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"A CONTROLLED CLINICAL STUDY OF HERBAL SCLEROSANT INJECTION OF APAMARGA KSHAR ON INTERNAL HAEMORRHOIDS (I^0 & II^0)".

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ABSTRACT

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. Out of these modalities Kshara karma is taken in study for I^o & II^o haemorrhoid as the signs mentioned by Sushruta for Arsha that can be treated by Kshara karma resemble that of I^o & II^o haemorrhoids. Previous works has been done on Kshara pratisaran in internal haemorrhoid using different Kshara. 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 degree internal haemorrhoid. These days Inj. Polidocanol 3% is used as sclerosant as having better result than other sclerosant and having minimal side effects, henceforth Inj. Polidocanol 3% is taken as control group for the study.

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. 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.

This Era is known as Era of Technology & Information. No one can deny that Ayurvedic approach towards the disease is holistic. Numerous therapies modalities have been advocated by our Aacharya in the management of each & every diseases, but their efficacy needs re-establishment by means of thorough & intensive researches.

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 under guidance of my guide.

KEY WORDS: Haemorrhoids, injection therapy, scerosant, apamarg kshar.

INTRODUCTION

Ayurveda is for maintenance of health, to prevent & to cure diseases. Basic principles of Ayurveda have significant Value in the life of modern era, hence one can't deny the implacability of principles, and these principles are based on strict experimental studies of several years. Results are outcome of those studies have been given a place in Ayurvedic texts. So nowadays people are coming back to the nature from synthetics, hence the Ayurveda will be the future medicinal science of the world, not only the India.

The Ayurvedic system of medicine has been prevalent in India since the Vedic period, and still remains the mainstay of medical relief to over 60 per cent of the population of the nation. It is the most ancient science of life having a holistic health approach. It is the science dealing with physical, mental and spiritual health, it not only deals with treatment of diseases but also deals with preventive measures of disease and life style management for a healthy living. Ayurveda is known to mankind since may be existence of mankind on earth. Its presence is mentioned in "*Atharvaveda*" and considered as Upveda of it. Though known since long time, Ayurveda was texted as a separate encyclopaedic and authorative classic book by Sushruta in 2000 B.C.

In this upcoming Era of Hurry, Worry & Curry, fast food, change or irregularity in diet & diet timing, sedentary life style, tremendous mental stress is there. All these factors disturb digestive system which result into so many diseases & one of the important group is become Ano-Rectal diseases. Such a wide spread disease offers a great challenge for the surgeon's world as well as to the patients also.

Haemorrhoid is a disease, which is very specific to human race only, due to its erect posture. Haemorrhoid is one of the commonest disease observed in Indian territory. Ayurveda recognizes this disease as very painful 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. Basically piles swelling or protrusion from the anus is the bunch of the haemorrhoidal veins which have become tortuous for some reason.

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 growths of polyp which are known as piles. 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 factor of Arsha, it is unavoidable in this busy modern lifestyle due to junk food habit and uncontrollable addictions. While working in Shalyatantra outdoor patient department and indoor patient department it was observed that percentage of patients suffering from haemorrhoid are significant and hence the disease is selected for the study.

The progressive pathogenesis of disease produce various symptoms in patients such as bleeding, prolapse, pruritis ano, pain etc. To treat this ailment numbers of modalities are present having their own importance. As described in Sushruta Samhita.

While working in Shalyatantra outdoor patient department and indoor patient department it was observed that percentage of patients suffering from haemorrhoid diseases are significant, hence I selected the topic for study.

Arsha covers a vast topic, so haemorrhoid as per modern medicine is taken into consideration in account of Guda-arsha irrespective of its "Doshas". While describing the treatment of "Guda-arsha" Aacharya Sushruta have mentioned four modalities of treatment viz.

1) Bhesajam i.e. treatment by medicines

2) Kshara pratisaran i.e. local application of Kshara(alkali of herbal drug) 3) Agani karma i.e. cauterisation

4) Shastra karma i.e. surgical treatment.

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. Out of these modalities Kshara karma is taken in study for I^o & II^o haemorrhoid as the signs mentioned by Sushruta for Arsha that can be treated by Kshara karma resemble that of I^o & II^o haemorrhoids. Previous works has been done on Kshara pratisaran in internal haemorrhoid using different Kshara. 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 degree internal haemorrhoid. These days Inj. Polidocanol 3% is used as sclerosant as having better result than other sclerosant and having minimal side effects, henceforth Inj. Polidocanol 3% is taken as control group for the study.

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. 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.

This Era is known as Era of Technology & Information. No one can deny that Ayurvedic approach towards the disease is holistic. Numerous therapies modalities have been advocated by our Aacharya in the management of each & every diseases, but their efficacy needs re-establishment by means of thorough & intensive researches.

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 under guidance of my guide.

AIMS

1) To evaluate the efficacy of Herbal sclerosant Apamarga kshar injection in I ^{0} & II ^{o} internal haemorrhoids
2) To evaluate mode of action of apamarga kshar injection as a herbal sclerosant.
3) To do the Animal studies of injection regarding the toxicological effects.
4) To do all established Laboratory tests of herbal sclerosant injection.

OBJECTIVES

1) To Establish Ayurvedic Sclerosant Injection in I ^{0} & II ^{o} internal hemorrhoids.

MATERIAL AND METHODS

Consent: - A well informed written consent of all patients included in study was taken before starting treatment.

Type of study

Prospective Open Randomized Controlled study.

Centre of Recruitment

Patients were selected from OPD and IPD of concerned Ayurveda hospital.

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

Group B (Control Group) = 50

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

Maximum Duration of Treatment for group A and B:

- 3 Weeks

Follow up

- 0, 1, 2, 3, 5, 8, 12, 21 days.

After that weekly once up to 1 month.

1) Method of preparation of drug

It includes following stapes

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

A) Preparation of Apamarga Kshara

Apamarga Kshara was prepared as per standard method described in Ayurvedic Text. It is prepared in Rasashastra and Bhaishajyakalpana Department of our institute.

Apamarga Kshara was prepared by procedure as mentioned in **Sharangdhar Samhita** for that Contents required:-

- Ash of the Completely combusted (burned)

Apamarga Panchanga – 1 part

- Distilled Water – 8 parts

Ash is mixed well into water. It was then filtered with a fine cloth of cotton. Filtered water was placed into large can for complete one night i.e. for 12 hrs. Supernatant layer of the water was separated without disturbing the lower solid material. This clear water was heated with continuous medium heat upto vaporization of water part. Small whitish remainant was collected and preserved as Apamarga Kshara.

This well prepared Apamarga kshara was sent to Pharmacy College for preparation of Herbal Sclerosant injection by available standard methods.

B) 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, SNDT Women's university, Santakruz, Mumbai.

2) Method of preparation of Injection

As supplied by pharmacy

Preparation of Kshara

Apamarga Kshara was prepared in usual way as described in Ayurvedic texts and handed over to the pharmacy for the manufacture of injectables since this facility was not available

with us. Obtained white kshara was collected carefully and immediately packed in dry and clean containers and sent to pharmacy.

In Pharmacy

1. The weighed quantity of Apamarga kshara was taken in a 150 ml beaker. To this 0.2 ml of PEG 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 r.p.m. 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.

3) Animal Study

Acute toxicity study of Apamarg Kshar injection

The Organization for Economic Co-operation and Development (OECD) panel of experts define acute toxicity as "The adverse effect occurring within a short time administration of a single dose of a test substance or multiple doses given within 24 hours."

Objective

The objective of the present animal study was 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 14^{th} day, treatment group, rats was killed and specimens taken away for hematological 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 behavioral pattern. They were also observed for presence of tremors, convulsions, salivation, diarrhea and lethargy.

b. Body weight

The mean group body weight of the control and test group animals was recorded on 0^{th}, 7^{th} and 14^{th} 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 0^{th}, 7^{th}, and 14^{th} 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 ($p<0.05$).

4) Clinical Study

Group A:

Herbal sclerosant injection of Apamarga Kshara

Group B:

Inj. Polidocanal 3% purchased from standard pharmaceutical company.

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

Route of Administration

Sclerosant injection was used by standard methods sclerotherapy which is used worldwide. Herbal Sclerosant injection as well as inj. Polidocanal 3% both administered by sub mucous route at the anal mucosa.

Clinical study of injection Apamarga Kshara

The patients were selected from the case papers prepared at Govt. Ayurvedic Hospital. They were selected on random basis in two groups.

Patients were admitted in the ward after investigations one day prior to the injection therapy. All preoperative preparations were carried out such as shaving around anal and perianal reg, and skin preparation.

Pre op:-

Inj. T.T. 0.5 ml IM

Inj. APK (Apamarga Kshara) sensitivity test 0.2 ml SC.

Informed Written Consent

Assessment of patient for medical fitness for surgery.

One day before operative (Injection Sclerotherapy) all patient receive soap water enema at least once. On the day of procedure, all patient received the inj. Atropine 0.6 mg IM.

Procedure: - All procedure was carried out under local anesthesia employing xylocaine jelly in lithotomy position. Patient was kept 15 min. for rest. Well lubricated slit proctoscope was then introduced in anal canal and thorough inspection of anal canal done. Internal hemorrhoid protruding inside the proctoscope through slit was cleaned with gauze piece. Previously prepared injection of sclerosant drug was then injected sub mucouslly at base of pile mass in such a way that drug should be deposited in space between wall of haemorrhoidal vessel and

mucosal layer of anal canal which is well indicated by Sunrise sign. Desired quantity is injected. Proctoscope was then removed outside, and inserted in other position as necessary. Bleeding, if any, was arrested with sterile gauze pad pressure. Patient is then kept in close observation for next few days.

Preoperative and post-operative assessment was recorded in previously prepared form.

Medium of Dissertation

Mostly in English but using Ayurvedic terminologies in Sanskrit wherever necessary.

Ethical clearance

Clearance from ethical committee of college was taken.

INCLUSION CRITERIA

1) Pt. of age more than 18 & less than 70 yrs
2) Pt. of both sexes (both male & female)
3) 1^0 & 2^0 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-comprimised (HIV positive), severe anemia (Hb% less than 4 %), HBsAg positive.

INVESTIGATIONS

- Blood

a) CBC
b) ESR
c) BT, CT

- BSL

a) Fasting
b) Post prandial

- Urine a) Routine
  b) Microscopic
- HBsAg
- HIV I and II

Criteria for assessment

(1) Per Rectal Bleeding

0:- No bleeding

1:- Mild bleeding with defecation (upto 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 labeled.

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

2:- Moderate

3:- Severe

Criteria for result assessment

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

RESULT

Cured / Improved / Relieved / Not cured

Observation

Observed data of all patient was collected and recorded in C.R.F and same were compared.

Statistical Analysis

All collected data assessed finally and subjected to appropriate statistical analysis.

1. Symptom score of Before Treatment (BT) and After Treatment (AT) of the single group are compared by using Wilcoxon Matched Pairs Signed Rank test which is used for qualitative (Non-Parametric) data. Z value was calculated.
2. Difference occurred in symptoms score due to interference of given drugs was compared with Mann-Vitney test which is used for comparison of difference between means of both group. Z value is calculated.
3. Total effect of study obtained in both group and stated in tabulated form is compared by Chi-Square test and significance is noted.
4. Demographic data was assessed for homogenesity by using Chi-Square test.

OBSERVATIONS AND RESULTS

The study entitled "A CONTROLLED CLINICAL STUDY OF HERBAL SCLEROSANT INJECTION OF APAMARGA KSHAR ON INTERNAL HAEMORRHOIDs (I^0 & II^0)" was planned to evaluate sclerosant action of Apamarga Kshar Injection on Internal Haemorrhoids (Abhtantar Arsha).

All Observations were recorded in following groups:

A) Animal Study

i) Behavioural Observation

ii) Histopathological findings.

B) Clinical Study

i) Demographic Analysis

ii) Subjective Analysis

A) Animal Study

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.

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.

Both groups were then observed for next fourteen days and on fourteenth day, mices 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

Histo-Pathological examination of Slides prepared by cross section of various organs like Liver, Kidney, Heart, Muscle, Brain and skin.

All above section shows no any specific pathological changes Except skin which shows sterile inflammatory changes.

Conclusion:- The Injection of Apamarga kshara produces local sterile inflammatory changes. 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.

B) Clinical Assessment

For this Apamarga Kshar Injection was used to one group of 50 patients of Internal Haemorrhoids for once. This group was termed as trial group **(Group A).**

To compare the result of Apamarga Kshar Injection**,** a standard known drug was selected for that Inj. Polidocanal was applied to another group of 50 patients of Internal Haemorrhoids as control group **(Group B).**

Prior to start the study in both groups, patients selected for the study were observed closely and detailed history was taken as per Performa of case record form mentioned in the ending of materials and methods. Also all the investigations were carried out prior to start the study. As well as the status of the patients was also recorded with respect to symptoms and signs found in the patients of the Internal Haemorrhoids of this series.

The status of all symptoms and sign were also noted after completion of the treatment. The data that has generated during the clinical study was grouped under two headings:

1) Demographic Analysis

2) Subjective Analysis

Demographic analysis:

Total 100 patients were registered for this study. The demographic Analysis of these patients is being presented there after.

(Table – 1) **Age wise distribution**

1. Table showing age wise classification of 100 patients:-

Age(In Yrs)	Group-A		Group-B		Total	
	No	%	No	%	No	%
18-30	8	16	8	16	16	16
31-40	17	34	21	42	38	38
41-50	14	28	13	26	27	27
51-60	10	20	6	12	16	16
61-70	1	2	2	4	3	3

Age distribution table shows that there are total 16 pts of age group 18-30 yrs of age, 38 pts of 31-40 yrs, 27 pts of 41-50 yrs, 16 pts of 51-60 yrs, 3 pts of 61-70 yrs of age group.

Age: - Patients included in the trial range from 18 to 70 years of the age.

8 patients (16 %) were from the age group 18 to 30 yrs.

17 patients (34 %) were from the age group 31 to 40 yrs.

14 patients (28 %) were from the age group 41 to 50 yrs.

10 patients (20 %) were from the age group 51 to 60 yrs.

1 patients (2 %) were from the age group 61 to 70 yrs.

Statistically, the distribution of patients according to age in above three groups is insignificant (P= 0.5618). Hence groups are homogenous.

(Table – 2) **Sex wise distribution**

Sex wise distribution

Table showing sex wise distribution of 100 patients included into study -

Sex	Group –A		Group-B		Total	
	No	%	no	%	No	%
Male	36	72	35	70	71	71
Female	14	28	15	30	29	29

Out of 100 patients under study 29% were female & 71% were male. 36 pts were male while 28 pts were female into trial group. Statistically, the distribution of patients according to sex in both groups is insignificant (P= 0.4128). Hence, both groups are homogenous.

(Table – 3) **Religion Status classification**

Religion wise distribution

Table showing occupation status wise classification of 100 patients included into the study :-

Religion	Group-A		Group-B		Total	
	No	%	No	%	no	%
Hindu	40	80	38	76	78	78
Muslim	6	12	5	10	11	11
Others	4	8	7	14	11	11

Out of 100 pts, 78 % belongs to Hindu religion, 11 % belongs to Muslims while 11 % people belongs to other religions such as Buddha, Christians, etc. Whereas in trial group 80% were Hindu, 12% were Muslims & 8% were from all other religions. Statistically, the distribution of patients according to religion in both groups is insignificant (P= 0.4515). Hence, both groups are homogenous.

(Table – 4) **Occupational Status Classification**

Occupational Status

Table showing occupation statuswise classification of 100 patients included into the study:-

	Group-A		Group-B		Total	
	No	%	No	%	No	%
Labour	6	12	10	20	16	16
Business	10	20	4	8	14	14

Job	17	34	21	42	38	38
Housewife	9	18	11	22	20	20
Others	8	16	4	8	12	12

Out of 100 pts, 16 % pts were working as labour, 14 % pts were doing their self Business, 38 % pts belonging to job, 20% were Housewives, 15 % were belonging to other occupation such as driver, students, etc. In trial group, 6 pts were working as labour, 10 pts were businessman, 17 pts had steady job, 9 pts were housewives & 8 pts had various other occupations. Statistically, the distribution of patients according to occupation, in both groups is insignificant (P=0.5079). Hence, both groups are homogenous.

(Table – 5) **Educational Status**

Table showing education status wise classification of 100 patients included into the study:-

Education	**Group-A**		**Group-B**		**Total**	
	No	**%**	**no**	**%**	**No**	**%**
Literate	4	8	10	20	14	14
Undergraduate	6	12	12	24	18	18
Graduate	40	80	28	56	68	68

Out of 100 pts under study, 14 % were illiterate, 18 % were Educated up to their graduation studies while 68 % patients were educated beyond graduation studies whereas in trial group, 4 pts were illiterate, 6 pts were educated up to their graduation studies while 40 patients were completed graduation studies. Statistically, the distribution of patients according to education status in both groups is insignificant (P= 0.0133). Hence, both groups are homogenous.

(Table – 6) **Marital Status**

Table showing marital status wise classification of 100 patients included into the study:-

Marital Status	Group-A		Group-B		Total	
	No	%	no	%	No	%
Married	47	94	44	88	91	91
Unmarried	3	6	6	12	9	9

Out of 100 pts under study 91 % were married & 9 % were unmarried while in trial group, 47 pts were married & 3 pts were unmarried. Statistically, the distribution of patients according

to marital status in both groups is insignificant (P = 0.0545). Hence, both groups are homogenous.

(Table – 7) **Diet Status**

Addiction Habit status wise classification:-

Following table shows addiction status wise classification of 100 patients included into the study:-

Diet	Group-A		Group-B		Total	
	no	%	No	%	No	%
Veg	19	38	28	56	47	47
Mixed	31	62	22	44	53	53

Above table shows the no. of patients according to their dietary habit. Out of 100 patients, 47% Patients had taking vegetarian diet while remaining 53% consumes both vegetarian as well as non-vegetarian foods. In trial group, 19 pts were having veg diet while 31 had taken mixed diet means both veg & non vegetarian diet. Statistically, the distribution of patients according to dietary habit in both groups is insignificant (P= 0.0545). Hence, both groups are homogenous.

(Table – 8) **Addiction Status**

Addiction Habit status wise classification:-

Table showing addiction status wise classification of 100 patients included into the study:-

Addiction	Group-A		Group-B		Total	
	No	%	no	%	No	%
Tobacco chewing	9	18	16	32	25	25
Smoking	5	10	13	26	18	18
Alcoholism	8	16	11	22	19	19
No	28	56	10	20	38	38

Above table shows the no. of patients addicted to Tobacco chewing, Smoking & Alcohol. Out of 100 patients, 25 % Patients were addict to tobacco chewing, 18% were consumes smoking, 19% were addicted for alcohol consumption while 38 % pts were non-addict. In trial group, 9 pts were habitual to tobacco chewing, 5 pts were smokers, 8 pts were alcoholic while 28 had no any addiction. Statistically, the distribution of patients according to

Addiction habits in both groups is insignificant (P =0.0010). Hence, both groups are homogenous.

SUBJECTIVE ASSESMENT

(Table – 9)

1) Table showing Percentage Relief in Symptoms of 50 patients in Trial group (Group A):

Sr No	Symptoms	BT	AT	Diff	%
1	Per Rectal Bleeding	103	15	88	85.44
2	Pain	99	12	87	87.88
3	Discharge	75	23	52	69.33
4	Burning	75	35	40	53.33
5	Haemorrhoidal Size	89	31	58	65.17

Above shown 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.

(Table – 10)

2) Table showing Percentage Relief in Symptoms of 50 patients in Control group (Group B):

Sr No	Symptoms	BT	AT	Diff	%
1	Per Rectal Bleeding	91	37	54	59.34
2	Pain	59	17	42	71.19
3	Discharge	57	25	32	56.14
4	Burning	70	41	29	41.43
5	Haemorrhoidal Size	93	34	59	63.44

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.

(Table – 11)

3) Table showing effect of therapy on symptom score in trial Group (Group A) **By Wilcoxon matched pairs signed rank test**

Sr. No.		Mean	S.D.	S.E.	W	n	Z Value	P	Result
1	**Per Rectal Bleeding**								
	BT	2.06	0.7398	0.1046	1176	48	6.031	< 0.0001	extremely significant
	AT	0.3	0.4629	0.0654					
	Diff	1.76	0.7969	0.1127					
2	**Pain**								
	BT	1.98	0.9792	0.1385	946	43	5.711	< 0.0001	extremely

	AT	0.24	0.4314	0.061					significant
	Diff	1.74	1.026	0.1452					
3	**Discharge**								
	BT	1.5	0.7626	0.1079	630	35	5.159	< 0.0001	extremely significant
	AT	0.46	0.6455	0.0912					
	Diff	1.04	0.8562	0.1211					
4	**Burning Sensation**								
	BT	1.5	0.7626	0.1079	528	32	4.936	< 0.0001	extremely significant
	AT	0.7	0.6468	0.0914					
	Diff	0.8	0.6999	0.0989					
5	**Haemorrhoidal Size**								
	BT	1.78	0.7083	0.1002	1035	45	5.841	< 0.0001	extremely significant
	AT	0.62	0.6966	0.09852					
	Diff	1.16	0.6181	0.08741					

Statistical Analysis of effects of therapy on symptom score in trial Group by Wilcoxon matched pairs signed rank test

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

(Table – 12)

4. Table showing effects of therapy on symptom score in control Group (Group B) **By Wilcoxon Matched Pairs signed rank test**

Sr No		Mean	S.D.	S.E.	W	n	Z Value	P Value	Result
1	**Per Rectal Bleeding**								
	BT	1.82	0.748	0.106	780	39	5.442	0.0089	Very significant
	AT	0.74	0.633	0.089					
	Diff	1.08	0.778	0.11					
2	**Pain**								
	BT	1.18	0.8	0.113	528	32	4.937	0.001	extremely significant
	AT	0.34	0.557	0.079					
	Diff	0.84	0.766	0.108					
3	**Discharge**								
	BT	1.14	0.756	0.107	465	30	4.782	< 0.0001	extremely significant
	AT	0.5	0.678	0.096					
	Diff	0.64	0.563	0.08					
4	**Burning**								
	BT	1.4	0.535	0.076	378	27	4.541	< 0.0001	extremely significant
	AT	0.82	0.661	0.093					
	Diff	0.58	0.575	0.081					
5	**Haemorrhoidal Size**								
	BT	1.86	0.756	0.107	861	41	5.579	0.0044	Very significant
	AT	0.68	0.713	0.101					
	Diff	1.18	0.8	0.113					

Statistical Analysis of effects of therapy on parameters in Group B By Wilcoxon Matched Pairs signed rank test

- **Analysis of Per Rectal bleeding**

Sum of all signed ranks was 780. The no. Of pair, used in calculations were 39, Z value was5.442 & P value was 0.0089, which was statistically very significant.

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

(Table – 13)

Comparison of Symptoms score of Both Group by Mann Vitney test

Sr	Gr	Mean	SD	SE	R1	R2	U	U'	Z Value	P	Result
1	**Per Rectal Bleeding**										extremely significant
	A	1.76	0.797	0.113	3070	1980	705	1795	3.343	0.0002	
	B	1.08	0.778	0.11							
2	**Pain**										extremely significant
	A	1.74	1.026	0.145	3135	1915.5	640.5	1860	3.85	< 0.0001	
	B	0.84	0.766	0.108							
3	**Discharge**										significant
	A	1.04	0.856	0.121	2842	2208	933	1567	2.138	0.0273	
	B	0.64	0.563	0.08							
4	**Burning**										not significant
	A	0.8	0.7	0.099	2726	2324	1049	1451	1.33	0.1613	
	B	0.58	0.575	0.081							
5	**Haemorrhoidal Size**										not significant.
	A	1.16	0.618	0.087	2523	2527	1248	1252	0.108	0.9916	
	B	1.18	0.8	0.113							

Statistical Analysis of comparison of effects of study on both Group By Mann-Vitney Test

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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.

- **Analysis of 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

(Table – 14)

Table Showing % relief in Individual Patients in Trial group:-

Sr. No.	Total				Result
	All BT	All AT	All BT-All AT	%	
1	8	2	6	75	Improved
2	12	4	8	66.6667	Improved
3	10	3	7	70	Improved
4	7	3	4	57.1429	Improved
5	10	1	9	90	Cured
6	9	2	7	77.7778	Cured
7	11	3	8	72.7273	Improved
8	11	1	10	90.9091	Cured
9	9	1	8	88.8889	Cured
10	10	0	10	100	Cured
11	11	1	10	90.9091	Cured
12	10	3	7	70	Improved
13	11	3	8	72.7273	Improved
14	10	2	8	80	Cured
15	11	3	8	72.7273	Improved
16	9	2	7	77.7778	Cured
17	10	2	8	80	Cured
18	8	2	6	75	Improved
19	10	0	10	100	Cured
20	7	1	6	85.7143	Cured
21	8	1	7	87.5	Cured
22	12	2	10	83.3333	Cured
23	10	1	9	90	Cured
24	11	4	7	63.6364	Improved
25	11	2	9	81.8182	Cured

26	10	3	7	70	Improved
27	11	2	9	81.8182	Cured
28	9	2	7	77.7778	Cured
29	11	2	9	81.8182	Cured
30	9	1	8	88.8889	Cured
31	9	2	7	77.7778	Cured
32	8	4	4	50	Relived
33	8	4	4	50	Relived
34	10	3	7	70	Improved
35	4	1	3	75	Improved
36	6	2	4	66.6667	Improved
37	4	1	3	75	Improved
38	7	4	3	42.8571	Relived
39	8	4	4	50	Relived
40	11	1	10	90.9091	Cured
41	4	2	2	50	Relived
42	8	5	3	37.5	Relived
43	6	3	3	50	Relived
44	10	4	6	60	Improved
45	8	3	5	62.5	Improved
46	6	2	4	66.6667	Improved
47	8	2	6	75	Improved
48	3	1	2	66.6667	Improved
49	8	4	4	50	Relived
50	9	5	4	44.4444	Relived

(Table – 15)

Table Showing % relief in Individual Patients in Trial group

Sr. No.	Total				Result
	All BT	All AT	All BT-All AT	%	
1	10	4	6	60	Improved
2	7	3	4	57.14286	Improved
3	5	2	3	60	Improved
4	6	3	3	50	Relived
5	6	1	5	83.33333	Cured
6	5	1	4	80	Cured
7	6	2	4	66.66667	Improved
8	7	4	3	42.85714	Improved
9	7	4	3	42.85714	Relived
10	9	5	4	44.44444	Relived
11	6	3	3	50	Relived
12	5	0	5	100	Cured
13	5	3	2	40	Cured
14	5	2	3	60	Relived
15	9	3	6	66.66667	Improved

16	8	2	6	75	Improved
17	7	3	4	57.14286	Improved
18	6	3	3	50	Relived
19	4	2	2	50	Relived
20	7	4	3	42.85714	Relived
21	8	6	2	25	Not Cured
22	10	5	5	50	Relived
23	11	3	8	72.72727	Cured
24	9	5	4	44.44444	Relived
25	7	2	5	71.42857	Improved
26	6	1	5	83.33333	Cured
27	7	2	5	71.42857	Improved
28	5	2	3	60	Improved
29	10	5	5	50	Relived
30	8	5	3	37.5	Relived
31	8	3	5	62.5	Improved
32	8	3	5	62.5	Improved
33	7	2	5	71.42857	Improved
34	8	1	7	87.5	Cured
35	10	5	5	50	Relived
36	8	3	5	62.5	Improved
37	7	4	3	42.85714	Relived
38	6	1	5	83.33333	Cured
39	8	5	3	37.5	Relived
40	9	5	4	44.44444	Relived
41	9	2	7	77.77778	Cured
42	9	5	4	44.44444	Relived
43	8	2	6	75	Improved
44	7	2	5	71.42857	Improved
45	8	4	4	50	Improved
46	6	4	2	33.33333	Relived
47	8	5	3	37.5	Relived
48	10	5	5	50	Relived
49	8	2	6	75	Improved
50	7	1	6	85.71429	Cured

(Table – 16)

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

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 was <0.05, Hence Apamarga Kshar Injection was more effective than control group drug, Inj. Polidocanal 3%.

Hence Null Hypothesis Rejected.

DISCUSSION

The modern day medical science is now trying to find solutions to so many unsolved problems from the great INDIAN methodology of life science i.e. Ayurveda. They also studied various Ano-Rectal diseases with all its regards. A wide spectrum of description is available including its definite etio-pathogenesis & a number of treatment methods. According to Ayurveda the disease comes under the heading of "Maharoga". As it is dirghakalanubandhi, dushchikitsya in nature tridoshik & involves the marma. Aacharya Sushruta had mentioned fourfold line of management – Aushadha, Kshara, Agnikarma & Shastrakarma. This approach seems to be graded on the basis of particular symptom complexes of the diseases.

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. But after operation patient feels pain, burning, eventual bleeding per rectum, etc. To relieve pain we use generally IV or Oral analgesics (NSAIDS). Still there is need of some locally acting analgesic drug because the severity of pain is sometimes much. Polidocanal 3% used worldwide but had some side effect. While some patients are allergic to the drug. So this is my humble effort to find out a remedial measure, which would ideally offer the cure of the disease in shorter time, free from complication & economically better.

Plan of study

Study was conducted in two stages

A) Animal study to rule out acute toxicity of drug 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 drug 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 14^{th} 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.

Controlled clinical study

Total 100 pts were included in the study according to the inclusion and exclusion criteria. After thorough examination, haematological and other laboratory tests, 50 patients were treated by Polyherbal sclerosant injection & called Group A i.e. Trial group While 50 patients were treated by Inj. Polidocanal & called Group B i.e. control group. Patients in each group was well examined in the OPD (Out Patient Department), Investigated thoroughly & then selected for the study. Those patients kept in IPD (Indoor Patient Department) for close observation. Under all aseptic & sterile preparation, sclerosant injection was given submucosally & this day was counted as day 0. Sclerosant was injected for once only & then follow up taken on day 1, 2, 3, 5, 8, 12, 21 & then after 1 month. During this treatment sitz bath with lukewarm water, Laxative, Antibiotics & Analgesic drugs as per severity of pain & other symptoms was given to the patient**.**

Observation & Result are discussed as follows

1) General discussion

2) Clinical parameter

3) Total effect of therapy.

A) GENERAL DISCUSSION

Age wise distribution shows that there are total 16 % pts of age group 18-30 yrs, 38 % pts of 31-40 yrs, 27 % pts of 41-50 yrs, 16 % pts of 51-60 yrs, 3 % pts of 61-70 yrs of age group. Patients included in the trial range from 18 to 70 years of the age. 8 patients (16%) were from the age group 18 to 30 yrs. 17 patients (34%) were from the age group 31 to 40 yrs. 14 patients (28%) were from the age group 41 to 50 yrs. 10 patients (20%) were from the age group 51 to 60 yrs. 1 patients (2%) were from the age group 61 to 70 yrs. This result shows 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, consumption of baked products, fast food, etc which is consumed more in middle age.

Sex wise distribution of disease shows that Out of 100 patients under study 29% were female & 71% were male. In trial group 36 pts were male while 14 pts were female. This difference may be due to shyness of female patient to discuss the ailment of private organs.

Religion wise distribution of disease shows that Out of 100 patients under study 78 % belongs to Hindu religion, 11 % belongs to Muslims while 11 % people belongs to other religions such as Buddha, Christians, etc. This data shows dominance of Hindu patients in the study. It may be due to dominance of Hindu population in the privilege of the working area of study.

Occupation wise distribution of disease shows that Out of 100 patients under study, 16 % pts were working as labour, 14 % pts were doing their self Business, 38 % pts belonging to job, 20% were Housewives, 15 % were belonging to other occupation such as driver, students, etc. In trial group, 6 pts were working as labour, 10 pts were businessman, 17 pts had steady job, 9 pts were housewives & 8 pts had various other occupations. This 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 shows that Out of 100 patients, 47% Patients had taking vegetarian diet while remaining 53% consumes both vegetarian as well as non-vegetarian foods. In trial group, 19 pts were having veg diet while 31 had taken mixed diet means both

veg & non vegetarian diet. This 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 at stool, as non vegetarian food doesn't has roughage and leads to constipation which later on develoups internal haemorrhoids.

In category of addiction 62 % patients are addict to alcohol, tobacco chewing and smoking, 38 % patients are non addict. So addict to any, causes Constipation & Agnimandya resulting into ano-Rectal diseases like internal haemorrhoids.

B) 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 patients complaints Per Rectal bleeding due to erosions developed over internal haemorrhoids by passage of hard stool.

In Group A, the per rectal bleeding was reduced by 85.436%whereas in Group B, it was reduced by 59.340%. This was put to further statistical analysis. By Wilcoxon Signed Rank test, the results were extremely significant in Groups A and while it is very significant in group B. In Group A, Z= 6.031, p< 0.0001 and in Group B, Z=5.4424, p<0.0089. The results of Mann Whitney Test, applied to compare the both groups, was extremely significant {P=0.0002 <0.05}

From Statistical analysis it shows that the control group drug is good in reducing the 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.

In Group A, pain was reduced by 87.87879% whereas in Group B, it was reduced by 71.1864%. This was put to further statistical analysis. By Wilcoxon Signed Rank test, the results were extremely significant in both Groups A and B. In Group A, Z= 5.711, p <0.0001 and in Group B, Z=4.9365, p =0.0010. Results of Mann Whitney Test, applied to compare both groups, was considered extremely significant {P =<0.0001) <0.05}

From Statistical analysis it shows that the control group drug is good in reducing the pain in internal hemorrhoids.

C) Discharge

In Group A the discharge was reduced up to 69.333% whereas in Group B it was reduced upto 56.1403%. This was put to further statistical analysis. By Wilcoxon Signed Rank test, the results were extremely significant in both the Groups A and B. In Group A, Z=5.159, p< 0.0001 and in Group B, Z=4.7821, p< 0.0001. Results of Mann Whitney Test, applied to compare the both groups, was significant {P=0.0273) < 0.05}

From Statistical analysis it shows that the control group drug is quite good in reducing the discharge.

D) Burning in Anal Canal

In Group A, burning was reduced up to 53.333% whereas in Group B it was reduced upto 41.4285%. This was put to further statistical analysis. By Wilcoxon Signed Rank test, the results were extremely significant in both the Groups A and B. In Group A, Z=4.936, p< 0.0001 and in Group B, Z=4.541, p< 0.0001. Results of Mann Whitney Test, applied to compare the both groups, was not significant {P=0.1613) > 0.05}.

From Statistical analysis, it shows that drug of both group had equivalent action on internal haemorrhoids in reducing burning in anal canal.

E) Haemorrhoidal size

In Group A, size was reduced up to 65.17% whereas in Group B it was reduced upto 63.4408%. This was put to further statistical analysis. By Wilcoxon Signed Rank test, the results were extremely significant in both the Groups A and B. In Group A, Z=5.841, p <0.0001 and in Group B, Z=5.579, p <0.0001. Results of Mann Whitney Test, applied to compare the both groups, was not significant {(P=0.9916) > 0.05}

From Statistical analysis it shows that drug of both group had equivalent action on internal hemorrhoids in reducing hemorrhoidal size in anal canal.

C) TOTAL EFFECT OF TREATMENT

In accordance to the clinical parameters, all patients get complete relief in Pain & Tenderness. But Polyherbal suppository is also effective on post operative Itching, burning,& PR bleeding. other way Diclo had no role on these symptoms.

	Trial Group (A)		Control 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

As out of 50 pts 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 desire effect. It indicates that Polyherbal Sclerosant injection of Apamarga Kshara has significant role on 1^0 & 2^0 internal haemorrhoids than injection Polidocanal, with the help of **Chi-square test** we concluded the result as p was <0.05, Hence Polyherbal Sclerosant injection of Apamarga Kshara was more effective than control group drug injection Polidocanal.

CONCLUSION

The study entitled **"A CONTROLLED CLINICAL STUDY OF HERBAL SCLEROSANT INJECTION OF APAMARGA KSHAR ON INTERNAL HAEMORRHOIDs (I^0 & II^0)"** was undertaken. After conducting the animal study & clinical trial based upon the clinical study, displayed in form of tables and graphs which is thoroughly discussed in previous chapters. From the study confident conclusion can be drawn as follows -

Injection Polidocanal is allready established sclerosant drug. Also Herbal sclerosant injection had good efficacy in internal haemorrhoids (I^0 & II^0). It is concluded that local sub mucous injection of Apamarga Kshara in total quantity of approximately 3 ml were sufficient to shrink the piles without complications and to give good result in the patients.

This treatment is quick, effective and cheap daycare surgical procedure and it can be done under local anaesthesia in any hospital. 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.

Therefore it can be surely stated that, Herbal sclerosant injection of Apamarga Kshara therapy is a good and promising alternative herbal sclerosant in I^0 and II^0 internal haemorrhoids.

Scope for further studies

1. Still there is need of long term study regarding anorectal mucosal absorption & systemic effects of Herbal sclerosant injection.
2. Testing of Herbal sclerosant injection like exact constitution of the injection, metals available in the drug & their longterm effect on human body, Efficacy study of injection over the animals, etc should be done under Standard SOP.
3. Though this study was carried out in limited patients .Mass study programming is needed for future more huge database statistical study. Therefore we may conclude that with this sample study which shows a positive result, a large scale study can also be undertaken in future.

REFERENCES