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 Original Research Paper

 Ayurveda

 CLINICAL STUDY TO EVALUATE THE EFFICACY OF MOCHRAS COATED KSHARSUTRA IN THE MANAGEMENT OF FISTULA-IN-ANO

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ABSTRACT fistula-in-ano is one of the grave and notorious disease due to its recurrence nature. Ksharasutra is para-surgical procedure effectively used in the management of Anal fistula. In this study snuhi latex was replaced by Mochras resin, thus new Mochras coated ksharasutra was made to cure anal fistula. **Aim:** To evaluate the efficacy of Mochras coated ksharasutra in the management of fistula-in-anoand to promote healing process & prevent reoccurrence of disease. **Material & Method:** The research study was performed with 30 patients of fistula-in-ano which were randomly divided in two equal group A & B of each 15 patient. Group A patient were treated with Standard/Apamarga ksharasutra and group B with Mochras coated ksharasutra. Patient were assessed on both subjective parameters i.e., pain, itching, burning sensation and objective parameter i.e., tenderness, pus discharge, unit cutting time (UCT) with "Healing status". Ksharasutra was effective in relieving all symptoms and showed statistically significant result in pain, itching, burning sensation & discharge while tenderness showed nonsignificant result. The mean UCT of group A was 7.56 days/cm while group B was 8.57 days/cm. Mochras ksharasutra has provided better Healing status i.e., wound healing due to varna ropanam & sandhanam property of mochras.

KEYWORDS : Bhagandara, fistula-in-ano, Mochras resin, Mochras coated Ksharasutra.

INTRODUCTION

Fistula-in –ano is a track lined by unhealthy granulation tissue which connects deeply in the anal canal or rectum and superficially on the skin around anus. Ksharasutra is para-surgical procedure which is found to be effective in the management of fistula-in-ano. Ksharasutra is basically a medicated thread having the coating of alkali material called Kshara. Kshara is prepared by using the ash of plant. Ksharasutra is routinely prepared with Snuhi Ksheera (latex), Apamarga Kshara and Haridra powder. In conventional method collection of Snuhi latex is time consuming and laborious.

Thus, we prepared new, advanced, remodeled ksharasutra i.e., *Mochras coated ksharasutra* for ligation. Here Snuhi ksheer was replaced by Mochras resin. *Mochras* i.e., gum resin of Salmalia Malabarica is easily available drug, can be kept for longer period & very safe to use. Mochras which is astringent³ in nature checks abnormal secretions, discharge, microbial growth⁴, bleeding and pain⁵. It pacifies kapha, pitta & Rakta, relieves bleeding disorder and burning sensation⁸. It promote wound healing⁷, good for binding purpose and used to reduces the symptoms & side effect of pain, itching, burning sensation, tenderness, discharge etc., While snuhi sheer availability is difficult, can't be kept for longer period, dry fast, unsafe and has many side effects.

AIMS & OBJECTIVES

1. To evaluate the efficacy of Mochras coated ksharasutra in the management of fistula-in-ano (*Bhagandara*).

2. To compare the efficacy of Mochras coated ksharasutra with Standard/Apamarga ksharasutra in the management of fistula in ano (*Bhagandara*).

3. To reduce the side effect of pain, itching, burning sensation, tenderness, discharge etc.

4. To compare the Unit Cutting Time of both Ksharasutra.

5. To promote healing process and prevent recurrence of disease.

6. To make treatment economical, easily available and use of sterile ksharasutra.

Clinical Study: MATERIAL & METHOD:

Study Design: Randomized Control Trial, Single Blind Trial.

Ethical Clearance:

This study was approved by Institutional Ethical Committee (IEC) of DSRRAU, Jodhpur with letter No. DSRRAU/UCA/IEC/17-18/45; dated 08/03/2017, before starting the clinical trial on patients of Fistula-in-ano.

Subjects:

The study was performed with 30 patients of Fistula-in-ano which were divided in two equal group of each 15 patients.

Selection Of Patient:

All the patients were randomly selected from the I.P.D. and O.P.D. of Ano Rectal Unit, Dept of *Shalya Tantra*, D.S.R.R.A.U., Jodhpur and registered for the present study.

The Drugs: Two types of Ksharsutra are as following...

- 1. Standard/Snuhi Apamarga Ksharasutra
- 2. Mochras coated Ksharasutra

Material Required For Ksharasutra Preparation –

- 1. Standard KsharaSutra (SnuhiApamargaKsharasutra)
- 1. Barbour's linen thread No.20
- 2. SnuhiKsheer
- 3. ApamargaKshar
- 4. Haridra Powder

2. Mochras Coated Ksharsutra (mochras Apamarga Ksharsutra)

- 1. Barbour's linen thread No.20.
- 2. Mochras Resin
- 3. Distil water
- 4. ApamargaKshar
- 5. Haridra Powder

Preparation Of Ksharsutra:

Mochras Coated Kshar Sutra (Mochras Apamarga

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Ksharsutra)

Method of Preparation: The method is same as preparation of Snuhi Apamarga Ksharsutra, except instead of Snuhiksheera, Mochras solution was used.

- To get semi liquid form of *Mochras* gum resin (collected from market), 1 part of mochras powder(5gm) was added in 2 parts of distill water (10 ml) & stir well so that it becomes pure & of desired consistency.

- Surgical Barbour's thread No.20 was tied through length on hanger.
- The Mochras solution was smeared on thread and hanger was dried under fan.
- The process repeated for 11 days, on 12th day again, the thread was smeared with *Mochras* solution & then coated with fine powder Apamarga kshar and then dried.
- The same procedure was repeated 7 days. On 19th day the thread was smeared with *Mochras* solution and fine powder of *Haridrachurna* coated over it and dried.
- The procedure was repeated for 3 days and dried.
- Prepared both Ksharsutra were kept in Ksharsutra cabinet for 12 hr. for 2 days under U.V. light radiation for sterilization.
- Then Ksharsutra was kept in air tight poly bags under proper hygiene using fumigate room, sterile gloves, mask and cap.

The *Mochras Coated Ksharsutra* contains the following ingredients –

Mochras-11 coating Mochras&ApamargaKshara-7 coatings Mochras&Haridra-3 coating

Criteria for selection of the patients:

Exclusion criteria:

Patients suffering from fistula in ano associated with following disease/criteria were excluded from study: Diabetes mellitus, Ulcerative colitis, Crohn's disease, Tuberculosis, CA of rectum, AIDS, Hepatitis B, Children.

Inclusion Criteria:

 All the diagnosed patients of fistula in ano between the age group of 20-70 yrs. other than those in exclusion criteria.
 Patients were selected randomly, irrespective to sex, economic status, educational status & marital status etc.

Duration Of Study:

The duration of the study was 8 weeks with 8 weeks of follow up.

Assessment Criteria: Assessment Criteria Through Modern Parameters:

- Subjective criteria: Pain, Itching, Burning sensation
- Objective criteria: Tenderness, Pus discharge, U.C.T.(Unit cutting time)

Grading of Assessment criteria:

Subjective Criteria:

It is based on feeling of patients. So, researcher has to depend on his patient for assessment. It is known as simple verbal scale. In this particular research work, subjective criteria are as follows:

Pain:

Pain is measured by Visual Analogue Scale. An imaginary line of 10cm will be marked to indicate intensity of pain to assess the pain in patients.

Grade	Explanations		Total number of days (from the 1^{st}
0	: No complain of pain	U.C.T. =	day to cut through the thread)
1	: Negligible or tolerable pain, no need of medication	0.0.1. =	Initial length of ksharasutra (in cm)

2	:	Localized tolerable pain relief by hot sitz bath
3		Tolerable pain, not relief by hot sitz bath, relived by oral analgesic.
4	:	Continuous and intolerable pain with sleep disturbance

Itching

Grade		Explanations
0	:	No complain of itching
1	:	Negligible itching, with 10-12 hours gap
2	:	Occasional itching, with 4-6 hours gap
3	:	Frequent itching, with 2-3 hours gap
4	:	Frequent & intolerable & continuous itching
		sensation

Burning

Grade		Explanations
0	:	No complain of burning sensation
1	:	Negligible burning sensation
2	:	Occasional tolerable burning sensation, relieved
		by oleation.
3	:	Constant tolerable burning sensation, slightly
		relived by local oleation
4	:	Intolerable burning sensation makes the patient
		uncomfortable and makes the patient to rush for
		medical help.

Objective Criteria:

The patients were assessed on the basis of relief of symptom and Investigation.

Tenderness-

Tenderness is mainly graded in two types Deep & superficial, and it detected by noticing the facial expression of the patient during examination.

Grade

Grade		
0	:	No tenderness detected
1	:	Slight /very pain detected on excessive pressure
2	:	Superficial pain detected on moderate pressure
3	:	Deep pain elicited on mild pressure
4	:	Very severe deep tenderness (pain on touch)
		detected.

Pus Discharge

Grade		
0	:	No discharge
1	:	Very scanty pus discharge was present while probing.
2	:	Scanty pus discharge was present without probing.
3	:	Profuse pus discharge came out while probing & squeezing the cavity
4		The cavity was filled with pus and continuous flowing of pus was elicited without squeezing the cavity

U.C.T. (Unit cutting time) -

The initial length, as well as the length of ksharasutra at each successive sitting has been measured and recorded. The gradual shortening of thread at the following sitting evidently corresponds to the cutting of tissue, which provides on idea of the progress of a particular case. This has been termed as unit cutting time (U.C.T.). Unit cutting time may be calculated as follows.

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Healing Status Of Wound

"Healing status" was divided in the following categories.

· 1) Complete healing	6/6
·2) Moderate healing	4-5/6
· 3) Mild healing	2-3/6.
·4) No healing	0-1/6

Statistical Analysis:

All in information which are based on various parameters was gathered and statistical calculation were carried out in terms of mean score Before treatment (BT), After treatment (AT), mean (x), standard deviation (S.D.) standard error (S.E.), Paired test (t value), Mann-Whitney Test (U test) and finally results were incorporated in term of probability (p) no.

p≤0.01 Significant(S) p≤0.001 Extremely Significant (E.S)

OBSERVATION & RESULT

Table: I & Figure: 1 Showing Intergroup Comparison of Group A(Standard ksharsutra) & Group B (Mochras ksharsutra)

S.	Assessm	nent	% Improv	vement	U	Р	Result
No.	Criteria		Group A	Group B	Value	Value	
1.	Pain		89.1%	95.1%	77.00	0.04	Signific
							ant
2.	Itching		85.6%	93.7%	76.500	0.04	Signific
	_						ant
3.	Burning		86.1%	97.3%	77.00	0.03	Signific
	Sensatio	n					ant
4.	Tenderne	ess	89.4%	94.4%	110.50	0.93	Not
							Signific
							ant
5.	Pus Disc	harge	86.1%	97.4%	76.00	0.04	Signific
							ant
100.0				97,39%			97.42%
98.0 96.0		5.13%	93.76%		94.4	16%	
94.0 92.0	10%						
90.0	89.18%				89.50%		
88.0		8	5.70%	86.13%		86.	13%
84.0	00%						
82.0							
78.0					5 B		
	Pai	n	Itching	Buming Sensation	Tendern	ess Pus	Discharge
		% Improv	ement Group A	s Impro	vement Gro	oup B	

Figure: 1

Table: II & Figure: 2 Showing Result Of Objective Parameter I.e Average U.C.T Of Both Groups:

S. No	Groups	No. of Patient	s Average U.C.T (Days/ cm)
1	Group A	15	7.5
	Standard Ksharsu	tra	
2	Group B	15	8.5
	Mochras Ksharsuti	ra	
	8.8 8.6 8.4 8.2 8 7.8 7.6		
	7.4		
	7.2	_	
	7	Standard Ksharsutra	Mochras Ksharsutra
Average U.C.T (Days/cm)		7.56	8.57

Table: III & Figure: 3 Showing Healing status of patients according to Ayurvedic parameters:

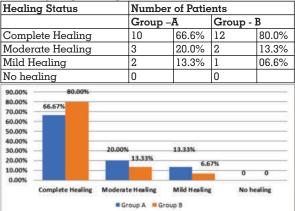


Figure: 3

DISCUSSION ON OBSERVATION AND RESULTS: Discussion On Unit Cutting Time (U.C.T.) • Average Unit Cutting Time:

The average UCT in group A was 7.56days/cm (approx. 7.50 days/cm), in group B it was 8.57days/cm (approx. 8.50 days/cm). The better UCT of group A is due to the properties of Snuhi ksheer. Due to Laghu *Tikshan Guna & Ushna* virya properties of *Snuhi* it enters in the tissue easily and due to chhedan, bhedan, lekhan guna of Kshar, it helps in cutting of the fistulous track, thus provides a better UCT in comparison to Group B.

Comparison Of Results Between Group A and Group B

The patients were assessed per week for continuous 8 weeks. Comparison was done on per week status in two groups and the final results are as follows according to the assessment criteria of disease.

Pain

In Group-A, the percentage of relief in pain are 89.177 % in 8^{th} week while in Group-B 95.133 %. This shows that *Mochras Ksharsutra* has a better pain reliving capacity.

Pain is due to vata, thus most probable cause behind the significant result of *Mochras Kshar-Sutra* in relief of pain is due to *snigdha*, *picchila guna*(sticky or lubricant) of *Mochras*, it forms protective film in track and avoid friction . *Mochras* has also anti-inflammatory action (Archana et al IJAPC 2016). Charak has mentioned Mochras in Vedanasthapana Mahakashya i.e., Sedative/ Analgesic/ sensostatic group of herbs. Thus, it relives pain. (Ch.su.4/47)

Itching

In Group-A, the percentage of relief in Itching, after application of Standard (*Snuhi Apamarga*) Kshar-Sutra is found as 85.698 % in 8^{th} week while in Group-B shows 93.764 %.

This reveals that percentage of relief in Itching was higher in Group B. The predictable cause may be the 'Kapha Pittashamak' property of Mochras. (Mentioned in Bhava Prakash Nighantu, Vatadi varg-29/56-57 Vol-1, Page No.538). Again according to Ayurveda, itching (Kandu) is a property of kapha and Pitta (Ch.su.20/15,) so any drug which will contain the kapha & pitta hara property will definitely play a key role to dwindle the symptom. Mochras pacifies the Kapha due to Kashyaras and pacifies Pitta due to its Sheetviry property., Thus reducing Kandu (Itching).

Burning Sensation

In Group-A, the relief from burning sensation was noticed in a percentage of 86.125% in 8^{th} week while in Group-B 97.394%. The cause behind it is, due to the effect of ushna virya of snuhi

Ksheer, it causes irritation and burning sensation in the fistulous wound, whereas by the effect of snigdha, picchila, him guna and sheet viry & Dahanut(relives burning sensation) property of Mochras, is able to dissolve the burning sensation in group-B(Mentioned in Bhava Prakash Nighantu, Vatadi varg-29/56-57 Vol-1, Page No.538). Burning sensation is caused due to Inflammation may be by the release of Histamine. Anti-inflammatory effect of Mochras and Apamarga (According to Kantha D. Arunachalam et all) may be suppressing release of Histamine, thus relieving Burning sensation. (Archana et al IJAPC 2016).

Tenderness

In Group-A the relief from tenderness was noticed in a percentage of 89.498 % in 8th week while in Group-B 94.458 %. The better result of Mochras Kshar-Sutra is due to the fact that tenderness is due to kapha; Mochras has kapha shamak effect due to laghu guna & kashay rasa (Dravyaguna-vijnana, Prof. PV.sharma, chapter5, page 492) and Kaphanut (shamak) property (Mentioned in Bhava Prakash Nighantu, Vatadi varg-29/56-57 Vol-1, Page No.538)., Thus reducing tenderness.

Anti-inflammatory & Anti-oxidant properties of Gallic acid & Tannic acid present in *Mochras* (Archana et al IJAPC 2016, Rameshwarvet al SAJP 2014) reduces tenderness.

Discharge

In Group-A the relief from discharge was noticed in a percentage of 86.1 % in 8th week while in Group-B 97.4 %. Acharyacharak mentioned Mochras in Shonit Asthapana Mahakashya i.e., group of herbs that checks bleeding. Thus, it cures Hemorrhagic disorder and acts as haemostatics. Mochras checks bleeding discharge from fistulous track. (Ch.su.4/46) Also in Pureesha Sangarhniya Mahakashya i.e. group of herbs that acts on pureeshavahasrotas (ano-rectal region) to checks abnormal secretions, discharge, microbial growth Etc. (Ch.su.4/31).

Mochras mentioned in Kashayaskanda i.e., Astringent group of herbs. It reduces pus discharge, checks bleeding & microbial growth etc. (Ch.vi.8/144)

According to Acharya Bhavprakash Mochras is pittaAsra nut i.e., Pacifies Pitta & Rakta, Him(coolant), Grahi(absorbant), kashaya(astringent) in nature. Thus relieves secretions, Bleeding disorder and reduces the pus discharge. (Vatadi varg-29/56-57)

Pus is due to *kapha*, *Mochras* is *kaphanut* (*shamak*), thus reduces pus discharge.

The reason for which pus discharge increased in the initial stage of treatment is due to the chhedan, bhedan and lekhan properties of kshar, which breaks down the pus pockets of micro abscesses, remained in the diseased track. Accordingly increase in the amount of pus discharge. As it turns to heal up, the discharges get diminished (S.S.38/7).

Another condition for continuous pus discharge is that in most of times, pus discharge is caused by microbial infection in the fistulous track. *Mochras* has antibacterial as well as antimicrobial properties (Antil v. IJPI 2013) thus pus discharge is reduced.

Comparison Of Healing Status According To Ayurvedic Parameter.

Group A – The data shows that complete healing was observed in 66.6% patients. Moderate and mild healing was found in 20.0% & 13.3% respectively.

Group B – Again 80.0% patients achieved complete healing in this group while Moderate and mild healing was observed in

13.3% & 06.6% patients respectively.

It shows that Group B was more healing status than Group A. This is due to more healing property of Mochras. Acharyacharak and Vagbhat mentioned mochras in SandhaniyaMahakashya i.e. groups of herbs are healers of wound. (Ch.su.4/5,As.s.su.15/10).AcharyaSusruta mentioned Mochras in Priyangvadigana i.e. group of herbs are union promoters & beneficial for healing of wounds. (Su.su.38/45). Hence helped in enhancing the healing effect of fistulous track.

The better result of Group-B is due to the specific property of of *Mochras* is *vranaRopana* and *Sandhankarm* which causes *Ropana* of the matured fistulous *vrana*. By the *ropana*-sandhan quality it sloughs away the debridement of necrosed tissue from the fistulous track, thus it helps in formation of healthy granulation tissue. (Su.Su.38/45).

Anti-oxidant & Anti-inflammatory properties of Gallic acid & Tannic acid present in *Mochras* (Archana et al IJAPC 2016, Rameshwarvet al SAJP 2014) also enhances healing process. It was found after cutting and healing of fistulous track, patients of Group-B showed uniform healing, uniform pigmentation giving skin a smooth appearance without any hypertrophy or any bad scar.

Overall Effect Of The Therapy:

In measuring the effect of overall therapy, it was seen that:

- Group A has provided a better result in U.C.T 7.5days/cm in comparison to Group B 8.5days/cm.
- Group B provided a better relief in pain (95.1%), Burning sensation (93.7%), itching (97.394%), Tenderness (94.4%) & discharge (97.4%) in comparison to Group A.
- Group B has provided a better result in intergroup comparison, it has seen that pain, itching, burning sensation and discharge showed significant result while tenderness showed non-significant result but on the bases of percentage pain, itching, burning sensation, tenderness & discharge showed significant results. (Table no. 6.41).
- Group B has provided a better result in Healing status i.e., complete healing with 80.0% in comparison to Group A 66.6%.
- It is seen that application of Mochras Kshar-Sutra provides better result in pain, itching, burning sensation, tenderness & discharge than Standard/Snuhi Apamarga Kshar-Sutra. By studying the overall effect, it can be concluded that trial group-B Kshar-Sutra showed markedly good results.

Probable Mode Of Action Of Mochras Kshar-sutra:

Till today, the detection of mode of action of a Ayurvedic drug or remedy on scientific basis has remained a difficult job for the researchers. In Ayurveda the action of a drug is best understood by the properties of its basic physiochemical factors- Raspanchak i.e., Rasa, Guna, Virya, Vipak and Prabhava. Here, too an effort is made to explain the probable mode of action of MochrasKshar-Sutra on the basis of abovementioned factors.

Fistula is nothing but a continuous track made up of unhealthy granulation tissue which manifests some alarming symptoms i.e. pain, itching, burning sensation, tenderness and most certainly pus discharge continuously flowing from the track.

- Mochrasin combination with Apamarga&Haridra hold of LaghuGuna by which it enter easily into the cell membrane and scrubbed out the necrosed tissue from the track with the help of Ropana and Sandhan property of Mochras.
 - Chhedan, Lekhan & Bhedan properties of Apamarga

Kshara, Teekshna Guna of Apamarga and by the Ushna virya of Apamarga and Haridra. Automatically the pus discharge reduced as a result of breaking of pus pockets of micro abscesses.

- Again, if the pus discharge was continuing due to secondary infection, the *krimighna*, Anti-bacterial, Antiinflammatory property of *Apamarga*& Haridra raise a battle against it.
- Mochras is ShonitAsthapana, PureeshaSangarhniya, Kashaya, kapha pittaAsra nut drug thus checks abnormal secretions. bleeding disorder, discharge, microbial growth etc.
- In most of the time pain causes due to accumulation of pus in cavity. If pus discharge diminishes, naturally pain disappears. Again, it has discussed Anti-inflammatory & Anti-oxidant properties of Gallic acid & Tannic acid present in Mochras (Archana et al IJAPC 2016, Rameshwar v et al SAJP 2014) reduces pain as well as pus discharge. The Snigdh, Pichhil guna and Vedanasthapana (Sedative/Analgesic/sensostatic group of herbs) property of Mochras, Vam Shodhan,Shothhar,shulaghn properties of Apamarga (Dravyaguna-vijnana, Prof. P.V.sharma,chapter5,page 492) and UshnaVirya of Apamarg and Haridra synergistically reduce the Vata, resulting reduction in pain.
- The itching (Kandu) is diminished by the Kapha Piita shamak property of Mochras due to Kashya ras & sheet virya. Apamarga & Haridra both have kandughna property due to Katu tikt rasa & ushna virya. Itching is due to release of histamine, Mochras, Apamarga and Haridra are anti-inflammatory, suppress the release of histamine thus relieving in itching.
- Burning sensation is caused due to ushna, tikshnaguna of snuhiksheer but here Mochras is used in place of SnuhiKsheer, thus reducing burning sensation due to snigdha, picchila, himguna, sheetviry&Dahanut propertyofMochras.
- May be, anti-inflammatory effect of Mochras, Apamarga and Haridra also helps in suppressing release of histamine, thus relieving in burning sensation.
- The Sothaghna and anti-inflammatory property of Apamarga and Haridra reduces the swelling. The Raktasodhak property of Haridra also help in it, thus reducing tenderness. Due to Kaphahar effect of Mochras, Apamarga and Haridra, laghu guna & kashay rasa of Mochras, tenderness is reduced.
- The Kashaya Rasa, VranaRopana and Sandhan property of Mochras&katu, tikt rasa, Vrana Shodhan quality of Apamarga and Haridra, Tavakdoshahar Apamarga and Vraniya, Rakt Prasad property of Haridra help in heal up the fistulous track.
- Anti-oxidant property of Mochras also enhances healing process.

CONCLUSION:

In this study efficacy of Mochras coated Ksharsutra (MochrasApamarg ksharsutra) was compared with Standard ksharasutra (Snuhi Apamarga Ksharsutra). Hence the conclusion are as follows:

- On observing the overall effect of therapy Mochras Kshar-Sutra was found to be more effective in relieving symptoms like pain, itching, Burning sensation, tenderness and pus discharge.
- Mochras Kshar-Sutra has provided a better result in intergroup comparison, pain, iching, burning sensation and discharge showed significant result while tenderness showed non-significant result.
- Though U.C.T of Mochras Kshar-Sutra is slightly higher than Standard/ Snuhi Apamarga Kshar-Sutra, but in assessment parameter Mochras Kshar-Sutra has been shown significant result in the form of percentage.
- Mochras Kshar-Sutra has provided a better result in

Healing status.

- Mochras Kshar-Sutra provides better wound healing due to Varna Ropanam&sandhanam property of Mochras. Due to alkaline pH of Kshara pathogens does not multiply and invade the cavity.
- Haridra is used for preparation of ksharasutra provides faster wound closure or healing effect.
- Post ligation complications like hypertrophied scar etc., are not seen.
- Easily available and cost effective.
- Mochras Kshar-Sutra should be used in combating this disease with further more research work.
- No recurrence of case was found in eight weeks of short follow-up study.

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