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AN OPEN LABEL COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF SHREEGANDHAMALLA LEPA AND PILOCID OINTMENT IN THE MANAGEMENT OF BAHYA ARSHA

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ABSTRACT

Haemorrhoidal Disease is one of the most common anorectal conditions encountered in daily practice by general practitioners, general surgeons and gastrointestinal surgeons in India. It has been projected that about 50% of the population would have haemorrhoids at some point in their life probably by the time they reach the age 50, and approximately 5% population suffer from haemorrhoids at any given point of time. Taking into account the devastating nature of the disease and high prevalence in India, the evidence-based practice appears essential in the management of haemorrhoids. Present practice parameters aim at developing evidence-based recommendations for the management of haemorrhoids in Indian perspectives.

INTRODUCTION

Haemorrhoidal Disease is one of the most common anorectal conditions encountered in daily practice by general practitioners, general surgeons and gastrointestinal surgeons in India. It has been projected that about 50% of the population would have haemorrhoids at some point in their life probably by the time they reach the age 50, and approximately 5% population suffer from haemorrhoids at any given point of time. Taking into account the devastating nature of the disease and high prevalence in India, the evidence-based practice appears essential in the management of haemorrhoids. Present practice parameters aim at developing evidence-based recommendations for the management of haemorrhoids in Indian perspectives. The word "Haemorrhoid" derived from the Greek words Haima means "blood" and Rhoos means "flowing" i.e blood to ooze & term "Piles" is derived from the Latin word Pile which means "a ball" i.e round mass Haemorrhoids is engorgement of the haemorrhoidal venous plexus i.e. the dilated veins within the anal canal and in the sub epithelial region formed by radicals of the superior, middle and inferior rectal veins characterized by bleeding per rectum, constipation, pain, prolapse and discharge. External Haemorrhoids associated with internal haemorrhoids results from progression of the later to involve both haemorrhoidal plexus and one best thought of being external extensions of internal haemorrhoid, external haemorrhoid located distal to the dentate line and are covered with anoderm which is richly innervated, thrombosis of an external haemorrhoid may cause significant pain. [2]

Hence having several similar features, the disease Haemorrhoids can be co-related with arshas. The word Arshas is derived from Rush+Ach (Sabdha kalpa druma), a disease having fleshy sprouts or shoots in the Guda Pradesh. Acharya charaka has explained arshas as an abnormal fleshy growth in Guda Pradesh. Acharya Vagabatta defines that arshas are fleshy growths that create obstruction in anal passage and troubles continuously. Madhukosha define it as a disease which tortures the life like an enemy and kills. He has used the word srinati, a derivative meaning to tear into pieces. Hence generally Arshas means growth in anorectal region even though there are other terms like Nasarshas, Yoniarshas etc. As it occurs very frequently and is more troublesome than any other type of Arshas. By the above definitions, it can be inferred that it is a clinical condition where the patient has agonising pain.^[3]

Indigenous folklore Shreegandhamalla was used as medicine in application of external haemorrhoids by Mr, Bhemappa Navalli @ Bandhiwad village near Hubblli for more than 10yrs. This compound is composed of Chandana and Malla/Gourpasana as actual treatment and other drugs like Vacha, Ela, Puga are used in bhasma form during follow up period and no any complication observed and there is reference in Rasatarangini (11/138-144) i.e. If Gouripasana used for external application this medicine acts like 'KSHARA' and its external application alleviates inflammation, burning sensation and local temperature⁴. To make this

as evidence-based medicine and revalidate it in current era the present study has been proposed.

Objectives of the study

❖ To compare effect of indigenous folklore Shreegandhamalla lepa and Pilocid ointment in management of Bahya arshas.

Source of data

a) Sample source: Randomized control trial of 40 patients came to OPD of SGVVT's S J G Ayurvedic medical college and hospital koppal.

Method of collection of data

Randomized control trial of 40 patient came to OPD of SGVVT's S J G Ayurvedic medical college and hospital koppal.

- I) Study design: An open label comparative clinical study.
- **II**) **Sample size:** A total 40 cases of Bahya arshas after considering the below mentioned criteria have been included for the study. These 40 cases randomly allotted into 2 groups namely group A and group B with 20 patients in each group.

III) Selection criteria

A) Diagnostic criteria

Diagnosis have been made on the basis of patient presented with external pile mass.

B) Inclusion criteria

- Patients age of 18 to 55 years.
- Patient of either sex.
- Patients with clinical features external pile mass.
- Patients who are not willing for surgery.

C) Exclusion criteria

- Thrombosed pile mass.
- Patient with IDV and HBsAg positive.
- Patient with uncontrolled Diabetes and HTN.

D) Screening criteria

• CBC.

- HBsAg.
- HIV I & II.
- RBS.

Study group

Table no. 01

Sl. No	No of days	Medicine	Explanation	Dietary instructions
1	Day-1 to day-3	Paste of Chandan ^[5] with Gouripashana ^[6]	This paste is given to patient for application at evening and left-over night.	Jwar ganji with butter milk tid.
	Day-4 to day-30	Mixture of burnt ash (Masi) viz (Ela ^[7] , Pogha ^[8] and Vacha ^[9])	This powder is given to patient for application with fresh Salted butter ^[10] at bedtime and leftover night. Use warm water for external use.	Food items; jawar, wheat, millet rice, gaggrey, sugar. Veg: raddish, ridge gourd. Seeds: pigeon pea, horse gram. Fruits: apple, dates. Avoid: non-veg, oil, Long-sitting & driving. Note: cooking is done with ghee, garlic & chilli powder.
2	Day-1 to day-30	Pilocid ointment	For application twice a day.	Easily digestable and fibre rich diet. Sitz bath after defecation.

Duration of treatment

Treatment duration: 30 days

Assessment days: On 1st day, 7th day, 14th day, 21st day and 30th day.

Total study duration: 30 days.

Assessment criteria

a) Subjective parameters

• **Pain:** Visual analogue scale (VAS)

0 – No pain.

10 – Severe pain.

Objective criteria

- Pile mass
- a) Present.
- b) Absent.

OBREVATION AND RESULTS

The clinical observations from different aspects approaching to the treatment for both subjects of trial and control groups have been represented showing the incidence, statistical analysis of effectiveness of trial drug along with clinical assessment of resultetc. The data of each item are explained and have been represented in the tabular formwith footnotes.

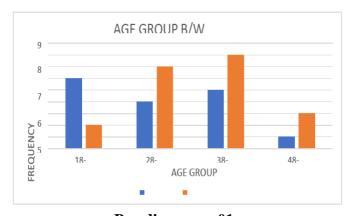
Age

The total cases taken up for the study of either group were categorized into four categories of age limits with intervals of 10 years. The lower limit of age was 18 years and the upper age limit was 55 year.

Table no. 02: Age wise distrubution of 40 subject.

Age	Group a	Group b	Frequency	Percentage
18-27	06	02	08	20%
28-37	04	07	11	27.5%
38-47	05	08	13	32.5%
48-55	05	03	08	20%

Incidence of age group



Bar diagram -01.

Among 40 subjects: 20% i.e. 8 subjects were belonging to 18-27 age group (Group A- 06 & Group B-02), 27.5% i.e. 11 subjects were belonging to 28-37 age group(Group A- 04 & Group B-07), 32.5% i.e. 13 subjects were belonging to 38-47 age group (Group A-05 & Group B-08), 20% i.e. 8 subjects were belonging to 48-55 age group (Group A- 05 & Group B-03)

Gender

The total cases taken up for the study of either group were categorized into two based on gender.

Table no. 03: Gender wise distribution of 40 subjects.

Gender	Group a	Group b	Frequency	Percentage
Male	10	10	20	50%
Female	10	10	20	50%

Incidence of gender across the group



Bar diagram – 02.

Among 40 subjects: 50% i.e. 20 subjects were MALE (Group A- 10 & Group B-10) and other 50% i.e. 20 subjects were FEMALE(Group A- 10 & Group B-10).

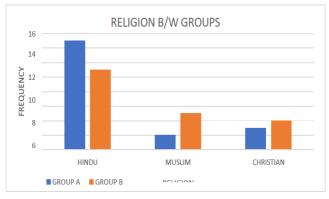
Religion

The total cases taken up for the study of either group were categorized into three categories based on religion ie, HINDU, MUSLIM, CHRISTIAN.

Table no. 04: Religion wise distribution of 40 subjects.

Religion	Group a	Group b	Frequency	Percentage
Hindu	15	11	26	65%
Muslim	02	05	07	17.5%
Christian	02	04	07	17.5%

Incidence of religion across the group



Bar diagram -03.

Among 40 subjects: 65% i.e. 26 subjects were Hindu (Group A- 15 & Group B-11), 17.5% i.e. 07subjects were Muslim (Group A- 02 & Group B-05) and 17.5% i.e. 07subjects were Christian (Group A- 03 & Group B-04).

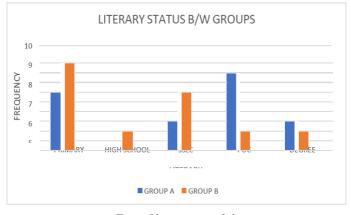
Literary status

The total cases taken up for the study of either group were categorized into five categories based on religion ie, PRIMARY, HIGH SCHOOL, SSLC, PUC, DEGREE.

Table no: 05: Literary status wise distribution of 40 subjects.

Literary	Group a	Group b	Frequency	Percentage
Primary	06	09	15	37.5%
High School	00	02	02	05%
Sslc	03	06	09	22.5%
Puc	08	02	10	25%
Degree	03	01	04	10%

Incidence of literary status across the group



Bar diagram – 04

2.5%

20%

Among 40 subjects: 37.5% i.e. 15 subjects were PRIMARY (Group A- 06 & Group B-09), 05% i.e. 02 subjects were HIGH SCHOOL (Group A- 00 & Group B-02) and 22.5% i.e. 09 subjects were SSLC (Group A- 03 & Group B-06), 25% i.e. 10 subjects were PUC (Group A-08 & Group B-02) and 10% i.e. 04 subjects were DEGREE (Group A- 03 & Group B-01).

Occupation

The total cases taken up for the study of either group were categorized into eight categories based on data collected wrt occupation.

Occupation	Group a	Group b	Frequency	Percentage
Farmer	03	04	07	17.5%
Housewife	07	07	14	35%
Worker	02	02	04	10%
Flower Seller	00	01	01	2.5%
Shopkeeper	00	02	02	5%
Merchant	01	02	03	7.5%

01

01

01

08

Table no. 06: Occupation wise distribution of 40 subjects.

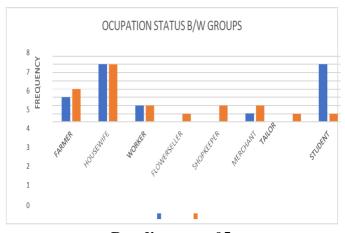
00

07

Incidence of ocupation status across the group

Tailor

Student



Bar diagram – 05

Among 40 subjects: 17.5% i.e. 07 subjects were FARMER (Group A- 03 & Group B-04), 35% i.e. 14 subjects were HOUSEWIFE (Group A- 07& Group B-07) and 10% i.e. 04 subjects were WORKER (Group A- 02 & Group B-02), 2.5% i.e. 01 subjects were FLOWER SELLSER (Group A- 00 & Group B-01), 5% i.e. 02 subjects were SHOPKEEPER (Group A-00 & Group B-02) and 7.5% i.e. 03subjects were MERCHANT(Group A-01 & Group B-02), 2.5% i.e. 01subjects were TAILOR (Group A- 00 & Group B-01), 20% i.e. 08 subjects were STUDENT (Group A- 07 & Group B-01).

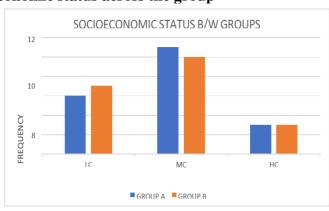
Socio-economic status

The total cases taken up for the study of either group were categorized into three categories based on SOCIO-ECONOMIC STATUS ie, LOWER CLASS, MIDDLE CLASS & HIGHER CLASS.

Table no: 07: Socio-economic status wise distribution of 40subjects.

S-e-status	Group a	Group b	Frequency	Percentage
Lc	06	07	13	32.5%
Mc	11	10	21	52.5%
Нс	03	03	06	15

Incidence of socio-economic status across the group



Bar diagram – 06

Among 40 subjects: 32.5 % i.e. 13 subjects were belonging to Lower Class group(Group A-06 & Group B-07), 52.5% i.e. 21 subjects were belonging to Middle Class group(Group A-11 & Group B-10), 15 % i.e. 6 subjects were belonging to Higher Class group(Group A-03 & Group B-03).

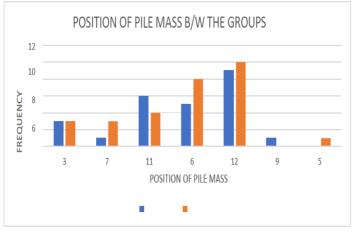
Position of pile mass

The total cases taken up for the study of either group were categorized into seven categories based on external pile mass wrt clock \(\preceit\) lithotomy position.

Table no: 08: Position of mass wise distribution of 40 subjects.

Position of Pile mass	Group a	Group b	Frequency	Percentage
3'0clock	03	03	06	11.11%
7'0 clock	01	03	04	7.40%
11'0 clock	06	04	10	18.51%
6'0 clock	05	08	13	24.07%
12'0 clock	09	10	19	35.81%
9'0 clock	01	00	01	1.85%
5'0 clock	00	01	01	1.85%

Incidence of pile mass wrt position across the group



Bar diagram – 07

Among 40 subjects: 11.11% i.e. 06 subjects presents mass at 3'o clock (Group A- 03 & Group B-03), 7.40% i.e. 04 subjects presents mass at 7'o clock (Group A- 01& Group B-03), 18.51 % i.e. 10 subjects presents mass at 11'o clock (Group A- 06 & Group B-04), 24.07% i.e. 13 subjects presents mass at 6'o clock (Group A- 05 & Group B-08), 35.81% i.e. 19 subjects presents mass at 12'o clock (Group A- 09 & Group B- 10), 1.58% i.e. 01 subjects presents mass at 9'o clock (Group A- 01 & Group B-00) & 1.58% i.e. 01 subjects presents mass at 5'o clock (Group A- 00 & Group B-01).

RESULTS

The subjective parameter Pain was considered for the assessment of the results in the present study. The results obtained were subjected to statistical analysis. The results are tabulated in the following tables.

Table no. 09: Showing the comparative reduction in Pain at the end of the treatment within the groups based on visual analogue scale (VAS) at each followup.

	Report									
		Pain bt	Pain f1	Pain f2	Pain f3	Pain f4	Pain f5	Pain at		
Gro up a	Mean	10.00	10.00	8.25	6.70	4.40	3.60	3.60		
	S.e	.000	.000	.190	.272	.400	.472	.472		
	Of									
	Me									
	An									
Gro	Me	10.00	9.90	8.10	6.20	4.15	3.20	3.20		
Up b	An									
	S.e	.000	.100	.228	.258	.264	.304	.304		
	Of									

	Me							
	An							
Total	Me An	10.00	9.95	8.17	6.45	4.28	3.40	3.40
Total	S. e Of mean	.000	.050	.147	.189	.237	.279	.279

Group A

Pain before treatment mean 10±0.00, during first follow-up 10±0.00 no changes were seen due to application of lepa, on 2^{nd} follow-up 8.25 ± 0.192 reduction pain seen about ±1.08 , on 3rd follow-up 6.70±0.272 reduction pain seen about ±3.028, on 4th follow-up 4.40±0.400 reduction pain seen about ±5.20, on 5th follow-up 3.60±0.472 reduction pain seen about ±5.072. data shows no pain relief seen after 7days, 10% after 14days, 30% after 21days, 52% after 28days and 50% after 30days.

Group B

Pain before treatment mean 10±0.00, during first follow-up 9±0.10 reduction pain seen about ±0.90 after application pilocid ointment, on 2nd follow-up 8.10±0.228 reduction pain seen about ± 1.672 , on 3rd follow-up 6.20 ± 0.258 reduction pain seen about ± 3.542 , on 4th followup 4.15±0.264 reduction pain seen about ±5.586, on 5th follow-up 3.20±0.304 reduction pain seen about ±6.496. data shows 10% of pain relief seen after 7days, 16 % after 14days, 35% after 21days, 55% after 28days and 64% after 30days.

Table no. 10: Showing the comparative reduction in Pain at the end of the treatment betweenthe groups based on visual analogue scale (VAS).

Chauna	ľ	Mean	%	S.D.	S.D. S.E.		' р'	'Z'	Remarks
Groups	BT	AT	Relief	S.D.	S.E.	'U'	þ	L	Kemarks
Group	10.0	3.60±.47	52.8	2.11	0.47	47,00	< 0.05	-	I.S.
A	0	2	%	3	2	0		.234	
(n=20)									
Group	10.0	3.20±.30	64.9	1.36	0.30	50,00	< 0.05	0.00	I.S.
В	0	4	%	1	4	0			
(n=20)									

The above statistical analysis shows that in case of **pain** the mean \pm S.E. The Group A showes before treatment was 10±0.00 and was reduced to 3.60±0.472 after 30days, the Group B showes before treatment was 10±0.00 and was reduced to 3.20±0.304 after 30 days, The test of significance shows that their is Significant to reduce pain with the groups and Insignificant between the groups.

Table no. 11: Showing the Overall Relief of Pain at the end of 30 days of treatment in **Group Aand Group B after treatment.**

Groups	Mean B.T.	Mean A.T.	% Relief of pain
Group A	10	5.28	52.8%
Group B	10	6.496	64.96%

At the end of 30 days, Group A showed a increase in the intensity of pain 52.8% over B.T. Mean of 10 where as Group B in the same duration had relief of pain of 64.96 % over B.T. Mean of 10 in patients who had respective lepa karma.

Table no. 12: Showing the Comparison between Group A and Group B in Relief of Pain at theend of 30 days of treatment.

Groups	S.D.	S.E.	'U'	ʻp'	Remarks
Group A	1.908	0.279	162	> 0.05	1 C
Group B	1.908	0.279	102	<i>></i> 0.03	1.S.

$$(n1 = 20) (n2 = 20)$$

The intensity of pain experienced by patients of Group B was significantly lower than the patients of Group A which was statistically Insignificant at the level of p > 0.05 (z=-1.080).

Table no. 13: Status of pain during study between the groups.

Group a & b Pain bt			Group a pain at Group b pain at				
Pile mass	Frequency	%	Frequency	%	frequency	%	
10-worst pain	40	10	00	0	00	0	
8- sever pain	0	0	00	0	00	0	
6- moderate pain	0	0	6	30	2	10	
4- moderate pain	0	0	7	35	8	80	
2- mild pain	0	0	4	20	10	50	
0- no pain	0	0	3	15	0	0	

Incidence of pain status across the group



Bar diagram – 08

Among 40 subjects: 20% i.e. 8 subjects were belonging to 18-27 age group, 27.5% i.e. 11 subjects were belonging to 28-37 age group, 32.5% i.e. 13 subjects were belonging to 38-47 age group, 20% i.e. 8 subjects were belonging to 48-55 age group.

Table no. 14: Status of pile mass during study between thegroups.

Group A & B	Mass bt		Group a	a mass at	Group b mass at		
Pile mass	Frequency	%	Frequency	Percentage	Frequency	Percentage	
Present	40	100%	06	15%	20	50%	
Absent	0	0	08	20%	00	00	
Reduced In size	0	0	06	15%	00	00	

Among 40 subjects: 100% i.e. 40 subjects were presented with pile mass before treatment, 15% i.e. 6 subjects were presented with pile mass after treatment & 50% ie, 20 subjects were presented with pile mass after treatment, 20 % i.e. 8 subjects were presented absences of pile mass after treatment, 6 subjects were presented with reduced in size of massafter treatment.

Table no. 15: Showing the reduction in SIZE OF MASS at the end of the treatment in boththe groups.

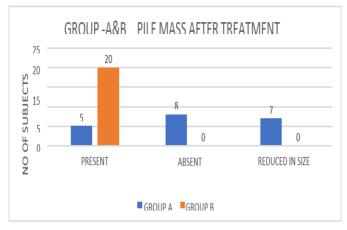
C	Mean		%	C D	C E	(T19	6 9	Dl
Groups	B.T.	A.T.	Relief	S.D.	S.E.	'U'	'p'	Remarks
Group A (n=20)	2.0	0.85	57.5%	0.813	0.182	26	>0.05	I.S.
Group B (n=20)	2.0	2.0	0.00%	0.00	0.00	50	>0.05	I.S.

In case of Size of pile mass the mean \pm S.E. under Group A before treatment was 2.00 \pm 0.00 and was reduced to 0.00 ± 0.85 & Group B before treatment was 2.00 ± 0.00 and was reduced to 2.00 ± 0.00 . The test of significance shows that In Significant to reduce Size of pile with the P-value > 0.05 with in the groups & between the groups respectively.

Table no. 16: Status of pile mass during study.

Group a & b	Freque	ency	Percentage		
Pile mass	Mass bt	Mass at	Mass bt	Mass at	
Present	40	25	100	62.5	
Absent	00	8	0	20.0	
Reduced in size	00	7	0	17.5	

Incidence of pile mass after treatment acrossthe group



Bar diagram - 09

Among 40 subjects: 100% i.e. 40 subjects were presented with pile mass BT (Group A- 20, Group B- 20), 62.5% i.e. 25 subjects were presented with pile mass AT (Group A- 05, Group B- 20), 20 % i.e. 8 subjects shows absences of pile mass AT (Group A- 08, Group B- 00), 17.5 % i.e. 7 subjects were presented with reduced in size of pile mass AT (Group A- 07, Group B- 00). Group A shows clinically significant than Group Bbut statistically insignificant.

DISCUSSION

The anorectal region is very complex area of controlling the mechanism of defecation, sphincters are the important structures here, usually the act of defecation seems to be the following sequence that the ano-rectal region get filled up the fecal matter causing stretch on lateral walls. This initiates as a stimulus per contraction causing closure of the upper part of the rectum and opening of the anal sphincters. The puborectalis, internal sphincter and external sphincter acts simultaneously as a whole and all these occurs at the lower 1 & 1/2 inch of the alimentary canal. The trigger area for contraction of the sphincter is the anal mucosa. In this context one has to review the piles which produce disturbance life style and fear for defecation. When they get inflamed, engorged, they start occupying the space causing stretch on lateral walls as well as stimulates the anal mucosa, strain during defecation and passage of hard stools, however results in the tense engorgement of the anal cushions. This may cause injury to the anal verge. With repeated straining the anal canal cushions are damaged so that the normal supports are stretched and the tendency to form cut wounds or protrude of skin at anal verge. Early in the evaluation of the disease the anal cushions reduce spontaneously, however with repeated episodes the situations become irreversible, these form a mass which gives pain on riding, sitting and defecating (gudankura).

The haemorrhoids are a major anal problem, and the patient may get complications such as strangulation, thrombosis, gangrene, suppuration and some timessevere anemia. In the modern surgery attempts have been made to solve the problem from various angles through various techniques, but satisfactory results are not found. Even through the ligation and excision is indicated for prolapsed piles, if propercare is not taken secondary hemorrhage can occur causing serious complications. Retention of urine & anesthetic complication, fecal impaction and anal stricture can also occur due to surgery. Similarly if a protruded anal pliexus membrane is removed along with pile mass the sphincter control may be permanently damaged.

Our acharyas considered the guda is the sadhyopranahara marma and its origin is mamsaja variety. Therefore every care should be taken meticulously to preserve this marma. Therefore mamsaja marma which is elastic in character can respond to antiinflammatory, antiseptic, antipruritic and analgesic therapies. As per as possible pile masses should regress itself if not surgery is inevitable, it should be planned safely. Even though the legation and excision is indicated in piles. But certain patients may not like to undergo surgery in inoperable conditions, such as severe anemia, DM & HTN & Immunosuppressed disease and Old age.

Under these circumstances we lookout our ancient literature for non- surgical measures which can achieve better results. The "Shreegandhamall lepa" as of folklore medicine for external application selected because of unique burning capcity for external pile mass.

In Ayurveda the management of arshas was dealt widely by various acharyas. Arshas may be treated by one of the four methods. Viz. - Bheshaja, Kshara karma, Agnikarma and Shastra karma, according to doshas involvement and condition of the patient. Bheshaja chikitsa can be administered by the two methods i.e., externally & internally. This present study is aimed to achieve the management of arshas by external application with "Shreegandhamall lepa".

For the present study the patients suffering with external haemorrhoids were included, patients were excluded those who are suffering from systemic disease, since these disease may either influence adversely or favorably. Care was also being taken in selecting the cases between age group of 18-55 years with different duration of illness. In the study both male and female patients are treated.

According to incidence

- > Out of 40 patients, 20 were females and the rest 20 were males due to their moderate work & sedentary life.
- > Out of 40 patients, 08 were found in the age group of 18-27, due lack of fiber diet and long sitting, 11 were found in the age group of 28-37, due to sedentary life style, 13 were found in the age group of 38-47, due mixed diet & working patteren,08 were found in the age group of 48-55, due constipation, sedentary life.
- > Out of 40 patients, 18 were found in hard working population, who are generally seen in middle class group.14- sedentary life & rest of them were students.
- > Out of 40 patients, 30 were found with mixed diet, due to the deficiency of fiber leads to constipation & rest are vegetarian with reduced intake of water.
- > Out of 40 patients, in 19 patients the site of pile mass was found in 12 'O' clock position & 13 patients the site of pile mass was found in 6 'O' clock position due to reprated cut wounds and injuries anal verge (constipation).

Pain

Group A

Data shows no pain relief seen after 7days, 10% after 14days, 30% after 21days, 52% after 28days and 50% after 30days. Because of ushna veerya, teekshna guna, and shoola prashamana of the drugs might be the cause to reduce the pain. "Shreegandhamalla lepa" is important to reduce the pain since it has an analgesic effect.

Data shows 10% of pain relief seen after 7days, 16 % after 14days, 35% after 21days, 55% after 28days and 64% after 30days. Because of it contains vishamusti (ageratum conyzodies), lajjalu (mimosa pudica), palandu (allumcepa), yatimadhu (glycyrrhiza glabra), keram tailam (cocus nucifera) over all combinations results in soothing, anti-inflammatory, styptic and antibacterial property.

Size

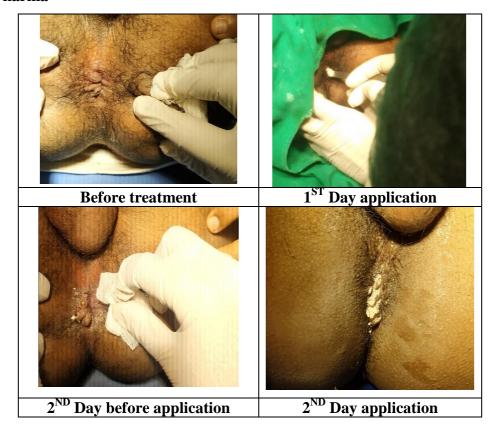
Probable mode of action of shreegandhamall lepa: the Kshara proterty of gouripashana and sheeta virya & dahaprashama karma of Chandana had worked on external pile mass significantly and eradicated mass too, Vranaropana drugs ie, sita virya and kapha-vatahara (rochana) karma of ela, ushna virya and kapha- vatahara (lekhaneeya) karma of vacha, sita veerya and karma kapha- pittahara (dipana, vikasi) karma of pugha. Which plays role of antibacterial, antiedema & analgesics helps the wound to heal after dahanakarma.

In Mode of action of **pilocid ointment**: It contains vishamusti (ageratum conyzodies), lajjalu (mimosa pudica), palandu (allum cepa), yatimadhu (glycyrrhiza glabra), keram tailam (cocus nucifera) over all combinations results in soothing, anti-inflammatory, styptic and antibacterial property. Due to lack of kshara property the size of the pile mass remains same after the compliation of the treatment.

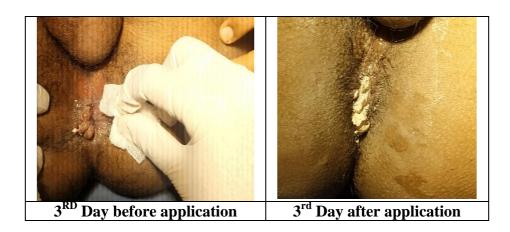
Hence it can be concluded that the administration of the "shreegandhamalla lepa" as external application was most effective to relieve the symptoms, complication were seen during self application by patients that is anal stitcher's, kissing ulcer & involvement of mucosal membrane and later procedure of application carried under surgeon then no complication were observed. The recurrences of masses were not seen during follow up period. But better pain relief is seen in control group along with wound healing and no size mass were reduced.

It shows that Group A medicine is for complete eradication of the disease. Which help the patient to get relief from symptoms and more over the present study helps to avoid the surgical intervention and its complications and helps to those patients who were unwilling for surgery. In this way the present study shows significant effects in relieving symptoms and brings the patients to the stage of palliative treatment to avoid the surgery.

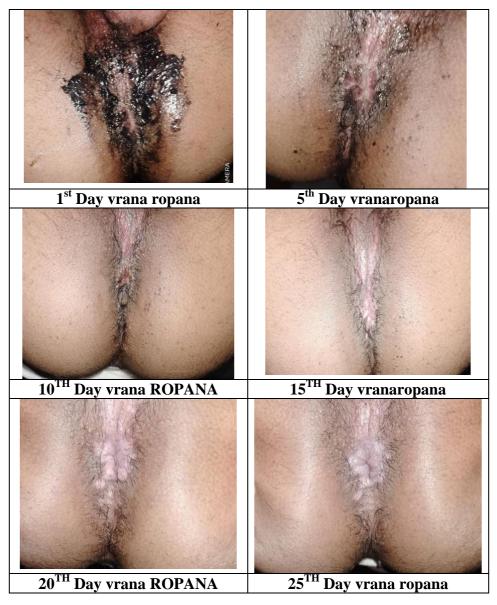
Kshara karma



1428



Vrana ropana





CONCLUSION

- In present era everybody needs non-surgical procedure which safer and equivalent surgical procedure. So, such study should be carried in major sectors to study in detail.
- No satisfactory result seen trail-group as patients discontinued due sever pain during the treatment. Pain managements should be used in form of external application & sitz bath too.
- > Clinically signification shown by trail Group in reduction of pile mass size but fails in pain management so, modification or upgradation of the aesthetic procedure should be advised.
- > In control group satisfactory result seen in relieving pain and healing cut wound. Lack of alkaline property in this drug fails to show the shrinking of mass. Which is the main reason many of patients discontinued the study and underwent surgery.
- > Eradication mass seen in trail group with greater pain, and greater pain relief and wound healing is seen in control group.
- > Because of this my study shows clinically significant but statistically insignificant.

REFERENCES

- 1. Niranjan Agarwal, Kumkum Singh, Parvez Sheik, Kushal Mittal, Varughese Mathai, Ashok kumar. Executive summary The Association of colon & Rectal Surgeons of Indian (ACRSI) Practice Guidelines for the Management of Hemorrhoids, Indian J Surgeons, Feb 2017; 79(1): 58-61.
- 2. SRB's Manual of surgery 5th edition by Sriram Bhat .M Published by Jaypee brothers medical Publishers new Delhi, 2017; Page no 905-913.
- 3. Dr. Rajasree.G; Anorectal Disorders ayurvedic approach Arshas Chapter No-4, Varanasi Chowakamba Orientalia, 2015; Page no 16-42.
- 4. Dr.Ravindra Angadi, A Text Book of Rasa shastra, Chaukamba Surbharati Prakashan Varanasi Gouripasana Chapter No 17.2 Reprinted Edition: 2018 page no 276, 277, 279.

- 5. Dr.J.L.N.Shastry, Dravya vijnana vol 2 Chowakamba orientalia, Chandhana, Chapter No 24, Reprinted Edition, 2012; Page no 478, 480, 481.
- 6. Dr.Ravindra Angadi, A Text Book of Rasa shastra, Chaukamba Surbharati Prakashan Varanasi Gouripasana Chapter No 17.2 Reprinted Edition: 2018; Page no – 276, 277, 279.
- 7. Dr.J.L.N.Shastry, Dravya vijnana vol 2 Chowakamba orientalia, Ela, Chapter No 114, Reprinted Edition, 2012; Page no 527, 529.
- 8. Dr.J.L.N.Shastry, Dravya vijnana vol 2 Chowakamba orientalia, Puga, Chapter No 176, Reprinted Edition, 2012; Page no 1010, 1011.
- 9. Dr.J.L.N.Shastry, Dravya vijnana vol 2 Chowakamba orientalia, Vaca, Chapter No 118, Reprinted Edition, 2012; Page no 545, 547.
- 10. Astang Hrudaya sutrastana, Dravadravya Vijnaneeya Adhyaya, Chapter no 5 page no 61.