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### RESEARCH ARTICLE

#### STUDY THE EFFECT OF AUTOMATED APAMARGA KSHARSUTRA IN THE MANAGEMENT OF BHAGANDARA.

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#### Abstract

Bhagandara is a condition described by various acharya in Ayurveda as a difficult disease to treat. It also considered as Ashtaumahagada means eight grave diseases. Ksharsutra is the prime treatment for Bhagandara. Ksharsutra is a unique and an established procedure for the management of Bhagandara in Ayurveda. This method is well accepted by modern surgeons too. Standardization of ksharsutra is the need of the hour. Therefore decided to work on a standardized form of ksharsutra as automated ksharsutra means machine made ksharsutra, to overcome the drawbacks of traditional ksharsutra.

**Materials & methods-** The study was a single blind clinical trial carried out at BharatiVidyapeeth Deemed to be University, College of Ayurved and hospital Pune. The procedure involved ligation of automated ksharsutra through Bhagandara or a fistulous tract, made over a specially designed machine. 20 patients with Bhagandara (fistula in Ano of crypto glandular origin) were selected and treated with ksharsutra. Every time ksharsutra was changed on every 7<sup>th</sup> day till cutting of tract.

**Result-** The cutting and healing occurred in all patients treated with automated ksharsutra. Although in this study cutting is faster followed by healing. The average unit cutting time was 5.8 with automated ksharsutra.

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#### Introduction:-

*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). In the present study, Ksharsutra application was used in the management of Bhagandara. Although the four modalities for the treatment of Bhagandara have been described, Kshara is the most used form.<sup>1-4</sup> It promises to be an efficient form of treatment. 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.<sup>5-6</sup>

Exploration of the Automated Standardisedksharsutra as a better substitute to traditional *ksharsutra* is the need of the hour. The rational of the study is to find out an effect of automated ksharsutra in the management of Bhagandara.

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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 explore a new manufacturing method for *ksharsutra* preparation. Its unique trial ever as far as previous study was concerned.

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

#### **Aim and Objectives:-**

##### **Aim:-**

'To study the effect of Automated Standardized *Apamargaksharsutra* in the management of *Bhagandara*'.

##### **Objectives:-**

To innovate new method of preparation of *ksharsutra*.

##### **Hypothesis:-**

Automated *ApamargaKsharsutra* has better cutting and healing effect.

#### **Materials and methodology:-**

The study/clinical trial was carried out at OPD/IPD of Shalyatantra department of College of Ayurved and hospital, Bharati Vidyapeeth Deemed to be University, Pune. The procedure involved ligation of automated *ksharsutra* through *Bhagandara* or a fistulous tract, made over a specially designed machine. 20 patients with *Bhagandara* (fistula in Ano of crypto glandular origin) were selected and treated with *ksharsutra*. Every time *ksharsutra* was changed on every 7<sup>th</sup> day till cutting of tract.

##### **Study group:-**

20 patients (Automated *Apamargaksharsutra*)

#### **Preparation of drug *ksharsutra*:**

##### **Automated *Ksharsutra*:-**

The *ApamargaKsharsutra* prepared by automated machine at Indu pharma (GMP and ISO certified), Jejuri MIDC, Pune.

The contents of *Standardised Ksharsutra* are -

1. *Snuhikshira* (*Euphorbia nerifolia*)
2. *Apamargakshara* (*Achyranthusaspera*)
3. *Haridrachurna* (*Curcuma longa*)

Preparation of *ApamargaKsharsutra* comprises smearing a long barber's linen thread no. 20 sequentially with fresh latex (*Snuhikshira*) of *Euphorbia nerifolia* Linn, a specially prepared alkaline powder known as *Apamargakshara* from *Achyranthusaspera* Linn, and powder of dried rhizomes of Turmeric (*Haridra*) *curcuma longa* Linn.

The thread coated with an automated machine (specially designed for *Ksharsutra* preparation) first with the latex eleven times, followed by seven alternate coating of latex and *Apamargakshara* and dried. In the final phase, three alternate coating of latex and turmeric powder are given and the thread will be dried and sterilized with UV rays. The threads thus prepared enveloped in a unique packing so that *kshara* will be maintained at *Ksharsutra* and loss of *kshara* will be avoided.

Advantage of automated made *Ksharsutra* will be smooth, firm and uniform coatings of *Snuhikshira*, *Apamargakshara* and *Haridra*. It facilitates the cutting and healing property of *ksharsutra* more effectively than manually made *Ksharsutra*.



#### Method of ksharsutra ligation:-

1. Pre-operative preparation
2. Operative procedure ksharsutra ligation under spinal Anesthesia
3. Postoperative measures
4. Ksharsutra Changing on 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>th</sup> & 28<sup>th</sup> days of follow up till healing of tract.

#### Selection and exclusion criteria of study participants

##### Inclusion criteria:-

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

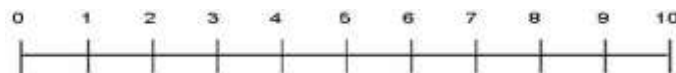
##### Exclusion criteria:-

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

#### Criteria of Assessment:-

##### Subjective parameters

**PAIN** – By visual analogue scale



##### 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)**

$$\text{UCT} = \frac{\text{Total No. of days taken to cut through}}{\text{Initial length of tract in cms}} \\ = \text{Days/cms.}$$

**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 1<sup>st</sup>, 7<sup>th</sup> & 14<sup>th</sup> days and observations recorded in a tabular form.

**Observations –****Table 1- Incidence of age**

Age group in years	No of patients.
Upto 20 yrs	02
21-30 yrs	06
31-40 yrs	08
41-50 yrs	02
51 and above	02
TOTAL	20

**Table 2- Incidence of Sex**

Sex	No of patients.
Male	13
Female	07
TOTAL	20

**Table 3- Types of Bhagandara**

Types of Bhagandara	No of patients.
Shataponaka	02
Ushtragreeva	03
Parisravi	11
Shambhukavarta	03
Unmargi	01
TOTAL	20

**Table 4- Types of Fistula in Ano**

Types of Fistula in Ano	No of patients.
Sub cutaneous	03
Sub mucous	05
Low anal	10
High anal	02
TOTAL	20

**Table 5- Incidence of new and old cases**

New and old(recurrence) cases	No of patients.
New cases	16
Old/recurrent cases	04
TOTAL	20

**Table 6 - Incidence of clockwise position of external opening**

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

**Table 7 - Incidence of initial length of tract**

Initial length of tract	No of patients.
Up to 5cm	12
5.1-10cm	04
10.1-15cm	03
Above 15 cm	01
TOTAL	20

**Table 8 - Incidence of UCT with different clockwise position**

Clockwise position	UCT
1	5.7
2	6.2
3	5.5
4	5.8
5	5.5
6	5.7
7	5.3
8	6.5
9	7.2
10	5.8
11	5.6
12	6.4
TOTAL	20

**Table 9 - Average UCT**

Standardized ksharsutra A Group	5.8
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**Discussion and conclusion:-**

1. Incidence of fistula in Ano was more common in the age group 31-40 years.(Table no.1)
2. Males were more prone to Bhagandara i.e. fistula in Ano as compared to females. (Table no.2)
3. In this study maximum patients having parisravibhagandar were recorded as compared to other type of Bhagandara. (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 were more in numbers as compared to old or recurrent cases. (Table no.5)
6. 5 clock position of external opening was found in maximum 8 patients compared to other position.(Table no.6)
7. Initial length of tract i.e. up to 0-5cm was recorded in maximum 22 patients. (Table no.7)
8. Maximum UCT was 7.2 at 9 o' clock position& minimum UCT was 5.3 at 7 o' clock position. (Table no.8)

**Conclusion:-**

Average UCT of Automated Apamarga ksharsutra was 5.8. It shows good cutting effect followed by healing in spite of simultaneous cutting and healing effect.

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