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Research Article

RECURRENCE OF FISTULA-IN-ANO (*BHAGANDARA*) AFTER *KSHARASOOTHRA* THERAPY -A SINGLE CENTRE PROSPECTIVE COHORT STUDY

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ABSTRACT

Fistula in ano is an abnormal communicating tract between anal canal and perianal skin which is lined by granulation tissue. It is a condition where surgical intervention is required. Recurrence is one of the common complications seen after surgeries. *Ksharasoothra* therapy is a para surgical procedure, is found more effective in the management of fistula in ano. The subjects who underwent *Apamarga Ksharasoothra* therapy for fistula in ano from the OPD and IPD of Govt. Ayurveda College, Trivandrum, were observed for one year after complete healing of fistulous tract to find out recurrence of fistula in ano. **Methods:** This study is a prospective cohort, of patients with fistula-in-ano who underwent *Ksharasutra* therapy followed by a specific dietary regimen. Fifty patients were followed for one-year post-therapy, and the recurrence rate was calculated. **Results:** Among the 50 observed samples 8, reported signs of recurrence. Among the 8 patients who experienced recurrence, the majority (5 cases, 10%) had recurrence at 6 months after complete healing. Recurrence at 3 months, 9 months, and 12 months was observed in 1 patient each (2% each). A striking and statistically significant association was found between adherence to *Pathya* (dietary and lifestyle regimen) and recurrence. **Conclusion:** This design is especially helpful in understanding the importance of *Pathya* and *Apathyas* in *Bhagandhara* which is identified in a study population. The recurrence of the disease was observed in those who did not follow the *Pathya*, highlighting the significant importance of adhering to these dietary and lifestyle recommendations.

INTRODUCTION

Fistula in ano is one of the most common anorectal diseases in which the chronic unhealthy granulation tract runs from the anal canal or rectum to the perianal skin or perineum and is associated with considerable discomfort and morbidity to the patient. There are many surgical procedures that described in text from ancient age to till date. Recurrence is one of the main complications even after surgery. In Ayurveda it is correlated with *Bhagandara*. Acharya Sushruta, the father of surgery has included this disease as one among the *Ashtamahagada* (diseases difficult to cure).[1]

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According to Ayurveda, *Pathya* and *Apathya* plays an important role in the management and prevention of recurrence and also enhancing overall treatment outcome. *Pathya* refers to the wholesome or beneficial aspect of diet, lifestyle, and behaviour that promote health and prevent diseases.

Patients with fistula-in-ano often delay seeking treatment due to various factors, including shyness, busy schedules, and a lack of severe pain. Furthermore, modern lifestyle changes have contributed to the development of this condition. These changes include a shift towards consuming hot and spicy foods, junk foods, and soft drinks, as well as a low-fiber diet that may include non-vegetarian items. Additionally, a sedentary lifestyle, prolonged periods of riding vehicle, sitting and suppressing natural urges have become increasingly prevalent, exacerbating the risk of developing fistula-in-ano. According to Acharya Susrutha, in the context of *Bhagandhara*, it is advised

to follow a strict regimen (*Pathya*) for a prolonged period, up to 1 yr, to minimize the risk of recurrence.[2]

Methodology

The study was conducted in 50 subjects having fistula in ano without control group. A prospective observational study consists of 50 participants who have done *Apamarga Ksharasoothra* therapy, registered in the outpatient department (OPD) and inpatient department (IPD) of the Government Ayurveda College Hospital, Thiruvananthapuram, satisfying the inclusion criteria were selected. They were observed up to one-year using a validated questionnaire and data collection form. The data was statistically analysed to interpret the results and observations.

AIM & OBJECTIVES

AIM

To assess the recurrence of fistula in ano after complete healing of the fistulous tract in subjects who underwent the *Apamarga Ksharasootra* therapy.

OBJECTIVES

To assess the recurrence of fistula in ano after complete healing of the fistulous tract in subjects who underwent the *Apamarga Ksharasootra* therapy in the Dept. of Salyathanthra Govt. Ayurveda College Thiruvanthapuram.

Selection Criteria

Inclusion criteria

The subjects whose fistulous tract has healed completely after *Apamarga Ksharasootra* therapy satisfying the inclusion and exclusion criteria in the IPD and OPD of Govt. Ayurveda College, Thiruvananthapuram.

Exclusion criteria

- Subjects who is not willing to participate in the study.
- Subjects who cannot be communicate during the study period.
- Participants who died or migrated during the study period.

To evaluate patient outcomes, various validated questionnaires were reviewed from previous research works.

Collection of data by using validated questionnaire

- Directly collected data from previously validated questionnaires, attached in annexures, from patients with fistula in ano who underwent *Apamarga kharasutra* and completely healed the track.
- Every three months, data is collected again by telephone or in person through questionnaires
- In this way, recurrence is investigated up to one year after the fistulas tract has completely healed.

Statistical analysis of data observed in the third step, by consecutive sampling technique 50 samples were selected. A survey was conducted among the study population by direct interview method using the validated questionnaire by obtaining their consent. The collected data was statistically analysed to make conclusion

Outcome measurement

To find out recurrence, assessed by discharge, swelling or pain in the healed tract.

RESULT

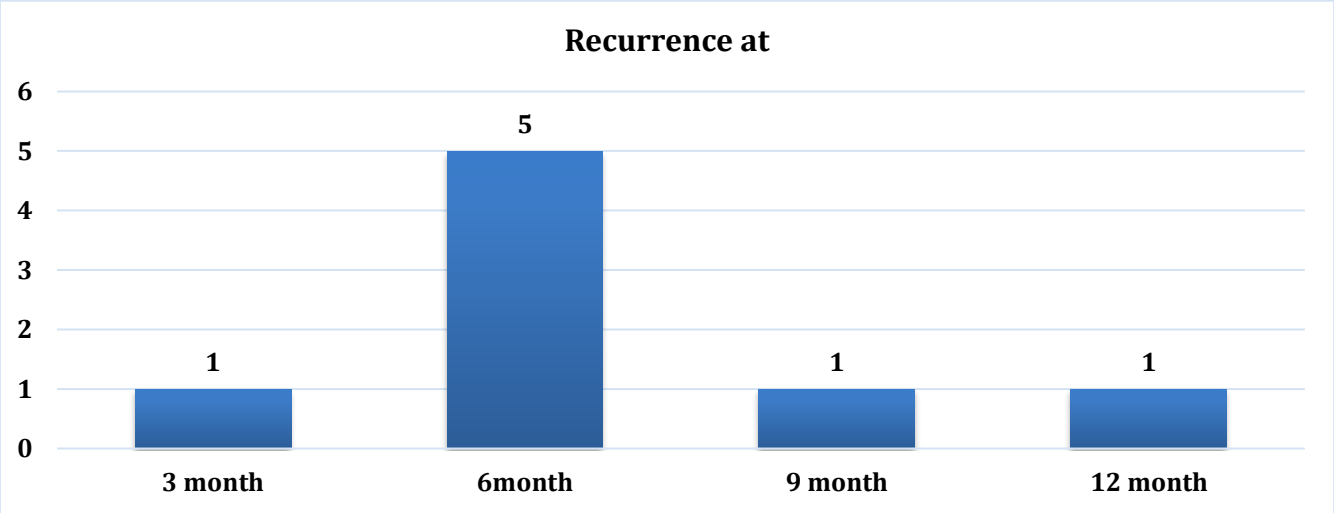
In the present study, fifty subjects whose tracts had healed completely after *Apamarga ksharasoothra* therapy, satisfying the inclusion and exclusion criteria, were observed for one year in the OPD and IPD of the Department of Salyathanthra, Government Ayurveda College, Thiruvananthapuram, to assess the recurrence.

Among the 50 observed samples 8 (16% of the study population) reported signs of recurrence. Among the 8 patients who experienced recurrence, the majority (5 cases, 10%) had recurrence at 6 months after complete healing. Recurrence at 3 months, 9 months, and 12 months was observed in 1 patient each (2% each). This shows that when recurrence occurred, it was most commonly noted around the 6-month follow-up period. Even though many factors such as lack of regular exercise, prolonged driving of vehicles especially two wheelers, mental strain at work place etc., were suggestive of possible significance, almost all of it failed to achieve statistical significance. Even though statistically insignificant since the sample with recurrence is very small, there is a notable finding in the type of fistula. [Table 1]

Table1: Recurrence of Fistula

Recurrence at	Count	Percentage %
3 months	1	2
6months	5	10
9 months	1	2
12 months	1	2
Total	**8**	**16**

Graph 1: Recurrence



Various data regarding the demography, socio economic status, patient habits and addictions, clinical findings etc. in the participants with and without recurrence were analyzed for identifying any statistically significant associations [Statistical test such as Chi square test, Fisher exact test, odds ratio etc. appropriate to the data were used. [Table 2] In this study, all patients in the recurrence group (100%) reported following *Apathya* (unsuitable or aggravating dietary/lifestyle habits), whereas none in the non-recurrence group followed *Apathya*. This difference was highly statistically significant ($p<0.0001$), suggesting a strong association between following *Apathya* and recurrence of fistula-in-ano. [Table 3]

Table 2: Clinical Profile and Follow-Up

Participant	Diagnosis	Type of Fistula	Ayurvedic Aspect	Time Taken for Complete Healing	Recurrence at 3 Months	Recurrence at 6 Months	Recurrence at 9 Months	Recurrence at 12 Months	Previous History of Fistula
1	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	Yes
2	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	Yes
3	Fistula in ano	Intersphincheric	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
4	Fistula in ano	Trans sphincheric	*Parikshepi*	4 months	Nil	Nil	Nil	Nil	No
5	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	Yes
6	Fistula in ano	Trans sphincheric	*Parisravi*	4 months	Nil	Nil	Nil	Nil	No
7	Fistula in ano	Submucosal	*Riju*	3 months	Nil	Nil	Nil	Nil	No
8	Fistula in ano	Submucosal	*Parisravi*	3 months	Yes	0	0	0	Yes
9	Fistula in ano	Trans sphincheric	*Parisravi*	5 months	Nil	Yes	0	0	No
10	Fistula in ano	Submucosal	*Parisravi*	4 months	Nil	Yes	0	0	Yes
11	Fistula in ano	Intersphincheric	*Parisravi*	5 months	Nil	Nil	Nil	Nil	No
12	Fistula in ano	Intersphincheric	*Parisravi*	4 months	Nil	Nil	Nil	Nil	Yes
13	Fistula in ano	Trans sphincheric	*Ushtreeva*	3 months	Nil	Yes	0	0	Yes
14	Fistula in ano	Submucosal	*Parisravi*	5 months	Nil	Nil	Nil	Nil	No
15	Fistula in ano	Intersphincheric	*Parisravi*	5 months	Nil	Nil	Nil	Nil	Yes
16	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	Yes
17	Fistula in ano	Submucosal	*Parisravi*	5 months	Nil	Nil	Nil	Yes	Yes
18	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Yes	0	No

19	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
20	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
21	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
22	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
23	Fistula in ano	Intersphincheric	*Ushtreeva*	3 months	Nil	Nil	Nil	Nil	Yes
24	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
25	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
26	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
27	Fistula in ano	Trans sphincheric	*Ushtreeva*	3 months	Nil	Nil	Nil	Nil	Yes
28	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
29	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
30	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
31	Fistula in ano	Trans sphincheric	*Ushtreeva*	3 months	Nil	Yes	0	0	Yes
32	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
33	Fistula in ano	Trans sphincheric	*Ushtreeva*	5 months	Nil	Nil	Yes	0	No
34	Fistula in ano	Trans sphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
35	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
36	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
37	Fistula in ano	Submucosal	*Parisravi*	4 months	Nil	Nil	Nil	Nil	Yes
38	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
39	Fistula in ano	Intersphincheric	*Parikshepi*	4 months	Nil	Nil	Nil	Nil	Yes
40	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
41	Fistula in ano	Intersphincheric	*Parikshepi*	3 months	Nil	Nil	Nil	Nil	Yes
42	Fistula in ano	Submucosal	*Ushtreeva*	3 months	Nil	Nil	Nil	Nil	No
43	Fistula in ano	Intersphincheric	*Parisravi*	3 months	Nil	Nil	Nil	Nil	Yes
44	Fistula in ano	Trans sphincheric	*Parikshepi*	3 months	Nil	Nil	Nil	Nil	Yes
45	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No
46	Fistula in ano	Intersphincheric	*Ushtreeva*	2 months	Nil	Nil	Nil	Nil	Yes
47	Fistula in ano	Suprasphincheric	*Ushtreeva*	4 months	Nil	Nil	Nil	Nil	No
48	Fistula in ano	Submucosal	*Parisravi*	2 months	Nil	Nil	Nil	Nil	No
49	Fistula in ano	Suprasphincheric	*Parikshepi*	4 months	Nil	Yes	0	0	No
50	Fistula in ano	Submucosal	*Parisravi*	3 months	Nil	Nil	Nil	Nil	No

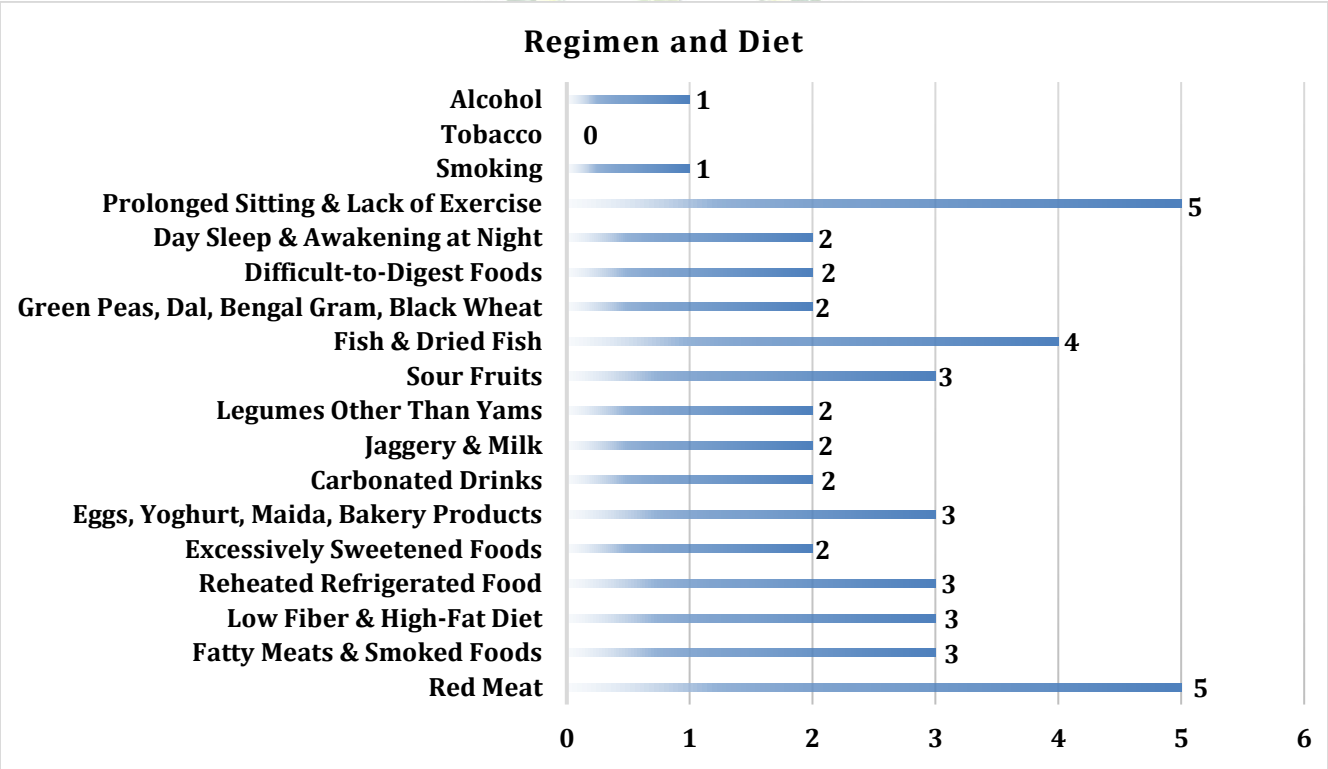
Table 3: Analysis on adherence to Pathya after treatment

Regimen and diet	**Recurrence**		**P value**
	Yes	**No**	
Red meat	5	3	<0.0001
Fatty meats and smoked foods	3	5	<0.003
Low fiber and high-fat diet	3	5	<0.003
Reheated refrigerated food	3	5	<0.003
Excessively sweetened foods	2	6	<0.023
Eggs, yoghurt, maida, bakery products	3	5	<0.003
Carbonated drinks	2	6	<0.023

Jaggery and milk	2	6	<0.023
Legumes other than yams	2	6	<0.023
Sour fruits	3	5	<0.003
Fish and dried fish	4	4	<0.0003
Green peas, dal, Bengal gram, black wheat	2	6	<0.023
Difficult-to-digest foods	2	6	<0.023
Day sleep and awakening at night	2	6	<0.023
Prolonged sitting and lack of exercise	5	3	<0.0001
Smoking	1	7	0.16
Tobacco	0	8	1
Alcohol	1	7	0.16

In the recurrence group (n=8), consumption of various unwholesome dietary items and regimens was reported, whereas none of the participants in the non-recurrence group (n=42) reported such practices. Fisher's exact test was applied to each item due to the presence of small cell counts and zero frequencies in the non-recurrence group. Odds ratios for these associations are not estimable due to complete separation (zero cell counts) in the non-recurrence group. Significant associations with recurrence were observed for red meat ($p< 0.0001$), fatty meats and smoked foods ($p<0.003$), low-fiber and high-fat diet ($p<0.003$), reheated refrigerated food ($p<0.003$), excessively sweetened foods ($p<0.023$), eggs, yoghurt, maida, bakery products ($p<0.003$), carbonated drinks ($p<0.023$), jaggery with milk ($p<0.023$), legumes other than yams ($p<0.023$), sour fruits ($p< 0.003$), fish and dried fish ($p<0.0003$), green peas, dal, Bengal gram, black wheat ($p<0.023$), difficult-to-digest foods ($p<0.023$), day sleep and awakening at night ($p < 0.023$), and prolonged sitting with lack of exercise ($p< 0.0001$). No statistically significant associations were observed for smoking ($p=0.16$), tobacco use ($p=1.00$), or alcohol consumption ($p=0.16$).

Graph 2: Number of participants who followed the prescribed diet and regimen



Among the 50 observed samples 8 (16% of the study population) reported signs of recurrence. Among the 8 patients who experienced recurrence, the majority (5 cases, 10%) had recurrence at 6 months after complete healing. Recurrence at 3 months, 9 months, and 12 months was observed in 1 patient each (2% each). This shows that when recurrence occurred, it was most commonly noted around the 6-month follow-up period.

DISCUSSION

- According to classical Ayurvedic views, improper diet and lifestyle habits (*Mithyahara Viharas*) can lead to the vitiation of *Doshas*, which accumulate and localize in the rectal region *(Guda*), specifically within one and a half *Angula*. This localization can cause the formation of abscesses or boils *(Pidakas*). If these *Pidakas* are left untreated, they can progress and develop into *Bhagandara.*
- Over a one-year follow-up period, 16% of the study population (8 out of 50 participants) exhibited signs of recurrence, with the majority (62.5%) of these cases occurring around the 6-month mark post-healing. Several lifestyle and occupational factors were explored for their potential association with recurrence, lack of regular exercise, prolonged two-wheeler driving, mental strain at the workplace are dominant among them. While these factors were suggestive of clinical relevance, none achieved statistical significance likely due to the small number of recurrence cases. However, their consistent appearance in patient histories warrants further investigation in larger cohorts.
- Among the participants who were advised to follow a *Pathyahara Vihara* chart for up to 1 year, 76% adhered to the regimen. Notably, the recurrence of the disease was observed in those who did not follow the *Pathya*, highlighting the significant importance of adhering to these dietary and lifestyle recommendations
- A striking and statistically significant association was found between adherence to *Pathya* (dietary and lifestyle regimen) and recurrence. All participants who experienced recurrence had failed to follow *Pathya*, yielding a P-value <0.001, indicating a strong correlation. This underscores the critical role of post-operative lifestyle and dietary discipline in ensuring optimal healing and preventing recurrence. *Pathya*, rooted in Ayurvedic principles, likely supports tissue regeneration, reduces inflammation, and minimizes infection risk factors essential for sustained recovery

CONCLUSION

This design is especially helpful in understanding the importance of *Pathya* and *Apathyas* in *Bhagandhara* which is identified in a study population. The recurrence of the disease was observed in those who did not follow the Pathya, highlighting the significant importance of adhering to these dietary and lifestyle recommendations. Over a one-year follow-up period, 16% of the study population (8 out of 50 participants) exhibited signs of recurrence, with the majority (62.5%) of these cases occurring around the 6-month mark post-healing. Several lifestyle and occupational factors were explored for their potential association with recurrence, lack of regular exercise, prolonged two-wheeler driving, mental strain at the workplace are dominant among them. All the participants with recurrence had failed to adhere to *Pathya*, providing a statistically significant (P value <0.001) association between adherence to *Pathya* and recurrence of fistula in ano.

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