentication and identification will be done. *Go Ghrita* will also be purchased and identification will be done.

Ghrita murrchana will be done using *manjistha kalka* and *kwath* according to *ghrita siddhi kalpana* as mentioned in *bhaisajya ratnavali*. Standardization of *siddha ghrita* will be done from the lab. This intervention will be combined with standard treatment. Application will be done on POD 0 to POD 10, data will be collected using Case Record Format for POD 0, POD 3, POD 7, POD 10 and follow up on POD 14. Parameters like *shula* (pain), *strava* (discharge), *varna* (color of wound) and will be noted from the observations. This collected data will be analysed by using wilcoxon signed ranked test, paired t-test. From the statistical analysis conclusion and result will be drawn.

Study Design

1. Type: Randomised Control Trial
2. Entire Study Duration: 2 Month
3. Duration of treatment: 10 Days
4. Postoperative: POD 0 to POD 10
5. Follow up after surgery: POD 0, POD 3, POD 7, POD 10
6. Follow up after treatment: POD 14
7. Study Site: IPD/OPD of Shalya Tantra, Department.
8. Study Population: 24 participants
9. Sampling method: Random.

Inclusion Criteria:

- Patient fulfilling the diagnostic criteria and undergoing surgery .

- Patient who will give consent for the use of treatment protocol.
- Patient irrespective of caste, gender and religion.
- Age group 18 to 60 years.

Exclusion Criteria:

- Patient with multiple fistula-in-ano, anal prolapse and anal cancer.
- Immuno compromised patients.
- Patients on anti-depressant and anti-psychotics drugs.
- K/C/O : Diabetes, Hypertension and Mentally retarded subjects.

Withdrawal Criteria:

- If a patient wants to discontinue the treatment .
- Any critical emergency or Adverse drug reaction (ARD's).
- If a patient is not responding to treatment and aggravation of symptoms are seen.
- If the patient refuses to continue with the treatment.
- Patient not giving proper follow up.

Sample Size and Sampling Technique

Sample Size: As the primary outcome variable (wound healing time in days) is continuous, the sample size is calculated according to the formula. [9] Formula $n = 2 (Z\alpha/2 + Z\beta)^2 \sigma^2 / (\mu_1 - \mu_2)^2$

Where:

n = sample size per group

$Z\alpha/2 = 1.96$ (for 95% confidence level, $\alpha = 0.05$) $Z\beta = 0.84$ (for 80% statistical power, $\beta = 0.20$) σ = standard deviation of wound healing time $\mu_1 - \mu_2$ = expected mean difference between groups $\mu_1 = 14 \pm 2.5$ days (control group) [21] $\mu_2 = 11 \pm 2.5$ days (trial group)

Substituting values

$$n = 2 (1.96 + 0.84)^2 (2.5)^2 / (12 - 9)^2 \quad n = 2 (2.8)^2 (6.25) / 9 \\ = 98 / 9 \approx 10.9 \approx 11 \text{ participants.}$$

By considering a 10% drop out rate, sample size is adjusted using the standard formula for

expected loss i.e. $n' = n / (1 - r)$

Where r = expected attrition rate (10% = 0.10).

$$n' = 11 / (1 - 0.10) = 11 / 0.9 = 12.2 \approx 12 \text{ participants per group.}$$

So, the adjusted sample size is 12 participants per group, totaling 24 participants.

From above calculation, 24 participants, 12 per side will be taken with 10% of drop out rate considered.

Intervention / Procedures:

Detail of drug:

Manjistha: [10]

मिञ्जिष्ठा मधुरा तक्ता कषाया स्वरवणकृत । गरुरुष्णा वषश्लेष्मशोथयोन्यक्षकणरुक् । रक्तातीसारकुष्ठासवीसपत्रणमेहनतु ॥१६७॥ भावप्रकाश-पत्र खण्ड-मश्रप्रकरण २. हरीतक्यादवग

As mentioned in *Bhavaprakash purvakhanda mishraka prakaran*, in *Haritkyadhi Varga manjistha* is *shoth hara* and *vrana ropana*.

Description of *Manjistha* [11] : *Manjistha* consists of dried stems of *Rubia cordifolia* Linn. (Fam Rubiaceae); a perennial herbaceous prickly creeper or climber up to 10m long, found throughout the country ascending to 3750m.

According to the API of *manjistha* it shows therapeutic uses in *Arsha Vyadhi*. [12]

Priyangvadi and *Ambasthadi Gana* :- [13]

प्रयङ्गुसमङ्गाधातकीपु त्रागनागपु श्यु चन्दनमोचरसाञ्ज्रकु म्भी कस्त्रोतो जपद्मके सरयोजनवल्यो दीघमलालू ॥ स.सू. ३८/४५ ॥

38/45 ॥

अम्बष्ठा धातकीकु समसमङ्गाकटङ्गमधु कु बल्वपेशकासावारोध्रपलाशनन्दीवक्शाह् पद्मके शराण

चेत॥ स.सू. ३८/४६ ॥ गणौ प्रयाङ्गुम्बष्ठादी पक्वातीसारनाशनौ । सन्धानीयौ हतौ पत्ते व्रणाम्नां चाप रोपणौ ॥ स.सू. ३८/४७ ॥

38/47 ॥

As mentioned by *Acharya Sushruta* in *Sutrasthana 38 Priyangvadi gana* has *Yojanvalli (Manjistha)* which has been used for its *vrana ropana* properties.

Gau Sarpi (Ghrita) [14]

In *Ayurveda* there is description of four types of '*Sneha*' viz. *Sarpi, Taila, Vasa, Majja*.

According to *Charak samhita Sarpi* is considered superior among all *sneha* due to its property of "*Sanskaranuvartan*". It means that if it is processed with another drug, it accepts all qualities of that drug without changing its own.

According to *Sushruta*: [15]

Acharya Sushruta mentioned that *Sarpi* is sweet in taste, soothing, soft and *sheetvirya*. It also acts as *snehanakara* and *shoolaghna*. Due to its *madhur* in *rasa*, *madhur* in *vipaka* & *sheetvirya*. It alleviates *vata, pitta* & *visha*. (Su. Su. 45/97). Also *Sarpi* has *Rakshoghna* property. (Su. Su. 45/66) Here *Rakshoghna* means antimicrobial. The ancient scholars were having an idea of microbes and therefore they also described the antimicrobial measures for it.

Vrana: [16]

In *Sushruta Sutras* Chapter 21, वणो त यस्माद रुढे अप व्रणवस्तु न नश्यत आदेह धारणातस्माद व्रण इत्यच्यते बध्ः ॥ स.सू. २१/४०

॥ स.सू. २१/४०

Acharya has clarified that as "the scars of a wound never disappear even after complete healing and its imprint persists lifelong, it (the lesion) is called *vrana* by the wise".

Rasa	Virya	Vipak	Guna	Karma
Madhur, Tikta, Kashaya	Ushna	Katu	Guru	krimighna, kaphapitta samaka, varnya, sothaghn

Sadhyo Vrana : [17,18]

सद्योव्रणा ये सहसा सम्भवन्त्यभघाततः । अनन्तरैव तैरे

गम्यन्ते जष्टमष्टधा ॥ अ.ह. २६/१ छत्रं भन्नं तथा

वद्धं क्षतं पिच्यतमेव घृष्टमाहुः सुस्थथा षष्ठं तषे ां

वक्ष्याम लक्षणम् ॥ स. ७ च. 2/9

In samhita, there are six types of sadhyo vrana.

chinn (excised), *bhinna* (incised), *viddha* (punctured), *kshat* (lacerated), *picchit* (crushed), *ghrusht* (abraded).

Treatment of *Sadhyo Vrana* : [19] कषाय मधराः

शीतः याः िस्नग्धाश्च योजयेत | सदोव्रणानां सप्ताहं पश्चात्

पुवु क्तमाचरेत् ॥ स. ७ च. 2/85

Accidental wounds should be treated for seven days with *kashaya* and *madhur*, *shita* and *snigdha* measures.

Intervention Table:

PAIN	GRADE	Severity
No Pain	Grade 0	None
1-3 in VAS	Grade 1	Mild
> 3-7 in VAS	Grade 2	Moderate
> 7-10 in VAS	Grade 3	Severe

Data Collection Methods

Data will be collected using prepared Case Record Format, data will be collected on POD 0, POD 3, POD 7, POD 10 during treatment and then follow up data will be collected on day POD

14.

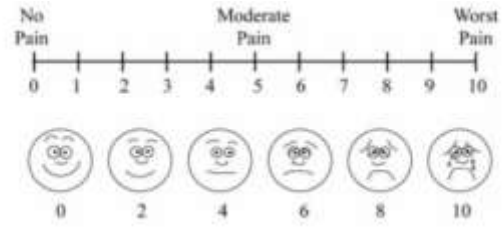
Parameters will be recorded are *Strava* (discharge), *Shula* (pain) and *Varna* (color of wounds) will be assessed.

Assessment Tools

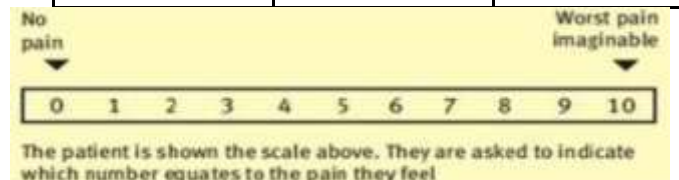
Assessment will be done with the help of subjective and objective parameters on the basis of before and after study.

Subjective Criteria:

1. PAIN:- (www.ncbi.nlm.nih.gov) VAS (Visual Analogue Scale)



Subject	Group A	Group B
Type	Trial	Control
Name of drug	<i>Manjistha ghrita</i>	<i>Lignocaine Jelly</i>
Route of drug administration	Local application	Local application
Common Treatment	3 days antibiotics Sitz Bath Syp. Cremaffin Analgesic (SOS)	3 days antibiotics Sitz Bath Syp. Cremaffin Analgesic (SOS)
Treatment Duration	From POD 0 TO POD 10	From POD 0 TO POD 10
No of Patients	12	12
Observation	During treatment: POD 0, 3, 7, 10 After treatment: POD 14	During treatment: POD 0, 3, 7, 10 After treatment: POD 14
Dose	Twice a day	Twice a day
Time of treatment	After sitz bath	After sitz bath



Grade	Numeric Pain Score
Grade 0	0
Grade 1	1-3
Grade 2	3-7
Grade 3	7-10

- Score 0 No pain
- 1-3 Pain doesn't interfere with your regular activities.
- >3-7 may interfere with your regular activities. You can
Ignore the pain at times makes it hard to concentrate.
- >7-10 can't do any of your regular work, including talking or sleeping pain is so intense that you have trouble talking.
(Allina health Pain assessment scale)

2. *Strava* (discharge)

Discharge from the wound site will be measured using this table.

Severity	Discharge	Grade
Normal	(No discharge)	0
Mild	(Discharge with single dressing)	1
Moderate	(Discharge with double dressing)	2
Severe	(Severe discharge with repeated dressing)	3

3. *Varna* (color of wound)

The color of the wound will be measured using this table.

Severity	Varna (color of wound)	Grade
Normal	Twak varna	0
Mild	Lalima varna	1
Moderate	Rakta varna	2
Severe	Kapot varna	3

Statistical Analysis

Collected data will be analysed using wilcoxon and paired t-test in SPSS software.

Novelty of Idea

Post operative wound comes under sadhya vana according to ayurved, sushruta mentioned sadhya vana chikitsa in sushruta chikitsa chapter 2 as kashaya rasa, madhur rasa, shita guna and snigdha guna are used for 7 days to heal sadhya vana. These rasa and gunas are present in manjishta and ghrita. Also previous study by Mali and Amilkanthwar (2015) [20] on burn wounds, which showed healing with efficacy and aid in tissue regeneration and lower infection risk. But the anorectal wound is different from other wounds as these wounds are in constant contact with water and feces. So, we are using these drugs to check the efficacy in the patient of post operative anorectal wounds.

The innovation is that the siddha ghrita will be converted into by combining it with base and excipients, as the ghrita application is not an effective and feasible way in post operative wound during summers as ghrita will be in liquid consistency due to atmospheric conditions. So we are converting the manjistha siddha ghrita in the and evaluating the efficacy of this intervention in patients of post operative anorectal wounds.

Null Hypothesis :

There is no significant difference between manjistha ghrita and standard treatment in postoperative wound healing.

Alternate Hypothesis :

There is a significant difference between manjistha ghrita and standard treatment in postoperative wound healing.

Research Question

Is Manjistha Ghrita effective in the management of post-operative ano-rectal wounds ?

Translational Value:

We are performing this study to check the efficacy of manjistha ghrita in post operative anorectal wounds, if this study gives good results another study can be conducted in future to check the efficacy in large sample size.

Implications :

This study may contribute to the development of an easy, cost-effective, and natural method for healing wounds following anorectal surgery. If Manjistha Ghrita works, it can speed up the healing of wounds without causing any negative side effects and discharge, skin discoloration. Patients may find it simpler and more comfortable to heal as a result. This kind of herbal formulation may also reduce the need for potent chemical-based, providing a safer and more environmentally responsible option. The results can assist connect ancient knowledge with contemporary surgical healing techniques and promote the broader use of Ayurvedic remedies in postoperative care.

Timeline/ Gantt Chart

	se pt	oc t	no v	de c	ja n	fe b	m ar	ap r	m ay
review of literature	x								
preparation of synopsis	x	x							
presentation of synopsis and approval from institutional ethical			x						

committee									
purchase of drug, formulation and standardization			x	x					
recruitment of participants					x	x			
data collection and follow up					x	x	x		
data analysis and project completion							x	x	
submission of project									x

Achievability of Objectives

As the time period for the study is 2 months, we have taken 12 participants in each group giving treatment to each patient till post operative day 7. And also on the 14th day follow up will be done. So if we recruit 3 participants per week, we can complete the study in stipulated time.

Ethical Consideration

Ethical Clearance will be obtained from the Institutional Ethical Committee.

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