



Research Article

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EVALUATION OF EFFECTS OF YAVAKSHAR OINTMENT ON ABHYANTAR ARSHA (INTERNAL PILES)

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ABSTRACT

A disease which anguishes patient's vital force or prana is called as Arsha according to Ayurveda. 'Arsha' is the gift of sedentary life style. One of its prime etiological factors is poor dietary habit which is unavoidable due to busy lifestyle. According to Sushruta the management of Arsha involves Aushadhi Chikitsa (conservative), Ksharkarma, Agnikarma and Shastrakarma (surgical). The 'Dhatuvaigunya' (Organic pathology local deformity) of anal structures requires local treatment. Ksharkarma is the treatment having more effect but needed intervention of another person for therapy. Concept of application of Kshar by patient himself was presumed and for this purpose the ointment of Kshar was used. The study was carried out in eight groups i.e. A, B, C, D, E, F, G, H and each group consists of about 25 to 30 patients. The patients of I II and III degree piles and P/R bleeding were included in this study. At the end of trial it was found that the application of Yava Kshar ointment of 10% having base Siktha Tailam was more effective than other ointments (i.e. Yava Kshar ointment 5% base Siktha Tailam, Yava Kshar ointment 5% base petroleum jelly, Yava Kshar ointment 10% base petroleum jelly, Faktu ointment, Trigol powder, plane Siktha Tailam and plane Petroleum jelly) to reduced the P/R bleeding markedly in minimal period and to reduced the degree of haemorrhoids up to certain extent.

Keywords: Yava Kshar, Internal piles, Abhyantar Arsha, Kshar Karma, Yavakshar Ointment.

INTRODUCTION

Ayurved is a science of life and Shalya Tantra is its important branch which represents the surgical field. One of prime important disease from Ashtamahagada is 'Arsha'¹. Ayurveda, the ancient science of medicine of India has detail information and description of Arsha. The word 'Arsha' is derived from the root 'Ru-gatau' after adding the suffix 'Asuna' which means 'to take life'². It is an entity in which muscular projections (Mansakeel) troubles the patient like an enemy³. The common people call them piles. A pile (Pila- a ball) is derived from Latin. The aristocracy calls them haemorrhoids. The word haemorrhoid is derived from Greek. (Haema- blood, Rhoos- flowing) and the lay man call them mulvyadh / bawasir / komb etc. how does it matter as long as you can cure them⁴. Arsha have been known to mankind for a long time and are one of the commonest diseases to affect human beings. 'Arsha' is the gift of busy life style. One of its prime etiological factor is 'Mithyaahar- Vihar'⁵ and is unavoidable due to busy lifestyle. While working in Out Patient Department, it was observed that the percentage of patients having Abhyantar Gudarsha was increased. Hence, this problem was selected for scientific study. According to Ayurvedic and Modern text, so many mode of treatment are available for Abhyantar Gudarsha. The treatment can be classified in to surgical, para-surgical and medicinal management. But none of them is perfect due to their associated disadvantages. The management of Abhyantar Gudarsha is mentioned in Ayurvedic Samhita like Charak, Sushruta and Ashtang Sangraha etc. But Acharya Sushruta has described in detail all about Arsha in Sushruta Samhita. According to Acharya Sushruta the management of Abhyantar Gudarsha is of four types. Aushadhi Chikitsa (Conservative), Ksharkarma, Agnikarma, Shastrakarma (Surgical). The

'Dhatuvaigunya' (Organic pathology local deformity) of anal structures requires local treatment⁶. Ksharkarma is the treatment having more effect which was reported previously. Yava-Kshar was selected as a Kshar ingredient in previous study and it was done by using Yava-Kshar Pratisaran and this project was the extension of previous study⁷. But for Pratisaran of Kshar, intervention of doctor is necessary and compulsory. Hence it was decided to make the process convenient for patient to apply the Kshar at internal haemorrhoid and to avoid doctor's intervention for application of Kshar. Concept of application of Kshar by patient was presumed and for this purpose the Ointment of Kshar was preferred. Here the study was carried out, to prove the effect of application of Yava Kshar ointment at internal haemorrhoid (Abhyantar Gudarsha). The Yava Kshar ointment was prepared with two different concentration i.e. 5% and 10% and also two different base were selected one was natural and other was synthetic i.e. Siktha Tailam and Petroleum Jelly respectively. During pilot study 5% and 10% composition was used to verify results and it was continued for final study. Due to minimum concentration of Yava Kshar the unwanted corrosion to normal mucosa was avoided.

Aim

To provide an effective local treatment, as local application in the form of Malhar (ointment) having the direct local effect in the management of Arsha (Internal Piles).

Objectives

- To modify the ancient mode of treatment in the scientific era.
- Evaluation of effects Yava-Kshar ointment application on Internal piles (Abhyantar Gudarsha)

MATERIALS AND METHODS

Preparation of Yava Kshar

Yava (*Hordeum vulgare* Linn.) sown in land and Yava was cultivated. It was grown fully approximately in 3 months. Then the soil was irrigated up to 8 days. After that the plants were pulled out along with roots. Plants were dried completely in sunlight in few days. The ash was obtained by burning the all dried Yava plants. That ash was dissolved in 6 times of water and maintained for one day. Next day that water was filtered by 12 folded fine cloth. The filtered water had appearance and smell like a cows urine. The filtered water was evaporated completely by heating it. Lastly the whitish Yava Kshar was obtained at bottom of container⁸.

Preparation of Ointment

Preparation of Yava Kshar ointment was carried out at Government Ayurved Pharmacy, Nanded, Maharashtra, India. By using base Petroleum jelly and Siktha Tailam⁹ (Bees wax + Sesame Oil) different compositions were prepared by mixture and grinder machine. Compositions were as follow

1. Petroleum Jelly + Yava Kshar 5% w/w
2. Petroleum jelly + Yava Kshar 10% w/w
3. Siktha Tailam + Yava Kshar 5% w/w
4. Siktha Tailam + Yava Kshar 10% w/w

Above said compositions were filled in different tubes using manual filling machine. Each tube was filled by 30 g of ointment separately.

Physicochemical Analysis

Analysis of Yava Kshar was done in Food and Drug Administration (FDA) approved laboratory yields good results. (Table 1 and 2)

Clinical Study

Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at Government Ayurved College, Nanded, Maharashtra, India.

Institutional Ethical Clearance (GACN/IEC/25-35/09 Dated-15/06/2009)

Patients (age group, 21 to 70 years) attending the Outpatient Clinic at Government Ayurved Hospital, Nanded, Maharashtra, India and meeting all the inclusion criteria were recruited in the trial. A written consent was obtained by counseling the patients of piles for participation in the study.

Selection Criteria for Patients

- Patients of piles of both sexes were included in this study.
- The study groups of age group between 21 years to 70 years age.
- The patients of I, II and III degree piles included in this study.
- All cases were fresh and had not received any local treatment.

Rejection Criteria for Patients

- The patients of piles having previous history of

haemorrhoidectomy were rejected.

- Patients of piles which were diabetic, malignant, AIDS, Koch's with fistula or having portal obstruction was rejected.
- Patients having Hb below 10g % were rejected.
- Pregnant woman was not included in this study.
- Patients suffering from chronic toxicity were excluded from this study.

The study was carried out in eight groups i.e. A, B, C, D, E, F, G, H and each group consists of about 25 to 30 patients. The process of Yava Kshar Pratisaran was modified according to nature of study. Patient was advised Mrudu-Virechan in the form of bowel regulator (Trifol powder) and Seitz bath regularly. The patient was advised to apply Yava Kshar ointment with the help of applicator provided with ointment tube twice daily.

A Group

Treated with local Yava Kshar 5% ointment (base petroleum jelly) with dietetic regime and bowel regulator

B Group

Treated with local Yava Kshar 5% ointment (base Siktha Tailam) with dietetic regime and bowel regulator

C Group

Treated with local Yava-Kshar 10% ointment (base petroleum jelly) with dietetic regime and bowel regulator

D group

Treated with local Yava Kshar 10% ointment (base Siktha Tailam) with dietetic regime and bowel regulator

E group

Treated with popular allopathic brand name 'Faktu ointment' (Contents policruselin 5%+Cinchocaine 1%) Manufactured by and GLAT company with dietetic regime and bowel regulator. This group taken as a comparative.

F Group

Received only bowel regulator adopting standard dietetic regime

G Group

Treated with local petroleum jelly application with dietetic regime and bowel regulator

H group

Treated with local Siktha Tailam application with dietetic regime and bowel regulator

Criteria for Assessment

Degree of Hemorrhoid

I - Hemorrhoids projecting slightly in lumen of anal canal, when veins are congested at defecation.

II - Hemorrhoids prolapsed out of the anus on straining, but return spontaneously to the anal canal when motion has been passed and the defecation has ceased.

III - Haemorrhoids prolapse but don't reduce spontaneously and remain prolapsed afterwards and have

to be replaced digitally.

IV – Completely irreducible haemorrhoids usually are long standing and acquire a component of skin.

P/R Bleeding Grade

I Grade – 0 to 5 drops

II Grade – 6 to 15 drops

III Grade – 16 and above drops

A special clinical record form (C.R.F.) was prepared to record the findings. Every patient was observed at regular follow up on 0th, 3rd, 10th, 17th and 24th day. For visual recording the regular photographs of selected patients from each group were taken for observing the local changes at internal haemorrhoid. Routine investigations of all patients and some specific investigations were carried out as and when required.

Dietetic Regime was used

- Diet rich in fibers was advised.
- Avoid Non Vegetarian Diet.
- Avoiding Spicy Diet.

Statistical Analysis

The confidence limit was fixed at 95% and the level of significance was at 5%. Paired and unpaired 't' test was applied for objective parameter and chi square test was applied for subjective parameter. Analysis of P/R bleeding in each group was done by applying 't' test to difference of P/R bleeding between each follow up and then before and after treatment.

Observations

In this study 219 volunteers were selected randomly and these volunteers were grouped under various groups mentioned above i.e. minimum 26 patients per group. The important demographic findings of these groups are compiled in Table 3 to 9.

Statistical Analysis and Interpretation

The confidence limit was fixed at 95% and the level of significance was at 5%. Paired and unpaired 't' test was applied for objective parameter and chi square test was applied for subjective parameter and ANOVA test was applied for comparison of effect of all ointments. Analysis of P/R bleeding in each group was done by applying 't' test to difference of P/R bleeding between each follow up and then before and after treatment. Maximum number of patients was from age group of 25 to 40 years. Maximum numbers of patients were consuming mix and spicy diet. The distribution of patient in all groups according to above said effective factors was equal. The observed difference was statistically insignificant. Hence all groups were from the same population and comparable at baseline. In all groups incidence of 3rd grade P/R bleeding was maximum and incidence of 1st grade P/R bleeding was minimum. This may be due to negligence of patients in less severity. It was observed that in all groups incidence of 2nd degree hemorrhoids were maximum due to inclusive criteria of groups. It was least in 1st degree hemorrhoids may be due to negligence of patients. (Table 10)

From Table 10 it can be concluded that the distribution of patient in all groups according to above said effective factors was equal. The observed difference was the statistically insignificant. Hence all groups were from the same population and comparable at baseline.

Group Yava Kshar ointment 5% base Petroleum Jelly

Above observation and significance test shown that difference of P/R bleeding before and after treatment was highly significant. Hence it can be said that change occurred may be due to treatment. (Table 11)

Group Yava Kshar ointment 5% base Siktha Tailam

Above observation and significance test shown that difference of P/R bleeding before and after treatment was highly significant. Hence it can be said that change occurred may be due to treatment. (Table 12)

Group Yava Kshar ointment 10% base Petroleum Jelly

Above observation and significance test shown that difference of P/R bleeding before and after treatment was highly significant. Hence it can be said that change occurred may be due to treatment. (Table 13)

Group Yava Kshar ointment 10% base Siktha Tailam

Above observation and significance test shown that difference of P/R bleeding before and after treatment was highly significant. Hence it can be said that change occurred may be due to treatment. (Table 14)

Faktu Ointment

Above observation and significance test shown that difference of P/R bleeding before and after treatment was highly significant. Hence it can be said that change occurred may be due to treatment. (Table 15)

Trifol (Table 16)

Siktha Tailam (Table 17)

Petroleum Jelly (Table 18)

From Table no. 16 to 18 it can be concluded that there was no difference occurred in these groups. Treatments were mostly ineffective.

From the Table 19 (a and b) it can be concluded that F value for degree of freedom 2, 81 is 3.15 and 4.98 for 0.05 and 0.001 level of significance. As F(2, 81) calculated is more than table value of F(2,81) there is significant difference in the three treatments i.e. Yavakshar ointment 5% (base Siktha Tailam), Yava Kshar ointment 10% (base petroleum jelly), Yava Kshar ointment 10% (base Siktha Tailam).

From the Table 20 (a and b) it can be concluded that F value for degree of freedom 5, 158 is 2.21 and 3.02 for 0.05 and 0.001 level of significance. As F(5, 158) calculated is less than table value of F(5, 158) there is insignificant difference in the six treatments.

Table 21 shows that the result of treatment of group D was best i.e. maximum numbers of patients were cured and all other relieved.

Table 1: Results of Physicochemical analysis of Yava Kshar

Test	Result
Moisture	38.42%
Total Ash	24.30%
Acid insoluble in Dil. HCl	3.7%
Specific Gravity	1.2156
Potassium	198mg/100gm
Sodium	23mg/100gm
Fluoride	15mg/100gm
pH Value	10.60

Table 2: Results of Physicochemical analysis of Yava Kshar ointment prepared by various concentrations

Name of Ointment	Pile Sikt 5%	Pile Gel 5%	Pile Sikt 10%	Pile Gel 10%
Moisture	0.14%	0.13%	0.11%	0.12%
Total Ash	1.20%	1.19%	2.42%	2.27%
Acid insoluble in Dil. HCl	0.17%	0.14%	0.38%	0.25%
Specific Gravity	0.9379	0.9312	0.9352	0.956
Potassium	10mg/100gm	9mg/100gm	21mg/100gm	19mg/100gm
Sodium	2mg/100gm	1mg/100gm	3mg/100gm	2mg/100gm
Fluoride	1mg/100gm	1mg/100gm	2mg/100gm	2mg/100gm
Iodine Value	6.96	7.1	6.56	6.32
Melting point	34 ^o C	33.4 ^o C	34.6 ^o C	35 ^o C
Saponification value	255.46	258.8	261.35	259.67
Acid Value	2.62	2.52	2.35	2.41
Unsaponifiable matter	0.59%	0.62%	0.68%	0.65%

Table 3: Sex wise incidences of patients in all groups

Groups	Male	Female	Total
A	23	3	26
B	25	3	28
C	24	3	27
D	25	4	29
E	21	5	26
F	25	3	28
G	24	4	28
H	21	6	27
Total	188	31	219
	X ² = 0.89424		P = P>0.05

Table 4: Age wise incidences of patients in all groups

Groups	25-40	40-55	55-70	Total
A	13	9	4	26
B	9	11	8	28
C	14	8	5	27
D	19	9	1	29
E	9	10	7	26
F	11	13	4	28
G	12	13	3	28
H	9	14	4	27
Total	96	87	36	219
	*Age in years		X ² = 0.25732	P = P>0.05

Table 5: Diet wise incidences of patients in all groups

Diet	Groups								Total	X ² value	p value
	A	B	C	D	E	F	G	H			
Mix	25	27	26	27	26	28	27	27	213	0.71847	p>0.05
Veg	1	1	1	2	0	0	1	0	06		
Spicy	26	28	27	27	26	27	27	26	214	0.54715	p > 0.05
Non spicy	0	0	0	0	2	1	1	1	05		

Table 6: Degree of P/R bleeding wise incidences of patients in all groups

Groups	3 rd	2 nd	1 st	Total
A	17	9	0	26
B	21	7	0	28
C	22	5	0	27
D	23	5	1	29
E	19	7	0	26
F	21	7	0	28
G	21	7	0	28
H	20	7	0	27
Total	164	54	1	219
	X ² = 0.81024		P = P > 0.05	

Table 7: Degree of hemorrhoid wise incidence of patient in all groups

Groups	3 rd	2 nd	1 st	Total
A	3	23	0	26
B	1	27	0	28
C	2	25	0	27
D	4	25	0	29
E	1	25	0	26
F	0	28	0	28
G	2	26	0	28
H	4	22	1	27
Total	17	201	1	219
	X ² = 0.39132		P = P > 0.05	

Table 8: showing the mean of PR bleeding on each follow up in different Groups

Group	0 th day		3 rd day		10 th day		17 th day		24 th day	
	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
A	2.654	0.485	2.077	0.628	0.808	0.801	0.038	0.196	0	0
B	2.75	0.441	0.607	0.786	0.179	0.39	0.036	0.189	0	0
C	2.759	0.511	0.31	0.66	0.069	0.371	0.034	0.186	0	0
D	2.815	0.396	0.704	0.775	0.296	0.542	0.037	0.192	0	0
E	2.731	0.452	2.615	0.496	1.346	0.629	0.654	0.689	0.385	0.496
F	2.75	0.441	2.643	0.488	2.5	0.509	2.321	0.612	2.036	0.744
G	2.741	0.447	2.63	0.565	2.704	0.542	2.667	0.555	2.63	0.565
H	2.75	0.441	2.679	0.476	2.786	0.418	2.75	0.441	2.714	0.46

Table 9: Showing the mean degree of haemorrhoid on each follow up in different groups

Group	0 th day		3 rd day		10 th day		17 th day		24 th day	
	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
A	2.115	0.326	2.115	0.326	2.115	0.326	2.115	0.326	2.115	0.326
B	2.036	0.189	2.036	0.189	2.036	0.189	2.036	0.189	1.857	0.448
C	2.074	0.267	2.074	0.267	2.074	0.267	2.074	0.267	1.815	0.396
D	2.138	0.351	2.138	0.351	2.138	0.351	2.138	0.351	1.69	0.604
E	2.038	0.196	2.038	0.196	2.038	0.196	2.038	0.196	2.038	0.196
F	2.00	00	2.00	00	2.00	00	2.00	00	2.00	00
G	2.111	0.424	2.111	0.424	2.111	0.424	2.111	0.424	2.111	0.424
H	2.071	0.262	2.071	0.262	2.071	0.262	2.071	0.262	2.071	0.262

Table 10: Analysis of Incidence

Attribute	X ²	p
Sex	0.89424	P> 0.05
Age	0.25732	P> 0.05
Diet (mix / veg.)	0.71847	P> 0.05
(Spicy / No spicy)	0.54751	P> 0.05
Degree of P/R bleeding	0.81024	P > 0.05
Degree of piles	0.39132	P > 0.05

Table 11: Showing the significance of difference in PR Bleeding on each follow up and after complete treatment

	0 th day	3 rd day	10 th day	17 th day	BT-AT
Mean of difference	0.577	1.269	0.769	0.038	2.077
S.D.	0.578	0.724	0.765	0.196	0.628
S.E.	0.113355	0.141988	0.150029	0.038439	0.123161
T	5.09	8.937	5.126	0.989	16.864
P	P< 0.05	P< 0.05	P< 0.05	P< 0.05	P< 0.05
	P < 0.001	P < 0.001	P < 0.001	P < 0.001	P < 0.001

Table 12: Showing the significance of difference in PR Bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	2.143	0.429	0.095	0.048	2.714
S.D.	0.891	0.507	0.301	0.218	0.463
S.E.	0.168	0.096	0.057	0.041	0.087
t	12.756	4.469	1.667	1.171	31.195
p	P< 0.05	P<0.05	P>0.05	P>0.05	P<0.05
	P< 0.001	P< 0.001	P< 0.001	P< 0.001	P< 0.001

Table 13: Showing the significance of difference in PR Bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	2.111	0.407	0.259	0.037	2.815
S.D.	0.847	0.501	0.447	0.192	0.396
S.E.	0.163005	0.096417	0.086025	0.03695	0.07621
t	12.951	4.221	3.011	1.001	36.937
p	P< 0.05	P<0.05	P<0.05	P>0.05	P<0.05
	P<0.001	P<0.001	P>0.001	P>0.001	P<0.001
	P< 0.001	P< 0.001	P< 0.001	P< 0.001	P< 0.001

Table 14: Showing the significance of difference in P/R bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	2.448	0.241	0.034	0.034	2.759
S.D.	0.87	0.435	0.186	0.186	0.511
S.E.	0.162	0.081	0.035	0.035	0.095
t	15.111	2.975	0.971	0.971	29.042
p	P<0.05	P<0.05	P>0.05	P>0.05	P<0.05
	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001

Table 15: Showing the significance of difference in PR Bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	0.115	1.269	0.692	0.269	2.231
S.D.	0.326	0.667	0.549	0.452	0.587
S.E.	0.063934	0.130809	0.107668	0.088644	0.11512
t	1.799	9.701	6.427	3.035	19.38
p	P>0.05	P<0.05	P<0.05	P<0.05	P<0.05
	P>0.001	P<0.001	P<0.001	P>0.001	P<0.001

Table 16: Showing the significance of difference in PR Bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	0.107	0.143	0.179	0.286	0.607
S.D.	0.315	0.356	0.67	0.763	0.786
S.E.	0.059529	0.067278	0.126618	0.144193	0.14854
t	1.797	2.126	1.414	1.983	4.086
p	P>0.05	P<0.05	P>0.05	P>0.05	P<0.05
	P>0.001	P>0.001	P>0.001	P>0.001	P<0.001

Table 17: Showing the significance of difference in P/R bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	0.111	-0.074	0.037	0.037	0
S.D.	0.32	0.267	0.192	0.192	0.392
S.E.	0.061584	0.051384	0.03695	0.03695	0.07544
t	1.802	-1.44	1.001	1.001	0
p	P>0.05	P>0.05	P>0.05	P>0.05	P>0.05
	P>0.001	P>0.001	P>0.001	P>0.001	P>0.001

Table 18: Showing the significance of difference in PR Bleeding on each follow up and after complete treatment

	0 th – 3 rd	3 rd – 10 th	10 th – 17 th	17 th – 24 th	BT – AT
Mean of difference	0.071	-0.107	0.036	0.036	-0.036
S.D.	0.262	0.416	0.429	0.744	0.637
S.E.	0.049513	0.078617	0.081073	0.140603	0.120382
t	1.434	-1.361	0.444	0.256	-0.299
p	P>0.05	P>0.05	P>0.05	P>0.05	P>0.05
	P>0.001	P>0.001	P>0.001	P>0.001	P>0.001

Table 19 (a): Differences in Degree of Hemorrhoid due to Treatment

	Petro 5%	Siktha 5%	Siktha 10%	Petro 10%	Faktu	Trifgol	PetroGel	Siktha Tailam
Mean	0	0.179	0.448	0.259	0	0	0	0
SD	0	0.39	0.506	0.447	0	0	0	0
SE	0	0.074	0.094	0.086	0	0	0	0
t	0	2.419	4.766	3.012	0	0	0	0
P	P>0.05	P<0.05	P<0.05	P<0.05	P>0.05	P>0.05	P>0.05	P>0.05
		P>0.001	P<0.001	P>0.001				

Grand Mean = 0.298 Degree of freedom (Total) = 83

Table 19(b): Difference in Degree of Hemorrhoid due to Treatment

Source of Variation	Degrees of freedom	Sum of Squares	Mean sum of square	F
T/T	2	8.535	4.268	38.8
Error	81	8.935	0.11	
Total	83	17.47		

Table 20 (a): Difference in P/R Bleeding due to Treatment

	Petro 5%	Siktha 5%	Siktha 10%	Petro 10%	Faktu	Trifgol	Petro Gel	Siktha Tailam
Mean	2.077	2.714	2.759	2.815	2.231	0.607	-0.036	
SD	0.628	0.463	0.511	0.396	0.587	0.786	0.637	0.392
SE	0.123	0.087	0.095	0.0762	0.1151	0.1485	0.1203	0.0754
t	16.864	31.195	29.042	36.937	19.38	4.086	-0.299	0
P	P<0.05	P<0.05	P<0.05	P<0.05	P<0.05	P<0.05	P>0.05	P>0.05
	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P>0.001	P>0.001

Grand Mean = 2.207 Degree of freedom (Total) = 163

Table 20 (b): Difference in P/R Bleeding due to Treatment

Source of Variation	Degrees of freedom	Sum of Squares	Mean sum of square	F
T/T	5	898.225	179.645	-37.7326
Error	158	-752.176	-4.761	-
Total	163	146.049	-	-

Table 21: Results of treatment of patients in all groups

Groups	Cured	Relived	Not cured	Total
A	0	26	0	26
B	5	23	0	28
C	7	20	0	27
D	14	15	0	29
E	0	17	9	26
F	0	0	28	28
G	0	0	28	28
H	0	0	27	27
Total	26	101	92	219

$X^2 = 236.1,$

$P < 0.05$

DISCUSSION

Haemorrhoid (pile) is the most frequently observed anal pathology. This disease has been recognized and treated since antiquity. Much more modern information is available on the pathogenesis of haemorrhoid. The basic pathology appears to be centered on the absence of valves in the haemorrhoidal vessels followed by lack of supportive structures around the vein and precipitating or provoking factors like increased intra abdominal and intrarectal pressure, improper dietary habit with addictions. Normal anatomical structure involved in haemorrhoids present in every one after birth, which are thought to play some part in anal continence. Internal haemorrhoids are considered as disease after the symptoms like bleeding, protrusion, inflammation and thrombosis.

The treatment must be aimed at

- Symptomatic relief and
- The correction of anatomical deformity.

Above mentioned treatment are achieved by means of conservation or surgical methods. Now a day various non surgical methods are an alternative to surgical ones. They aim at tissue fixation with or without tissue destruction like sclerotherapy, photocoagulation/IRC (Infra Red Coagulation) and Barron's Band Ligation. Increasing number of therapies themselves proves that there is no universally acceptable technique in the management of haemorrhoids. Since, the haemorrhoid problem is not a threat to life excepting few conditions; the least invasive treatment is most desirable. Ksharkarma is the treatment having more effect which was proved previously. Yava Kshar was selected as a Kshar ingredient as previous

study was performed using Yava-Kshar Pratisaran and this project was the extension of previous study. There were some procedural problem in study like possibility of application to other than diseased site, variability in amount of Kshar, no assurance of shelf life due to hygroscopic nature of Kshar and needed intervention of doctor. To overcome the above problems there was need to bring the Kshar in new dosages form i.e. Ointment. Hence some remolding of established modality of treatment was done in present study. To make it user friendly and less complicating, new drug dosage formation i.e. ointment in different percentage of Yava Kshar and different bases was included in this study. Observations noted were analyzed using confidence limit which was fixed at 95% and the level of significance which was at 5%. Paired and unpaired 't' test was applied for objective parameter and chi square test was applied for subjective parameter and ANOVA test was applied for comparison of effect of all ointments. Total 219 well diagnosed patients suffering from II° internal haemorrhoids, not responding to conservative treatment were included in the study. The maximum incidence of Arsha in men of age 25 to 55 years was observed and only 31 female were participated in the trial. The less number of female patients could be due to ignorance and shyness. The male sex prevalence may be due to haemorrhoid disease precipitating dietary habit and addictions. With reference to diet, those patients who were taking non-vegetarian and spicy diet were more sufferer than patient taking vegetarian and non-spicy diet. This may because of non-vegetarian spicy diet which is prone to develop constipation and increases intra-rectal resting pressure and provoking engorgement of the haemorrhoidal vessels.

Constipated hard stool having maximum friction to the anal, congested haemorrhoidal mass and produces symptomatic mass and produces symptomatic haemorrhoids. Regularization of the dietary habit along with avoidance of constipation and friction by stool softening agent has their own importance. Therefore, identical ideal dietary regimen and stool softening agents advised in all the groups. The patients were also scrutinized according to 'Habitat'. This observation shows that maximum patients were having same type of habitat and it was interpreted that these patients were more prone to develop internal haemorrhoid.

Degree of P/R Bleeding

On Day 0

All group had nearly same mean of P/R bleeding.

On 3rd Day

Mean change in P/R bleeding occurred in group Yava Kshar ointment 10% (base Siktha Tailam), Yava Kshar ointment 10% (base Petroleum Jelly) and Yava Kshar ointment 5% (base Siktha Tailam). Mean change in P/R bleeding was maximum in group treated with Yava Kshar ointment 10% (base Siktha Tailam), very slight change occurred in groups treated with Yava Kshar ointment 5% (base Petroleum Jelly), Faktu ointment, Trifgol, Petroleum Jelly and Siktha Tailam. Maximum P/R bleeding was in group treated with Petroleum jelly.

On 10th Day

Decrease in P/R bleeding was observed in group Yava Kshar ointment 5% (base petroleum jelly), Yava Kshar ointment 5% (base Siktha Tailam), Yava Kshar ointment 10% (base Siktha Tailam), Yava Kshar ointment 10% (base petroleum jelly) and Faktu ointment. P/R bleeding was minimal in Yava Kshar ointment 10% (base Siktha Tailam) and then in Yava Kshar ointment 5% (base Siktha Tailam). Slight decrease was observed in Trifgol. There was increase in P/R bleeding in group treated with Siktha Tailam and Petroleum jelly.

On 17th Day

Negligible P/R bleeding was observed in groups treated with Yava Kshar ointment 5% (base petroleum jelly), Yava Kshar ointment 5% (base Siktha Tailam), Yava Kshar ointment 10% (base Siktha Tailam) and Yava Kshar ointment 10% (base petroleum jelly). Slight P/R bleeding observed in patients treated with Faktu ointment. Very slight decrease in P/R bleeding was in groups Trifgol, Siktha Tailam and Petroleum jelly. This may be due to softening of stools.

On 24th day

No P/R bleeding reported by patients of group Yava Kshar ointment 5% (base petroleum jelly). Yava Kshar ointment 5% (base Siktha Tailam), Yava Kshar ointment 10% (base Siktha Tailam) and Yava Kshar ointment 10% (base petroleum jelly). Incidence of P/R bleeding was minimal in group treated with Faktu ointment. Negligible changes in P/R bleeding occurred in group Trifgol, Siktha Tailam, Petroleum jelly, in which decrease was more in

group Trifgol.

The probable mode of action of the drug may be due to corrosive action. As 'Yava Kshar' i.e. potash alkali, reduces bleeding and stabilizes vascular endothelium by its chemical cauterization effect. This action may help to control P/R bleeding which is the most important clinical feature of the internal haemorrhoid¹⁰.

Degree of hemorrhoids

Till 17th day

No change in degree of haemorrhoid was observed in all groups.

24th day

The changes were observed in group Yava Kshar ointment 5% base Siktha Tailam, Yava Kshar ointment 10% base petroleum jelly and Yava Kshar ointment 10% base Siktha Tailam. Maximum changes were observed in Yava Kshar ointment 10% base Siktha Tailam. No changes observed in groups Yava Kshar ointment 5% base petroleum jelly, Faktu ointment, Trifgol powder, plane Siktha Tailam and plane petroleum jelly. Though the difference in degree of haemorrhoid was not found to the marked extent, some other local effects were found which were supposed to support the haemorrhoidal plexuses and not to prolapsed haemorrhoid. The fibrotic (blackish in colour) changes were observed at the site of haemorrhoid, which were recorded in photographs. It may be due to chemical cauterization. In delayed follow ups, it was observed that, the size of haemorrhoid was reduced but not reduced totally. May be after few months, it changes to normal mucosa. Hence it is effective for internal hemorrhoid. Prolapsing haemorrhoidal mass and P/R bleeding due to which there was decreased chances of cloth spoilages and improvement of local hygiene by Seitz bath also. Due to decrease in Prolapsing mass overall psychological disturbance of the sufferer was also minimizes as the patient becoming symptoms free. At the same time having tikshna, ushna properties along with katu rasa causes 'Lekhan, Ksharan and Kshapan' i.e. scrubbing of the tissue and decreases size of haemorrhoid. This action may helps to reduce the size of prolapsing haemorrhoid mass¹⁰.

Assessment of Drug Dose

Different concentration of Yava Kshar in different ointment was helpful in accessing proper dose of Yava Kshar for local application with reducing complications. It was observed that Group having Yava Kshar 10% had good results.

Assessment of Different Bases

Different bases were used i.e. Natural base (Siktha Tailam) and synthetic base (Petroleum jelly). These helped in accessing utility of small dose of Kshar in different bases. As both these bases were tried as a control group and didn't show any significant action, it can be said that action was due to Yava Kshar and not due to bases. Yava Kshar ointment 5% (base Siktha Tailam), Yava Kshar ointment 10% (base petroleum jelly), Yava

Kshar ointment 10% (base Siktha Tailam) are statistically significant in reducing degree of Haemorrhoid. Moreover it was found that Yava Kshar ointment 10% having base Siktha Tailam was most effective than other ointments. Because of more concentration of Yava Kshar and more solubility of Siktha Tailam comparative to Petroleum jelly and by medicinal scrubbing (i.e. Lekhan, Ksharan and Kshapan) property of Yava Kshar. Faktu ointment was less effective in reducing degree of haemorrhoids. Finally, all Yava Kshar ointments cure P/R bleeding within less time i.e. 3 to 7days as compared to Faktu ointment i.e. to 14days.

CONCLUSION

The P/R bleeding was decreased significantly in each group ($p < 0.05$) except in simple Siktha Tailam and simple Petroleum jelly. The Faktu ointment and Trifgol required 10 days approximately to reduce the P/R bleeding where as other all Yava Kshar ointment required 3 days approximately to reduce P/R bleeding and it was highly significant ($p < 0.001$). Though the difference in degree of haemorrhoid was not found to the marked extent however some other local effects were found, which were supposed to give a strong support to the haemorrhoidal plexuses and not to prolapsed haemorrhoid. The fibrotic (blackish in colour) changes were observed at the site of haemorrhoid, which were recorded in photographs. It may be due to chemical cauterization. In delayed follow ups, it was observed that, the size of haemorrhoid was reduced significantly but not totally. May be after few months, it changes to normal mucosa. Hence it is effective for internal haemorrhoid. It was concluded that the application of Yava Kshar ointment of 10% having base Siktha Tailam was more effective than other ointment (i.e. Yava Kshar ointment 5% base Siktha Tailam, Yava Kshar ointment 5% base petroleum jelly, Yava Kshar ointment

10% base petroleum jelly, Faktu ointment, Trifgol powder, plane Siktha Tailam and plane Petroleum jelly) in reducing the P/R bleeding markedly within minimal period and in reducing the degree of haemorrhoids up to certain extent.

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