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## ASSESSMENT OF EFFICACY OF *GAMBHARI PHALA GEL* IN POST FISSURECTOMY WOUND HEALING - A CASE SERIES

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### Abstract:

**Background:** Post-operative anorectal pain is unavoidable which needs appropriate management. The goal for post-operative pain management is to reduce or eliminate pain and discomfort with minimal side effect. There is need of soothing ointment which can reduce irritation, relieve pain & promote wound healing. **Objective:** To study the effect of *Gambhari Phala* gel in the management of post fissurectomy wound healing. **Methods:** The present case series was conducted in OPD and IPD of Dept. of Shalyatantra, 10 patients in the age group of 18 – 60 years of either gender operated for fissurectomy were enrolled after informed consent and randomized into two groups. In 05 patients enrolled in trial group, the wound was cleaned with normal saline & dressed with *Gambhari Phala* gel where as in 05 patients enrolled in control group, the wound was cleaned with normal saline & dressed with betadine ointment. Regular follow-up of two groups for 21 days was taken. The criteria for efficacy assessment were Pain (VRS), Pain (NRS), Burning sensation (*Daha*), Granulation and wound Discharge in post fissurectomy wound were applied. The data were subjected to unbiased statistical analysis to draw valid conclusions. **Results:** The average age of patients in trial and control groups were  $34.20 \pm 5.31$  years and  $39.60 \pm 11.68$  years respectively with statistically insignificant difference. The difference in all efficacy parameters in two groups were statistically insignificant. The days required for wound healing in trial and control groups were  $21.20 \pm 2.78$  days and  $24.60 \pm 2.07$  days respectively with statistical insignificant difference. No adverse events were observed in both the groups during study duration. **Conclusion:** *Gambhari phala* gel and conventional method (betadine ointment) have shown equally effective results in post fissurectomy wound.

**Keywords:** *Gambhari phala* gel, post fissurectomy wound care.

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**INTRODUCTION:**

*Shalya-Chikitsa*, a well-developed branch of Ayurveda, predominantly deals with the anorectal surgeries. Description of *Parikartika* described in *Brihat-trayi* is very much suggestive of the modern ailment fissure-in- ano when it is limited to anal-region. It is one of the most upsetting disorders of the Ano-rectal region. Chronic anal fissure needs surgical intervention in form of fissurectomy, which is considered to be the gold standard method of management of chronic fissure<sup>[1]</sup>. Post-operative wound care of fissurectomy varies from many other surgical wounds due to various reasons. These wound causes post-operative pain, burning & irritation at anal region. The wound, being at the delicate place, makes it inconvenient to patients to perform their routine activities. Defecation causes irritation, severe pain along with burning sensation. Faecal material contaminates the wound further. Unlike wounds on other places, the dressing of these wounds needs to be changed frequently. For better outcomes, the fissurectomy wound needs care unlike other wounds as mentioned above.

The goal for post-operative pain management is to reduce or eliminate pain and discomfort with nominal or no side effects. To overcome this severe pain in the post-operative phase, the surgeons prefer opioids and NSAIDs. Both these opioids and NSAIDs have got adverse effects like respiratory depression, vomiting, drug

dependency etc. Prolonged administration of NSAIDs may suppress the symptom but causes gastric irritation. Application of soothing ointments produces sufficient relaxation of sphincter, but causes toxicity and headache and recurrence rate is 16% to 50% in this particular method of management<sup>[2]</sup>.

There is need of soothing ointment which can reduce irritation, relieve pain & promote wound healing. In *Dravya Sangrahaniya Adhyaya* of *Sushrut Samhita*, Acharya Sushrut explains *Gana* which deals with the general classification of drugs according to their therapeutically properties. This *gana* can be use in single *dravya* or group of *dravyas* for specific disease.

Acharya Sushrutahas explained the *Sarivadi Gana* in *Dravya Sangrahaniya Adhyaya* which includes *Sariva*, *Madahuka*, *Chandana*, *Kuchandana*, *Padmaka*, *Kashamari (Gambhari) phala*, *Madhuka-Pushpa* and *Ushira*. Acharya Sushruta considered it as *Visheshad Dahanashana* therapeutically<sup>[3]</sup>. The single *Dravya* or group of *Dravya* from a *Gana* can be used for treatment of specific disease.

*Gambhari Phala* was chosen for the following reasons<sup>[4]</sup>

1. Guna - Guru, Tikta-Kasaya-Madhura Rasa, Tridosha shamaka, Daha prasamana, Snehana and Raktapittaghna.
2. Easy availability.
3. Cost effective.

4. Devoid of complications.

In the present case series, *Gambhari Phala* was used in the form of gel which is easier to apply compared to *Churna, Kashaya, Taila* or *Ghrita*. *Gambhari Phala* gel was used as *Lepana* for healing purpose in post fissurectomy wound. The primary objective was to study the effect of *Gambhari Phala* gel in the management of post fissurectomy wound healing.

**Aim:** To evaluate the effect of *Gambhari Phala* gel in the management of post fissurectomy wound healing.

#### Materials and methods:

##### Source of data

- Literary Source: The source of parikartika and fissure-in-ano is collected from the various classical texts of ayurveda & modern science, updated with journals and internet.
- Clinical Source: The present comparative case series was conducted at OPD and IPD of Dept. of Shalyatantra Dr.G.D.Pol Foundation's Y.M.T. Ayurved Medical College and Hospital, Kharghar, Navi Mumbai.
- c) Drugs: The trial drug "Gambhari Phala" is collected from the local area and certified by the Alarsin Ayurvedic Drugs Company.

##### Methods of preparation

Here *kwatha* is the liquid preparation obtained by boiling 1 part of *dravya* in along with 16 parts

of distilled water which is reduced to 1/8<sup>th</sup> part and filtered, the filtrate is taken as *kwatha*.

**Table 1 Preparation OF Gambhari Phala Kwatha<sup>[5]</sup>:**

Sr.No.	Dravya	Proportion
1	Gambhari Phala	One Part
2	Distilled water	Sixteen times of dravya

**Table 2 Preparation of Gambhari Phala gel<sup>[6]</sup>:**

Carbomer934	2gm
Methylparaben	0.2gm
Propyl paraben	0.05gm
Triethanolamine	1.65ml
Gambhari Phal Kwath	100ml

prepared 1000ml of *Gambhari Phala Kwath* was taken in to the planetary mixer of 2 L capacity having maximum speed of 3000 rpm and stirring was started. In vessel 2% of Carbomer (20gm) was added subsequently. The mixture was stirred at speed of 300 rpm for initial 15 minute gradually increased after every 5 minutes. after 2 hours of continuous staring, a homogenous mixture was obtained, stirring was stopped and 1% of methyl paraben 2gm and propyl paraben 0.5 gm was added and trietatahnoalamine1.65% (165ml) was added

and again stirred at 3000 rpm for 5 minutes. Then gel filled in empty sterile container.

#### Method Of Collection of Data:

Selection Of the study participants: Patients of either sex diagnosed to have fissure-in-ano and operated for fissurectomy were selected randomly. Immuno-compromised patients, patients with Secondary Infected wound and Uncontrolled Diabetes mellitus were excluded from the study.

A detailed Case Record Form (CRF) was prepared considering all the points pertaining to history, signs, symptoms & examinations as mentioned in classical Ayurvedic texts & allied sciences to confirm the diagnosis.

#### Study Design:

Allocation of subjects: 10 patients were selected for the study who fulfilled the inclusion criteria. The subjects were randomly divided into two groups with 05 subjects in each group.

1. **Trial Group:** 05 patients enrolled in this group; the wound was cleaned with normal saline & dressed with *Gamhbari Phala* gel.
2. **Control Group:** 05 patients enrolled in this group; the wound was cleaned with normal saline & dressed with betadine ointment.

Duration of Study: Total duration of study was 21 days or till the *Daha* and *Vedana* persist. Regular Follow ups were taken on done on

0,7,14 and 21 days.

**Criteria of Assessment:** The patients' responses were assessed on the basis of following parameters:

3. Pain<sup>[7]</sup> - its intensity was recorded and graded as per the pro forma. Tools for pain assessment used were PAIN (Numerical rating scale) (NRS) and PAIN (Verbal rating scale) (VRS) – on 0 to 3 scale
4. Burning sensation (*Daha*)<sup>[8]</sup>– on 0 to 3 scale
5. Granulation– on 0 to 3 scale
6. Discharge – present or absent

#### Plan for Statistical Analysis:

The study data generated and collected was put to statistical analysis to reach to the final results and conclusions. Appropriate parametric or non-parametric tests were applied to data. GraphPad In Stat Version 4.0 ([www.graphpad.com](http://www.graphpad.com)) software was used for statistical analysis of data. P value < 0.05 was considered statistically significant.

#### Results:

The average age of patients in trial and control groups were  $34.20 \pm 5.31$  years and  $39.60 \pm 11.68$  years respectively with statistically insignificant difference.

Table no 3 Clinical Assessment of Patients :

Sr. No	Assessment Parameter		Trial Group		Control Group		Inter-Group Comparison
1	Pain (VRS)	Day 0	3 (2 -3)	0.0008, extremely significant.	3 (2 -3)	0.0083, very significant.	0.6634, considered not significant
		Day 14	2 (1 -2)		2 (1 -2)		0.6634, considered not significant
		Day 21	0 (0 -1)		1 (0 -2)		0.1122, considered not significant
2	Pain (NRS)	Day 0	3 (2 -3)	0.0083, very significant.	3 (2 -3)	0.0083, very significant	0.3329, considered not significant
		Day 14	2 (1 -2)		2 (1 -2)		0.6634, considered not significant
		Day 21	0 (0 -1)		1 (0 -2)		0.2412, considered not significant
3	Daha(Burning sensation)	Day 0	3 (2 -3)	0.0083, considered very significant	3 (3 -3)	0.0008, considered extremely significant	N. A.
		Day 14	0 (0 -1)		2 (1 -2)		0.0356, considered significant
		Day 21	0 (0 -0)		1 (0 -1)		N. A.
4	Granulation	Day 0	1 (1 -1)	0.0067, considered very significant	1 (1 -2)	0.0136, considered significant	N. A.
		Day 14	0 (0 -0)		0 (0 -1)		N. A.
		Day 21	0 (0 -0)		0 (0 -0)		N. A.

It was observed that Pain got reduced to significant level after treatment in both groups. The inter-group difference was found to be insignificant on all follow up visits. Burning sensation (Daha) also got reduced to significant

level after treatment in both groups. The inter-group difference was found to be insignificant on all follow up visits. Granulation was found to be significant in both the groups. Discharge from the post operative wound was observed in one

patient in the Trial Group and two patients in the Control Group on Day 0. No discharge was observed on Day 14 and Day 21 in any patients from both the groups. No inference can be drawn from this data. It is found that the difference in all efficacy parameters in two groups were statistically insignificant. The days required for wound healing in trial and control groups were  $21.20 \pm 2.78$  days and  $24.60 \pm 2.07$  days respectively with statistical insignificant difference. No adverse events were observed in both the groups during study duration.

#### DISCUSSION:

Fissure-in-ano is the ailment that does not have any direct correlation in the Ayurvedic text. 'Parikartika' is a condition occurring due to improper administration of *Virechana* and *Basti* can be compared with fissure-in-ano, since both the conditions occur in *Guda* and have similar clinical manifestations. Since the location, nature of pathology and the predominant clinical feature are same, it can be said that the condition *Parikartika* is the clinical condition known in current surgical practice as fissure in ano. *Vata* and *Pitta Doṣha* have dominancy in the development of the disease *Parikartika*, but *Vata* is predominant. Sedentary life style and hard work and stressful life like businessmen, in the modern era, is having a key role in occurrence of the disease *Parikartika* (fissure-in-ano). Fissure-in-ano was present commonly at 6 o'clock position and most of the time it is a

single fissure only. However, the fissure at 12 o'clock or at other site may also be found either alone or in combination. Excessive consumption of *Lavaṇa*, *Katu*, *Tikta*, *Rukṣha*, *Uṣhṇa*, *Lagu ahara* and irregular diet and diet timings are the main precipitating factors of this condition. In this study *Gambhari Phala* gel was selected to evaluate its role in the post fissurectomy wound healing of *Parikartika* because it has *Vrana Ropana*, *Shothahara*, *Varṇa Prasadana*, *Rakta Stambhana* in actions. The treatment with *Gambhari Phala* gel and betadine ointment in each follow up showed good efficacy in respective trial and control groups. There was statistically insignificant difference in inter-group comparison which showed that *Gambhari Phala* gel is comparable to Betadine ointment in post fissurectomy wound healing.

Some *dravyas* act by *rasa*, some by their *Virya*, some by their *Guna*, some by their *Prabhava*, when *rasa* etc are of equal strength then, *rasa* is over powered by *vipaka*, both these are over powered by *Virya*, all these are over powered by *Prabhava*, this is verily the way of natural strength. *Gambhari Phala* has *Tikta*, *Kashaya* and *Madhura Rasa*, *Ushna Veerya* and *Katu Vipaka*. Because of its *Rasa* and *Veerya*, it worked as *Vrana-Ropana* and *Shothahara*. The gel form made it easier for application and thus led to good compliance.

**CONCLUSION:**

On clinical and statistical analysis, it was found that dressing with *Gamhbari Phala* geland conventional method (betadine ointment) has shown equally effective in Pain (VRS), Pain (NRS), Burning sensation (*Daha*), Granulation and wound Discharge in post fissurectomy wound care. Hence, patient who are allergic to betadine ointment we can use *Gamhbari Phala* gel in post fissurectomy wound.

**Suggestion:**

As chronic conditions may need long term therapy for achieving better results and to avoid reoccurrence so, in future same topic should be taken for further research to overcome some lacunas if found, for better results a greater number of samples.

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