



“An Open Label Single Arm Clinical Study to Revalidate Sushrutokta Langalaka Incision Followed by Agnikarma in Vataja Bhagandara”

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KEYWORDS

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Vedana,
Srava.

ABSTRACT:

Bhagandara is a chronic and recurrent anorectal disorder that causes considerable discomfort, pain, and psychological distress to the patient. Though not life-threatening, it severely affects the quality of life. In modern medicine, Fistula-in-Ano usually originates from an anal gland infection leading to abscess and tract formation. Despite various surgical advancements, its management continues to be a challenge due to frequent recurrence and risk of sphincter injury. In Ayurveda, Acharya Sushruta has described Bhagandara as one among the Ashtamahagada because of its chronicity and difficult management. Among its five types, Vataja Bhagandara is characterized by severe pain, dryness, and hard swelling with scanty discharge, indicating Vata predominance. Acharya Sushruta has emphasized Chedana Karma (incision) as the prime line of treatment and mentioned various incision types according to the Dosha predominance and nature of the tract. For Vataja Bhagandara, he advocated the Langalaka incision, suitable for deep and painful tracts. Following the incision, Agnikarma (therapeutic cauterization) is advised to destroy residual unhealthy tissue, prevent recurrence, and promote healing.

MATERIALS AND METHODS

Subjects fulfilling the Diagnostic criteria approaching OPD and IPD of JSS Ayurveda Medical college and Hospital, Mysuru. Medical camps and other referrals were considered. An open-labelled clinical trial design was adopted for this study, comprising a single group of 30 subjects. The subjects were selected based on specific diagnostic, inclusion, and exclusion criteria. They were treated with Langalaka ‘T’-shaped incisions, which were made around the external opening of the fistulous tract, this was followed by Agnikarma performed using bipolar cautery.

RESULTS

Based on the assessment criteria and overall outcomes of the treatment, implementing the Sushrutokta Langalaka incision followed by excision of the fistulous tract and Agnikarma performed using bipolar cautery yielded better results in terms of postoperative pain reduction, discharge control, and wound healing. This procedure effectively addressed the ramifications of the fistulous tract, thereby minimizing the chances of recurrence and promoting early wound healing.



CONCLUSION

The study demonstrated highly significant results in reducing Vedana and Srava. It also showed promising outcomes in decreasing the size of the wound and induration, promoting the development of healthy granulation tissue, and achieving early wound healing. Hence, it can be concluded that the Sushrutokta Langalaka incision followed by Agnikarma provided results that were both statistically and clinically significant, with faster wound healing rates and reduced recurrence rates.

INTRODUCTION

Bhagandara, as delineated in classical *Ayurvedic* texts, is a chronic and challenging condition recognized as a difficult surgical disease in both ancient and modern medical sciences. Its recurrent nature complicates treatment, making it a significant concern for healthcare providers. The most scientific description of *Bhagandara* is provided in the *Sushruta Samhita*, where it is categorized among the *Astamahagada*¹, underscoring its clinical complexity and the need for effective management strategies. According to *Acharya Sushruta* the one which causes *Daran* (tear) of *Bhag* (vulva), *Guda* (anal region) and *Basti Pradesh* (pelvic region) is known as *Bhagandara* at first it is present as *Pidika* in *Apakwa* condition and when it becomes *Pakwa* it is called as *Bhagandara*². In contemporary medical practice, *Bhagandara* is correlated with Fistula-in-Ano. It is an abnormal tract or cavity with an external opening in the perianal area that is communicating with the rectum or anal canal by an identifiable internal opening. Most fistulas are thought to arise as a result of cryptoglandular infection with resultant perianal abscess.

The incidence of Fistula-in-Ano developing from an Anal abscess ranges from 26% to 38%, with a global prevalence rate of approximately 8.6 cases per 100,000 population. In men, the prevalence is 12.3 cases per 100,000, and in women, it is 5.6 cases per 100,000. The male to female ratio is 8:1³.

Ancient *Ayurvedic* texts provide detailed surgical approaches for managing *Bhagandara*. *Acharya Sushruta* and *Acharya Vagbhata* have described various incisions for the management of *Vataja Bhagandara*. Specifically, for interconnected fistulae with multiple openings, four types of incisions are recommended: *Langalaka* (T-shape), *Ardha Langalaka* (L-shape), *Sarvatobhadraka* (Circular shape), and *Gotirthaka* (S-shape). Among these, the *Langalaka* incision, resembling

the shape of a plough (*Langala*), is particularly noted for its effectiveness in addressing complex fistulous tracts. The incision, characterized by two perpendicular arms extending on either side, allows for precise excision and drainage of the interconnected tracts, facilitating better healing outcomes⁴.

The current *Ayurvedic* surgical approach for *Bhagandara* includes *Ksharasutra*, Partial Fistulectomy, and IFTAK10 (Interception of Fistula tract with Application *Ksharasutra*). However, there is a paucity of research evaluating the efficacy of the *Langalaka* incision in the management of *Vataja Bhagandara*. Therefore, this study aims to revalidate the *Langalaka* incision followed by *Agnikarma* in the treatment of *Vataja Bhagandara*, assessing its effectiveness in modern clinical practice.

AIMS AND OBJECTIVES

To revalidate the efficacy of *Langalaka* incision followed by *Agnikarma* in *Vataja Bhagandara* vis-à-vis Fistula-in-Ano with multiple openings.

MATERIALS AND METHOD

The ethical clearance was obtained by the Institutional Ethical Committee (JSSAMC/1543/2023-24) for the conduction of the study. The trial has been registered in CTRI on 25/07/2023 with registration number CTRI/2024/10/075405.

SOURCE OF DATA

Literary Source- All classical literature and contemporary texts including the journals and concerned websites were reviewed and documented for the study.

Sample Source- Subjects fulfilling the Diagnostic criteria approaching OPD and IPD of JSS Ayurveda Medical college and Hospital, Mysuru. Medical camps and other referrals were considered.



Inclusion Criteria:- Subjects aged between 18 to 70 years, irrespective of Gender, Religion, Occupation, Place and Socio-economic status. Subjects with *Vataja Bhagandara* with multiple opening around the anal canal. Subjects with Recurrent Anal Fistula.

Exclusion Criteria:- Pregnant and lactating women. High Anal Fistula connected to PNS. Rectovesical fistula, Rectovaginal fistula, Rectoscrotal fistula, Fistula caused secondary to Tuberculosis, Crohn's disease, Ulcerative colitis, CA of rectum, HIV, Hepatitis B, uncontrolled DM (HbA1C is more than 7 /RBS above 200mg/dl) and other Systemic disorders.

DIAGNOSTIC CRITERIA

Diagnosis will be established by confirming the following signs and symptoms of *Vataja Bhagandara* after thorough Per-Rectal and Proctoscopic examination of the subjects like,

The subjects with presence of multiple external openings, *Vedana*, *Srava* and TRUS.

METHODOLOGY OF SUSHRUTOKTA LANGALAKA INCISION

Requirements:

- Sterile Surgical Gloves, Sterile drapes, Sterile Gauze pieces, Sterile pads
- Probe, Sterile kidney tray, hole towel, Cotton balls,
- Artery forceps, Allis forceps, BP handle, Surgical blade no 11 or 21, Sponge holding forceps, Proctoscope, Sim's speculum, Scissor
- Bipolar Cautery Betadine and hydrogen peroxide
- Methylene blue,
- Lignocaine jelly 2%
- 10ml syringe.
- Gally cup, Surgical spirit.

INTERVENTION

Poorva Karma

- Physical fitness obtained from physician.
- Informed Consent were taken for surgery.

- Subjects were kept NBM 6 hours prior to surgery.
- Part preparation (peri anal area) were done.
- Procto glycerin enema were given twice before shifting subject to the OT.
- Injection TT 0.5 ml IM Stat dose
- Injection Xylocaine test dose 0.1ml S/C.

Pradhana Karma:

- Under all aseptic precautions.
- Subjects were shifted to OT, under Spinal Anesthesia, subjects were made to lie on Lithotomy position.
- Part was painted and draped. Lords four finger dilatation were achieved.
- Primary external opening was identified, and Internal opening were identified with the help of per rectal examination and proctoscope.
- Probing was done with the help of lubricated probe through the external opening; fistula track was identified. *Langalaka'* incision (T-shaped) will be taken over the external opening of the Fistula track followed by *Agni karma* using Bipolar Cautery. The same procedure will be carried out for other Fistula tracts.
- Complete Heamostasis will be achieved.
- Dressing will be done using *Jatyadi Taila*.

Paschat Karma:

- Restricted head movements.
- Foot end elevation were given up to 4 hours.
- Subjects were allowed to take liquids after appreciating bowel sounds.
- Vitals were Monitored.
- Taila poorana with *Jatyadi taila* (10 ml) twice daily.
- Tab. Gandhaka Rasayana (2-0-2)A/F were given after food with Luke warm water for 10 days.
- Tab Triphala Guggulu (2-0-2)A/F were given after food with Luke warm water for 10 days.
- Triphala choorna (0-0-10gms) will be given before food with lukewarm water.



ASSESSMENT CRITERIA

Subjective parameters: *Vedana* (Pain) and *Srava* (Pus discharge).

<i>Vedana</i> (Pain)	0	Absence of pain/no pain.
	1	Mild – pain that can be easily ignored
	2	Moderate – pain that cannot be ignored interferes with function and needs treatment from time to time.
	3	Severe – pain not relieved even after using analgesics

<i>Srava</i> (Discharge)	0	No discharge/dry dressing
	1	Mild – if wets 1 gauze piece of 4x4cm gauze piece.
	2	Moderate – if <i>Vrana</i> wets 2 gauze pieces of 4x4cm.
	3	Severe- if <i>Vrana</i> wets more than 2 gauze pieces of 4x4cm.

Objective parameters: Size of the wound, induration and granulation tissue

Size of the wound.	0	Healed.
	1	Within 1-2 X 0.5-1 X 0.5-1cms.
	2	Within 2-3 X 1-2 X 1-3cms.
	3	Within 3-5 X 2-4 X 3-6cms.
	4	Within 5-7 X 4-6 X 4-8cms.
Granulation tissue	0	Healthy granulation without slough
	1	Moderate granulation with slough.
	2	Unhealthy granulation with slough or hyper granulation
	3	Granulation tissue absent

Induration	0	No induration
	1	Induration up to ½ cm
	2	Induration up to 1cm
	3	Induration up to 2cm or more than 2 cm

OBSERVATION PERIOD:

On 1st, 7th, 14th, 21st and 28th day Parameters are assessed in specially designed case proforma.

DURATION OF THE STUDY:

Total study duration was 28 days.

FOLLOW UP OF THE STUDY:

On completion of the treatment the subjects will be asked to visit the OPD on the 41st day.

OBSERVATIONS

A total of 30 subjects were included in the study with no dropouts. Most participants belonged to the 31–40 years age group (33.3%), followed by 23–30 years (26.7%), and females constituted the majority (63.3%). The study population was predominantly Hindu (93.3%), with most being housewives (33.3%) and married (80%). A large proportion belonged to the middle socio-economic class (70%), and the habitat distribution was equal between rural and urban areas (50% each).

Clinically, most subjects had a gradual onset of disease (86.7%), with symptom duration commonly between 1–3 months (30%) and 6–12 months (23.3%). The majority had no previous surgical history (60%), followed a mixed diet (76.7%), had a moderate lifestyle (63.3%), and reported irregular sleep patterns (56.7%), while nearly half (46.7%) had no addictive habits.

Regarding *Ayurvedic* parameters, most subjects had *Mandagni* (63.3%), *Krura Koshta* (70%), constipation



(86.7%), and a urinary frequency of about five times per day (43.3%), with *Vata-Kapha Prakruti* being the most common constitution (40%).

On local examination, the fistula was most commonly located in the right lateral quadrant (36.7%), followed by the anterior quadrant (30%). All subjects had two external openings (100%), most had no operated scar mark (66.7%), and moderate discharge (56.7%). The

external opening was usually located 1.5–2 inches from the anal verge (70%), the tract was more often straight (56.7%), and the most common tract length was 3–4 cm (50%).

RESULTS

Tests used: Friedman test (follow-up comparisons), Wilcoxon signed rank test (before vs. after).

1. Pain: Follow up wise result by Friedman test as follows



Pain	Mean Rank	Test Statistic	P value
Day 1	5.72	141.653	0.001
Day 7	5.05		
Day 14	4.07		
Day 21	3.03		
Day 28	1.78		
Day 41	1.35		

Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Parameter	Mean		% of improvement	Negative rank	Positive rank	Tie	W	P VALUE
	BT	AT						
Pain	2.87	0.37	87.11	30	0	0	-4.930	<0.001

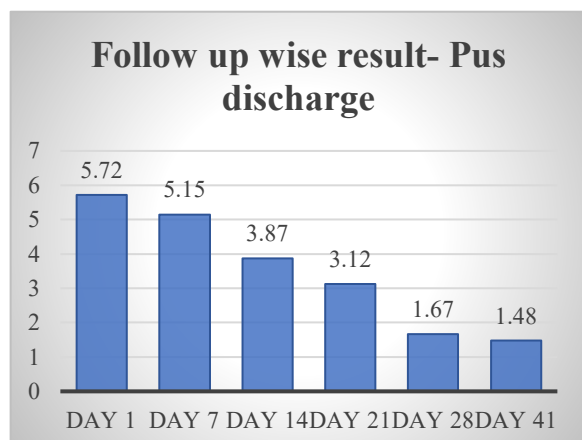
Interpretation:

The mean rank of pain showed a steady and marked decline throughout the treatment period, decreasing from 5.72 on Day 1 to 1.35 on Day 41. The Friedman test ($\chi^2 = 141.653$, $p < 0.001$) indicated a highly significant difference in pain levels across follow-up visits.

Similarly, the mean pain score reduced significantly from 2.87 before treatment (BT) to 0.37 after treatment (AT), reflecting an overall improvement of 87.11%. All 30 subjects demonstrated a reduction in pain, with no positive ranks or ties observed. The Wilcoxon Signed-Rank Test ($W = -4.930$, $p < 0.001$) further confirmed that this reduction was statistically highly significant



2. Pus discharge: Follow up wise result by Friedman test as follows:



Result of before and after treatment by **Wilcoxon signed rank test** as follows:

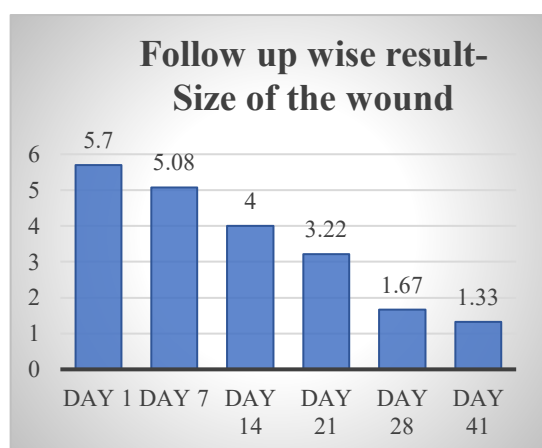
Pus discharge	Mean Rank	Test Statistic	P value
Day 1	5.72	142.235	<0.001
Day 7	5.15		
Day 14	3.87		
Day 21	3.12		
Day 28	1.67		
Day 41	1.48		

Parameter	Mean		% of improvement	Negative rank	Positive rank	Tie	W	P VALUE
	BT	AT						
Pus discharge	2.57	0.13	94.94	30	0	0	-4.939	<0.001

Interpretation: The mean rank of pus discharge demonstrated a consistent and marked decline over the treatment period, decreasing from 5.72 on Day 1 to 1.48 on Day 41. The Friedman test ($\chi^2 = 142.235$, $p < 0.001$) revealed a highly significant difference in pus discharge levels across the follow-up visits. Similarly, the mean pus discharge score reduced significantly from 2.57 before

treatment (BT) to 0.13 after treatment (AT), reflecting an overall improvement of 94.94%. All 30 subjects exhibited a reduction in discharge, with no positive ranks or ties observed. The Wilcoxon Signed-Rank Test ($W = -4.939$, $p < 0.001$) further confirmed that this reduction was statistically highly significant.

3. Size of the wound: Follow up wise result by Friedman test as follows:



Size of the wound	Mean Rank	Test Statistic	P value
Day 1	5.7	143.605	<0.001
Day 7	5.08		
Day 14	4.00		
Day 21	3.22		
Day 28	1.67		
Day 41	1.33		



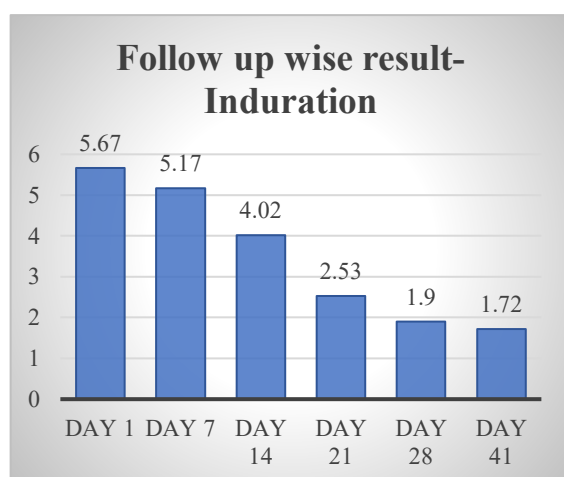
Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Parameter	Mean		% of improvement	Negative rank	Positive rank	Tie	W	P VALUE
	BT	AT						
Size of the wound	2.93	0.33	88.74	30	0	0	-4.939	<0.001

Interpretation: The mean rank of wound size showed a steady and pronounced decline over the treatment period, decreasing from 5.70 on Day 1 to 1.33 on Day 41. The Friedman test ($\chi^2 = 143.605$, $p < 0.001$) indicated a statistically highly significant reduction in wound size across the six follow-up visits. Similarly, the mean wound size score decreased significantly from 2.93 before

treatment (BT) to 0.33 after treatment (AT), representing an overall improvement of 88.74%. All 30 subjects demonstrated a reduction in wound size, with no positive ranks or ties observed. The Wilcoxon Signed-Rank Test ($W = -4.939$, $p < 0.001$) further confirmed that this reduction was statistically highly significant.

4. **Induration:** Follow up wise result by Friedman test as follows:



Induration	Mean Rank	Test Statistic	P value
Day 1	5.67	139.339	0.045
Day 7	5.17		
Day 14	4.02		
Day 21	2.53		
Day 28	1.90		
Day 41	1.72		

Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Parameter	Mean		% of improvement	Negative rank	Positive rank	Tie	W	P VALUE
	BT	AT						
Induration	2.33	0.13	94.42	30	0	0	-5.108	0.049

Interpretation: The mean rank of induration showed a steady decline over the treatment period, decreasing from

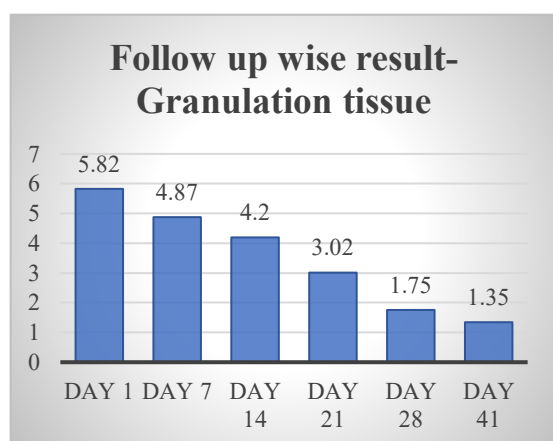
5.67 on Day 1 to 1.72 on Day 41. The Friedman test ($\chi^2 = 139.339$, $p = 0.045$) indicated a statistically significant



reduction in induration across the six follow-up visits. Similarly, the mean induration score decreased significantly from 2.33 before treatment (BT) to 0.13 after treatment (AT), representing an overall improvement of 94.42%. All 30 subjects demonstrated a

reduction in induration, with no positive ranks or ties observed. The Wilcoxon Signed-Rank Test ($W = -5.108$, $p = 0.049$) further confirmed that this reduction was statistically significant.

5. **Granulation tissue:** Follow up wise result by Friedman test as follows:



Granulation tissue	Mean Rank	Test Statistic	P value
Day 1	5.82	142.789	<0.001
Day 7	4.87		
Day 14	4.20		
Day 21	3.02		
Day 28	1.75		
Day 41	1.35		

Result of before and after treatment by **Wilcoxon signed rank test** as follows:

Parameter	Mean		% of improvement	Negative rank	Positive rank	Tie	W	P Value
	BT	AT						
Granulation tissue	2.93	0.3	89.76	30	0	0	-4.964	<0.001

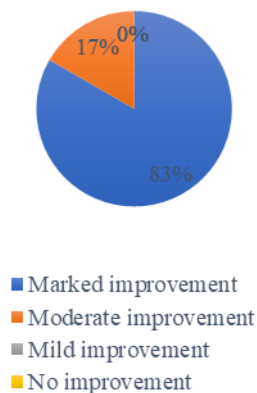
Interpretation: The table shows a progressive increase in granulation tissue, with mean ranks declining from 5.82 on Day 1 to 1.35 on Day 41, indicating healthy tissue development. The Friedman test ($\chi^2 = 142.789$, $p < 0.001$) confirmed a highly significant improvement over time. Similarly, granulation tissue scores improved from 2.93 before treatment to 0.30 after treatment (89.76% improvement), with all 30 subjects showing negative ranks. The Wilcoxon Signed-Rank Test ($W = -4.964$, $p < 0.001$) confirmed this improvement, demonstrating that the treatment was highly effective in promoting granulation tissue formation.

OVAERALL ASSESSMENT

	Frequency	Percentage %
Marked improvement	25	33 %
Moderate improvement	5	17 %
Mild improvement	0	0
No improvement	0	0



OVERALL EFFECT



DISCUSSION

Bhagandara arises due to vitiation of *Vata Dosha*, which localizes in the *Guda Pradesha*, affecting *Rakta* and *Mamsa Dhatu* and leading to fistula formation, often following an untreated perianal abscess. Among the types described, *Vataja Bhagandara* is characterized by pain, profuse discharge, multiple openings, and chronicity⁵.

This single-arm clinical study evaluated the efficacy of *Sushrutokta Langalaka (T-shaped)* incision followed by *Agnikarma* in 30 patients of *Vataja Bhagandara*. The *Langalaka* incision allowed complete deroofing of the primary and secondary tracts while preserving sphincter integrity, and *Agnikarma* helped in tissue sterilization, reduction of infection, and prevention of recurrence⁶.

Demographically, most patients were middle-aged, married, middle-class individuals with sedentary

lifestyles, constipation, *Mandagni*, and features of *Vata* predominance. Clinically, right lateral fistulas with straight tracts and moderate discharge were most common.

The intervention produced statistically highly significant improvements in pain (87.11%), discharge (94.94%), wound size (88.74%), induration (94.42%), and granulation tissue formation (89.76%). No major postoperative complications or recurrence were observed during follow-up.

Based on the results of all the evaluated parameters, *Langalaka* incision followed by *Agnikarma* was found to be significantly effective in the management of *Vataja Bhagandara* (Fistula-in-Ano) with multiple openings. The study demonstrated highly significant improvements in reducing *Vedana* (pain) and *Srava* (discharge) along with a reduction in wound size and induration, enhanced formation of healthy granulation tissue, and early wound healing.

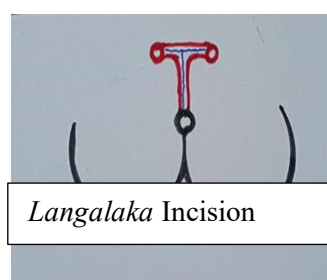
CONCLUSION

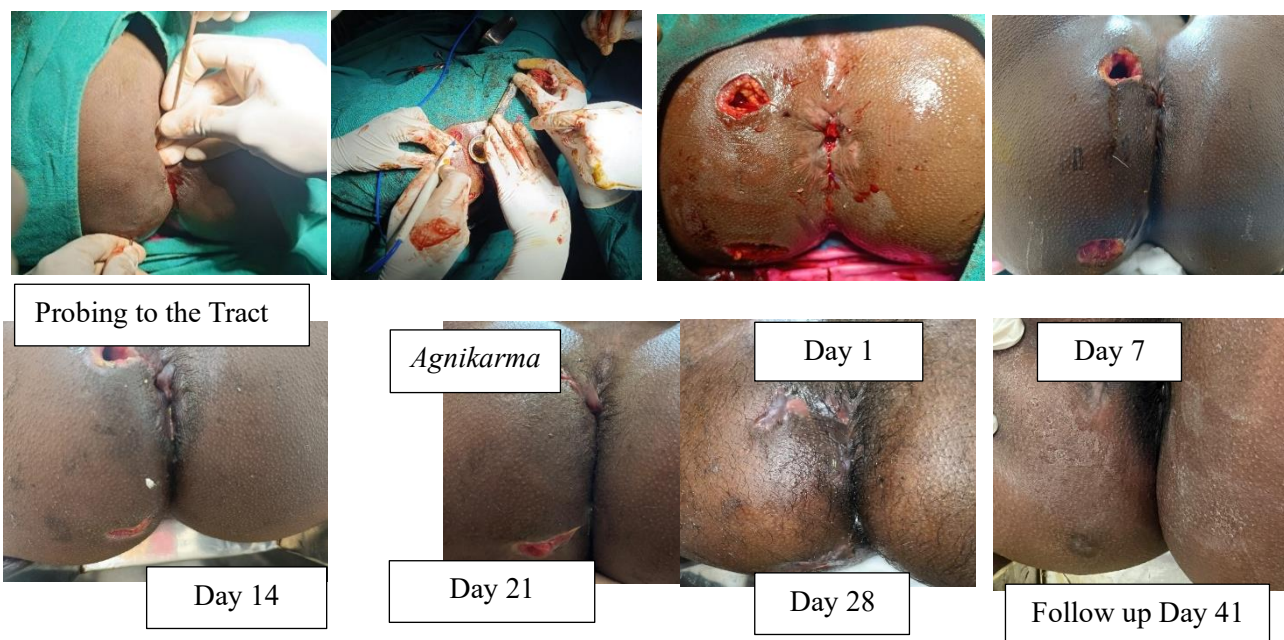
The present clinical study was undertaken to revalidate the efficacy of *Sushrutokta Langalaka* Incision followed by *Agnikarma* in the management of *Vataja Bhagandara* in 30 subjects.

The study clearly demonstrates that *Langalaka* incision followed by *Agnikarma* is highly effective in the management of *Vataja Bhagandara* (Fistula-in-Ano) with multiple openings, showing both statistical and clinical significance.

ANNEXURE

Case treated with *Langalaka* incision followed by *Agnikarma* in *vataja Bhagandara*





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Conflicts of interest:

There are no conflicts of interest.

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