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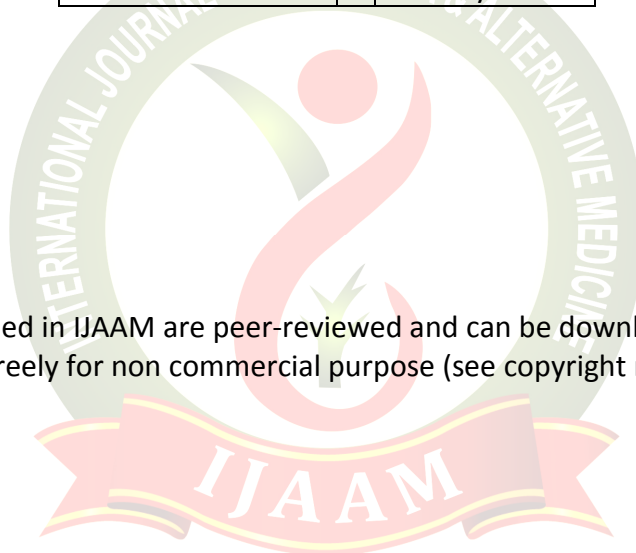
CONTROLLED CLINICAL STUDY OF HERBAL SCELORASANT INJECTION OF *APAMARGA KSHAR* ON INTERNAL HAEMORRHOIDS (I^o & II^o)

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CONTROLLED CLINICAL STUDY OF HERBAL SCELORASANT INJECTION OF *APAMARGA KSHAR* ON INTERNAL HAEMORRHOIDS (I^o & II^o)

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ABSTRACT:

Haemorrhoid is one of the trouble shooter diseases in most tropical and sub-tropical countries. The preferred treatment for I^o & II^o internal haemorrhoid is sclerotherapy, Rubber band ligation, Cryotherapy. Sclerosant agents available in market had more or less adverse effects like burning, bleeding, nausea, etc. which induces local pain, irritation, etc. As per ancient surgeons, *Ksharkarma* is well known specialised treatment for internal haemorrhoids. *Apamarga kshara* is preferred drug for the same, which had the *Arshoghna* properties. But result is not up to mark and had profuse discharge. Herbal sclerosant injection of *Apamarga Kshara* prepared in collaboration with Dept of Pharmachemistry, C U Shah College of Pharmacy, Santacruz, Mumbai and also animal study for acute toxicity and dose 100 patients of internal haemorrhoids were selected for the study and were randomly classified in to two groups of 50 cases each. The group A was treated with Herbal sclerosant injection & group B Inj. Polidocanol was treated with in standard dosage by standard sclerotherapy method. Both groups have shown highly significant results in relieving the symptoms of internal haemorrhoids. Herbal Sclerosant injection group 42% patients are completely cured, whereas in Polidocanol group only 20 % patients are completely cured. Hence Herbal Sclerosant injection seems to be more effective in internal haemorrhoids.

Key Words : Internal Hemorrhoids, Herbal Sclerosant Injection, Inj. Polidocanol, Sclerotherapy

INTRODUCTION:

In this upcoming Era of Hurry, Worry & Curry, fast food, change or irregularity in diet, sedentary life style and tremendous mental stress is there. All these factors disturb digestive system which result into so many anorectal diseases & one of the important is hemorrhoids [1]. Haemorrhoid is a disease, which is very specific to human race only, due to its erect posture [2]. Ayurveda recognizes this disease having discomfort and is simulated to a trouble-shooter like enemy. These are painful or painless swellings protruding out from the anus. They may bleed enough to cause condition like anaemia [3].

In *Ayurveda*, the description of piles is given in ancient *samhita* as "*Arsha*". The deranged *vayu*, *pitta*, *kapha* etc. become dislodged from their natural seats in the body and carried down through large intestine in the descending colon and getting lodged there to give rise to growth which is known as piles [4]. These growths chiefly appear in persons suffering from impaired digestion. Since then *Arsha* (haemorrhoid) is known to mankind as a common anorectal disease and difficult to treat. According to *Ayurveda*, *Mithya aahar vihar* is one of the major aetiological factors of *Arsha*; it is unavoidable in this busy modern lifestyle due to junk food habit and

uncontrollable addictions. The progressive pathogenesis of disease produces various symptoms in patients such as bleeding, prolapse, pruritis ano, pain etc. To treat this ailment, number of modalities are present having their own importance.

There are many herbal preparations described in ancient scriptures to cure haemorrhoids. Most of these are to be taken by oral route while some are for local application [4]. Out of these modalities *Ksharkarma* is taken in study for I^o & II^o haemorrhoid as the signs mentioned by *Sushruta* for *Arsha* that can be treated by *Ksharkarma* resemble that of I^o & II^o haemorrhoids. Previous works has been done on *Kshara pratisaran* in internal haemorrhoid using different *Kshara* [5]. *Apamarga Kshara pratisaran* (applying directly on pile mass) has also been done, but this procedure shows some difficulties and adverse effects. So same *Apamarga kshara* is choosen for study and it is administrated by sub mucous route to overcome the difficulties which occurs in local application. In modern surgical practice sclerosant injection is used for treatment of I^o & II^o internal haemorrhoid. These days Inj. Polidocanol 3% is used as sclerosant as having better result than other sclerosant and having minimal side effects [6].

This work may help to give a better treatment for I^o & II^o Internal haemorrhoid. In this study we would like to establish the exact mode of action of *Apamarga Kshara* injection. Patients were observed for a period of one month. Their history, investigation & progress were noted in standard proforma. Observations were noted and conclusions were drawn. Thus herbal sclerosant injection is taken with a view to evaluate its properties & efficacy clinically in I^o & II^o haemorrhoids. This research work is a sincere effort for bringing herbal sclerosant injection in limelight with the goal of introducing better, safer & cost effective treatment.

Materials and methods:

Consent: - Well informed written consent of all patients was taken before starting treatment.

Type of study: - Open Randomized Controlled study. Computer generated randomization chart was used to generate randomization chart.

Centre of Recruitment:- from OPD and IPD of M. A. Podar hospital, Dr. A.B.Rd, Worli, Mu-18

No. of patients:-Group A (Trial Group) = 50 pts
Group B (Control Group) = 50 pts

Drug used:-

Group A: Herbal Sclerosant injection of *Apamarga Kshara* consists of well prepared drug in liquid form which is packed into vials and then stored in dry and cool place, previous to use.

Group B: Polidocanol 3% (In form of Inj. Asclerol which is available in market)

Duration of Treatment: 3 Weeks

Follow up:- on 0, 1, 2, 3, 5, 8, 12, 21 days and After that weekly once upto 1 month then after 3 months and 6 months.

Method of preparation of drug: It includes following stapes:-

1. Preparation of *Apamarga Kshara*
2. Preparation of Herbal Sclerosant injection.

Preparation of Apamarga Kshara: *Apamarga Kshara* was prepared as per standard method described in *Ayurvedic Text*.^[7]

Preparation of Herbal Sclerosant injection

Herbal sclerosant injection was prepared by using this *Kshara*, which is well prepared by standard methods. Herbal sclerosant injection was prepared by a pharmacist, working at a C. U. Shah College of Pharmacy, SNT Women's university, Santacruz, Mumbai.

1. The weighed quantity of *Apamarga kshara* was taken in a 150 ml beaker. To this 0.2 ml of PEG (Polyethylene Glycol) 400 was added with

sterile water for injection (q.s.) and mixture was stirred for 1 minute on a magnetic stirrer at a speed of 30 rpm. and then preservative was added to the solution. Then the final solution was transferred into a vial following filtration. All this steps were carried out in aseptic precautions.

2. Solution was filtered with help of micro filters (Millipore) twice to ensure particle free solution. The solution was collected in glass container which was previously made clean and sterile.
3. This filtered solution was then sent to pharmacy's analytical laboratory to ensure about standards laid down by the pharmacy.
4. Solution was then sent to ampoule filling section where it is filled into sterile vials in quantity of 5 ml each in a aseptic way on the automatic vial filling, sealing and cutting machine.
5. The manufactured vials were then checked for presence of residual particles and again sterilized and then sent to analytical laboratory for process checking.
6. These were labeled and packed suitably, then handed to author for experimental purpose.
7. The final concentration of injectable was 150 mg/ml or 750 mg/vial.

Animal Study: - Acute toxicity study of Apamarg Kshar injection:

Objective: - To investigate the prepared injection for any adverse or toxic effects.

Grouping of Animals: The animals were divided into two groups:

- **Normal control:** This group of animals received 0.9% Saline
- **Treatment group:** This group receives the injection by submucosal route.

Procedure: Swiss albino mice in the weight range of 18-22 gm were divided into five groups, 3 animals per group. The doses selected were 5, 50, 300, 2000 mg/kg body wt. as per OECD 423 guidelines. Animals were observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours and daily thereafter, for a total of 14 days. On 14th day, treatment group, rats was killed and specimens taken away for haematological and histopathological examinations. Specimens are Blood, Skin, Liver, Kidney, spleen, Heart, and Brain.

Criteria for observation:

a. Clinical signs: Animals were observed daily for clinical signs such as gross changes in the activity and behavioural pattern. They were also observed

for presence of tremors, convulsions, salivation, diarrhoea and lethargy.

b. Body weight: The mean group body weight of the control and test group animals was recorded on 0th, 7th and 14th day respectively.

c. Mortality: Animals were observed daily for mortality during the period of study.

d. Food consumption: The quantity of food consumed by control and test groups was recorded on 0th, 7th, and 14th day respectively.

Statistical Analysis of study: The data was analysed for statistical significance by one way Analysis of variance (ANOVA) followed by Dunnett's t-test for the comparison with the control groups. The difference is considered to be significant at 5% level ($p < 0.05$).

Clinical Study

Group A: Herbal sclerosant injection of Apamarga Kshara

Group B: Inj Polidocanol 3% purchased from standard pharmacy.

Ayurvedic purgatives with Luke warm water are given as per body constituents & prakruti of patients in both groups to relieve constipation.

Route of Administration: Submucous route at anal mucosa, by standard methods sclerotherapy.

Inclusion criteria

- 1) Pt. of age more than 18 & less than 70 yrs
- 2) Pt. of both sexes (both male & female)
- 3) 1^o & 2^o internal hemorrhoids.
- 4) Both bleeding & Non-Bleeding type of Hemorrhoids.

Exclusion criteria

- 1) External Hemorrhoids.
- 2) Thrombosed Prolapsed internal piles, inflamed piles.
- 3) Pt. of internal hemorrhoids associated with other anal pathology like Fissure-in-Ano, Fistula-in-Ano, ulcerative colitis, crohn's disease, Ca rectum etc
- 4) Pt. with generalized debility disorders like Immuno-compromised (HIV positive), severe anemia (Hb% less than 4 %), HBsAg positive.

INVESTIGATIONS

- Blood:- a) CBC
b) ESR
c) BT, CT
- BSL - Fasting and Post prandial
- Urine – Routine and Microscopic
- HBsAg
- HIV I and II

Criteria for assessment

(1) Per Rectal Bleeding:-

- 0:- No bleeding
- 1:- Mild bleeding with defecation (up to 10 drops)
- 2:- Moderate bleeding (upto 10-20 drops)
- 3:- Profuse bleeding (more than 20 drops)

(2) Pain: - For assessment of pain

Visual Analogue Scale (VAS) : The following scale was used to help out assessing the severity of pain. Patients were asked to locate a finger at any of the numerical over the scale and the severity of pain was assessed according to that for which the numerical are labelled.

0	1	2	3	4	5	6	7	8	9	10
No pain	Mild	Discomforting			distressing		horrible		excruciating	
Nil	Mild	Moderate				Severe				

- No : 0
- Mild : 1
- Moderate : 2
- Severe : 3

(3) Discharge:-

- 0:- Absent
- 1:- Discharge seen only after or before defecation without soiling of undergarments
- 2:- Pt. feels some discharge in anal region with soiling of undergarments
- 3:- Profuse discharge with soiling of undergarments, making it necessary to change.

(4) Burning :-

- 0:- No burning
- 1:- Mild (upto 1 -2 hrs after defaecation)
- 2:- Moderate (more than 3 hrs after defaecation)
- 3:- Severe (continuous burning)

5) Haemorrhoidal Size:-

- 0:- No
- 1:- Mild (Swelling visible in proctoscopy but not coming outside of anus)
- 2:- Moderate (Swelling reduces automatically)
- 3:- Severe (Requires digital reposition)

Criteria for result assessment

- **Cured-** More than 75% relief in signs & symptoms.

- **Improved**-Above 50 but below 75% relief in sign & symptoms.
- **Relieved**-Relief in signs & symptoms between 25 to 50%.
- **Not cured**- Less than 25% relief in signs & symptoms.

Ethical Guidelines:

Before the initiation off the study, the study protocol and related documents were reviewed and approved by IEC at R A Podar Medical (Ayu) College and M A Podar Hospital, Worli, Mumbai-18. **IEC approval no. – RAP/V.V.-2/IEC/6083/2012** dated **03/08/2012**. The study was conducted in accordance with schedule Y of drugs and cosmetics act 1945, India, amended in 2005 and ICMR ethical guidelines for biomedical research on human participants.

RESULTS

All Observations and results were recorded in following groups:

Animal Study (Table 1):

Prior to the study, animal study was conducted for acute toxicity of the drug in animals. Study of toxicological effect and inflammatory response of Herbal Sclerosant injection of Apamarga Kshara in Swiss albino mice by submucous route:-

Swiss albino mice in the weight range of 18-22 gm were divided into eight groups, 3 animals per group. The doses selected were 5, 50, 300, 2000 mg/kg body weight as per OECD 423 guidelines. Animals were observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours and daily thereafter, for a total of 14 days. Both groups were then observed for next fourteen days and on fourteenth day, minces were killed which were Group No. 2 and specimens taken away for haematological and histopathological examinations. Specimens were Blood, Skin, Liver, Kidney, spleen, Heart and Brain.

Histopathological Examination Report:-

1. Histo-Pathological examination of Slides prepared by cross section of various organs like Liver, Kidney, Heart, Muscle, Brain and skin.
2. All above section shows no any specific pathological changes Except skin which shows sterile inflammatory changes.

Conclusion: - a. The Injection of Apamarga kshara produces local sterile inflammatory changes.
b. The systemic effect of local injection of Apamarga kshara on important vital organs is NIL,

when the quantity of injection was 450 mg in 3 ml injection.

Clinical Assessment:-

Demographic analysis: Various demographic values are given below into tables (Table 2 – 9). Statistically all groups are homogenous.

Subjective assessment:-

Percentage Relief in Symptoms of 50 patients in Trial group (Group A) **(Table -10):**

Trial group of 50 pts indicate, 85.44 % relief in Per Rectal Bleeding, 87.88 % relief in associated pain, 69.33 % relief in Burning Sensation while 65.17 % relief in Size of haemorrhoids.

Percentage Relief in Symptoms of 50 patients in Control group (Group B) **(Table -10):**

Control group of 50 pts shows, 59.34 % relief in Per Rectal Bleeding, 71.19 % relief in associated pain, 56.14 % relief in Burning Sensation while 63.44 % relief in Size of haemorrhoids.

Effect of therapy on symptom score in trial Group (Group A) By Wilcoxon matched pairs signed rank test

Per rectal bleeding: Sum of all signed ranks was 1176. The no. Of pair, used in calculations were 48, Z value was 6.031 & P value was <0.0001, which was statistically extremely significant.

Pain: Sum of all signed ranks was 946. no. of pair, used in calculations were 43, Z value was 5.711 & P value was <0.0001, which was statistically extremely significant.

Discharge: Sum of all signed ranks was 630. no Of pair, used in calculations were 35, Z value was 5.159 & P value was <0.0001, which was statistically extremely significant.

Burning sensation in anal canal: Sum of all signed ranks was 528. The no. Of pair, used in calculations were 32, Z value was 6.031 & P value was <0.0001, which was statistically extremely significant.

Haemorrhoidal Size: Sum of all signed ranks was 1035. The no. Of pair, used in calculations were 45, Z value was 5.841 & P value was <0.0001, which was statistically extremely significant.

Effects of therapy on symptom score in control Group (Group B) By Wilcoxon Matched Pairs signed rank test

Per rectal bleeding: Sum of all signed ranks was 780. The no. Of pair, used in calculations were 39, Z value was 5.442 & P value was 0.0089, which was statistically very significant.

Pain: Sum of all signed ranks was 528. no. Of pair, used in calculations were 32, Z value was 4.937 & P value was 0.001, which was statistically extremely significant.

Discharge: Sum of all signed ranks was 465. no. Of pair, used in calculations were 30, Z value was 4.782 & P value was <0.0001, which was statistically extremely significant.

Burning sensation in anal canal: Sum of all signed ranks was 378. The no. of pair, used in calculations were 27, Z value was 4.541 & P value was <0.0001, which was statistically extremely significant.

Haemorrhoidal Size: Sum of all signed ranks was 861. The no. Of pair, used in calculations were 41, Z value was 5.579 & P value was 0.0044, which was statistically very significant.

Comparison of Symptoms score of Both Group by Mann Vitney test

Per Rectal bleeding: -Difference between symptom score of BT and AT in Trial was 3070 and that of control group was 1980. The difference of symptom score was 1.76 ± 0.97 for trial group and 1.08 ± 0.77 that of control group. Z Value was 3.343 and $p=0.0002 < 0.05$, Statistical analysis shows that there is no difference in both the group.

Pain : - Difference between symptom score of BT and AT in Trial was 3135 and that of control group was 1915.5. The difference of symptom score was 1.74 ± 1.026 for trial group and 0.84 ± 0.76 that of control group. Z Value was 3.85 and $p < 0.0001 < 0.05$, Statistical analysis shows that there is no difference in both the group. Whenever patient comes to OPD with 1st and 2nd degree haemorrhoids, patient gave history of discomfort, which they can't explained, so they described as pain.

Discharge: Difference between symptom score of BT and AT in Trial was 2842 and that of control group was 2208. The difference of symptom score was 1.04 ± 0.85 for trial group and 0.64 ± 0.56 that of control group. Z Value was 2.13 and $p=0.027 < 0.05$, which is statistically significant.

Burning sensation in anal canal: Difference between symptom score of BT and AT in Trial was 2726 and that of control group was 2324. The difference of symptom score was 0.8 ± 0.7 for trial group and 0.58 ± 0.57 that of control group. Z Value was 1.33 and $p=0.1613 < 0.05$, which is considered statistically not significant. Statistical analysis shows that trial group drug has better effect than control group.

Haemorrhoidal Size: Difference between symptom score of BT and AT in Trial was 2523 and that of control group was 2527. The difference of symptom score was 1.16 ± 0.61 for trial group and 1.18 ± 0.8 that of control group. Z Value was 0.108

and $p=0.9916 < 0.05$, which is considered statistically not significant. Statistical analysis shows that trial group drug has better effect than control group

Total Effect of Therapy (Table 11): As out of 50 patients of trial group 21 pts were cured, 20 pts were Improved, 9 pts were relieved, while out of 50 pts of control group 10 pts were cured, 19 pts were improved, 20 pts were relieved & 1 pt. Does not had any significant effect.

It indicates that Apamarga Kshar Injection has significant role on Internal Haemorrhoids than Inj. Polidocanal 3% with the help of. Chi-square test we concluded the result as $p < 0.05$, Hence Apamarga Kshar Injection was more effective than control group drug, Inj. Polidocanal 3%.

DISCUSSION

After getting to much conservative line of treatment finally pts came to decision of doing surgery. There are so many options available for operative procedure that can be done in 1 & 2 degree internal haemorrhoids, but sclerotherapy is the best & safest one. In Modern daycare practice, Inj. Polidocanal is used in abundance as a sclerosant agent & it is accepted worldwide. To relieve bleeding per rectum with other symptoms we use generally aerobic, anaerobic with laxative and local ointments but if the treatment is stopped then patient again gets increased pile masses and symptoms. Polidocanal 3% used worldwide but had some side effect, while some patients are allergic to the drug. So this is my effort to find out a remedial measure and alternative herbal sclerosant, which would ideally offer cure of the disease in shorter time, free from complications and piles.

Plan of study: Study was conducted in two stages

- A) **Animal study** to rule out acute toxicity of herbal sclerosant injection and estimate safety of the drug for given dose as well as route of administration.
- B) **Controlled clinical study** to prove the efficacy of the herbal sclerosant injection in humans.

Animal study

1. The animals treated at different dose levels with the Apamarg kshar injection in all the groups exhibited normal activity and behavioural pattern.
2. There were no clinical signs of tremor, convulsions, salivation, diarrhoea and lethargy.

3. Animals from different dose groups exhibited normal body weight gain during the study.
4. Food intake of the vehicle control group and other formulation group was also similar.
5. The above findings revealed that the formulations were safe at doses 5, 50, 300 and 2000 mg/kg.
6. None of the animals were found to be in moribund condition in all groups at the dose as high as 2000 mg/kg until the 14th day of study.
7. The doses used for acute toxicity study were much higher than those doses, which could be used in any study and hence the formulations were safe.

Clinical study:

General Discussion:

Age wise distribution shows that the incidence of internal haemorrhoids is middle age (Age group of 31 – 40 yrs) persons more suffering from ano-rectal problems. It could be due to the sedentary lifestyle, unusual food habits, Hurry-Curry-Worry, etc which is consumed more in middle age.

Sex wise distribution of disease shows that the difference may be due to shyness of female patient to discuss the ailment of private organs.

Religion wise distribution of disease shows dominance of Hindu patients in the study which may be due to dominance of Hindu population in the privilege of the working area of study.

Occupation wise distribution of disease shows incidence of haemorrhoids is more in peoples who had a sedentary job. Those peoples who works by sitting in the office for some long hours are more prone for developing internal haemorrhoids.

Diet wise distribution of disease indicates that the patients having mixed diet variety are more prone to develop internal haemorrhoids. In accordance to the dietary habit not all patients are in mixed diet variety but approximately all take spicy, junk foods & some peoples had much quantity of non-veg diet in it, Causing constipation leading to increased abdominal pressure due to straining during the defecation, as non vegetarian food doesn't has roughage and leads to constipation which later on develops internal haemorrhoids.

Addict to any addiction causes Constipation & Agnimandya resulting into ano-Rectal diseases like internal haemorrhoids.

Clinical parameter: Considering the signs and symptoms during the treatment and subsequent follow up, generated data is subjected to appropriate statistical test i.e. Wilcoxon-matched-pair sign-rank test and Mann-Whitney test, which suggests the effect of treatment as follows:

A) PR bleeding: Some patient's complaints Per Rectal bleeding due to erosions developed over internal haemorrhoids by friction of hard stool and straining. From Statistical analysis it shows that the herbal Sclerosant injection is good in reducing per rectal bleeding in internal hemorrhoids.

B) Pain: Statistical data shows both Trial drug & Control one were effective in post operative pain management. pain is more on 3rd day due to inflammatory changes which is later on resolved by 8 day. From Statistical analysis it shows that the both groups are good in reducing the pain in internal hemorrhoids.

C) Discharge: From Statistical analysis it shows that the herbal Sclerosant injection is quite good in reducing the discharge.

D) Burning in Anal Canal : From Statistical analysis, it shows that drug of both group had equivalent action on internal haemorrhoids in reducing burning. Burning, initially which is vary less, increases after giving both sclerosant injections initially, and later on relieves the burning more clearly by Herbal Sclerosant injection.

E) Haemorrhoidal size: From Statistical analysis it shows that drug of both group had equivalent action on internal hemorrhoids in reducing hemorrhoidal size.

Total Effect of Treatment : Herbal Sclerosant injection of Apamarga Kshara has significant role on I⁰ & II⁰ internal haemorrhoids than injection Polidocanol, with the help of **Chi-square test** we concluded the result as p was <0.05, Hence herbal Sclerosant injection of Apamarga Kshara was more effective than control group drug injection Polidocanol.

CONCLUSIONS

1. Local sub mucous injection of Apamarga Kshara, in total quantity of approximately 3 ml (1 ml in each pile pedicle) was sufficient to shrink the I⁰ and II⁰ internal haemorrhoids. Without complications and to give good result in the patients except burning at initial stage.
2. This treatment is ideal, alternative, effective, ambulatory, daycare surgical procedure and it can be done under local anesthesia I⁰ and II⁰ internal haemorrhoids in any hospital at rural and urban area.
3. In the present study, it was observed that Herbal sclerosant injection of Apamarga Kshara does not produces any local or systematic toxicity as per animal study and similarly does not have any adverse effect during study and it is also safety.
4. Herbal sclerosant injection of Apamarga Kshara therapy is a good and promising

- alternative herbal sclerosant in I^o and II^o internal haemorrhoids.
5. It could be the good alternative herbal sclerosant injection as like modern sclerosant

injection if multicentric trials are carried out with SOP and with large number of patients.

Table 1: Animal Study: the weight of animal and their food intake are given below

Group	Dose (mg/kg)	Mortality	Food intake (g)			Weight of animal (g)			LD ₅₀ (mg/kg)
			0 th day.	7 th day	14 th day	0 th day	7 th day	14 th day	
Vehicle control (0.9% Saline)	5	0/3	5.1	5.1	5.3	26.5±0.5	27.4±0.6	28.0±0.6	>2000
	50	0/3	5.1	5.2	5.4	28.7±0.3	29.7±0.4	30.2±0.7	
	300	0/3	5.2	5.2	5.4	26.8±0.3	27.5±0.3	28.3±0.2	
	2000	0/3	5.2	5.2	5.4	29.5±0.5	30.1±0.7	30.5±0.8	
Apamarg Kshara injection	5	0/3	5.2	5.3	5.6	28.3±0.4	29.0±0.6	29.50±0.9	>2000
	50	0/3	5.3	5.2	5.3	29.5±0.6	29.9±0.6	30.3±0.7	
	300	0/3	5.3	5.2	5.2	27.0±0.3	28.2±0.1	29.3±0.2	
	2000	0/3	5.4	5.5	5.3	29.2±0.9	29.9±0.9	30.7±0.9	

Values are expressed as Mean ±SEM, n=3.

* p<0.05, considered significant.

Table 2 : Age wise classification of 100 patients

Age(In Yrs)	Group-A	Group-B	Total
18-30	8	8	16
31-40	17	21	38
41-50	14	13	27
51-60	10	6	16
61-70	1	2	3

Table 6 : Education status wise classification

Education	Group-A	Group-B	Total
Literate	4	10	14
Undergraduate	6	12	18
Graduate	40	28	68

Table 3 : Sex wise distribution

Sex	Group -A	Group-B	Total
Male	36	35	71
Female	14	15	29
Total	50	50	100

Table 7 : Marital status

Marital Status	Group-A	Group-B	Total
Married	47	44	91
Unmarried	3	6	9

Table 4 : Religion wise distribution :

Religion	Group-A	Group-B	Total
Hindu	40	38	78
Muslim	6	5	11
Others	4	7	11

Table 8 : Dietary Habit status

Diet	Group-A	Group-B	Total
Veg	19	28	47
Mixed	31	22	53

Table 5 : Occupational Status :

Occupation	Group-A	Group-B	Total
Labour	6	10	16
Business	10	4	14
Job	17	21	38
Housewife	9	11	20
Others	8	4	12

Table 9: Addiction Habit status

Addiction	Group-A	Group-B	Total
Tobacco	9	16	25
Smoking	5	13	18
Alcoholism	8	11	19
No	28	10	38

Table 10: Percentage Relief in Symptoms of 100 patients in both groups

Sr No	Symptoms	Group - A				Group - B			
		BT	AT	Diff	%	BT	AT	Diff	%
1	Per Rectal Bleeding	103	15	88	85.44	91	37	54	59.34
2	Pain	99	12	87	87.88	59	17	42	71.19
3	Discharge	75	23	52	69.33	57	25	32	56.14
4	Burning	75	35	40	53.33	70	41	29	41.43
5	Haemorrhoidal Size	89	31	58	65.17	93	34	59	63.44

Table 11: Total Effect of Therapy

	Group A		Group B	
	No	%	No	%
Cured	21	42	10	20
Improved	20	40	19	38
Relived	9	18	20	40
Not Cured	0	0	1	2
Total	50	100	50	100

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