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Comparative study of standardized *apamarga ksharsutra* and traditional *ksharsutra* in the management of *bhagandara* w. s. r. fistula in ano.

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Abstract:

Fistula in Ano is condition which has been recognized as difficult surgical diseases in all ancient & modern medical sciences of the world. In Ayurvedic text it is described as Bhagandara. Ksharsutra is a unique and an established procedure for the management of Bhagandara in Ayurveda. It has brought upheaval in the Indian system of Surgery. The aim of the study was to compare standardized or traditional ksharsutra therapy in the management of fistula in Ano.

Materials & methods- The study was randomized clinical trial carried out at anorectal unit of Shalya tantra department of College of Ayurved, Bharati Vidyapeeth Deemed to be University, Pune. The technique involved passing a medicated *seton* (*Ksharsutra*) through fistulous tract. 40 patients with fistula in Ano were selected and divided into two groups of twenty patients each. Group A was treated with standardized ksharsutra and Group B with the traditional ksharsutra.

Result- The healing occurred in all patients treated either with standardized or traditional ksharsutra. The average unit cutting time was 5.8 for standardized ksharsutra and 6.7with traditional ksharsutra. Statistical analysis was done.

Keywords- *Bhagandara*, fistula in Ano, *ksharsutra*

Introduction (Back ground information)

Bhagandara (Fistula in Ano) at modern parlance is a common anorectal condition prevalent in the populations worldwide and its prevalence is second highest after *Arsha* (hemorrhoids). Fistula in Ano is a tract lined by granulation tissue which opens deeply in the anal canal or rectum & superficially around the anus.[1]Although the four modalities for the treatment of Bhagandara have been described, Kshara is a widely used form. It promises to be an efficient form of treatment[2-5]. Hence this is the field we decided to exploit. In modern science surgery is one of the methods of treating Bhagandara. *Kshara Sutra* is one

of the chief modalities in the treatment of *Bhagandara* in Ayurvedic science.[6-7]

Exploration of the Standardised ksharsutra as a better substitute to traditional *ksharsutra* is the need of the hour. The rational of the study is to find out an effective alternative as Standardised preparation of *Apamarga ksharsutra* over a ksharsutra made by traditional method.

Ksharsutra is a scientifically validated treatment in the management of *Bhagandara. Ksharsutra* treatment heals the fistulous tract with the integrity of sphincters and the existing data reveal negligible chances of recurrence.

The *Apamarga ksharsutra* is well proven to be an effective treatment for fistula in Ano, so we decided to use Apamarga ksharsutra manufactured with specially designed machine which provides firm and smooth layered ksharsutra. It has also unique packaging which avoids loss of kshara from ksharsutra.

Need of the study

All previous research was done on various types of ksharsutra and its comparative study and other form of treatment modalities. But here we explored a new manufacturing method for ksharsutra preparation. Its unique trial ever as far as previous study was concerned.

Traditional ksharsutra may loss its coatings and uniformity while packaging. Also may cause infection due to handling. So we decided to use standardized ksharsutra.

CCRAS also prioritized the invention of such ksharsutra made with automated machine.

Aim and Objectives

Aim: 'To evaluate the efficacy of Standardized Apamarga *ksharsutra* in the management of *Bhagandara'*.

Objectives: To compare the clinical efficacy of Standardized Apamarga *ksharsutra* with traditional ksharsutra.

Hypothesis: Standardized *ksharsutra* works better than traditional ksharsutra.

Materials and methodology

The study was randomized clinical trial carried out at OPD/IPD of ano-rectal unit of *Shalyatantra* department of College of Ayurved, Bharati Vidyapeeth Deemed to be University, Pune. Ethical committee permission was taken prior to study. The technique involved passing a medicated seton (Ksharsutra) through fistulous tract. 40 patients with fistula in Ano (Bhagandara) were selected and divided into two groups of twenty patients each. Group A was treated with standardized ksharsutra and Group B with the traditional ksharsutra

- **Group A-** 20 patients (Standardised Apamarga ksharsutra)
- **Group B-** 20 patients. (Traditional ksharsutra)

Preparation of ksharsutra:

Standardized Apamarga ksharsutra prepared with specially designed machine, which gives uniform coating of snuhi latex as well as Apamarga kshara. It also provides unique packaging to avoid loss of kshara from sutra. Traditional ksharsutra prepared according to acharya chakradutta as snuhi and haridra.

***Method of* ksharsutra *Application*:-**

- Pre-operative preparation
- Operative procedure ksharsutra ligation under spinal Anesthesia
- Postoperative measures
- Ksharsutra Changing on every7th day after ligation of ksharsutra till cutting of tract.

Selection and exclusion criteria of study participants

Inclusion criteria:-

1. Patients having anal fistula were randomly selected.
2. Selection is irrespective of sex, religion & socio- economical class.
3. Age between 15 to 60 years.

Exclusion criteria:-

1. Patients having bleeding disorders, patients on anti -coagulation drugs and Ca rectum.
2. Patient of age below 15 year & above 60 years were excluded.
3. Pregnant women.
4. Chronic or acute ulcerative colitis.
5. Intestinal and pelvic malignancies.
6. Veneral diseases and HIV.
7. Multiple fistulae originating mainly due to Tuberculosis.
8. Crohn's disease.
9. Uncontrolled DM

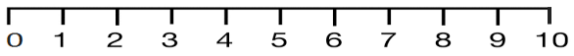
Efficacy parameters.

Criteria of Assessment:

Subjective parameters

A} PAIN – By visual analogue scale

Pain will be assessed by visual analogue scale.



- Mild - 0 - 1
- Moderate - 2 - 5
- Severe - 6 - 8
- Unbearable - 9 – 10

B} ITCHING ;-

- No Itching- - 0
- Mild & occasional- 1
- Moderate & occasional- 2
- Moderate & Frequent - 3
- Severe & continuous - 4

Objective parameters

A} DISCHARGE

- No Discharge - 0
- Mild (If wound wet 1 cm gauze piece)- 1
- Moderate (If wound wet 2 cm gauze piece) - 2
- Severe (If wound wet more than 2 cm gauze piece) - 3
- Excruciating (continuous & profuse) - 4

B} NATURE OF DISCHARGE

- Blood -0
- Serous -1
- Purulent- 2

C} LENGTH OF TRACT

Initially length of tract is measured with the help of probe and length of thread/ksharsutra within the tract then on

every follow up length of previous ksharsutra within tract is measured with scale and considered as length of tract.

D} UCT (UNIT CUTTING TIME)

UCT= Total No. of days taken to cut through / Initial length of tract in cms

= Days/cms.

Investigations

Routine hematological, biochemical, urine and stool examinations were done to rule out the pathological conditions mentioned above.

Radiological examinations

1. X-ray chest PA view (if required)
2. Fistulography (in high anal and recurrent fistulae)
3. MR fistulogram (if required and in selected cases)

Follow Up:-

Follow up is taken on 1st, 7th & 14th days and observations recorded in a tabular form.

Observations –

Table 1- Incidence of age

Age group in years	**No of patients. A- Group (standardized)**	**No of patients. B- Group (Traditional)**	**Total**
Up to 20 yrs	02	01	03
21-30 yrs	06	05	11
31-40 yrs	08	09	17
41-50 yrs	02	03	05
51 and above	02	02	04
TOTAL	20	20	40

Table 2- Incidence of Sex

Sex	No of patients. A- Group (standardized)	No of patients. B- Group (Traditional)	Total
Male	13	11	24
Female	07	09	16
TOTAL	20	20	40

Table 3- Types of Bhagandara

Types of Bhagandara	No of patients. A- Group (standardized)	No of patients. B- Group (Traditional)	Total
Shataponaka	02	01	03
Ushtragreeva	03	03	06
Parisravi	11	14	25
Shambhukavarta	03	02	05
Unmargi	01	00	01
TOTAL	20	20	40

Table 4- Types of Fistula in Ano

Types of Fistula in Ano	No of patients. A- Group (standardized)	No of patients. B- Group (Traditional)	Total
Sub cutaneous	03	04	07
Sub mucous	05	03	08
Low anal	10	12	22
High anal	02	01	03
TOTAL	20	20	40

Table 5- Incidence of new and old cases

New and old(recurrence) cases	No of patients. A- Group (standardized)	No of patients. B- Group (Traditional)	Total

New cases	16	18	34
Old/recurrent cases	04	02	06
TOTAL	20	20	40

Table 6- Incidence of clockwise position of external opening

Clockwise position of external opening	No of patients. A- Group (standardized)	No of patients. B- Group (Traditional)	Total
1	00	01	01
2	01	02	03
3	01	01	02
4	02	02	04
5	04	04	08
6	03	02	05
7	01	00	01
8	02	01	03
9	02	02	04
10	01	01	02
11	02	04	06
12	01	00	01
TOTAL	20	20	40

Table 7 - Incidence of initial length of tract

Initial length of tract	No of patients. A- Group (standardized)	No of patients. B- Group (Traditional)	Total
Up to 5cm	12	10	22
5.1-10cm	04	07	11
10.1-15cm	03	02	05
Above 15 cm	01	01	02
TOTAL	20	20	40

Table 8 - Incidence of UCT with different clockwise position

Clock wise position	UCT A- Group B- (standardized)	UCT C- Group D- (Traditional)
1	5.7	6.9
2	6.2	6.5
3	5.5	7.4
4	5.8	6.7
5	5.5	6.9
6	5.7	7.5
7	5.3	6.8
8	6.5	7.0
9	7.2	5.2
10	5.8	6.4
11	5.6	6.8
12	6.4	6.5
TOTAL	20	20

Table 9 - Average UCT in both groups

Standardized ksharsutra A Group	**5.8**
Traditional ksharsutra B Group	**6.7**

Discussion

1) Incidence of fistula in ano is more common in the age group 31-40 years.(Table no.1)
2) Males are more prone to *Bhagandar* i.e. fistula in ano as compared to females. (Table no.2)
3) In this study maximum patients having *parisravi bhagandar* were recorded as compared to other type of *Bhagandar*. .(Table no.3)
4) Maximum patients of low anal fistula were recorded during the study as far as types of fistula are concerned. .(Table no.4)
5) New or fresh cases are more in numbers as compared to old or recurrent cases. . (Table no.5)
6) 5 clock position of external opening is found in maximum 8 patients compared to other position. .(Table no.6)

7) Initial length of tract i.e. up to 0-5cm is recorded in maximum 22 patients. .(Table no.7)
8) Maximum UCT in Group A was 7.2 at 9 0 clock position& minimum UCT was 5.3 at 7 0 clock position.
9) Maximum UCT in Group B was 7.5 at 6 0 clock position& minimum UCT was 5.2 at 9 0 clock position.

Conclusion:

Average UCT in group of standardized *ksharsutra* is 5.8.Average UCT in group of Traditional *ksharsutra* is 6.7. So results indicates that standardized *ksharsutra* is statistically more effective than traditional *ksharsutra*.

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