



A COMPARATIVE CLINICAL STUDY OF KADALI KSHAR PRATISARAN AND INJ. SETROL IN THE MANAGEMENT OF ABHYANTAR ARSHA W.S.R. TO INTERNAL HAEMORRHOIDS.

Ayurveda

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ABSTRACT

There is a very peculiar role of "Kshar Karma" (an Anushastra), in the management of Arsha, as described by Sushrutacharya. Acharyas have mentioned Kadali as suitable for the Kshara formulation. Patients suffering from Abhyantara Arsha are subjected to KadaliPratisaraneeyaKshar and efficacy of KadaliKsharPratisaran and inj. Setrol is compared in the management of AbhyantarArsha. In Clinical study an Open randomized controlled clinical trial is conducted of trial group A and control group B for 30 patients in each group. In observations a detailed explanation is given about distribution of patients according to age, sex, occupation. The results of the study are analyzed statistically compared and are presented in tables and graphs form. By highlighting the outcome of the study along with limitations and scope of further improvement it is concluded that KadaliKsharPratisarana gives potent effects in AbhyantarArsha.

KEYWORDS

Arsha, Ksharpratisaran, Inj. Setrol

INTRODUCTION

Arsha is a disease characterized by formation of ankuras (nodules) at GudaPradesh (anal region). Inclusion of Arsha (Haemorrhoids) in Ashtamahagada by Sushrutacharya depicts its importance¹. References of Arsha are found since Vedic period. This disease is very specific to human race because of our erect posture. As revealed from recent statistics irrespective of age, sex and socioeconomic status more than 04% of the population suffers from this disease. Its increased incidence today is due to today's food habits, sedentary life style.

Improper treatment or negligence of Arsha may develop complications like thrombosis, strangulation, portal pyaemia, fibrosis, suppuration, haemorrhage etc³. Sushrutacharya states that landing in complications makes ArshaYappa or Asadhy². Unfortunately all its management procedures like Sclerotherapy, Band ligation, Cryosurgery, Laser therapy etc⁴, have limitations and postoperative complications. Hence, it leaves a scope to find a remedial measure.

Sushrutacharya has considered Ksharakarma as most effective procedure amongst Anushastras due to its properties like Chedana, Lekhana, and Ropana⁵. Acharyas have mentioned Kadali as suitable for the Kshara formulation⁶. Kadali being Pittahar, Balya, Sheetaviryatmak is useful in Arsha. Also previous works carried out on Arsha as Pratisaran with ApamargaKshar, ChitrakKshar revealed that these Kshara being more Teekshnain nature, are more corrosive and cause severe burning pain which may land patient into postoperative complications. KadaliKshar was never tried earlier so in order to formulate and standardized it and as an effort to find a procedure free from postoperative complications, cost effective, minimal invasive in the management of Abhyantara Arsha, this research was carried out. In present study, patients suffering from Abhyantara Arsha are subjected to KadaliPratisaraneeyaKshar as explained in classical texts.

3) HYPOTHESIS

- H₀- KadaliKshara karma procedure is not useful in the management of Abhyantara Arshas.
- H₁ -KadaliKshara karma procedure is useful in the management of Abhyantara Arsha.

4) AIM & OBJECTIVES

Aim:

To evaluate and compare the efficacy of KadaliKsharPratisaran and inj. Setrol in the management of AbhyantarArsha.

Objectives:

1. To observe any adverse effect of KsharaKarma and inj. Setrol on patients of AbhyantarArsha.
2. Compare the effects of KadaliKshar and InjSetrolin treatment of AbhyantarArsha.

5) MATERIALS & METHODOLOGY (STUDY DESIGN STATISTICAL ANALYSIS):-

This is an Open randomized controlled clinical trial. The study was conducted on the patients visiting the OPD and IPD of Shalyatantra department BVDU Ayurveda Hospital.

Study medication:

KadaliKshar is used for this study in trial group. Kadaliwas standardized as per the criteria mentioned in the Ayurvedic Pharmacopeia of India⁷.

Comparator:

Inj. SETROL (Each ml contains: Sodium Tetracycl Sulphate Concentrate Equivalent to Sodium Tetracycl Sulphate 30 mg) was used as a control group⁸.

Selection and Exclusion criteria:

Irrespective of sex and socioeconomic status, the patients reporting complaints of P/R bleeding, constipation or any symptoms of AbhyantarArsha were screened along with proctoscopic examination and eligible patients were included in the study.

1. Inclusion criteria:

- Diagnosed Patients of Abhyantara Arsha with I, II degree.
- Patients in age group of 18-70 years.
- Patients with controlled systemic diseases like Diabetes and Hypertension.

2. Exclusion Criteria:

- Abhyantara Arsha of secondary origin and /or associated pathology of colon and anal canal like Ulcerative colitis, Crohn's diseases, condyloma, Parikartika i.e. Fissure in Ano and Bhagandara i.e. Fistula in Ano, Malignancy of rectum and anal canal.
- Patients having Hb% less than 8 gm%.
- Patients associated with uncontrolled systemic diseases like Diabetes and Hypertension.
- Pregnant women.
- Patients with infective conditions like H.I.V. and Hbs.Ag.

Method of randomization:

Patients befitting the eligibility criteria were selected randomly by chit method and divided into two groups.

Study groups: Two groups –

Group A: - Trial Group KadaliKsharLepa

Dose: As per requirement for KsharLepa on each Arsha

Sitting- Single sitting for each Arsha

Application procedure for KsharaPratisaran-

Lithotomy position given, anal canal and peri anal area painted with antiseptic solution, draping done. Arshalocated with Proctoscopic examination. Haemorrhoid was made to protrude into the slit proctoscope. Protruded mass encircled by cotton to avoid spillage of Kshar on normal mucosa. Kshara applied over hemorrhoid with the help of applicator for VaakshatamatraPramana i.e. approximately 90 seconds. When colour of mass became pakwajambuphalasamana i.e. Reddish black in colour, Kshara was washed with Kanji for neutralization. Same procedure repeated over other mass, after one week if present. Patient observed for any adverse effects.

Group - B:-Control group Inj. Setrol

Active medication Inj. Setrol

Dose Maximum 1ml for each Arsha

Sitting Single sitting for each Arsha

Application procedure for injSetrol-

Arsha made to protrude in to the slit proctoscope. Then inj. Sterol 0.5 ml was diluted with 0.5ml distilled water and injected sub mucosal in each Arsha. Color change was noted. Same procedure repeated over the other mass, if present. Patient was observed for any adverse effects.

Sample size: 30 patients in each Group

Treatment details: Post procedure medication

AnulomakDravya- GandharvaHaritaki 1gm / night for 14 days with KoshanaJala.
Shoolaghna- TriphalaGuggulu 500mg Twice in a day, for 7 Days with KoshanaJala.
AvgahaSweda- AvgahaSweda with Lukewarm water twice in a day for 7 Days

follow up Procedure & medicine was started. Assessment of patients before treatment was done. Follow up of patients taken on 4th, 7th, 14th, 21st day and assessment of patients after treatment was done.

Investigations –

- **BLOOD COMPLETE HAEMOGRAM WITH E.S.R.**
- **BLOOD SUGAR FASTING AND P.P.**
- **BT, CT AND PTINR**
- **HIVI AND IIL**
- **HBS, AG.**
- **URINE**

Post procedure medication, Screening and follow up, Investigations are same in both group.

6) ASSESSMENT OF EFFICACY

PARAMETERS:

1. DEGREE OF HAEMORRHOIDS – ACCORDING TO INTERNATIONAL SCORE⁹

- 0- NO HAEMORRHOIDS
- 1- Ist HAEMORRHOID DOES NOT COME OUT OF THE ANUS.
- 2- IInd HAEMORRHOIDS COME OUT ONLY DURING DEFECTION & IS REDUCED SPONTANEOUSLY AFTER DEFECTION
- 3- IIIrd HAEMORRHOIDS COME OUT ONLY DURING DEFECTION & DO NOT RETURN BY THEMSELVES, BUT NEED TO BE REPLACED MANUALLY
- 4- IVth HAEMORRHOIDS ARE PERMANENTLY PROLAPSED & PROPER REPLACEMENT IS NOT POSSIBLE.

2. P/R BLEEDING

- 0- no bleeding
- 1- Once in a while
- 2- 1-2 times in a week
- 3- Regular Bleeding since last few days
- 4- Profuse Bleeding

The following criteria were used to assess the efficacy of the procedure, in the corresponding groups,

- Relief in the signs and symptoms.
- Occurrence of SamyakDagdhaLakshanas.

- Time taken for complete dissolution of Arshankura.
- Occurrence of complications.
- Convenience of the procedure.

OBSERVATIONS

Table A-1 : AGE

Age group in year	No. of patient in Group A	No of patient in Group B
25-30	14	13
30-35	11	10
35-40	3	6
40-45	2	1

Table A-2 : SEX

	Group A		Group B	
Sex	Male	Female	Male	female
Patients	21	9	20	10

Table A-3 : OCCUPATION

Occupation	No. of patient Group A	No. of patient Group B
Service	11	9
Labour	9	10
House wife	5	6
Driver	5	5

Table A-4 : HABBITS

Habbits	Group A	Group B
Tobacco chewing	6	6
Tea/coffee	14	15
Alcoholic	4	5
Bidi/cigarette	6	4

Table A-5 : PRAKRUTI

Prakruti	VK	VP	PK
No. of Patient in Group A	11	11	8
No. of patient in Group B	12	9	9

Table A-6 : BLEEDING

Bleeding				
	Group A		Group B	
Sevity	BT	AT	BT	AT
Mild	9	0	15	0
Moderate	16	0	13	0
Severe	5	0	2	0

Symptom levels significantly reduced here, hence H₀ is rejected, so both groups are equally effective.

BLEEDING GROUP A

	Pre	Post	t-cal	t-table	Result
Mean	1.866	0	15.259	2.66	Reject H ₀
S.D.	0.67	0			

Since t cal > t table then we reject H₀, i.e. Treatment is effective on bleeding

GROUP B

	Pre	Post	t-cal	t-table	Result
Mean	1.566	0	15.966	2.66	Reject H ₀
S.D.	0.5374	0			

Since t cal > t table then we reject H₀, i.e. Treatment is effective on bleeding

	Group A	Group B	t-cal	t-table	Result
D	1.866	1.566	1.91	2.66	Reject H ₀
S.D.	0.67	0.5374			

t cal < t table hence group A & Group B are equally effective.

Table A-7 : degree of Arsha

Degree of Arsha				
	Group A		Group B	
	BT	AT	BT	AT
I	21	0	25	0
II	9	0	5	0

Levels significantly reduced hence H₀ is rejected, so both groups are equally effective.

GROUP A

	Pre	Post	t-cal	t-table	Result
Mean	1.3	0	15.539	2.66	Reject H ₀
S.D.	0.458	0			

Since t cal > than t table hence H₀ rejected..Treatment is effective on colour

GROUP B

	Pre	Post	t-cal	t-table	Result
Mean	1.166	0	17.496	2.66	Reject H ₀
S.D.	0.3652	0			

Since t cal > than t table then we reject H₀.e. Treatment is effective on colour

	Group A	Group B	t-cal	t-table	Result
Mean	1.3	1.166	1.25	2.66	Reject H ₀
D.	0.458	0.3652			


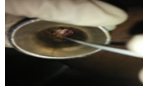
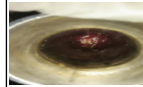



tcal < t table hence group A & Group B are equally effective.

DISCUSSION

KadaliKsharPratisaran is cost effective treatment. KadaliKsharpratisaran in Arshais an easy method to perform on OPD basis with significant result,fewer side effects.Probable action of KadaliKshar is corrosive. It acts as the cauterization of the bleeding pile mass. Less or minimal complications (sometimes local edema if applied on external haemorrhoids i.e. below dentate line) is occurred as compared with inj. setrol which may cause proctitis, sensitivity etc. Inj. SetrolIts action is on the lipid molecules in the cells of the vein wall, causing inflammatory destruction of the internal lining of the vein and thrombus formation eventually leading to sclerosis of the vein. Maximum patients of Arsha are Vatadhik Pitta and VatadhikKaphaPrakrutiwere found. As far as age is concerned, the occurrence of the Arshais very common in age group 25yrs to 35 yrs. Arsha disease affects persons, irrespective of sex .In this study more male patients are found than female. Most patients of Arshawere workers, laborers and service class. Among most of all the patients were addicted to Tea, Tobacco, smoking or alcohol. Agnimandya which is the main cause of Arsha was also found in majority of patients. Arsha is found generally associated with Malavibandh (Constipation) in patients, as stated in texts.In Arsha a large group of anaemic patients were found.

CONCLUSION AND RESULT

1. KadaliKsharpratisarana gives potent effects in AbhyantarArsha (internal hemorrhoids).
2. The KadaliKshar is easy to prepare.
3. In the management of Arsha's two symptoms i.e. bleeding and colour of pile mass; better result in KadaliKshar is observed, so we can conclude that treatment given in trial group is equally efficient to treatment given to control group.
4. The both drugs have no side effects are quite safe and easy to apply.
5. From the socio-economic view the KadaliKshar is relatively cheap.
6. Ksharpratisaran in the management of Arsha is one of the good ambulatory types of treatment in area of parasurgery (anushalya).

Photo graphs	Before treatment	During treatment	After treatment
KadaliKshar			
Inj. setrol			

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