



Research Article

CLINICAL STUDY TO EVALUATE AND COMPARE THE EFFICACY OF TWO AYURVEDIC TREATMENT REGIMENS INCLUDING *CYATHULA PROSTRATA* AND *ACHYRANTHES ASPERA* IN MANAGING BLEEDING PILES

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ABSTRACT

Background: Sri Lankan Ayurveda physicians mostly recommend *Rathkaralheba* (*Cyathula prostrata*) decoction as a treatment for *Sraviarshas* (bleeding piles) while some patients use *Gaskaralheba* (*Achyranthes aspera*) as it is available everywhere. This study was planned to evaluate the effectiveness of two Ayurvedic regimens including *Rathkaralheba* and *Gaskaralheba*.

Methods: 100 patients with bleeding piles randomly allocated into two groups. Patients of Group A and B were given treatment regimen A and B respectively. Treatment regimen A contained *Gaskaralheba* decoction, *Triphala* tablets and sitz bath. Treatment regimen B included *Rathkaralheba* decoction, *Triphala* tablets and sitz bath. Duration of the treatment was two weeks. Eight clinical parameters relating to bleeding piles were monitored. **Results:** Data collected from 92 cases (46 cases in each group) were analyzed. The study results showed that statistically highly significant reduction ($p < .001$) of bleeding, pain and constipation in both groups. Size of the mass has significantly reduced ($p < .05$) in both groups. In group A, itching was reduced significantly ($p < .05$) and reduction of prolapse was not significant. In group B, prolapse was reduced significantly ($p < .05$) but itching was not reduced significantly. **Conclusion:** Both treatment regimens A and B were found to be equally effective in the treatment of *Sraviarshas* specially reducing the symptoms of bleeding, pain and constipation

KEYWORDS: *Sraviarshas*, *Achyranthes aspera*, *Cyathula prostrata*, *Rathkaralheba*, *Gaskaralheba*, bleeding piles.

INTRODUCTION

The disease *Arshas* (haemorrhoids) is an ano-rectal disorder as old as mankind. It can be regarded as one of the diseases from which vast number of people of the world suffers. Although haemorrhoids are widely agreed to be common, there is not much satisfactory evidence as to how common they are. A health care program for colorectal cancer screening, held in Vienna in the years 2008 and 2009, revealed the fact that 38.93 per cent of the adult population in Austria suffered from haemorrhoids and most of them (55.26%) reported no symptoms.^[1] Ten million people in the United States complained of haemorrhoids in 1983-1985, corresponding to a prevalence rate of 4.4%^[2]. In both genders, a peak in prevalence is noted between 45-65 years of age and the development of haemorrhoids before the age of 20 is unusual.^[3]

For haemorrhoidal disease a good number of surgical, para surgical and medicinal treatments have been advocated in Allopathic medicine and in Ayurveda as well. Every clinician claims his method or procedure to be superior to the previously existing methods. This suggests the fact that none of the methods are superior. Patient compliance relates to less morbidity, shorter hospitalization, early return to work and the absence of complications. Patients generally prefer to take medicinal treatment over surgery. In allopathic medicine, topical ointments and suppositories are used with a high residue diet or bulk of laxatives to combat constipation.

In Ayurveda, Acharya Sushruta classified *Arshas* (haemorrhoid) patients into six separate categories according to *Doshic* condition. In that classification both *Pittajaarshas* and *Raktajaarshas* in

which bleeding occur are included under the category of *Sraviarshas*.

Acharya Sushruta has mentioned the management of *Arshas* under four headings such as medicines, chemical cauterization by alkaline substances, thermal cauterization and operative surgery. The first priority has been given to medicinal treatment and rests of the therapies are to be considered when medicines are not sufficient to cure. In such cases also medical regimen is needed to avoid the recurrences of the disease. According to Sushruta, the medical treatment can be tried even in a case where surgery is advised, as surgery should not be the option when the disease can be cured by medicines. That statement is valid in the past and present, as well.

The most common presenting symptom of haemorrhoids is rectal bleeding. Many other conditions may mimic haemorrhoids.^[4] These include anal fissures, fistulae or colorectal cancers.^[5] Therefore a careful evaluation should be made in individuals complaining of haemorrhoid related symptoms.^[6]

In Sri Lanka, Ayurvedic physicians mostly recommend *Rathkaralheba* (*Cyathula prostrata*) decoction as a common treatment for *Sraviarshas* (bleeding piles). This plant cannot be found universally and is not available in Ayurvedic raw drug shops. Most people are unable to identify the required medicinal herbs. Consequently, some prepare decoction out of similar herb named *Gas Karalheba* (*Achyranthes aspera*) which is commonly available. Both these varieties have been recommended for the management of *Arshas* in texts. Ayurvedic therapy is a holistic system and as such the efficacy of the treatment cannot be decided on the success or failure of the application of a single drug. Therefore, my attempt is to organize two regimens of treatment.

In this research, efficacy of two Ayurvedic treatment regimens which include decoctions of *Rathkaralheba* and *Gas karalheba* as the specific drugs between two clinical groups was tested to confirm the effectiveness of freely available drugs.

Aim of the study

To evaluate and compare the efficacy of two treatment regimens in the management of *Sraviarshas* (bleeding piles)

MATERIALS AND METHODS

Study population

Total 100 patients who came to the Shalya clinic of the National Ayurvedic Teaching Hospital and diagnosed as *Sraviarshas* (bleeding piles) were

registered for the study so that each group (A and B) contains 50 patients.

Study design

This was a randomized prospective double blind comparative clinical study.

Inclusion criteria

The cases diagnosed as *Sraviarshas* which can be correlated with internal, mixed or external haemorrhoids having the feature of bleeding per rectum were included. Patients with first degree haemorrhoids (without prolapsed mass), second degree haemorrhoids (mass come out and reduced after defecation) and third degree haemorrhoids (mass come out and need to manually reduce) were included. The patients within the age 18 to 70 years only selected irrespective of sex.

Exclusion criteria

Patients with fourth degree haemorrhoids, rectal prolapse, anal fissure, fistula in ano, abscess, malignancy, ulcerative colitis, rectal polyp, diverticulitis, pregnancy, severe hepatic renal disorders or severe heart diseases and patients without therapy compliance were excluded.

Drugs used

Plants materials and drugs were identified and authenticated by Prof. M.H.A. Tissera, Head of Dravyaguna Department, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka. Voucher specimens were deposited (IIM/DGV/HS/003-011) in Dravyaguna Department, Institute of Indigenous Medicine, University of Colombo, Sri Lanka.

Group A – Treatment regimen A

1. Decoction of *Achyranthes aspera* 120 ml twice a day
2. *Triphala* tablet 3g twice a day
3. Sitz bath once a day for 10 minutes

Group B – Treatment regimen B

1. Decoction of *Cyathulaprostrata* 120 ml twice a day
2. *Triphala* tablet 3g twice a day
3. Sitz bath once a day for 10 minutes

Infusion water for sitz bath was prepared from the powdered barks of *Thespesia populnea*, *Ficus bengalensis*, *Azadirachta indica* for both groups.

Procedure

History of presenting complaints was taken and rectal examination (digital rectal examination and proctoscopic examination) was done to confirm the diagnosis. Data of the assessment criteria of the patients were collected at three time points such as before the treatment, after the treatment (after 2 weeks) and in follow up after 6 months. Those, who

were given the treatment regimen A, were named as group A and those, who were given treatment regimen B, were named as group B. As mentioned above, all the patients were given *Thriphala* tablets and sitz bath and patients were randomized in a blinded method to receive either *A. aspera* (group A) or *C. prostrata* (group B). Pounded raw drug *A. aspera* and *C. prostrata* were packed separately in a covered material so that inside contents cannot be identified. Then each packet was labeled with computer generated random numbers by the lecturer in charge of the pharmacy of the Institute of Indigenous medicine. The document which includes the random numbers pertaining to each drug was kept sealed until the trial finished. The packets were dispensed randomly to patients, who were selected for the study, by a house officer in the Shalya clinic and noted the random number of the packet with the name of the patient. The treating physician was unaware of the randomization code.

Criteria for assessment

Assessment of treatment was done according to the relief of the signs and symptoms, with the help of scoring pattern. The details of the scores adopted for the chief signs and symptoms in the study as follows.

(a) Bleeding frequency score

- 0 = no bleeding
- 1 = bleeding once a week
- 2 = bleeding 2-3 days per week
- 3 = bleeding 4-6 days per week
- 4 = bleeding every day

(b) Bleeding volume score (measurements taken by inquiring patient as number of teaspoonful)

- 0 = no bleeding
- 1 = a few drops/ staining stools
- 2 = 5-10 ml
- 3 = >10-20 ml
- 4 = over 20 ml

(c) Pain severity score (according to Won Baker face scale)

- 0 = no pain
- 2 = Hurts little bit
- 4 = Hurts little more
- 6 = Hurts even more
- 8 = Hurts whole lot
- 10 = Hurts worst

(d) Pain frequency score

- 0 = no pain
- 1 = once in last 4 defecations
- 2 = two times in last 4 defecations
- 3 = three times in last 4 defecations
- 4 = every time in last 4 defecations

(e) Haemorrhoidal mass score

- 0 = < 0.5 cm
- 1 = 0.5 cm to 1 cm

2 = >1cm – 2 cm

3 = > 2 cm

(f) Grade of prolapse score

- 0 = pile mass does not come out
- 1 = pile mass come out, but reduce spontaneously
- 2 = pile mass come out and need to be replaced manually

(g) Itching frequency score

- 0 = no itching
- 1 = sometimes
- 2 = most of the time
- 3 = always

(h) Constipation score

This tool, constipation score is a modification of Rome criteria.^[7] By this tool, constipation was diagnosed and evaluated objectively concerning the straining, hardness of stool, sensation of incomplete evacuation, sensation of anorectal obstruction, digital evacuation and frequency of bowel movements. It is a twenty five points score: 0 = no constipation at all; 24 = extremely.

Ethical approval

Ethical approval for the study was obtained from the ethics review committee of the Institute of Indigenous Medicine, University of Colombo, Sri Lanka (ERC 12/13) (<http://iim.cmb.ac.lk/ercim>). The patients were given detailed explanation of the study. Written consents of patients were obtained prior to commencement of the study.

RESULTS AND DISCUSSION

In this clinical study total 100 patients were registered and randomly allocated them into two groups so that each group contains 50 patients. Four patients from each group did not attend the clinic after the treatment and therefore they were removed from the study. Therefore, data collected from 46 cases of A group and 46 cases of B group were analyzed.

Demographic result found in the study

The mean age of the sample was 43.28 years (SD 14.29). Out of 92 patients 54 (58.7%) were males. 44 (47.8%) patients were engaged sedentary work. In diet wise distribution majority (91.3%) was having mixed diet and 43 (46.7%) patients used to get more spicy foods. 55 (60.0%) patient were with good appetite. The majority of patients (87.0%) was with a previous history of bleeding per rectum 55 (59.8%) were with family history of haemorrhoids. Out of seven types of *Prakruti*, maximum number (25.0%) of patients was with *Pittaprakruti*. According to Ayurvedic fundamental theories, *Sraviarshas* occurs due to *Pitta dosha* aggravation.

Apart from bleeding per rectum, 47 cases (51.1%) were present with pain. They may be with intero-external or external haemorrhoids. 35 (38.0%) patients were with prolapse of pile mass. Only 47 (51.1%) patients were with constipation. It reveals the fact that constipation may be a causative

factor for bleeding piles for some patients but not for all. Only 27 (29.3%) patients came without previous history of treatment (Table 1). It shows that recurrences are more common in this disease, even after surgery. The majority (58.7%) had taken conservative treatments early.

Table 1: Distribution of Patients According to Treatment History

Treatment taken	Group A	Group B	Total	
			Number	%
No	12	15	27	29.3
Conservative	31	23	54	58.7
Sclerotherapy	0	3	3	3.3
Band ligation	2	2	4	4.3
Excision	1	3	4	4.3

Table 2: Distribution of Patients According to Site of Pile Masses

Site of pile mass	Group A	Group B	Total	
			Number	%
Internal	28	23	51	55.4
External	6	10	16	17.4
Intero-external	12	13	25	27.2

Clinical assessment of patients

Therapeutic objectives in the treatment of bleeding piles include preventing bleeding from the rectum, relieving pain and itching in the anal region, shrinkage of pile mass and relieving constipation. Wilcoxon signed rank test was applied to compare the changes in the mean or median scores of the each symptom before and after treatment. The significance level (α) was set at 0.05 at all tests.

Table 3: Effect of Therapy on Clinical Features in Group A

Criteria	Mean score (SD)		Mean difference	Z value	P value
	Before treatment	After treatment			
Bleeding frequency score	3.11 (1.10)	0.24 (0.85)	2.87	5.807	.000
Bleeding volume score	2.89 (1.34)	0.20 (0.58)	2.69	5.945	.000
Pain frequency score	1.41 (1.87)	0.24 (0.87)	1.17	3.656	.000
Pain severity score	2.04 (2.97)	0.26 (1.00)	1.78	3.757	.000
Haemorrhoidal mass score	1.87 (0.65)	1.5 (0.81)	0.37	3.231	.001
Prolapse score	0.72 (0.89)	0.63 (0.88)	0.09	0.966	.334
Itching score	0.37 (0.83)	0.07 (0.33)	0.30	2.739	.006
Constipation score	5.67 (5.43)	0.52 (1.43)	5.15	4.872	.000

Table 4: Effect of Therapy on Clinical Features in Group B

Criteria	Mean score (SD)		Mean difference	Z value	P value
	Before treatment	After treatment			
Bleeding frequency score	3.41 (.93)	0.26 (0.74)	3.15	5.98	.000
Bleeding volume score	2.83 (1.39)	0.17 (0.44)	2.66	5.99	.000
Pain frequency score	2.30 (1.94)	0.35 (1.14)	1.95	4.46	.000
Pain severity score	3.30 (3.05)	0.26 (0.80)	3.04	4.66	.000
Haemorrhoidal mass score	1.76 (0.52)	1.50 (0.69)	0.26	2.97	.003
Prolapse score	0.52 (0.81)	0.43 (0.75)	0.09	2.00	.046
Itching score	0.11 (0.43)	0.02 (0.15)	0.09	1.63	.102
Constipation score	6.20 (6.16)	0.70 (2.15)	5.50	4.46	.000

The study results (Table 3 and 4) showed that reduction of bleeding, pain and constipation has achieved in a greater extent in both groups. Size of the mass has significantly reduced in both groups but of a lesser extent. Treatment regimen A has shown a lesser effect of reducing the itching, but treatment regimen B has shown no significant effect in reducing itching. Treatment regimen B has shown a lesser effect in reducing the prolapse of the pile mass, but the treatment regimen A has shown no significant effect in reducing the prolapse of the pile mass.

The non-parametric Mann Whitney U test was used to test the difference in scores between groups. The Mann-Whitney test for comparison of two groups showed that no significant difference between the scores of after the treatment in group A and Group B in bleeding frequency ($Z = -0.594$, $p = .552$), in bleeding volume ($Z = -0.461$, $p = .645$), in pain frequency ($Z = -0.064$, $p = .949$), in pain severity ($Z = -0.334$, $p = .739$), in haemorrhoidal mass ($Z = -0.102$, $p = .918$), in prolapse ($Z = 1.044$, $p = .297$), in itching ($Z = 0.596$, $p = .551$) and in constipation ($Z = 0.506$, $p = .613$).

Even though both treatment regimens have the equal potent in reducing the bleeding, pain and constipation in patients with bleeding piles they have failed to show much improvement in reducing the size and prolapse of the pile mass and itching within this short period of treatment. Sometimes it may need more time duration of this treatment. In some cases specially prolapse of the pile mass may need other treatment methods in Ayurveda *Shalyachikitsa* recommended for *Sraviarshas* such as *Kshara karma*

(alkaline treatments) and *Shastra karma* (operative treatment).

CONCLUSION

Both treatment regimens A and B were found to be equally effective in the treatment of *Sraviarshas* specially reducing the symptoms of bleeding, pain and constipation. Further large trials need to be conducted to confirm the results.

Conflict of interest

We declare that we have no conflict of interest.

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Dried *Cyathulla prostrate*



mixture of pieces of 3 barks for sitz bath



Bark of *Thespesia populnea*



Dried *Achyranthus aspera*



Bark of *Azadirachta indica*



Bark of *Ficus bengalensis*



Triphala tablets