

**EFFECTIVENESS OF KSHAR SUTRA AND NAVKARSHIK GUGGLU
IN BHAGANDARA W.S.R. TO FISTULA- IN -ANO IN BETWEEN TWO
DIFFERENT AGE GROUPS- A COMPARATIVE STUDY**

**Dr. Anant Saznam^{1*}, Dr. Chandan Kumar Pathak², Dr. Rakesh Raushan³ and
Dr. Deepali Sundari Verma⁴**

¹PG Scholar, Department of Shalya Tantra, Govt. Ayurvedic College & Hospital, Patna,
Bihar.

²PG Scholar, Department of Shalya Tantra, Govt. Ayurvedic College & Hospital, Patna,
Bihar.

³Associate Professor, Department of Shalya Tantra, Govt. Ayurvedic College & Hospital,
Patna, Bihar.

⁴Professor & Head of Department of Shalya Tantra, Govt. Ayurvedic College & Hospital,
Patna, Bihar.

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***Corresponding Author**

Dr. Anant Saznam

PG Scholar, Department of
Shalya Tantra, Govt.
Ayurvedic College &
Hospital, Patna, Bihar.

ABSTRACT

Bhagandara (fistula- in- ano) is a disease of anorectal region, and characterized by single or multiple sinus. It is inflammatory tract which has an external opening in the peri anal skin and an internal opening in the anal canal or rectum. The tract is lined by unhealthy granulation and fibrous tissue. In ayurveda text it is known as bhagandara and is included in eight mahagada. Shushruta has described bhagandara under eight mahagada, which are supposed to be difficult to cure, bhagandara literary means Daran around Guda, Yoni and Basti. Kshar Sutra is a unique and an established procedure for difficult surgical disease because of negligible recurrence rate, no need of hospitalization and being economical and less invasive. In the conservative treatment of Bhagandara “Navakarshik Guggulu” is used.

KEYWORDS: Bhagadara, Kshar Sutra, Navkarshik Guggulu.

INTRODUCTION

In *Ayurved*, *Acharya Sushruta* described *Bhagandara* (Fistula-in-ano) under eight major diseases (*Ashtomahagada*).^[1] *Acharya Sushruta* has mentioned that all types of *Bhagandara* are difficult to treat.^[2] In modern surgery also, it is known for its callus nature to cure with high recurrence rate. In many of the cases, recurrence is seen after being treated by modern surgical conventional methods like fistulectomy or fistulotomy.

“वातव्याधिः प्रमेहश्च कुष्ठमर्शो भगन्दरम् अश्मरी मूढगर्भश्च तथैवोदरमष्टमम्।

अष्टावेते प्रकृत्यैव दुश्चिकित्स्या महागदाः॥” su.s. 33/4

Bhagandara (fistula- in- ano) is a disease of anorectal region, and characterized by single or multiple sinus. It is inflammatory tract which has an external opening in the peri anal skin and an internal opening in the anal canal or rectum. The tract is lined by unhealthy granulation and fibrous tissue.

ते तु भगगुदवस्तिप्रदेशदरणाच्च भगन्दरा इत्युच्यन्ते अपववाः पिडकाः, पववास्तु भगन्दरा | su.ni. 4/4

Due to daran of bhag, guda and vasti. It is called Bhagandara, In the early condition and age it is called ‘Pidika’, later on it is named as Bhagandara, These are called fistula in ano because they break through the perineum (Bhag) anus and with an opening. This disease starts with deep rooted boil known as pidika around Guda with two finger circumferences. The ancient writer *Acharya Vagbhata* describe pidika occurring in one or two finger around the anal orifice, due to vitiated Doshas and bursts either external or internal is known as “Bhagandara.”

Kshar Sutra therapy requires a minimal setup, minimal equipments and instruments. It is a minimal invasive para-surgical measure. Moreover, the best benefit to the patient is that patient remains ambulatory during the whole course of treatment. It is simple, safe and comparatively sure treatment and being globally accepted. The Indian Council of Medical Research (ICMR) has validated this therapy by conducting multicentre research trial and concluded that Kshar Sutra is better than conventional surgery in fistula-in-ano.^[3]

Kshar Sutra is routinely prepared with *Snuhi Ksheera*, *Haridra Churna* and *Apamarga Kshara*. It is known as the conventional *Apamarga Kshar Sutra*.

Our classical text states Navkarshik gugglu has a very good effect on Bhagandara. By knowing this fact my curiosity inspired me to do the same over the patients suffering from Bhagandra.

DRUG REVIEW

This yoga is mentioned in Bhishajyaratnawali Adhyay-51(Bhagandara chikitsa).^[4] Our classical text states Navkarshik gugglu has a very good effect on Bhagandara.

Navkarshik Guggulu is a simple formulation made up of only 5 ingredients 3 fruits of Triphala, Guggulu and Pippali.

Content of Kshar-sutra

1. Snuhi ksheera
2. Apamarg Kshar
3. Haridra Powder

MATERIALS AND METHODS

Number of Patients-28 patients has been selected in two age groups from OPD of Govt. Ayurvedic College and Hospital, Patna.

Both groups consist of 14 patients respectively.

One group consisting patient below 35 years of age and the other one consisting patient above 35 years of age.

-Patients will be examined thoroughly as per the case sheet which is specially prepared for this research work.

-The patients selected for Kshar-sutra ligation were taken for study.

AIMS AND OBJECTIVE

1. Preparation of Kshar sutra & Navkarshik gugglu, by following SOP and its standardization.
2. To evaluate their efficacy in the context of Bhagandara.

INCLUSION CRITERIA

- (a) All the patients between age group of 21-60 years suffering from Low Anal type of Fistula.
- (b) Classically diagnosed patients will be taken for the purpose.

EXCLUSION CRITERIA

- (a) Patients having serious cardiac, nephrotic, hormonal and other major illness.
- (b) Patients below the age of 21 years & above 60 years.
- (c) Criteria shown in our ancient text books.

INVESTIGATIONS

- a. Urine analysis-Routine and Microscopic examination
- b. Haematological Investigation- CBC, BSR, Blood Urea, Serum Creatinine, BT, CT, HIV, HCV, HBsAg etc.
- c. Radiological study- chest X-ray P/A view, Fistulogram.

CRITERIA FOR EXAMINATION AND ASSESSMENT

The assessment will be carried out on the basis of improvement in **objective parameters**

- a) Healing status
- b) UCT
- c) Discharge
- d) Pain

Subjective Parameters

- a) Pain
- b) Itching
- c) Burning sensation

EXAMINATION OF PATIENT

Each case was thoroughly examined and investigated by detailed proforma designed for the present Clinical study on Bhagandara. Each patient was examined under following headings.

1. History of the Patient

2. Systemic Examination

3. Local Examination

It was done under following headings.

-Inspection

-Palpation

-Digital Rectal Examination (DRE) Probing

It is an important examination which provides accurate knowledge regarding

- The track, whether it was complete or not
- The extent of the track
- The direction of the track

OBSERVATION AND RESULTS

All data will be observed and statistically analyses. It provides basis of analysis of the problem and effects of the method adopted for its cure. A clinical study was conducting of Kshar sutra and Navkarshik guggulu in Bhagandara w.s.r. to Fistula- in –Ano.

Selection of Patient

Number of Patients-30 patient will be selected from OPD of Govt. Ayurvedic College and Hospital, Patna.

DOSE

Navkarshik Guggulu is given is in vati form (Dose- 1gm in a day in two divided doses).^[5]

FOLLOW UP

Follow up will be done on every 15 days to assess the changes.

Statistical Analysis

All information which are based on various parameters was gathered and statistical calculation were carried out in terms of mean (X), standard deviation (S.D.) standard error (S.E.), paired test (t value) and finally results were incorporated in term of probability (p) as

$P \geq 0.05$ Insignificant

$P \leq 0.020$ Moderately significant

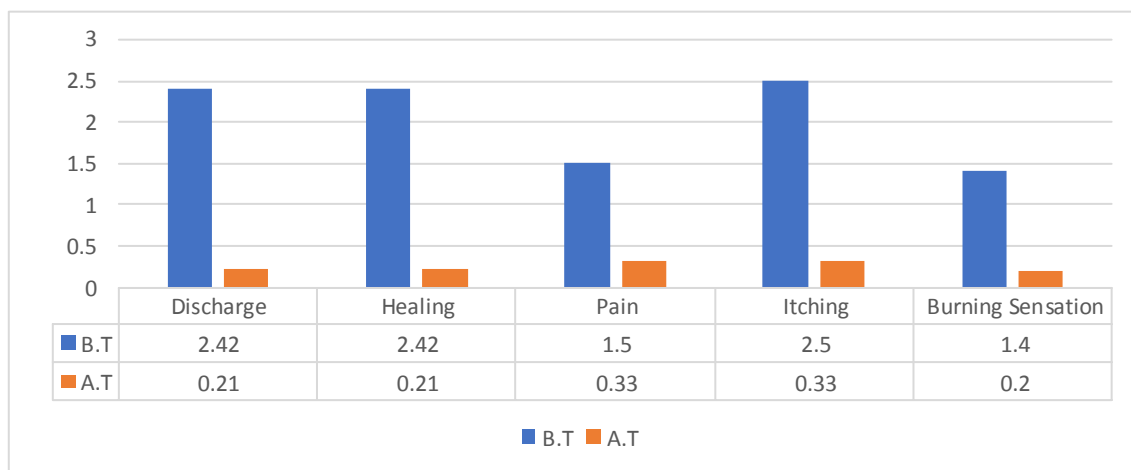
$P \leq 0.010$ Significant

$P \leq 0.001$ Highly significant

Effect of the Therapy Above 35 years Age Groups

Effect of Navkarshik Guggulu and Kshar sutra Application on Bhagandara

S. No.	Criteria	Mean		%age Diff.	SD	SE	t	P
		BT	AT					
1.	Discharge	02.42	0.21	91.17	0.89	0.23	9.28	<0.001
2.	Healing	02.42	0.21	91.17	0.69	0.18	11.84	<0.001
3.	Pain	1.5	0.33	77.77	0.40	0.16	7	<0.001
4.	Itching	2.5	0.33	86.66	0.40	0.16	13.	<0.001
5.	Burning sensation	1.4	0.2	85.71	0.44	0.2	6	<0.001



A. Effect of Therapy on Discharge

The mean score of UCT, before treatment was 2.42 and after treatment it changed to 0.21 giving 91.17 % difference in mean score which was highly significant statistically ($p < 0.001$).

B. Effect of Therapy on Healing

The mean score of Discharge, before treatment was 02.42 and after treatment it changed to 0.21 giving 91.17% difference in mean score which was highly significant statistically ($p < 0.001$).

C. Effect of Therapy on Pain

The mean score of Healing, before treatment was 02.46 and after treatment it changed to 0.28 giving 88.40% difference in mean score which was highly significant statistically ($p < 0.001$).

D. Effect of Therapy on Itching

The mean score of Pain, before treatment was 1.50 and after treatment it changed to 0.33 giving 77.77% difference in mean score which was highly significant statistically ($p < 0.001$).

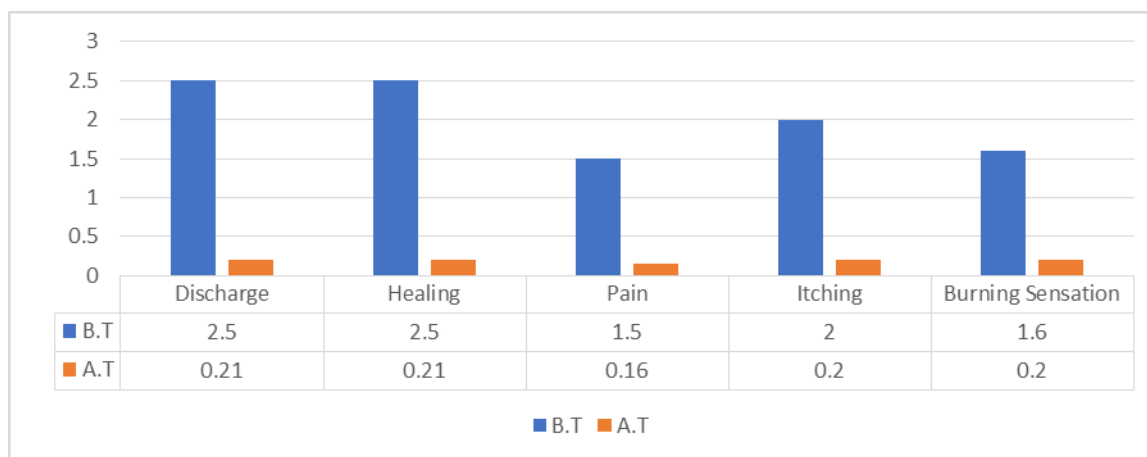
E. Effect of Therapy on Burning sensation

The mean score of Itching, before treatment was 2.50 and after treatment it changed to 0.33 giving 86.66 % difference in mean score which was highly significant statistically ($p < 0.001$).

Effect of the Therapy Below 35 years Age Groups

Effect of Navkarshik Guggulu and Kshar sutra Application on Bhagandara

S. No.	Criteria	Mean		%age Diff.	SD	SE	t	P
		BT	AT					
1.	Discharge	2.5	0.21	91.42	0.91	0.24	9.35	<0.001
2.	Healing	2.5	0.21	91.42	0.72	0.19	11.77	<0.001
3.	Pain	1.5	0.16	88.88	0.51	0.21	6.32	<0.001
4.	Itching	2	0.2	90	1.30	0.58	3.08	<0.05
5.	Burning sensation	1.6	0.2	87	0.54	0.24	5.71	<0.001



A. Effect of Therapy on Discharge

The mean score of UCT, before treatment was 2.50 and after treatment it changed to 0.21 giving 91.42 % difference in mean score which was highly significant statistically ($p < 0.001$).

B. Effect of Therapy on Healing

The mean score of Discharge, before treatment was 2.50 and after treatment it changed to 0.21 giving 91.42 % difference in mean score which was highly significant statistically ($p < 0.001$).

C. Effect of Therapy on Pain

The mean score of Healing, before treatment was 1.50 and after treatment it changed to 0.16 giving 88.88% difference in mean score which was highly significant statistically ($p < 0.001$).

D. Effect of Therapy on Itching

The mean score of Pain, before treatment was 2 and after treatment it changed to 0.2 giving 90 % difference in mean score which was highly significant statistically ($p < 0.001$).

E. Effect of Therapy on Burning sensation

The mean score of Itching, before treatment was 1.60 and after treatment it changed to 0.2 giving 87% difference in mean score which was highly significant statistically ($p < 0.001$).

Average Unit Cutting Time

No of Patients	Mean Unit cutting
28	10.41 days/cm

The table reveals that average U.C.T is 10.41 days/cm in which Kshar Sutra was applied along with Navkarshik Guggulu.

DISCUSSION

Age: - On observation it was found that maximum number of patients **30%** were between the age group of **21-30** years which suggests that this age group is more prone to suffer from fistula-in-ano. The probable cause may be due to busy life style of this age group. They are more prone for exposure with the etiological factors of *Bhagandara* i.e. improper diet, riding bicycle, continue sitting and excess work. In present era the middle-aged men are doing more travelling due to their various duties and responsibilities.

Sex: - In this study, **96.67%** patients were **males** and **03.33%** patients were females, which goes hand in hand with a study conducted by Sainio P. et.al concluded that the prevalence rate is double in males as compared to females.^[6]

Religion: - Incidence of fistula-in-ano in **Hindu** community was noticed with **100%** in the present study. As there is no any proven fact of relation with religion to disease *Bhagandara*, but it may be due to the study centre Patna is Hindu dominance geographical area.

Marital status: - In this study out of 30 cases 24 patients (**80.00%**) were married and 20 % were Unmarried.

Habitat: - Total **30%** patients were registered from **rular areas** and 70% were from urban areas, which shows that number of urban patients were little more which might be due to being unhealthy life styles. But it is difficult to say that more prevalence in urban on the basis of this small sample study.

Socio-economic status: - In this study **90 %** patients belonged to **middle class** followed by 03.33 % patients belonged to poor class. Socio - economically, the people who belonged to

middle class were observed more as patients of such economical background are first prefer a good government hospital. It is observed generally that majority of the poor patients do not seek medical treatment earlier, sometimes due to less awareness about the disease. Most of them first prefer to take home based remedies, but when the condition causes disturbance in their daily life, either a general practitioner refers or the patient himself comes to a specialised medical centre which is affordable to him.

Occupational status: - 23.33 % patients were doing **Private job**, 23.33% were doing Agriculture, 23.33 % were Students and 10% patients were engaged to Govt. job. As most of them were adapted a private job and agriculture and they had to do more and long time travelling by motorcycle, bicycle, etc. Many had to sit on a chair for long time during working hours in sedentary job. These factors may cause prolonged pressure in the peri-anal area and excessive sweating might lead to abscess formation and ultimately fistula-in-ano.

Nature of diet: - In this study 03.33 % patients were consuming vegetarian **diet** while 96.66% patients were consuming mixed diet (Table no. 20). Due to the high percentage of people is naturally consuming Mixed diet having spices and junk food might be responsible for *Bhagandara*.

Prakriti and type of *Bhagandara*: - In this study, observation showed that Majority of the patients belonged to **Pittaj Prakriti (43.33%)** follow by **Vataj Prakriti (40%)** and Kaphaj Prakriti (16.66%). The *Samprapti* of *Bhagandara* starts with the vitiation of *Vata Dosha* in all type of *Bhagandara* and it implies that irrespective of *Prakriti* it is equally prone for the disease of *Bhagandara*.^[7]

Psychological status: - Maximum 46.66 % patients were depressed, 43.33 % patients were worried 03.33 % of patients were irritative and only 06.66 % of patients were happy, but from this small sample study it is difficult to say that there is no psychological involvement in the cases of *Bhagandara*.

Addiction: - Total 36.66 % patients were addicted to tobacco chewing, a common habit observed among the people of Saurashtra. 03.33 % of the patients were addicted to smoking and only 03.33 % patients had addiction of alcohol. It is a proven fact that the tobacco consumption affects the wound healing time. Though exact relation of tobacco consumption

and *Bhagandara* is not much clear but due to tobacco addiction GIT disturbances and constipation might be the indirect cause for *Bhagandara*.

Position of external opening: - In most of the cases external openings were found at 1 o'clock position with a percentage of 43.33 %, followed by 36.67 % external openings at 5 o'clock position and 20.00 % external opening at 7 o'clock. The position of external opening at posterior half was maximum 56.67 % while external opening at anterior half of anus was 43.33 %. It is obvious that the occurrence of the fistula-in-ano is most common in posterior aspect of anal canal. This might be due to posterior wall of anal canal is more fixed to surrounding musculature than anterior wall. Another cause might be due to fixity of posterior wall there is more chance of stagnation of infection, which infects an anal gland of posterior wall. The anal glands are 4-8 in number and most of them are situated at posterior portion of anal canal.^[8]

Clinical features of *Bhagandara*: - The Pain, Itching, Burning-sensation and Discharge are the cardinal symptoms of *Bhagandara* because of infection which causes inflammation in fistulous tract. 40.00% patients had pain, 100% patients had Pus discharge and 33.33 % patients had Burning sensation. Other symptom like itching is due to excessive discharge and improper perianal hygiene so it was found in 36.66 % of patients only.

PROBABLE MODE OF ACTION OF KSHARSUTRA

Kshar Sutra

In this clinical trial *Kshar Sutra* was used in patients. The ingredients are *Snuhi*, *Apamarga*, *Kshara* and *Haridra Powder*. *Apamarga Kshara* has properties of *Kshara* i.e. *Chhedana*, (excision) *Bhedana* (incision), *Lekhana* (scrapping) and *Tridoshaghna* (alleviating all *Dosha*).^[9] *Haridra* powder has the properties like *Rakta Shodhana* (blood purifying), *Twaka Doshahara*, *Shothahara* (anti-inflammatory), *Vatahar* (allivate vata), *Vishaghna* (antimicrobial) and it is useful in *Vrana Ropana* (wound healing).^[10] *Snuhi* has the properties like *Laghu*, *Rooksha Guna*, *Ushna Veerya*, Karma:- *Kaphavatahara*, *vedanasthapana*, *lekhana*, *tikshnavirechaka*, *raktashodhaka*, *shothahara*, *kaphanissaraka*, *twakadoshahara* and useful in Immunomodulatory Activity^[11] Wound healing Activity^[12] Anti-Bacterial activity^[13] Hepatoprotectiveactivity^[14] Anti-inflammatory-Analgesic activity.^[15]

Due to all above properties, *Kshar Sutra* have the properties like *Chhedana*, *Bhedana*, *Lekhana*, *Krimighna*, *Vrana Shodhaka* and *Vrana Ropaka*. The effect of *Kshar Sutra* has the

combined effect of all ingredients and found effective in cutting and healing of the fistulous tract. *Kshar Sutra* cuts unhealthy portion of the tract and provides simultaneous healing due to above properties. Hence, it advances tract outwards day by day and the length of the tract cut by the *Kshar Sutra* which was measured as the Unit Cutting time (UCT). Healing from the base of the fistulous tract runs parallel to the cutting of tract. Ultimately, one day the *Kshar Sutra* comes out by cutting through the entire fistulous tract with simultaneous healing from its base. At last, a small linear scar remains at the site of fistula. The *Chhedana Karma* of the *Kshar Sutra* is facilitated by *Vrana Shodhana*, *Vrana Ropana*, *Sophahara*, *Krimighna* and *Vishaghna Karma*. It reduces inflammation by *Shophahara Karma*. Due to *Krimighna* and *Vishaghna* properties, it destroys the micro-organisms in the tract and thus controls the infection at local site. In cases of fistula-in-ano infection is one of the factors which do not allow to heal fistula. With the *Vrana Shodhana* property, it keeps the tract clean, providing the *Suddha Vrana Avastha* and only a *Suddha Vrana* can heal properly. Due to *Vrana Ropana Karma* of the *Kshar Sutra*, the healing process runs simultaneously. As a whole, it can be said that the *Kshar Sutra* acts by gradual chemical excision of the *Bhagandara* (fistula - in-ano) with simultaneous healing of tract as observed in this study.

PROBABLE MODE OF ACTION OF NAVKARSHIK GUGGULU

Navkarshik Guggulu was prescribed in *Vati* form, 500 mg 2 times a day up to completion of the treatment. The ingredients of *Navkarshik Guggulu* are *Bibhitaki*, *Haritaki*, *Amalaki*, *Pippali* and *Suddha Guggulu*. *Triphala* having properties of *Kashaya*, *Tikta Rasa*, *Ruksha Guna*, and *Mridu-Anulomaka* worked as *Kledashamaka*, *Puyakandunashaka* and *Vranaropaka*. Individually, *Haritaki* is an *Ushna* and *Anulomaka* drug can act as *Ama Dosha* and *Mala Pachana* and *Nirharana*. *Pippali* having *Rasayana*, *Madhura Rasa*, *Anushna guna*, it can act as *Shulaghna*, *Shothahra* and *Navadhatunirmana*. So, it's helped in the post-operative pain management and also in wound healing. *Guggulu* is *Sukshma*, *lekhnika* and *Sara* which helped in *Shodhana* and *Ropana* of fistulous tract. Due to *Jantughna* properties of *Guggulu* its also use as antibiotic. Finally, it can be summarised that *Navkarshik Guggulu* is an anti-inflammatory, analgesic and antibiotic drug.

CONCLUSION

Aim of present study is to find out the efficacy and applicability of Apamarg Kshar Sutra in the management of Bhagandara. Based on the above clinical statistical data it may be concluded as follows.

- kshar sutra is more effective.
- A fistula-in-ano is an epithelial-lined tract connecting the anal canal to the perianal skin. Anal fistulas can have many causes but are most commonly the result of an anorectal abscess.
- It has shown better UCT and it can be useful in recurrence / fibrosed fistula in-ano.
- It causes more burning sensation in Pitta Dosha predominant patients.
- The result of the effects of the therapies on Pain, Discharge, Itching, Burning Sensation and Healing Status were found statistically highly significant.
- No any complication and recurrence were seen during follow-up period.
- There was not any adverse effect of any of the drugs observed during the course of study.
- The Age group Above 35 yrs. showed better result in the treatment on Parameters with respect to Age group Below 35 yrs. This was probably due to their Paripakwa Dhatu which entails the beneficial effect of medicine.
- Majority of the patients had complained of discharge during the treatment period.
- Kshara Sutra a para-surgical procedure can be practiced with minimum operative set up and is a well-established method for treatment of Bhagandara (fistula-in-ano).
- Wound healing after cut through was faster.
- Most commonly practiced surgical “lay open” technique to treat fistula-in-ano (a common anorectal pathology) has high rate of recurrence and anal incontinence. Alternatively, a nonsurgical cost-efficient treatment with Kshar sutra (cotton Seton coated with Ayurvedic medicines) has minimal complications.

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