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To evaluate the efficacy of *Gomutra Ghan Sutra* in the management of *Bhagandara* (fistula-in-ano).

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ABSTRACT:

From the onset of civilization, the human being suffered from various diseases and among the many uncomfortable condition, Bhagandara was the one of the most important one. Acharya Sushruta, paid great attention towards Bhagandara. Sushruta while dealing the management of the disease employed surgical, parasurgical measures. In this study, inspite of Standard Ksharsutra i.e. Apamarga Ksharsutra, Arka kshar is replaced by Gomutra ghan. Where, Gomutra Ghan acts as bio-enhancer, antifungal, anti-microbial, anti-bacterial.

KEYWORDS: gomutra ghana sutra, bhagndar, fistula in ano

INTRODUCTION: The Bhagandara is widely prevalent and numerous options are being practiced for its management. However none of them could provide solace to the suffering patients. Ano-rectal disorders are progressively increasing in the society. According to Ayurveda, few important causes are; always riding an

elephant, horses etc., sitting on hard seats and improper sitting posture, indulging factors causing Arsha, practice of Apathya Ahara-vihara, ill deeds of the previous life and outraging of sages. Anorectal diseases like Arsha (piles) and Bhagandara (Fistulain ano) are said callous to be cured and among them Bhagandara is considered under the Ashtoumahagadas (Eight grave disorders).

AIM AND OBJECTIVES:

- 1. To evaluate the efficacy of Gomutra Ghan Sutra in the management of Bhagandara (Fistula-in-ano).
- 2. To compare the clinical efficacy of Gomutra Ghan Sutra with standard (Apamarga) Ksharsutra.
- 3. To establish probable mode of action of Gomutra Ghan Sutra in the management of Bhagandara.
 - 4. To search potent alternative of Standard Ksharsutra with due modification.

REVIEW OF LITERATURE

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AYURVEDIC REVIEW

The Bhagandara considered being one of the 'Ashtoumahagad' (maharog) by the acharyas of Ayurveda. So, they give much importance to its etio-pathogensis and management. It is commonly associated with symptoms like Bhagandar-pidikotpatti (Boils at perianal region), Puyastrava (Pus discharge), Gudakandu (Itching at anal region), Gudavedana (Pain at anal region), etc.

In 'Bruhattrayee' specially Sushtruta Samhita a detailed description including its Gudasharir (Anatomy), Parikshan Nidan (Examination), (Causative factor), Purvarupa, Rupa and Symptoms), Samprapti (Signs (Pathogensis), Sadhya-asadhyatwa (Prognosis), Chikista-upkrama (Medicinal, surgical and Parasurgical procedure) its Upadrava and (complication) is seen.

AYURVEDIC REVIEW OF BHAGANDARA -

Defination -

The daran of Bhaga, Guda and basti (tear in the area of pelvis, rectum and urinary bladder) with surrounding skin surface called Bhagandara. Further he has described that a deep rooted apakva pidika within two angula circumference of Guda Pradesh associated with pain and fever is called Bhagandara pidika. When it suppurates and burst open, is called Bhagandara.

The word 'Daran' means splitting, tearing, rending or making openings in the perianal skin. Hence, in the cases of Bhagandara there are symptoms like irritation, uneasiness and having discharging opening.

Nidan / Aetiology -

Nidan i.e. causes of bhagandara is mainly described by Acharya Vaghbhata as follows –

Traveling on elephant, horses etc. sitting on hard seats and improper sitting posture, indulging factors causing arsha, apathya ahara-vihara, ill deeds of previous life and outranging of sages.

Acharya Sushruta has considered separately the aetiology of bhagandara to each type in relation to the classification of the disease.

Samprapti / Pathogenesis –

No dosha singularly is able to produce the disease. The three doshas take part in development of Bhagandara. Rakta (blood) does not take part as a dosha in the formation of bhagandara. Acharya Vaghbhata has clearly told that bhaganadara is located about one to two fingers away from the anal margin within the rakta and mamsa dhatu. (REF A. H. uttar 28/2-3)

Acharya Sushruta state that mamsa and shonita as the dushya for shatoponaka bhagandara and repeats the 'purvavadaawasthitaha' for the pathogenesis of other variety of bhagandara. (su. Ni. 4/6)

Where, enumerating the inflammatory diseases, Acharya Sushruta has included vidradhi, pidaka, gudapaka and arsha in the category of which owe their origin to rakta. (Ref su. Su. 24/11). In the sharirsthana he also state that the site of bhagandara is mamsadhara kala. According to this data we can say that the vitiated Rakta and Mamsa dhatu produces Bhagandara. The vitiated Rakta burns the Mamsa dhatu and formed the abscess and further discharge also. In this whole procedure pakvawastha of Mamsa its daran occurs and hence abscess followed by nadivrana called bhagandara is produced.

Purvarupa of Bhagandara -

According to Acharya Sushruta, the vitiated dosha take place in guda region get lodged there causing symptoms like, after any travelling or while passing stool there is kandu (kandu), ruja (pain), daha (burning), shofa (swelling), etc. arises at Payu and Guda.

Classification of Bhagandara -

From the text of the different samhitas it is clear that Acharya Sushruta has mentioned that there are five types of Bhagandara according to vata, pitta, kapha, sannipataj and agantuj.

- 1. Shatponak (Vataj)
- 2. Ushtragriva (Pittaj)
- 3. Paristravi (Kaphaj)
- 4. Shambukavarta (Sannipataj)
- 5. Unmargi (Agantuj)

Where, Acharya Vaghbhata considered the Dwidoshaj types and mentioned the total eight types of the Bhagandara.

Three types are from the vatadi dosha, three from the dwandaj dosha and one from the agantuj.

- 6. Parikshepi (Vata + Pitta)
- 7. Riju (Vata + Kapha)
- 8. Arshobhagandara (Pitta + Kapha)

SADHYASADHYATA -

Opinion of Acharya Sushruta -

All the types of bhagandara are difficult to treat. The bhagandara which produce by combination of all doshas like shambukavarta and kshataja (unmargi) bhagandara are in curable.

BHAGANDARA CHIKITSA

According different acharyas from the ancient Ayurvedic classics the treatment of bhagandara mentioned on the

basis of stage of the disease (i.e. Pakwa and Apakwa) and according to the type of bhagandara.

CURATIVE MEASURE

If apakwa pidaka is not treated in the earlier stage it gets suppurated and turns into Bhagandara. Then the curative treatment should be done. There is various types of the curative treatment is described various acharyas for same. These are described under four headings as follows –

- A) General principal of management
- B) Surgical methods
- C) Medical treatments
- D) Para surgical treatments

D) PARA SURGICAL TREATMENT

Acharya Chakradatta mentions

Kshar karma (chemical cauterization)

It is associated with the surgical intervention and is used to achieve haemostasis and in whom the surgery is contraindicated like weak, timid and emaciated.

APPLICATION OF KSHARASUTRA IN BHAGANDARA MATERIALS AND METHODS

Ksharsutra therapy has been found very effective in the management of fistula-in-ano has been reported by a team of surgeon at the BHU headed by Dr. P.J.Deshpande. They standardized it in the present form.

Though ksharsutra treatment has been found very effective in the management of fistula-in-ano, but major problem involved in ksharsutra treatment is, its prolonged duration of wound healing

associated with itching, pain and excess amount of purulent discharge.

The preparation of Apamarga kshar for standard Apamarga ksharsutra preparation is time consuming method and not so easily available as compare to availability and preparation of Gomutra Ghan powder.

CRITERIA FOR SELECTION – INCLUSION CRITERIA –

- 1) Patients between the age group of 20 yrs. to 60 yrs. were selected Irrespective of sex, religion.
- 2) Diagnosed cases of low-level fistula-in-ano were selected.
- 3) Patients were selected irrespective of Prakriti and chronicity.

EXCLUSION CRITERIA -

- 1) Patients suffering from systemic diseases like uncontrolled Diabetes Mallitus, Tuberculosis, Ulcerative colitis, Osteomyelitis of coccyx, HIV, HbsAg, VDRLpositive patients.
- 2) High level fistula-in-ano is excluded.
- 3) Multiple fistula-in-ano is excluded.
 - 4) Patients having Prolapsed rectum, Crohn's disease, Ulcerative Colitis, Proctitis, Rectal polyp, Condyloma, Anal epithelioma, CA-Anus and rectum is excluded.
 - 5) Pregnant and lactating mothers were excluded.

PLAN OF STUDY – NO. OF PATIENT SELECTED FOR STUDY

To conduct these study 60 patients of fistula-in-ano were selected from OPD and IPD of our Ayurved college hospital randomly.

GROUPS OF PATIENT

Selected patients were divided into 2 groups. 30 patients were in each group.

GROUP – **A** - Treated by Gomutra Ghan sutra

GROUP – B - Treated by Standard Apamarga Ksharsutra.

The threads were changed at weekly interval. And orally Triphala Guggulu 500 mg tablet twice a day. The duration of treatment along with oral medication i.e. Triphala Guggulu was till the track completely cut through and heals for both groups with anupana luke warm water. Maximum duration for each case was 12 weeks.

The detailed information of patients like history, Investigation and progress was noted in a standard proforma prepared in the department. The threading was done in operation theater as well as in OPD by standard technique under Local or General anaesthesia.

PREPARATION OF GOMUTRA GHANSUTRA KSHARSUTRA –

The Ksharsutra treatment and technique is derived from ancient Ayurvedic literature and then it was modified on the basis of a number of experiments and trials. Chakrapanidatta is the authorative commentator of ksharsutra prepared by smearing the Snuhikshira and Haridra powder repeatedly on a thread.

REF shlok – Chakrapanidatta Arshodhikar

GOMUTRA GHANSUTRA -

Gomutra Ghansutra is the modified ksharsutra. Gomutra Ghansutra is the only replacement of Apamarga Kshar by Gomutra Ghan.

PREPARATION OF STANDARD APAMARGA KSHARSUTRA –

Preparation of Standard (Apamarga) Ksharsutra was done followed by the reference of 'Rasa Tanrangini'.
"सुधादुग्धे वस्त्रपुत हरिद्रा चुर्ण संयुते ।
निषिक्तेन तु तुलेन स्वल्पेन खलु यत्नतः ॥
प्रलिप्तं सुदृढं सूत्रं छायायामध शोषयेत् ।
विलिप्य सप्तधा ह्येवं शोषयेद भिषजां वरः ।
सुत्रमेतत्समाख्यानं क्षारसुत्रं तु नामतः ॥
गुदांकुरः च्छेदनार्थम मोहास्त्रमिदं मतम् ।
भगन्दर च्छेदनार्थमष्येत द्विनियुज्यते॥"

र.त.२४/५२७-५२९

UNIT CUTTING TIME -

The initial track length as well as the length of Ksharsutra at each successive changed was measured and recorded. The gradually shortening of the thread after each successive changed corresponds to cut the tissue, which provided an idea of the progress of a particular case.

U.C.T.

=

Total no.of days required to cut through the track
Initial length of track

U.C.T. indicates the average time in days taken to cut through 1 cm of fistulous track. Unit of unit cutting time is days per cm. Here the cutting time not only indicates the cutting rate of the track but also it covers healing status.

OBSERVATIONS:

UNI	UNIT REDUCTION IN PAIN (GRADES/WEEK)								
Group -A					Group – B				
Sr.	Grade	Weeks	Grades per week	Sr.	Sr. Grade Weeks Grades				
No.				No.					
1	20	2	10	1	30	4	7.5		
2	20	2	10	2	20	3	6.67		
3	20	3	6.67	3	30	5	6		
4	20	3	6.67	4	30	3	10		
5	30	3	10	5	20	3	6.67		
6	30	3	10	6	30	3	10		
7	30	3	10	7	20	4	5		
8	30	3	10	8	30	3	10		
9	30	3	10	9	30	6	5		
10	30	3	10	10	30	4	7.5		
11	30	4	7.5	11	30	5	6		
12	30	2	15	12	20	3	6.67		
13	30	3	10	13	30	4	7.5		
14	30	3	10	14	30	4	7.5		
15	20	2	10	15	30	6	5		
16	30	3	10	16	30	5	6		
17	30	3	10	17	30	3	10		
18	30	3	10	18	30	5	6		
19	30	3	10	19	30	4	7.5		

20	30	3	10	20	30	3	10
21	30	3	10	21	20	3	6.67
22	30	3	10	22	30	5	6
23	30	2	15	23	20	4	5
24	30	3	10	24	20	4	5
25	30	3	10	25	20	3	6.67
26	30	4	7.5	26	20	3	6.67
27	30	3	10	27	30	3	10
28	30	3	10	28	10	3	3.33
29	20	3	7.5	29	20	4	5
30	10	1	10	30	30	4	7.5

UNI	UNIT REDUCTION IN ITCHING (GRADES/WEEK)								
Grou	Group -A				Group – B				
Sr.	Grade	Weeks	Grades per week	Sr. Grade Weeks Grades per week					
No.				No.					
1	30	3	10	1	30	5	6		
2	30	2	15	2	30	4	7.5		
3	30	3	10	3	30	5	6		
4	30	4	7.5	4	30	3	10		
5	30	4	7.5	5	20	4	5		
6	20	6	3.33	6	30	4	7.5		
7	20	3	6.67	7	10	3	3.33		
8	30	3	10	8	30	3	10		
9	20	3	6.67	9	30	6	5		
10	20	3	6.67	10	30	4	7.5		
11	20	4	5	11	30	6	5		
12	20	2	10	12	30	5	6		
13	30	4	7.5	13	20	3	6.67		
14	20	4	5	14	20	5	4		
15	30	3	10	15	20	6	3.33		
16	30	3	10	16	20	5	4		
17	30	5	6	17	20	3	6.67		
18	30	4	7.5	18	30	5	6		
19	30	5	6	19	20	3	6.67		
20	30	4	7.5	20	30	4	7.5		
21	30	4	7.5	21	20	3	6.67		
22	30	4	7.5	22	30	5	6		
23	20	4	5	23	30	5	6		
24	30	4	7.5	24	30	5	6		
25	30	3	10	25	30	4	7.5		

26	20	3	6.67	26	20	4	5
27	30	4	7.5	27	10	4	2.5
28	20	3	6.67	28	20	4	5
29	20	3	6.67	29	20	4	5
30	20	3	6.67	30	30	4	7.5

UNI	UNIT REDUCTION IN DISCHARGE (GRADES PER WEEK)								
Grou	up –A			Group – B					
Sr.	Grade	Weeks	Grades per week	Sr.	Grade	Weeks	Grades per week		
No.				No.					
1	20	2	10	1	20	3	6.67		
2	00	0	0	2	10	2	5		
3	20	3	6.67	3	30	4	7.5		
4	10	3	3.33	4	20	3	6.67		
5	10	2	5	5	10	4	2.5		
6	20	4	5	6	20	3	6.67		
7	10	2	5	7	10	2	5		
8	20	2	10	8	20	2	10		
9	20	2	10	9	30	3	10		
10	10	3	3.33	10	20	2	10		
11	20	4	5	11	20	4	5		
12	20	2	10	12	20	4	5		
13	10	5	2	13	20	2	10		
14	10	4	2.5	14	20	2	10		
15	20	6	3.33	15	30	4	7.5		
16	20	2	10	16	20	3	6.67		
17	30	4	7.5	17	20	2	10		
18	30	3	10	18	20	3	6.67		
19	20	3	6.67	19	20	2	10		
20	30	3	10	20	20	3	6.67		
21	10	2	5	21	20	3	6.67		
22	20	3	6.67	22	10	3	3.33		
23	20	3	6.67	23	20	4	5		
24	20	2	10	24	30	3	10		
25	20	2	10	25	20	3	6.67		
26	20	2	10	26	10	3	3.33		
27	30	3	10	27	20	3	6.67		
28	10	2	5	28	10	4	2.5		
29	10	2	5	29	10	3	3.33		
30	20	3	6.67	30	30	3	10		

UNIT REDUCTION IN LOCAL TENDERNESS (GRADES PER WEEK)

Grou	up –A			Group – B				
Sr.	Grade	Weeks	Grades per week	Sr.	Grade	Weeks	Grades per week	
No.				No.				
1	30	2	15	1	30	4	7.5	
2	30	2	15	2	20	3	6.67	
3	30	2	15	3	30	3	10	
4	20	2	10	4	30	3	10	
5	30	3	15	5	20	2	10	
6	30	3	15	6	20	2	10	
7	20	2	10	7	20	2	10	
8	20	2	10	8	20	2	10	
9	30	2	15	9	30	3	10	
10	30	2	15	10	30	3	10	
11	30	3	10	11	30	3	10	
12	30	2	15	12	30	3	10	
13	30	4	7.5	13	30	3	10	
14	20	2	10	14	30	3	10	
15	30	2	15	15	20	4	5	
16	30	2	15	16	30	3	10	
17	30	3	10	17	30	3	10	
18	30	3	10	18	20	2	10	
19	30	3	10	19	30	3	10	
20	30	3	10	20	30	3	10	
21	20	2	10	21	30	3	10	
22	20	2	10	22	30	3	10	
23	20	2	10	23	30	3	10	
24	20	2	10	24	30	3	10	
25	30	3	10	25	30	3	10	
26	30	3	10	26	20	2	10	
27	30	2	15	27	20	2	10	
28	20	2	10	28	20	2	10	
29	30	2	15	29	10	2	5	
30	20	2	10	30	30	3	10	

STATISTICAL ANALYSIS

The observations with respect to objective and subjective symptoms were recorded before treatment and after the complete cut throughout the fistulous track. For comparative study of subjective and objective parameters of these 2 groups un-paired 't' test is applied. For pain, itching, Discharge and Local tenderness 4 -

Grades scale is used. According to severity of symptoms the score 30 is given to most severe, 20 for moderate, 10 for mild and 0 for absence of symptoms.

Note - For large sample, 't' distribution tends to normal distribution.

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1. Pain -

For studying effectiveness of the therapy in reducing 'pain', the unpaired 't' test is used. Here, the null hypothesis is - H_0 : $\mu_a = \mu_b$ i.e. effect of Gomutra Ghan Sutra is not more effective as compared to Standard Apamarga Ksharsutra in reducing pain.

Alternative hypothesis is -

 H_1 : $\mu_{a \geq \mu_b}$ (one tailed alternative) i.e. Gomutra Ghan Sutra is more effective than Standard Apamarga Ksharsutra in reducing pain.

Under H_0 , the test statistic is –

$$t = \frac{x - y}{\sqrt{\Box \sigma^2 \left(\frac{1}{n_1} + \frac{1}{n_2}\right)}} \approx t_{n_1 + n_2 - 2}$$

Where, $\sigma^2 = \frac{n_1}{n_2}$

Here calculated value of |t| comes out to 6.2589 which is greater than critical value of 't' at 5% level of significance i.e.1.6715. Hence we reject H_0 at 5% level of significance and conclude that treatment given to Group A is more effective in reducing pain than treatment given in Group B.

Now, applying same test for other parameters, 't' value and critical 't' value is calculated in same manner and they are as follows:

DESCRIPTIVE STATISTICAL TABLE

Parameters	Mean	Mean	Calculated 't'	Critical 't'	Result
	A	В	value	value	
Pain	9.8613	6.9450	6.2589	1.671553	Significant
Itching	7.6507	6.0280	3.1385	1.671553	Significant
Discharge	6.6780	6.8340	0.2189	1.671553	Insignificant
Local	11.9167	9.4723	4.5147	1.671553	Significant
Tenderness					
UCT	9.6417	12.1723	8.0083	1.671553	Significant

From above statistical analysis we can conclude that Gomutra Ghan Sutra is significantly effective in reducing pain, itching, local tenderness and unit cutting time. The Gomutra Ghan Sutra is not more effective as compared to Standard Apamarga Ksharsutra in reducing discharge. Hence H_0 is accepted.

It means that treatment given in trial group shows significant recovery.

DISCUSSION

In this study it is observed that, though the Standard Apamarga Ksharsutra is highly effective in the management of Bhagandara (fistula-in-ano), but pain, Itching, irritations and difficulty in preparation has limited its use. Thus various type of Ksharsutra has been

practiced for their efficacy in different characteristics. In this present study efforts are made to define the probable mode of action of Gomutra Ghansutra and to evaluate its efficacy in the management of Bhagandara (fistula-in-ano).

CONCLUSION

The present Clinical study has been undertaken to assess the efficacy of Gomutra Ghansutra under the title "Clinical study to evaluate the efficacy of Gomutra Ghansutra in the management of Bhagandara (Fistula-in-ano). The study reveals highly significant results in patients of Group-A both subjective and objective parameters.

As per observations, results and statistical analysis of present study following conclusions can be drawn.

- ✓ Observations of the present study illustrates that males are more prevalent to Bhagandara than females.
- ✓ As per our observations incidence of Bhagandara is higher in the people of age group 30-50 years.
- ✓ Bhagandara (fistula-in-ano) is more prevalent in people of middle class socio-economic group (it is because of may be our study carried out in mass population of middle class socio-economic status).
- ✓ As per the observations Unit Cutting Time of Gomutra Ghansutra (Mean UCT is 9.6417 Days/cm) was found less than that of Standard Apamarga Ksharsutra (Mean UCT is 12.1723 Days/cm).
- ✓ On the basis of comparison of the effect of both groups it can be said that Gomutra Ghansutra provided better relief in pain itching and local tenderness in comparison to Standard Apamarga Ksharsutra because of its properties as Vedanasthapak, Kandughna, Krumighna and Shothaghna.
- ✓ Gomutra Ghansutra is very safe. No clinically significant adverse reactions or effects were reported during entire study period.
- ✓ So, here we can conclude that Gomutra Ghansutra is very effective in the management of Bhagandara (fistula-inano).

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