Anal manometry study in guggulu based kshara sutra in the management of fistula in ano

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Abstract

Anal manometry can be regarded as single most important investigation to study ano-rectal sphincter mechanism. In the Ayurvedic text, fistula in ano has been described as "Bhagandara". Sushruta (800 B.C.) has adopted surgical, para surgical and conservative measures for the fistula in ano. Under the para surgical management 'Ksharsutra' also known as a medicated thread had been introduced. There is growing evidence that even division of the internal anal sphincter, leaving the puborectalis and external sphincter undisturbed, may cause impaired continence after successful elimination of the fistula. These conflicting objectives pose a challenge for the colorectal surgeon. In one hand recurrent sepsis and fistulation must be avoided, and on the other hand continence must be preserved. The present study was conducted at the Ano-rectal Clinic at Gampaha Wickramarachchi Ayurveda Teaching Hospital. 100 patients participated in the present study – 50 patients of fistula in ano treated by Guggulu based kshara sutra and 50 patients under the control group for the anal prèssure recording by using anal manometer. Pre-treatment, post-treatment and follow up pressure were recorded in the study group. In this study in the patients treated in kshara sutra there were no significant reduction of the resting anal pressure ($P>0.05$) observed either post treatment or follow up, but the squeeze anal pressure was found to be significantly reduced ($P<0.01$) after treatment and it insignificantly reduced ($P>0.05$) in the follow up for high anal fistula.

Introduction

The anorectal disorders have been known to man from its inception of evolution of Medical science. Anorectal disorders are usually not life threatening. They cause a lot of symptoms and social embarrassment through clinical features such as fecal incontinence. The diseases of fistula in ano is a condition therefore which requires in depth study so as to ensure better status of life. In the Ayurvedic text, fistula in ano has been described as "Bhagandara". *Sushruta* (800 B.C.) elaborately described various ano-rectal disorders for the first time in the history among which fistula in ano is a prominent one [1].

Susrutha has adopted surgical, para surgical and conservative measures for the fistula in ano. Under the para surgical management 'kshara sutra' also known as a medicated thread that had been introduced.

Surgical treatment of fistula in ano is associated with significant risk recurrence and high risk of impaired continence. There is growing evidence that even division of the internal anal sphincter, leaving the puborectalis and external sphincter undisturbed, may cause impaired continence after successful elimination of the fistula [2]. Nevertheless, unless all the secondary tracks are also attended to, there is a risk of recurrent sepsis and fistulation. These conflicting objectives pose a challenge for the colorectal surgeon. In the one hand recurrent sepsis and fistulation must be avoided on the other hand continence must be preserved.

Anal manometry [3] can be regarded as single most important investigation to study ano-rectal sphincter mechanism. The balloon system was a convenient method to use, pressure was reproducible and easy to estimate and motility details were well shown [4] was adopted in this study.

The goal of kshara sutra treatment of fistula in ano by virtue of the properties of its content which has necrolytic action on tissues. During application of kshara sutra there is a continuous drainages of fistulous track and ingredients used in the thread help in healing. There is no doubt about the efficacy of kshara sutra treatment in fistula in ano which has been almost confirmed by the modern surgeons [5].

At present no studies have been pursued for regarding the assessment of anal continence and pressure profile of anal canal after the kshara sutra therapy. Therefore factors associated with incontinence have not been assessed. Thus this study focuses on the assessment of the reliability of kshara sutra as a mode of treatment for the fistula in ano.

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The main advantage of Guggulu based kshara sutra was its uniform thickness (non beaded shape), enhanced binding of drugs to the thread less hygroscopic nature and causation of significantly less pain and burning sensation to the patient.

The patients were treated by kshara sutra consisting high anal cases with recurrence having high internal opening or an abscess cavity above the levator ani muscle and supra sphincteric with supra levator abscess. High transsphincteric [6], multiple track and high horse fistula. This type of fistulae invariably ends up with complication after surgery in the form of injury to the anal sphincter leading to incontinence. In this study it has been observed that there are no significant pressure reduction either resting anal pressure or squeeze anal pressure in both post-treatment and follow up.

Materials and Methods

The present study was conducted at the Ano-rectal Clinic at Gampaha Wickramarachchi Ayurveda Teaching Hospital. Thus clinical study was planned on the patients of bhagandara attending the Ano-rectal Clinic. The study was conducted in 100 cases, out of this 50 patients of fistula in ano and 50 patients under the control group (without evidence of anorectal disorders).

The patients were divided into 02 groups of 50 each.

Group - I 50 cases of controls as healthy volunteers.

Group - II 50 cases of fistula in ano treated by kshara sutra treatment.

A. **Selection of controls:**

The patients coming to hospital, surgical out patient department without any evidence of ano-rectal disorder were taken as controls. A thorough questionnaire was made to rule out symptoms of ano-rectal disorder. Any neurological disease was also ruled out.

All patients underwent detailed examination of the abdomen and perianal area including per rectal examination, proctoscopy and anal manometry. These patients were further divided into groups according to sex and age.

B. **Selection of cases:**

Patients coming to hospital surgical out-patient department from March, 2009 to March, 2010 with symptoms of fistula in ano were taken as cases in the study groups. All patients were given the questionnaire to evaluate symptoms and their degree. The cases selected for study groups only had chronic of cryptoglandular origin. All had history of previous perianal suppuration drained either surgically of spontaneously. Patient with superficial fistula associated with fissure, inflammatory bowel disease heamatologic malignancy preoperative incontinence and those who underwent primary fistulostomy at time of draining the access were not included.

Anal incontinence was assessed by using anal manometry and questionnaire from the Cleveland clinic, Oliveira 1996

Incontinence type	*Never*	*Rarely (a) (< 1 month)*	*Sometimes (b) (> 1 month < 1 week)*	*Usually (c) (> 1 week < 1 day)*	*Always (d) (< 1 day)*
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Flatus	0	1	2	3	4
Use of pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

(a) Less than once a month.

(b) More than once a month, less than everyday.

(c) More than once a week, less than everyday.

(d) Everyday.

- Score '0' – Perfect continence
- Score '20' – Complete incontinence

Anal manometry reading

Distance from analverge	Resting	Squeeze Pressure
1 cm		
2 cm		
3 cm		
4 cm		
5 cm		

Internal sphincteric pressure

External sphincteric pressure

All patients were examined in lithotomy position. Fistula was classified according to the criteria of parks et al. Anal manometry in both controls and in patients with fistula in ano was performed by the following technique:

Instrument design and anal pressure recording (anal manometry)

Pressures in the anal canal were measured with a small water filled latex balloon prepared from condom, of approximately one centimeter in diameter. The device was somewhat similar to that, used by Lusnniss et al [7]. This balloon was connected to a "U" tube mercury manometer via a low compliance circuit. The circuit was filled with water and made air free to avoid variations in pressure recordings due to compressibility of air. The probe thus constructed was marked in centimeters to know the proper position of balloon in the anal canal.

All manometric measurements were done without any prior preparation. Patient was kept in left lateral position and after anal inspection to see any external pathology probe with balloon at the tips was inserted up to 1 cm from anal verge with small amount of non anaesthetic lubricating jelly.

After stabilization, i.e. after about 30 seconds, pressure was recorded at 2 cm, 3 cms, and 4 cms, above anal verge. The maximum pressure recorded at any of these positions was taken as maximum resting anal pressure. Then with balloon positioned in the anal canal patient was asked to squeeze the anal canal as if he or she wants to postpone the defecation. The pressure, thus recorded was taken as maximum squeeze pressure. These steps were repeated at least twice and maximum recorded pressure obtained in these steps was taken as maximum squeeze pressure.

Patients were followed up and the symptom analysis as well as manometric evaluation was done after 60 days of kshara sutra treatment.

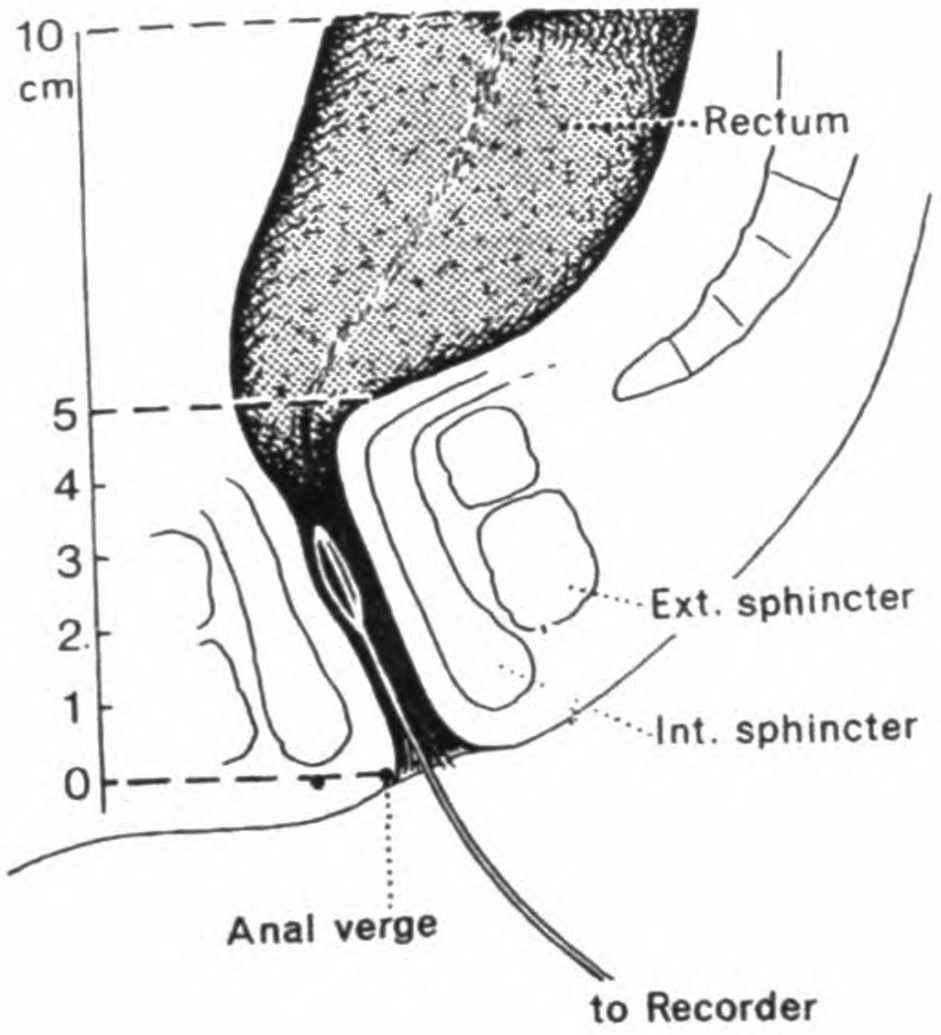

Diagram of the pressure recording units in situ with the help of a small balloon

Observation and Results

Table 1: Mean ± SD value of anal manometric pressure profile (mm Hg) of controls (group- I)

	Overall (n=50)	*Male (n=32)*	*Female (n=18)*
Mean maximum resting pressure	54.40 ±2.87	54.78 ±2.80	53.72 ±2.95
Mean maximum squeeze pressure	116.82 ±5.23	117.81 ±5.42	115.06 ±4.49

The longitudinal resting anal pressure profile of controls by station pullout technique is shown in Figure 1.

Resting anal pressures have been found almost equal at all the stations in both males and females, except at 5 cm from anal verge, where resting anal pressure in females was significantly lower than that in males at same distance.

Figure 1

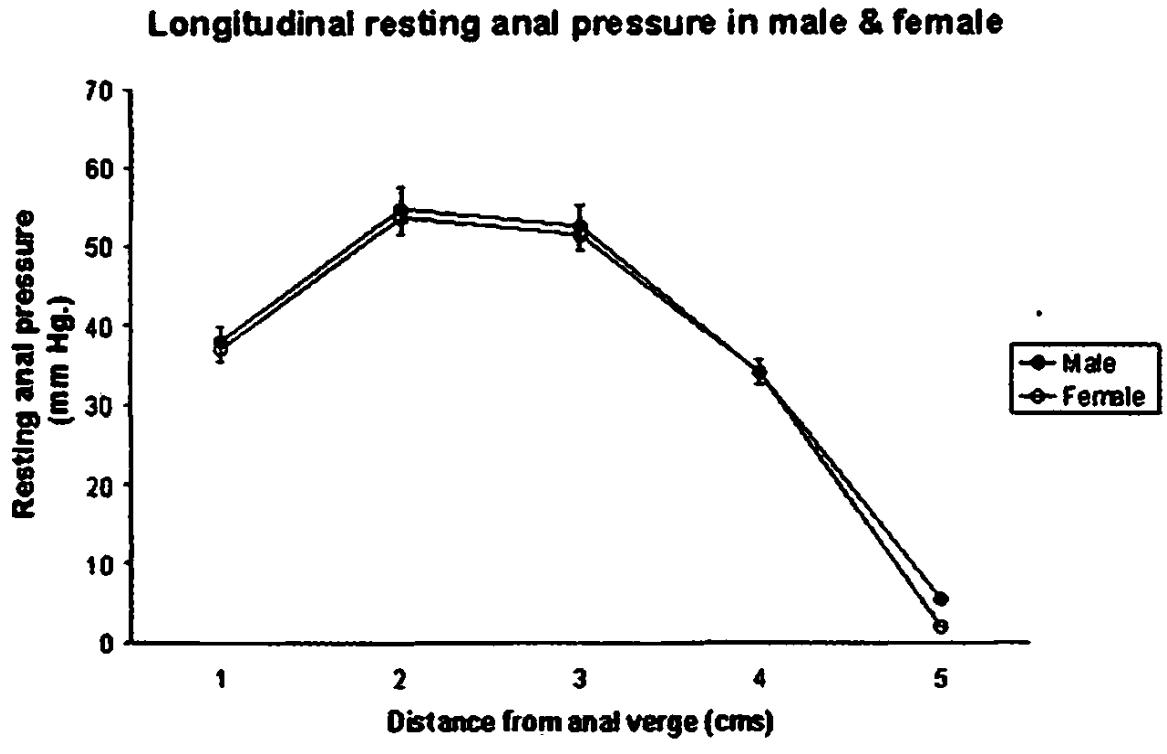

Table 2: Comparison of pre-manometric anal pressure profile in control (group I) and study groups (group- II)

Group	*Maximum resting pressure (mmHg) mean ± SD*	*Maximum squeeze pressure (mmHg) mean ± SD*
Group I control (n=50)	54.40 ± 2.87	116.82 ± 5.23
Group II (n=50)	56.72 ± 4.20	117.80 ± 8.78

Maximum resting anal pressure pre-treatment value have been marginally increased in group II as compared to the control group. This may be due to the inflammatory process of the disease but maximum squeeze anal pressure has not been followed.

In 30 patients of the low anal fistula in group IV whose pre value for maximum resting anal pressure was (55.83 ± 7.54) slightly found to be reduced to (54.70 ± 5.02) in post treatment. This difference was not statistically significant. Maximum squeeze anal pressure was also found to be reduced from pre-value (111.70 ± 5.17) to post value (110.20 ± 6.05) This difference was statistically not significant (Table 3).

Table 3: Maximum resting anal pressure and squeeze pressure in response to kshara sutra treatment (n = 30). (within the group comparison low anal fistula – group II)

Maximum resting pressure (mmHg) mean ± SD			*Maximum squeeze pressure (mmHg) mean ± SD*		
Pre-treatment	*Post-treatment*	*t=test (pre - post)*	*Pre-treatment*	*Post-treatment*	*t=test (pre - post)*
55.83	54.70	t=0.89	111.70	110.20	t=1.24
±7.54	±5.02	p>0.05	±5.17	±6.05	p>0.05
		N.S.			N.S.

Table 4: Maximum resting anal pressure and squeeze pressure in response to kshara sutra treatment (n=20). (within the group comparison high anal fistula – group II)

Maximum resting anal pressure (mmHg) mean ± SD					*Maximum squeeze pressure (mmHg) mean ± SD*				
Pre Treatment	*Post Treatment*	*Follow up*	*t = test (pre-post)*	*t = test (pre-follow)*	*Pre Treatment*	*Post Treatment*	*Follow up*	*t = test (pre-post)*	*t = test (pre-follow)*
54.89	52.65	53.10	t=1.21	t=0.2	110.75	107.50	109.70	t=3.53	t=0.99
±5.02	±6.21	±9.51	p>0.05	p>0.05	±7.47	±7.42	±8.14	p<0.01	p>0.05
			N.S.	N.S.				H.S.	N.S.

20 cases of high anal fistula in group II the maximum resting anal pressure was slightly found to be reduced from pre-value (54.89 ± 5.02) to post-value (52.65 ± 6.21). The pressure value for follow up was 53.10 ± 9.51. Pressure reduction in both the post-treatment and follow up are statistically not significant (Table 4).

Consequently the maximum squeeze anal pressure was also found to be reduced from pre-value (110.75 ± 7.47) to post-value (107.50 ± 7.42).

Table 5: Comparison of the unit cutting time in the group II

Group	*Unit cutting time (U.C.T.) (Days)*
Group II	5.10

Unit cutting time (U.C.T.) is defined as the number of days required for the excision of unit (1 cm) of the fistulous track.

$$\text{U.C.T.} \frac{\text{Total no. of days}}{\text{Initial length in cm}}$$

Table 6: Incontinence and recurrences in kshara sutra group

Group	*Procedure*	*Patients number*	*Recurrence number*	*%*	*Incontinence*	*%*
Kshara sutra group (group II)	Kshara sutra	50	01	1	-	-

1% recurrence was observed in this study but no patient was found to be incontinence in kshara sutra series.

Discussion

Several authors have tried to define manometric values for the normal anal canal. Significant pressure variations have been described in normal subjects chiefly with regard to gender and age.

In this study we didn't get significant difference between the anal pressures for male and female (Table 1).

In this study the resting anal pressure in males at 5cm from anal verge was significantly higher than in females (Figure 1). This indicate shorter anal canal length in females. Though in this study the exact length of anal canal could not be measured which is more precisely measured by perfusion pressure recording system.

There is no significant pressure reduction observed in low anal fistula. So the low anal fistula could be successfully managed without risk because the low anal fistulae the track that does not extend above the level of the anal crypts and indeed usually is formal to be open at this level to the anal canal.

In group II the patient treated in kshara sutra, no significant reduction of the resting anal pressure has been observed either post-treatment or follow up but the squeeze anal pressure was found to be significantly reduced after treatment and it insignificantly reduced in the follow up for high anal fistula.

The high rectal fistulas are the most difficult varieties. It denotes the type of fistula having exceptionally long tracks and includes high anal and anorectal varieties. The high anal fistula lies above the middle belly of external sphincter and the ano rectal varieties lies above the leavatorani muscle [8].

In these cases a vast area of multilation is required during operative procedures resulting in significant fall in resting and squeeze anal pressures and dreadful complications.

The high anal fistulae the track rises to a higher level and is in relation to the upper parts of the anal sphincters, it may extend close to the anorectal ring.

High transsphincteric fistula track passes through both the internal and external sphincters before exiting to the skin and also pass dangerously close to the anorectal ring before it enters the ischeorectal fossa and the perineum. According to the study of Belliveu et al falling in resting pressure to less then 50% of the pre-operative value in patient having trans sphincteric fistuloctomy [9].

The patients consist of group II treated by kshara sutra consist high cases with recurrence having high internal opening or an abscess cavity above the levator ani muscle and supra sphincteric with supra levator abscess. High transsphincteric, multiple track and high horse fistulas. This type of fistulae invariably ends up with complication after surgery in the form of injury to the anal sphincter leading to incontinence. In this study it was observed that there are no any significant pressure reduction in resting anal pressure in both post-treatment and follow up. In the post-treatment a significant reduction of squeeze anal pressure in both groups was observed. It is transient and may be perhaps related to the stage of cutting through the anal sphincters by the thread, which subsequently become complete during the follow up.

Faecal incontinence is mainly caused as a result of direct injury to anal sphincter and also due to the spinal cord injury. There were no incontinence cases observed in the patients treated in kshara sutra of group II.

Conclusions

There is no age or sex related difference in maximum resting anal pressure and squeeze anal pressure. Patients in fistula in ano had marginally higher maximum resting anal pressure compared to the control group, this may be due to the inflammatory process of the disease.

Kshara sutra appear to be the best option for the management of high anal fistula where there were no post-treatment incontinence and least recurrence rate. Further there were no significant reduction of resting or squeeze pressure at the time of follow up.

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