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Effect of *Acacia catechu* and alum hot sitzbath on post-operative pain in patients treated with herbal seton

Sreelekshmi V.S. *, *Rajeshwari P.N.*, *Rabinarayan Tripathy*

Amrita School of Ayurveda, Department of Shalyatantra (Surgery), Amritapuri, Amrita Vishwa Vidyapeetham, India

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ABSTRACT

Background: Post-operative pain is the major consequence of Kṣārasūtra, Seton technique employed in Ayurvedic management of Low anal fistula. Surgeons are forced to prescribe Opioids and NSAIDs with pronounced untoward effects. Non pharmacological measures like Balneotherapy are used to improve circulation and relieve spasm in contemporary sciences.
Aim: To compare the efficacy of Khadira (*Acacia catechu*) and Sphaṭika (Potash alum) hot sitzbath with plain hot sitzbath in patients of low anal fistula treated with Kṣārasūtra.
Method: The study was single blind, double armed; prospective, randomized control clinical trial in which 30 patients were randomly allocated into two groups of 15 each on the basis of inclusion and exclusion criteria. Group A received hot sitzbath using *Acacia catechu* and alum infusion twice daily for 21 days. Group B received hot sitzbath using warm water for 21 days. The assessments were made on pain, post-surgical satisfaction burning sensation, tenderness, discharge, constipation, itching and incontinence.
Result: The disease was prevalent in the 4th decade of life, more in males (86.67%) involved in sedentary work (53.33%) residing in urban domicile, consuming mixed diet (100%). Both groups showed statistically significant improvement in outcome measures like pain, burning sensation, tenderness, discharge, constipation and itching.
Conclusion: On comparative analysis Acacia and Alum hot sitzbath was more effective in outcomes like pain, surgical satisfaction, burning sensation and discharge. There was no difference in the effect of both interventions with respect to outcome measures like constipation, itching and incontinence.

* *Corresponding author.*
E-mail: vasanthasree93@gmail.com (S. V.S.).
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Efeito do banho quente de assento com *Acacia catechu* e alume na dor pós-operatória em pacientes tratados com *seton* à base de plantas

PALAVRAS-CHAVE:
Acacia catechu
Alume
Banho quente de assento
Pós-operatório
Seton

RESUMO

Justificativa: A dor pós-operatória é a principal consequência da técnica que utiliza seton de Kṣārasūtra no tratamento ayurvédico de fístula anal baixa. Os cirurgiões são impelidos a prescrever opiáceos e AINEs que possuem efeitos indesejáveis pronunciados. Medidas não farmacológicas como a balneoterapia são usadas nas ciências contemporâneas para melhorar a circulação e aliviar o espasmo.

Objetivo: Comparar a eficácia do banho quente de assento com Khadira (*Acacia catechu*) e Sphaṭika (Potash alum) com apenas banho de assento em pacientes com fístula anal baixa tratados com Kṣārasūtra.

Método: Estudo clínico prospectivo, cego e controlado de dois braços randomizados, no qual 30 pacientes foram alocados aleatoriamente em dois grupos de 15 pacientes cada com base nos critérios de inclusão e exclusão. O Grupo A recebeu banho de assento com *Acacia catechu* e infusão de alume duas vezes ao dia por 21 dias. O Grupo B recebeu banho de assento com água morna por 21 dias. Os desfechos avaliados foram dor, satisfação pós-cirúrgica, sensação de queimação, sensibilidade, corrimento, constipação, prurido e incontinência.

Resultado: A doença foi prevalente na 4ª década de vida, mais frequente no sexo masculino (86,67%), nos envolvidos em trabalho sedentário (53,33%), nos residentes em domicílios urbanos e nos que consumiam dieta mista (100%). Ambos os grupos apresentaram melhora estatisticamente significativa na avaliação dos resultados, tais como dor, sensação de queimação, sensibilidade, corrimento, constipação e prurido.

Conclusão: Na análise comparativa, o banho quente de assento com acácia e alume foi mais eficaz nos desfechos de dor, satisfação cirúrgica, sensação de queimação e corrimento. Não houve diferença em relação ao efeito de ambas as intervenções sobre os desfechos de constipação, prurido e incontinência.

Introduction

Post-operative pain is an inevitable consequence of any surgery. Poorly managed post-operative pain causes increased systemic morbidity, delayed recovery, high economic burden, development of chronic pain and quality of life impairment.[1] The incidence of anorectal diseases is progressively increasing, with changes in diet and lifestyle. Bhagandara (fistula-in-ano) is such a disorder enumerated under Aṣṭamahāgada (8 diseases that are difficult to cure) as per Suśruta. The results of surgery are less satisfactory, resulting in faecal incontinence and recurrence. Though not a fatal condition, it poses challenge to the surgeon owing to difficulty in management and hampers the quality of life of patient.

Kṣārasūtra, the Ayurvedic technique used in management of fistula-in-ano is detailed by Suśruta inthe context of Sinus and by Caraka in the management of inflammation. On comparing with current practises, it has benefits like, minimal trauma, blood loss, scarring, less involvement of sphincter mechanism, reduced recurrence rate, low treatment cost and less hospital stay making it the Gold Standard in Fistula management. Clinical trial conducted by Indian Council for Medical Research (ICMR) concluded that it is more convenient and effective compared to surgery.[2] It has been praised equivalent to the one-stage fistulotomy in patients with intersphincteric and distal trans-sphincteric fistulae by modern surgery text books. Cutting Seton in modern surgery[3] and Karanool Sigitchai in Siddha tradition[4] are techniques similar to Kṣārasūtra.

The major consequence of Kṣārasūtra ligation is intolerable pain during primary threading and subsequent thread changings. Opioids and NSAIDs are employed in such conditions that have adverse effects like urine retention and gastro-intestinal bleeding respectively. In this regard, antinociceptive herbal remedy with minimum untoward effect is the need of the hour. Non pharmacological measures like Balneotherapy are used to improve circulation and to relieve spasm in contemporary sciences.

As per Aṣṭānga Hrudaya, Avagāha (Sitzbath) a type of fomentation in which the water is medicated with suitable drugs is indicated in pain associated hemorrhoids and dysuria. As per Suśruta, it is indicated following the surgical management of Fistula-in-ano. Likewise, hot sitzbath is a mandatory post-operative procedure in contemporary anorectal practices also.

In order to pacify the severe pain associated with Kṣārasūtra therapy, *Acacia catechu* and Alum hot sitzbath has been practised in Minor Operation Theatre (MOT), under the Dept. of Shalya Tantra, Amrita School of Ayurveda since past 8 years. It is supported with preliminary data from MOT records

for the past 3 years before initiation of the study. This work intends to assess the efficacy of *Acacia catechu* and Alum hot sitzbath over plain water hot sitzbath in post-operative pain of patients treated with Kṣārasūtra.

Methods

Inclusion criteria

Patients within 20–60 years irrespective of gender with low anal fistula operated with Kṣārasūtra.

Post-operative period, less than 24 h.

Patients presenting with post-operative pain.

Patients who have voluntarily agreed to participate in this study.

Exclusion criteria

Pregnant women and nursing mothers.

HBsAg and HIV positive patients.

Uncontrolled Diabetes and other systemic disorders

Study design

The comparison of an indigenous formulation for hot sitzbath consisting of *Acacia catechu* and Alum with plain hot sitzbath was carried out under the Dept. of Shalya Tantra, in IPD (In-Patient Department) of Amrita School of Ayurveda on 30 patients in two groups with 15 each. After a thorough conceptual study and the approval of Institutional Ethical Committee (IEC) through Certificate of Ethical Clearance (IEC-AIMS-2017-AYUR-261/10-7-2017), the study was registered under the Clinical Trial Registry of India with reference number; CTRI/2018/02/012254. It was conducted as a uni-centric, single blind, double armed, prospectively designed, randomized controlled clinical trial that planned to be completed within 18 months. It was based on subjective assessments on two primary outcome measures and 6 secondary outcome measures. Both groups received the interventions for 3 weeks twice daily.

Administration of hot sitzbath

Group A: Sample size: 15 patients

Trial medication – The tub or basin is filled with *Acacia catechu* aqueous extract and Alum powder infusion (5 g/10 litres of boiled water) was taken at tolerable temperature (38–42 °C) so that perineal region of patient could be immersed in water.

Group B: Sample size: 15 patients.

Control medication: The tub or basin is filled with plain warm water was taken at tolerable temperature (38–42 °C) so that perineal region of patient could be immersed in water.

Duration: 20 min twice daily for 21 days.

Blinding – The procedure was carried out in a room provided with dim lighting in order to maintain the subjects blinded regarding the intervention they received.

Internal Medications – Āragvadhādi Kaṣāya 15 mL diluted in 45 mL of water and Ġuggulupancapala Cūrṇam 5 g twice daily with honey which are wound healing in action were advised to both groups. Trial was conducted for assessment of pain, so no pain killer was administered till the completion of trial.

Table 1 – Scoring system for pain.

Grade	Scoring		Grade points
Go	0	No pain, Absolutely no pain.	0
G1	1–3	Mild pain, can be ignored	1
G2	4–6	Moderate pain, interferes with routine activities	2
G3	7–9	Severe	3
G4	10	Excruciating pain	4

Table 2 – Scoring system for post-surgical satisfaction.

Grade	Scoring	Grade point
G0	Not satisfied	0
G1	Somewhat satisfied	1
G2	Satisfied	2
G3	Very much satisfied	3
G4	Extremely satisfied	4

Table 3 – Scoring system for tenderness.

Grade	Scoring	Grade point
G0	No tenderness	0
G1	The patient says the area is tender	1
G2	Patient winces due to pain	2
G3	Patient winces and withdraws the affected part	3
G4	Patient doesn't allow touching the affected part	4

Clinical parameters

Pain

To assess severity of pain Visual Analogue Scale (VAS) was adopted and grading was made with numeric rating scales (Table1).

Post-surgical satisfaction

Post-surgical Satisfaction was assessed using psychometric scale known as 5 point post-surgical satisfaction likert scale (Table 2). A Likert scale range captures the intensity of the feelings of participants against a given item. Usually a 5–7 point symmetric scale is used for assessment in surveys.

Burning sensation

It was assessed on the basis of the symptom present or absent and graded with corresponding numerical value as G1for burning sensation present/G0-Absent

Table 4 – Scoring system for discharge.

Grades	Scoring	Description	Gradepoint
Go	No discharge	Patient does not demand change of dressing in 24 h	0
G1	Change of dressing with 1 pad in 24 h	Patient demands change of dressing once in 24 h	1
G2	Change of dressing in with 2 pads in 24 h	Patient demands change of dressing twice in 24 h	2
G3	Change of dressing with more than 2 pads in 24 h	Patient demands change of dressing more than twice in 24 h	3

Table 5 – Scoring system for anal incontinence.

Incontinence type	Never	Rarely	Sometimes	Usually	Always
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

Tenderness

It was assessed by following the scoring for tenderness in Hutchison's Clinical Methods and graded numerically (Table 3).[5]

Discharge[6]

It was assessed by dressing with a sterile gauze pad of 4 × 4 cm and analyzed with number of pad changes after the pads were made wet with discharge (Table 4).

Constipation

Constipation was assessed with the help of Constipation Scoring System, Cleveland Clinic Questionnaire (Agachan et al., 1996) with score up to 30 and was graded according to severity to the numerical scoring of 0–3. G0 for no constipation, G1 for scores 1–10, G2 for 1–20, G3 for 21–30.

Itching

Out of the parameters of measuring Pruritis, grading was made with numeric rating scales as G0 means no itching, G1 for mild itching, G2 for moderate itching interrupts routine, but not sleep, G3 for Severe itching disturbs both routine and sleep (Grade points 0–3, respectively).

Incontinence

It was assessed using questionnaire described in a manual on fistula in ano and *Kṣārasūtra* therapy published by the National Resource Centre on *Kṣārasūtra* therapy as sited in Table 5.[7]

Results

The observations made out of the study revealed that, fistula-in-ano was prevalent in 4th and 5th decades of life. It was found more in males rather than females with a ratio 6.5:1. It affected people with sedentary habit, who consumed mixed diet and those resided in urban areas. Most affected occupation was shopkeepers. Pain and burning sensation were sure presentation in all participants. It was followed by Tenderness and Discharge (96.67%). Next to that constipation and Itching were presented (56.67%). Incontinence was a very rare presentation (6.67%). No adverse event was reported during the course of intervention.

The procedural effect of hot sitzbath was same for both the groups imparted by the thermal and mechanical benefits of hydrotherapy from the physical properties of water like its buoyancy, fluid pressure, and temperature.[8] The active bioflavonoids in Khadira viz. Catechin, Quercetin, Epicatechin and Procyanidin have analgesic, anti-inflammatory, cytoprotective and anti-oxidant properties respectively.[9]

The statistical analysis for the effects of therapy on outcome measures like pain, post-surgical satisfaction, burning sensation, tenderness, discharge, constipation, itching and incontinence before treatment and on each assessment were tabulated under separate headings. Statistical Analysis was done using SPSS VER 20. Wilcoxon Sign Rank test was used for comparison of subjective parameters within the group and Mann–Whitney U test for comparison between the groups.

Group A (trial/intervention)

In Group A statistically significant improvement was found in all outcome measures viz, pain (0.000) surgical satisfaction (0.001), burning sensation (0.000), tenderness (0.001), discharge (0.001), constipation (0.004) and itching (0.006) at the end of 21st day except for the parameter: incontinence.

Group B (control)

Group B also showed statistically significant improvement in pain (0.001), burning sensation (0.000), tenderness (0.001), discharge (0.000), constipation (0.014) and itching (0.008) at the end of 21st day except surgical satisfaction and incontinence.

Group A vs. Group B

Primary outcome measures

Group A i.e, the trial group with Khadira and Sphaṭika hot sitzbath was more effective in post-operative pain and surgical satisfaction with statistical significance of p-value 0.000 and 0.001 respectively when compared to the effect of Group B, i.e, control group with plain hot sitzbath.

Secondary outcome measures

Group A showed statistically significant improvement in tenderness and discharge with p-values 0.004 and 0.000, respectively

There was no difference in the effect of both interventions in outcome measures like burning sensation, constipation, itching and incontinence between two groups.

Discussion

Pain

Aqueous extract of *Acacia catechu*, has anti-nociceptive property[10] and the bioflavonoid Catechin in it is responsible for its analgesic effect.[11] Hot Sitzbath improves circulation causing vasodilatation, enhanced supply of Oxygen, nutrients, polymorphs, Endorphins, absorption of substance P and neural receptor stimulation. Balneotherapy has multidimensional mode of action viz; Thermal, Mechanical and Chemical. According to Ayurveda Vāta is the main causative factor for pain and it is pacified by hot, penetrating and unctuous attributes of Sitzbath which is a type of dravasveda (Balneotherapy).[12] Alum is also having Uśna vīrya (hot) and Tridoṣahara property.

Burning sensation

The excessive tissue irritation caused by a new Kṣārasūtra due to presence of excessive coating of alkali is pacified when exposed to the wealkly acidic nature of Alum water. Cold potency of Acacia allieviates the kṣatoṣma (burning pain) of the newly formed wound at the site of threading.

Tenderness

Anti-inflammatory, anti-oxidant and cyto-protective activity of the bioflavonoids present in Khadira viz, Catechin, Quercetin, Epicatechin and Procyanidin can reduce the inflammation and tissue necrosis. Thermal and chemical effect of Alum water also modulates noxious stimulus and reduces inflammation.

Discharge

Both the ingredients of the formulation viz. Khadira and Sphaṭika are Kaṣāyarasa (astringent) which is kleda śoṣaṇa, viśada and stambhana. Alum is known for its styptic property since antiquity. Khadira is having Kapha Pittahara property which can reduce oozing from the tract. Khadira is the best choice for skin diseases according to Āyurveda.

Constipation

Hydrostatic pressure exerted by thermal water improves process of excretion by 50%. When the smooth muscle spasm is relieved constipation also gets cured. Here the procedural effect is more when compared to the pharmacological action of the drug combination.

Itching

The itching of wound site is probably due to foreign body sensation than infection in the initial days. Kandu is mainly due to Kaphadoṣa. It is pacified by the uśna, tīkṣṇa properties of Avagāha.

Incontinence

The control of involuntary muscles can be regained only on a longer duration after the cut through. It cannot be studied within a short duration of 3 weeks especially when it was not presented as a major symptom.

Post-surgical satisfaction

The collective effect of all the other parameters is reflected on this single assessment criterion.

Benefits of avagaha an ayurvedic variant of balneotherapy

Avagaha enhances metabolic activity, blood flow to perineum, stimulates neural receptors in the perianal skin, moisturises the wound and reduces inflammation. Thermal water provides dilatation of the arterioles that branch to nearby dermal structures and provide nourishment of epidermis. It offers more oxygen, nutrients, polymorphs and endorphins release to the affected area which is beneficial for healing of local pathology. Heat has a direct effect on the blood vessels, causing vasodilatation. Water molecules diffused through the skin helps in softening the adhesions and scars. Mobilization and stretching becomes easier after Avagaha. In the post-operative condition the micro circulatory channels may be altered from their normal structure and function they do not possess their normal suppleness and elasticity. Avagāha, by thermal and osmotic properties is capable of penetrating microcirculatory channels and performing clarification. Fomentation is the best among those which produce softness, as per Caraka so it restores suppleness and elasticity.

Conclusion

On comparing both groups to find which more beneficial in the management of pain and associated features in patients treated with Kṣārasūtra, Group A showed significant improvement in management of Pain, Tenderness, Discharge and Surgical Satisfaction than plain hot Sitzbath. In the search for an alternative herbal remedy in post-operative pain management in Kṣārasūtra operated cases rather than NSAIDs; the study was able to propose the efficacy of Khadira and Sphatika Hot Sitzbath to the world as a relatively effective procedure to manage post-operative pain within a period of 21 days. Thus the standard operating procedure of hot sitzbath as post-operative management was modified with a simple herbo-mineral combination. This particular combination of Khadira and Sphatika in post-operative pain management and improving surgical satisfaction in patients treated with Ksharasutra.

Conflicts of interest

The authors declare no conflicts of interest.

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