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ANTIMICROBIAL ACTION OF TILANALA KSHARASUTRA IN THE MANAGEMENT OF BHAGANDARA WITH SPECIAL REFERENCE TO FISTULA-IN-ANO

Radhakrishna Reddy D[1], Shivalingappa J Arakeri[2], Ravi R Chavan[3]

[1]Assistant Professor, [2]Professor & HOD, [3]Professor & HOD
[1]Dept of Rasashastra & Bhaishajya Kalpana, SJG Ayurvedic Medical College and Hospital, Gavimath Campus, Koppal, Karnataka, India
[2]Dept of Shalya Tantra, Taranath Govt Ayurvedic Medical College and Hospital, Ballari, Karnataka, India
[3]Dept of Rasashastra & Bhaishajya Kalpana, Taranath Govt Ayurvedic Medical College and Hospital, Ballari, Karnataka, India

Corresponding Author: drrkreddy19@gmail.com

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ABSTRACT

Introduction: The disease *Bhagandara* is an Ano rectal condition which can be co-related with Fistula-in-ano in Allopathic medical science. In modern surgery we have multiple surgical invasive techniques where analgesics/NSAIDS for the management of post operative pain and broad spectrum of antibiotics to prevent infection are mandatory in return they do have their own complications. In the field of Ayurveda the concept of antimicrobial action of ksharasutra need to be focused on because antibiotics are the mandatory prescription for the post-operative case in both surgical and parasurgical procedures which do have their adverse effects and also the bacteria getting resistance to most of the antibiotics which is one of the biggest threats to global health hence an attempt is made to evaluate the antimicrobial action of Tilanala ksharasutra in bhagandara has been carried out. **Aim And Objectives:** To assess the antimicrobial action of Tilanala ksharasutra in the management of Bhagandara with special reference to Fistula-in-Ano. **Materials And Methods:** A total number of 30 patients of Bhagandara those fulfilling the criteria were included for the study and were randomly allotted into two groups

namely Group – A and Group – B with 15 patients each. No of drop out patients – 4 patients (2 in each group) **Results:** After statistical interpretation of comparative antimicrobial results of both Group A and Group B by unpaired't' test showed non-significant results (P >0.05) i.e., there is no much significant difference in the antimicrobial results of both Group A and Group B. **Discussion**: Tilanala ksharasutra having bacteriostatic, bactericidal actions which encouraged the early cutting and healing of the fistulous tract with marked antimicrobial action was observed. **Conclusion:** Hence infiltrating Betadine 10% solution into the fistulous tract has no specific antimicrobial action than Tilanala ksharasutra hence Tilanala ksharasutra alone can act as antimicrobial in the management of Bhagandara.

Keywords: Bhagandara, ksharasutra, krimighna, antimicrobial

INTRODUCTION

The disease *Bhagandara*[1] is an Anorectal condition, the literal meaning of *Bhagandara* is *daarana* which is splitting up/bursting up of *Pakwa pidaka* in the *bhaga, guda, bastipradesha* results in the formation of a communicating tract, thus causing discomfort to the patient. *Bhagandara* can be co-related with Fistula-in-ano in Allopathic medical science.

Ayurvedic line of treatment for *Bhagandara* includes medical, para-surgical, and surgical management. Parasurgical management includes *Ksharakarma, Agni karma,* and *Varti*. The *Ksharasutra*[2] treatment was first mentioned in the *Naadivrana Adhikara*, and while explaining the indication *Acharya* has mentioned *Bhagandara*. In modern surgery, we have multiple surgical invasive techniques where analgesics/NSAIDs for the management of post-operative pain and a **broad spectrum of antibiotics** to prevent infection are mandatory in return they do have their own complications.

In the present study, *Tilanala* is chosen, ***Tilanala*** is mentioned under *kshara panchaka*[3] and *ksharaashtaka* [4,] and in the field of Ayurveda the concept of antimicrobial action of Ksharasutra needs to be focused on because antibiotics are the mandatory prescription for the post-operative care in both surgical and para surgical procedures which do have their adverse effects and also the bacteria getting resistance to most of the antibiotics which is one of the biggest threats to global health hence an attempt is made to evaluate the antimicrobial action of Tilanala Ksharasutra in Bhagandara has been carried out.

AIM AND OBJECTIVES:

To assess the antimicrobial action of Tilanala Ksharasutra in the management of Bhagandara with special reference to Fistula-in-Ano.

MATERIALS AND METHODS:

STUDY DESIGN: A total number of 30 patients of Bhagandara who fulfilled the criteria were included in the study and were randomly allotted into two groups namely Group – A and Group – B with 15 patients each. No drop outpatients – 4 patients (2 in each group)

Group A: For the patients in Group A, Tilanala Ksharasutra prepared as per standard methods under strict aseptic precautions were applied (as shown in Figures no.1, 6 & 7) followed by Betadine 10% solution infiltration (as shown in Figure no.4)

Group B: For the patients in Group B, Tilanala Ksharasutra prepared as per standard methods under strict aseptic precautions were applied without Betadine 10% solution infiltration.

Duration of treatment: Till complete cutting of the track (as shown in Figure no.8)

The procedure of pus collection for both the groups: Under all aseptic precautions the fistulous opening was cleaned and the fresh pus from the fistulous tract was collected with a sterile pus culture swab (as shown in Figures no.2 &3) and subjected to aerobic culture and sensitivity test at Dept of Microbiology VIMS Ballari.

PARAMETERS FOR ASSESSMENT OF ANTIMICROBIAL ACTION:

1. Bacteria detected
2. Reduction in the number of pus cells (at last sitting)
3. Overall Progress insensitivity to the 1st line of antibiotics
4. Overall Reduction in resistance to the 1st line of antibiotics

ASSESSMENT OF RESULTS:

This is done to access the improvement of the patient, so the cases that have responded to treatment were grouped into 4 categories; this was done to confirm the findings of an assessment of the responses obtained for both groups.

- **Marked response:** 75% to 100% relief in all the features
- **Moderate response:** 50% to 74% relief in all the features

Table 1: GRADING PARAMETERS: FOR ANTIMICROBIAL STUDY

SL NO	PARAMETER	GRADINGS
1	Bacteria detected	0-no bacteria detected 1-single bacteria detected 2- 2 bacteria detected 3-more than 2 bacteria detected
2	Reduction in the number of pus cells (at last sitting)	0-culture yielded no growth. 1-Few cells to occasional pus cells/LPF 2- 3-4 pus cells/LPF 3- >4-5 Pus cells/LPF
3	Overall Progress in sensitivity to the 1st line of antibiotics	0-75%-100% sensitive/culture yields no growth 1- 50% - 74% sensitive 2- 25% – 49% sensitive 3 - <25%/no change in sensitivity
4	Overall Reduction in resistance to the 1st line of antibiotics	0- Reduced up to 0-24% 1-Reduced up to 25%-49% 2- Reduced up to 50%- 74% 3- 75%-100% resistance

- **Mild response:** 25% to 49% relief in all the features
- **Poor response:** 0-24% relief from all features

Results were statistically analyzed within the group and between the groups using the student t-test & conclusions were drawn.

OBSERVATIONS AND RESULTS:

All the 26 patients of *Bhagandara* have been analyzed for the assessment parameters like Bacteria detected, Reduction in the number of pus cells (at last sitting), Overall Progress insensitivity to the 1st line of antibiotics, Overall Reduction in resistance to the 1st line of antibiotics (as shown in Table no.1) and among 30 patients 4 patients were dropouts from the study.

RESULTS OF PARAMETERS:

The result of all the assessment parameters was noted and statistical value was calculated to know whether the prepared *Ksharasutra* was highly significant or significant concerning antimicrobial action in the management of *Bhagandara*.

Table2: Showing the comparative results of Group-A and Group-B

	Group A			Group B		
Sign and symptoms	Mean Score		% of relief	Mean Score		% of relief
	BT	AT		BT	AT	
No.of Bacteria detected	1.30	0.46	64.61%	1.61	0.92	42.85%
No. of pus cells	1.46	0.46	68.49%	2.07	0.76	63.28%
Sensitivityto1st line Of antibiotics	1.23	0.53	56.91%	1.46	0.30	79.45%
Resistance to 1st line Of antibiotics	1.15	0.53	53.91%	1.53	0.46	69.93%

Result of Group A

The percentage of improvement in Group A on No. of Bacteria detected is 64.61%, No. of pus cells is 68.49%, Progress in Sensitivity to 1st LOA is 56.91% and Decline in Resistance to 1stLOAis 53.91% (as shown in Table no.2)

Result of Group B

The percentage of improvement in Group A on No. of Bacteria detected is 42.85%, No. of pus cells is 63.28%, Progress in Sensitivity to 1st LOA is 79.45% and decline in Resistance to 1st LOA is 69.93% (as shown in Table no.2)

Table 3: OVERALL ANTIMICROBIAL RESULTS OF GROUP A–PAIREDT TEST

	n	Mean score		%	SD	SE	T	P
		BT	AT	Relief			value	value
No. of bacteria detected	13	1.30	0.46	64.61%	0.277	0.077	11.987	<0.001
No. of pus cells	13	1.46	0.46	68.49%	0.640	0.177	6.053	<0.001
Progress in Sensitivity	13	1.23	0.53	56.91%	0.630	0.175	3.956	<0.01
Reduction in Resistance	13	1.15	0.53	53.91%	0.767	0.213	2.886	<0.02

Result of Group A: In Group A there are highly significant results on reduction in the number of bacteria detected and reduction in no. of pus cells (<0.001) and significant results on progress in sensitivity to 1st line of antibiotics (<0.01) (as shown in Table no.3)

Table 4: OVERALL ANTIMICROBIAL RESULTS OF GROUP B–PAIREDT TEST

	n	Mean score		%	SD	SE	T	P
		BT	AT	Relief			value	value
No. of bacteria detected	13	1.61	0.92	42.85%	0.806	0.223	3.103	<0.01
No. of pus cells	13	2.07	0.76	63.28%	0.630	0.175	7.472	<0.001
Progress in Sensitivity	13	1.46	0.30	79.45%	0.898	0.249	4.622	<0.001
Reduction in Resistance	13	1.53	0.46	69.93%	1.037	0.288	3.736	<0.01

Result of Group B: In Group A there are highly significant results on reduction in no. of pus cells and progress in sensitivity to 1st line of antibiotics (<0.001) and significant results on reduction in the number of bacteria detected and reduction in resistance to 1st line of antibiotics (<0.01) (as shown in Table no.4)

Table 5: Comparative Antimicrobial Results of Group A & Group B Using Unpaired 'T-Test And 'P-Value

	Mean score			SE	T value	P value	Remark
	Group A(AT)	Group B (AT)	A-B				
No. of bacteria detected	0.462	0.923	0.462	0.255	1.809	>0.05	**NS**
No. of pus cells	0.462	0.769	0.308	0.220	1.400	>0.05	**NS**
Progress in Sensitivity	0.538	0.308	0.231	0.253	0.911	>0.05	**NS**
Reduction in Resistance	0.538	0.462	0.077	0.259	0.297	>0.05	**NS**

1. After statistical interpretation of comparative antimicrobial results of both Group A and Group B by unpaired 't-test showed non-significant results (P>0.05) (as shown in Table no.5) i.e., there is not much significant difference in the antimicrobial results of both Group A and Group B. Group B i.e., Tilanala Ksharasutra without Betadine 10% solution infiltration has shown equal antimicrobial action as that of Group A i.e., Tilanala Ksharasutra with Betadine 10% solution infiltration.
2. Hence infiltrating Betadine 10% solution into the fistulous tracts as no specific antimicrobial action than Tilanala Ksharasutra hence Tilanala Ksharasutra alone can act as antimicrobials in the management of Bhagandara.
3. Tilanala showed promising antimicrobial results
4. In the management of Bhagandara (Fistula-in-ano).


Fig. 1 Tilanala ksharasutra


Fig. 2 Pus discharge


Fig. 3 Pus collection


Fig. 4 Betadine infiltration


Fig. 5 Probing


Fig. 6 Thread change


Fig. 7 Khsarasutra


Fig. 8 Complete cutting

DISCUSSION

Among 30 patients a total of 4 patients i.e., 2 patients from each group were dropped out of the study.

Reasons for the dropout:

1. Patients were intolerant to the pain.
2. Patients were from Remote areas that were unable to come every week for the thread change.
3. Lack of continuity in regular thread change, hence patients were excluded from the study.

DISCUSSION ON THE RESULT OF THE THERAPY

The assessment of results is mainly based on parameters like

1. Action on Reduction in the no. of Bacteria:

The most common bacteria in Ano-rectal diseases are E. coli (60%). Others are Staphylococcus, Bacteroid, Streptococcus, and B. proteus. Commonly occurs due to infection of the anal gland in the perianal region. 95% of anorectal abscesses are due to infection of anal glands about crypts – cryptoglandular disease. These are important as this often culminates in Fistula-in-ano. The bacteria about Anorectal pathology are more Neutrophiles i.e., they grow optimally at a pH within one or two pH units of the neutral pH of 7. The pH of Tilanala Ksharasutra was 9.65±0.10 hence the Ksharasutra in its alkaline environment in the fistulous tract allows neither their growth nor their survival till the coatings persist. Hence there was a gradual deterioration seen in the number of bacteria detected in the culture. Soon after the thread sheds all its coatings the bacterial growth may start again hence the weekly thread change has been suggested to the patients. As kshara has the krimighna property so it does special in reduction of the bacteria detected.

2. Action on Reduction in several Pus cells:

As the number of pus cells in the culture indicates the dead neutrophils or the immune response of the system to the bacteria, there was a decline in the pus cells from the first sitting to the very next sitting in most the cases which indicates that there is no further marked bacterial growth in the tract which need to be combated by the immune systems hence the Ksharasutra does both bactericidal and bacteriostatic action parallelly.

3. Action on the progressive increase in the sensitivity to the antibiotics:

Tilanala by its bactericidal and bacteriostatic activity inhibits bacterial survival by destructing the favorable environment for their pair, chain, or colonial growth of the bacteria which in turn declines the bacterial load and weakens the bacteria which gradually become sensitive to most of the first line of antibiotics was observed in the progressive sittings during the study.

4. Action on the progressive decrease in the Resistance to the antibiotics:

Though it mimics the increase in sensitivity to the antibiotics there was a slight change observed in their rate of increase and decrease to specific antibiotics. By the action of TKS, the bacterial load decreases and its alkaline property weakens the bacteria where it starts losing its resistance to antibiotics and becomes sensitive parallelly.

Discussion on Anti-microbial action of Tilanala Ksharasutra in the control group:

As both the study and control group are having the same medicine i.e., Tilanala Ksharasutra there was not much difference in the antimicrobial action observed. Since Group A is infiltrated with Betadine 10% solution into the fistulous tract it acted as a supportive measure for Tilanala Ksharasutra.

Discussion on Overall Results of Antimicrobial study:

After statistical interpretation of comparative antimicrobial results of both Group A and Group B by unpaired 't-test showed non-significant results (P >0.05) i.e., there is not much significant difference in the antimicrobial results of both Group A and Group B. Group B i.e., Tilanala Ksharasutra without Betadine 10% solution infiltration has shown equal antimicrobial action as that of Group A i.e., Tilanala Ksharasutra with Betadine 10% solution infiltration. Hence infiltrating Betadine 10% solution into the fistulous tract has no specific antimicrobial action than Tilanala Ksharasutra hence Tilanala Ksharasutra

alone can act as antimicrobials in the management of Bhagandara.

Discussion on Microbes involved in Anorectal disorders:

Though the microbes include the Fungal, Bacterial, Viral and other organisms with special emphasis on the Bacteria involved in the pathology of Ano-rectal diseases have been focused on this study because of their prevalence in the Ano-rectal pathology, most importantly their development in the resistance towards antibiotics which will be the global threat in the future. Hence in the present antimicrobial study, the bacteria are given special emphasis.

Discussion on Tilanala Ksharasutra:

Tilanala Ksharasutra contains Tilanala kshara, haridra, and snuhi ksheera as the prime ingredients. As Tilanala Ksharasutra contains curcumin euphol, tannins, flavonoids, and inorganic compounds like sodium and potassium which are having analgesic, anti-inflammatory, immune boosting, wound healing, antibacterial i.e., bacteriostatic, bactericidal actions which encouraged the early cutting and healing of the fistulous tract with marked antimicrobial action was observed.

CONCLUSION

Assessment of No of Bacteria detected, No of pus cells, Progress in Sensitivity to 1st LOA, Decline in Resistance to 1st LOA in Group A showed 64.61%, 68.49%, 56.91%, 53.91% improvement respectively and in Group B 42.85%, 63.28%, 79.45%, 69.93% improvement respectively with p-value >0.05 which is not significant i.e., there is no much significant difference in the antimicrobial results of both Group A and Group B. B i.e., Tilanala Ksharasutra without Betadine 10% solution infiltration has shown equal antimicrobial action as that of Group A i.e., Tilanala Ksharasutra with Betadine 10% solution infiltration. Hence infiltrating Betadine 10% solution into the fistulous tract has no specific antimicrobial action than Tilanala Ksharasutra hence Tilanala Ksharasutra alone can act as antimicrobials in the management of Bhagandara. Tilanala showed promising antimicrobial results in the management of Bhagandara. Thus, Tilanala Ksharasutra has no significant difference in its antimicrobial action with Betadine 10% solution infiltration in the management of Bhagandara.

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