

COMPARATIVE CLINICAL STUDY OF APAMARGAKSHARATAILA INJECTION AND INFRARED COAGULATION IN THE MANAGEMENT OF ARSHA (1ST AND 2ND DEGREE HEMORRHOIDS)

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ABSTRACT

Introduction: In anorectal disorders, incidences of hemorrhoids and fissures are increasing in Indian population due to western lifestyle. Many surgical methods are available to cure anorectal disorders, but now a days, demand for *Ayurveda* and *herbal* preparation is increasing in society. **Materials and Methods:** In this study, *ApamargaKsharaTaila Injection submucosal Route* (Group A) and infrared coagulation (Group B) procedure were administered for the management of internal hemorrhoid (*Arsha*). This study was an open labelled, prospective, interventional study, in which patients of hemorrhoids [$n=30(15\text{eachgroup})$] were selected from OPD of Institutional hospital. *ApamargaKsharaTaila Injection* application submucosally on internal hemorrhoids and IRC was applied at the base of hemorrhoids. In all the two groups, the patients were assessed every week for 4 weeks and were followed up for another 4 weeks for relief in signs and symptoms. **Results:** Obtained results were analyzed and encouraging results were observed after completion of the treatment. **Conclusion:** The study concluded that *ApamargaKsharaTaila Injection* is the most effective treatment for the management of internal hemorrhoid of 1st and 2nd degree in comparison to IRC procedure.

Keywords: *ApamargaKshartaila*, *Arsha*, *Ayurveda*, hemorrhoids

INTRODUCTION

Hemorrhoids is one of the common anorectal disorders that equally affect men and women.¹ The worldwide prevalence of hemorrhoids is around 4.4% and incidences increase with age. The pregnancy is also a predisposing risk factor for the development of symptomatic hemorrhoids in females.² The symptoms of hemorrhoids are bleeding, pain, protrusion of hemorrhoids, and perianal itching. Conservative medical treatment of hemorrhoids includes use of fiber supplements; lifestyle modifications may include relieving constipation, avoiding straining, proper fluid intake, better anal hygiene and sitz baths.³ If the patients do not respond to conservative measures, Rubber Band Ligation, Sclerotherapy, Infrared Coagulation (IRC) And Cryosurgery are some outpatient department (OPD) procedures.⁴ Hemorrhoidectomy is indicated in 4th Grade when symptoms of bleeding, pain and prolapsed hemorrhoids compromise the quality of life. In this context, *Sushruta* has mentioned four types of treatment modalities such as medical management *Ksharakarma* (use of *Kshara/Ksharasutra*), *Agnikarma* (cauterization) and surgery according to the nature of *Arsha* (hemorrhoids) as the last option.⁵

Treatment by the use of herbs is known to human beings since centuries. Recently, herbal treatments have gained popularity with documented effects on the influence of blood vessel wall tone, decrease of capillary permeability, improved circulation, decrease of edema and blockage of inflammatory mediators.⁶ It has been observed that anorectal disorders such as hemorrhoids can be managed by submucosal administration of *ApamargaKshara Taila* and IRC procedure that offer a significant and faster relief resulting in improved quality of life. Hence, the study has been planned to compare the efficacy of *ApamargaKshara Taila* Injection and IRC in the management of internal hemorrhoid (1st and 2nd degree).

Materials and Methods

This study was an Open, Prospective, Interventional for 4 weeks, Patients were assessed every week for 4 weeks and were followed up for another 4 weeks for relief in signs and symptoms. Patients having complaints of internal hemorrhoid of 1st and 2nd degree were selected from the Shalyatantra OPD,

Sriganganagar Ayurvedic Hospital, Rajasthan. Detailed clinical history and physical and local P/R examination findings were recorded in clinical research proforma.

Inclusion criteria

Patients of either Sex between 18 and 65 years; with 1st and 2nd degree int. hemorrhoids; with *Mridu*, *Prastruta*, *Avagadha*, and *Uchrita* type of *Arsha*; with controlled blood pressure, diabetes mellitus and cardiac disorders were included in the study.

Exclusion criteria

- Patients of either Sex < 18 years and >65 years
- Patients with 3rd and 4th degree hemorrhoids
- Patients having rectal prolapse, fissure and fistula-in-ano having uncontrolled HT, diabetes mellitus and High-risk cardiac disorders
- Patients with CA.
- Pregnant women and HBV, tuberculosis, HIV and VDRL positive cases were excluded from the study.

Investigations

- Routine Hb%.
- BT, CT.
- FBS & PPBS.

Ingredients of trial drugs: *Apamarga Kshara Taila* [Table 1] was prepared by following standard guidelines of *Bahishajya Ratnavali* in the laboratory.⁸ The finished product was packed in sterile containers to avoid possibilities of contamination.

Grouping:

- Group A: *ApamargaKshara Taila* Injection submucosally
- Group B: IRC procedure was done for one sitting on Hemorrhoids.

Do's and dont's: Patients were advised to consume fibre-rich diet, green vegetables, plenty of water and buttermilk and advised to avoid spicy, non-vegetarian diet, junk foods and daily morning walk for half an hour.

Assessment criteria: Efficacy was assessed weekly for reduction in intensity of the following signs and symptoms. Bleeding P/R, painful defecation, prolapsed hemorrhoids and discharge P/R based on gradations were

assessed. Overall assessment was done as shown in Table 2.

Statistical analysis: Statistical tests “Student’s paired t-test,” “Wilcoxon signed-rank test” were applied to assess the results.

Observations and Results

In this study 30 patients were selected, 23 male patients and 7 female patients. Male predominance was found higher, which might be due to reporting of more male patients to the anorectal department. 26 patients were from the age group of 18 and 40 years and the remaining 4 between 41 and 65 years, which showed that most of the patients were of the middle-age group. 6 patients reported a family history of hemorrhoids although considering this small sample study it is difficult to say that hemorrhoids and fissures are hereditary diseases as it requires survey study on more samples. Of 30 patients, 19 patients had irregular bowel habits and 11 patients complained of constipation and hard stools. The constipation and irregular bowel movement are the main etiological factors of hemorrhoids and fissure.

In this study, bleeding P/R was present in 16 patients, which was moderate in 15 patients. In maximum 11 patients bleeding P/R was dropping in nature. In relation to defecation, a maximum of 16 patients had bleeding after defecation. A total of 22 patients had prolapse hemorrhoids P/R, where a maximum of 17 patients had spontaneous reduction of hemorrhoids. A maximum of 21 patients had painful defecation, among them 18 patients had burning type of pain and 15 patients had mild pain. In 12 patients, serous type of discharge per rectum was reported.

Effect of therapy: In bleeding P/R, Group A, maximum improvement was noted on 21st day with 100% relief. This is due to the properties of *Kshara* such as *Stambhana*, *Pachana* and *Dahana* mentioned in the texts. In Group B, maximum improvement was noted on the 21st day with 62.50% relief. IRC beam leads to scarring and tissue fixation, which leads to shrinking of hemorrhoids. [Table 3] In painful defecation, Group A, maximum improvement was noted on the 21st day with 100% relief. Painful defecation might be taken care off due to *Ksharana*, *Pachana*, *Amahara* (detoxifying) and

Tri-Doshahara properties of *ApamargaKshara Taila*. In Group B, maximum improvement was observed on 14th day with 55.55% relief. due to the fact that heat produced coagulates the engorged part of the vein, reducing painful defecation during strain. [Table 4] In prolapse P/R, Group A, maximum improvement was noted on the 14th day with 100% relief. Prolapse of pile mass might be reduced due to *Vilayana* (melting), *Shodhana*, *Shoshana*, and *Lekhana* properties of *Kshara*. In Group B, maximum improvement was noted on 14th day with 42.85% relief. Heat created by infrared light causes a firm scar tissue which fixes nearby veins and mucosa in place, so they do not bulge out much into the anal canal. [Table 5]. In discharge P/R, Group A, maximum improvement was noted on the 7th day onwards with 100% relief. Discharge P/R may be tackled due to *Shoshana*, *Tikshana*, *Stambhana* and *Dahana* properties. In Group B, maximum improvement was noted on the 14th day with 50% relief. [Table 6] so the laboratory investigations were done in these patients before and after the treatment to assess the effect of treatment. The findings showed that the changes occurred with treatment is not enough to exclude the possibility that the difference in value is due to chance [Table 7].

Overall assessment

Overall effect of therapy in Group A showed 80% (n = 12) complete remission. In Group B, showed 20% (n=3) complete remission. Hence, it can be stated that the patients with hemorrhoids of 1st and 2nd shows highly significant by Group A [Table 8].

DISCUSSION

The present study of *ApamargaKshara Taila* Injection and IRC was designed to evaluate the efficacy of each treatment in the management of hemorrhoids. Statistically highly significant results were obtained in patients of 1st and 2nd degree hemorrhoids. In cases of internal hemorrhoids, highly significant result was seen in features of bleeding P/R and prolapse of hemorrhoids irrespective of the decrease in size of hemorrhoids in Group A. The percentage of relief after treatment has been calculated statistically; in Group A, 100% relief was noted in bleeding P/R, 75% relief was noted in both painful defecation and discharge P/R and 87.50% relief

was found in prolapse of hemorrhoids per rectum. In Group B, 87.50% relief was noted in bleeding P/R, 62.50% relief was noted in painful defecation, 50% relief was noted in discharge P/R and 42.86% relief was noted in prolapse of hemorrhoids. *ApamargaKshara Taila* Injection exerts its *Ksharana* property, in the form of local application. It is due to its properties such as *Pachana, Tikshana, Vilayana, Shodhana, Shoshana, Amahara, Dahana, Stambhana* and *Lekhana* that reduced all the symptoms in case of internal hemorrhoid.⁷ IRC results in less scarring and tissue fixation, which shrinks hemorrhoids⁵

CONCLUSION

The study concluded that Group A – *Apamarga KsharaTaila* Injection application has better potential to treat internal hemorrhoids upto 2nd degree in comparison to Group B - IRC. The procedure is cost and time effective and without adverse effects.

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Table 1: *Apamargakshartaila*

Drugs	Rasa	Guna	Virya	Vipaka	Karma/actions/Doshaghna
<i>Apamarga (Achyranthesperal.)</i>	<i>Katu, Tikta</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kapha-Vatahara, Shirovirechan Deepana, Pachana, Medohara</i>
<i>Teel Taila</i>	<i>Katu, Madhura</i>	<i>Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Kapha-Vatahara Deepana, Pachana, Vranaropana Vranshodhana Vedanasthapana</i>

Table 2: Overall Assessment of Study

Effect	Percentage (relief)
Complete remission	80-100
Marked improvement	65-79
Moderate improvement	40-64
Mild improvement	25-39
Unchanged	<25

Table 3: Effect of therapy on Bleeding P/R

Days	Group A (%)	Group B(%)
7 th day	44.44	29.42
14 th day	60	33.33
21 st day	100	62.50
28 th day	100	62.50

Table 4: Effect of therapy on Painful defeacation

Days	Group A (%)	Group B (%)
7 th day	57.14	18.18
14 th day	100	55.55
21 st day	100	55.55
28 th day	100	55.55

Table 5 Effect of therapy on Prolapse Hemorrhoids

Days	Group A(%)	Group B (%)
7 th day	81.81	0
14 th day	100	42.85
21 st day	100	42.85
28 th day	100	42.85

Table 6: Effect of therapy on Discharge P/R

Days	Group A (%)	Group B (%)
7 th day	100	0
14 th day	100	50
21 st day	100	50
28 th day	100	50

Table 7: Laboratory investigation

Inv	Mean		SD	SE	dF	t	P
	BT	AT					
Hb (%)	12.33	12.61	0.46	0.14	-0.28	1.92	0.08
BT	2.33	2.33	0.2	0.064	0.005	0.0078	0.94
CT	4.33	4.2	0.36	0.11	0.13	1.13	0.28
FBS	93.6	954.5	-	-	860.9	1.001	0.34
PPBS	100.3	100.3	40.85	-57	0.0	0.0	0.99

Table 8: Overall Effect of therapy (n=15 each)

Group	Cured, N (%)	Marked improvement, (%)	Moderate improvement, n (%)	Mild improvement, n (%)	Unchanged, (%)
Group A	12(80)	3 (20)	0	0	0
Group B	3(20)	3 (20)	6(40)	3 (20)	0

Source of Support: Nil

Conflict of Interest: None Declared

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