

**“A CONTROLLED STUDY OF POLYHERBAL GUDAVATIKA AS A
RECTAL SUPPOSITORY IN POST OPERATIVE ANO-RECTAL
DISEASES.”**

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ABSTRACT

Ayurveda is for maintenance of health, to prevent & to cure diseases. In the present scientific era, people are fed up with the side effects & after effects of the most effective & fast acting modern drugs, which are lowering the human immunity. Basic principles of Ayurveda have significant Value in the life of modern era, hence one cannot 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 now a day's 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. 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. While working in Shalyatantra outdoor patient department and indoor patient department it

was observed that percentage of patients suffering from Ano-Rectal diseases are significant, hence I selected the topic for study.

KEYWORDS: Anorectal diseases, polyherbal gudavartika, suppository, diclofenac.

INTRODUCTION

Acharya Sushruta had given fourth fold treatment namely Bhesaja, Kshra, Agni & Shastra karma for Arshas. Similarly they had given sthanik snehana, swedana, deepan, pachana, anuloman chikitsa in various ano-rectal diseases. Out of these Shastra karma is one of the important way to treat the diseases. After surgery, in post-operative management on withdrawn of anaesthesia patient had lot of pain in ano-rectal area. Thus surgeons need to be aware of all aspects of approaching the patient with anorectal diseases, as ultimate recovery and function depend on accurate and proper evaluation and management so. Apart from parental route of analgesic drugs, administration of locally acting drug need to be used.

Rectal drug administration could represent a convenient, alternative route of drug administration. So rectal route can provide satisfactory pharmacokinetics & acceptable local tolerance.

Diclofenac sodium suppository is used worldwide mostly in post-operative pain management, still having some side effects like Rhinosinusitis, angioedema, urticaria, GI problems, headache, Renal & Hepatic function impairment, Hyperkalemia, Edema etc. To overcome this, I prepared polyherbal gudavartika which might be fruitful in post-operative pain management along with minimal or no side-effects.

Acharya Charaka mentioned Shulprashaman, Kandughna, dahaprashaman, Sandhaniya, Shonitstapan Vedanasthapan gana in various aspects. After correlating Acharya Charaka's Mahakashaya Gana & Acharya Sushruta's Mishrak Gana, the drugs which are common to both & having multiple properties along with analgesic, anti-inflammatory & soothing effect, such drugs are taken in this study.

The Rectal mucosa is richly vascularised. This important blood supply comprises inferior & middle rectal veins which are directly connected to systemic circulation. & the superior rectal vein which is connected to portal system. This Ensure that drug in suppository form which are absorbed in the upper rectum will not Bi-Pass the hepatic first –pass elimination responsible for the metabolism & rapid clearance of many orally administered drugs.

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 Acharya's in the management of each & every diseases, but their efficacy needs re-establishment by means of thorough & intensive researches.

Thus polyherbal gudavatika is taken with a view to evaluate its properties & efficacy clinically in various post operated ano-rectal cases. This research work is a sincere effort for bringing polyherbal gudavatika in limelight with the goal of introducing better, safer & cost effective treatment.

AIMS

1. To study analgesic effect of polyherbal gudavatika as a rectal suppository in post operated ano-rectal patients.
2. Apart from analgesic action, also to assess role of polyherbal gudavatika in post-operative ano-rectal Itching & local burning.
3. To study the possible actions of mechanism of polyherbal gudavatika as a rectal suppository in post-operative ano-rectal management.

OBJECTIVES

1. To compare effect of analgesic action of polyherbal gudavatika With diclofenac sodium suppository in management of post operated ano-rectal diseases.
2. To overcome the adverse effect of diclofenac sodium suppository.
3. To study the literary review & mechanism of action of ingredient of polyherbal gudvatika.

MATERIAL AND METHODS

The study was carried out in shevgaon ayurved hospital. The clinical parameters of examination & follow up was strictly as per CRF.

CRITERIA OF SELECTION OF PATIENTS

Patients of Both sexes between age group 5-50yr.

(A) Inclusion criteria

- After anal stretching.
- After Kshar sutra application & Change of Kshar sutra

- Post-operative patients of External & Internal haemorrhoid I.e. after haemorrhoidectomy.
- Post op. patient of Sphincterotomy.
- Post op. patients of Fistulotomy & Fistulectomy.
- Post-operative cases of all types of abscesses such as Perianal, Ischiorectal abscess.
- None operated paediatric patients c/o pain & Itching due to fissure in Ano.

(B) Exclusion criteria

- i. Imperforated Anus.
- ii. Stricture of Anus.
- iii. Ca Rectum.

(C) Withdrawal criteria= Patients suffering from any adverse effect during study, was withdrawn & was shifted for further management.

GROUPING OF PATIENT = randomly selected patients was divided in Group A & Group B.

Trial Group A= 1. Ajmoda = 25 mg

2. Daruharidra = 25 mg

3 Raktachandan =10 mg

4. Lajjalu = 15 mg

5. Yashtimadhu = 15 mg

6. Shirish = 10 mg

First I Prepared Kwath of this drugs as per Standard Bhaishajaratnawali siddhant. Then I siddha Go-Ghrut from kwath. After adding Bee wax & Molding Polyherbal suppository prepared.

Control Group B =Diclofenac sodium Suppository (100mg).

DURATION OF TREATMENT = 10 DAYS Application of this polyherbal Gudvatika just after Surgery & BD for 10 days, depends upon Severity post-operative ano- Rectal pain.

FOLLOW UP = Once a week for 1 month.

CLINICAL EXAMINATION = Post-operative Perianal Region, Anal verge Examination was done. If Required PR & PS Examination can also be done to assess internal condition.

PARAMETERS FOR CLINICAL ASSESMENT

A) Assessment of pain = Visual Analogue Scale

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			

B) Assessment of Tenderness

0 –No tenderness.

1- Mild tenderness.

2-Moderate tenderness.

3-Severe tenderness.

C) Assessment of local itching

0 – No itching.

1-Mild itching.

2-Moderate itching.

3-Severe itching.

D) Assessment of local burning

0 – No burning sensation.

1 - Mild burning sensation.

2-Moderate burning.

3-Severe burning.

E) Assessment of PR bleeding

0 – No bleeding PR.

1 – up to 5-6 drops of blood.

2 – 7-10 drops of blood.

3 – above 10 drops of blood.

Criteria for result assessment

1. Cured-Complete relief in signs & symptoms.
2. Improved-Above 50 but below 100% relief Sign symptoms.
3. Relieved-Below 50% relief in signs & symptoms.
4. Not cured-No change in signs & symptoms.

OBSERVATIONS AND RESULTS**Demographic analysis**

Age wise distribution =Table showing age wise classification of 60 patients.

Group A

Age	No.of patients.	%
5-20 yrs.	0	0%
21-30 yrs.	8	26.66%
31-40 yrs.	15	50%
41-50 yrs.	7	23.33%

Group B

Age	No.of pts.	%
5-20 yrs.	0	0%
21-30 yrs.	7	23.33%
31-40 yrs.	15	50%
41-50 yrs.	8	26.66%

Age	Out of 60 pts	%
5-20 yrs.	0	0 %
21-30 yrs.	15	25 %
31-40 yrs.	30	50 %
41-50 yrs.	15	25 %

Above table shows that there are total 30 pts of age group 31-40 yrs. of age.15 pts of 21-30 yrs. & 15 pts of 41-50 yrs. of age group.

Statistically, the distribution of patients according to age in above three groups are insignificant. Hence groups are homogenous.

Sex wise distribution

Table showing sex wise distribution of 60 patients.

Sex	Total no of pts in Group A	% of Group A	Total no of pts in Group B	% of Group B	Group A + Group B	Total %
Female	11	36.66%	10	33.33%	21	35 %
Male	19	63.33%	20	66.66%	39	65 %

Out of 60 patients under study 35% were female & 65% were male. Statistically, the distribution of patients according to sex in both groups is insignificant. Hence, both groups are homogenous.

Religion wise distribution of 60 pts.

Religion	Grp A 30	% of Group A	Grp B 30	%of Group B	Total no Of pts.	Total %
Hindu	27	90 %	25	83.33%	52	86.66%
Muslim	3	10 %	5	16.66%	8	13.33%

Out of 60 pts 86.66% belongs to Hindu religion, & 13.33% belongs to Muslims.

➤ Marital status wise distribution of 60 pts.

Marital Status	Grp A 30	% of Grp A	Grp B 30	% of Grp B	Total no Of pts.	Total %
Married	27	90%	24	80%	51	85%
Unmarried	3	10%	6	20%	9	15%

Out of 60 pts under study 85% were married & 15% were unmarried.

➤ Occupational wise distribution of 60 pts.

Occupation	Grp A 30	% of Grp A	Grp B 30	% of Grp B	Total 60 pts.	% of Total pts.
Sedentary	12	40%	14	46.66%	26	43.33%
Barber	0	0%	1	3.33%	1	1.66%
Driver	3	10%	6	20%	9	15%
Housewife	8	26.66%	7	23.33%	15	25%
Student	2	6.66 %	2	6.66%	4	6.66%
Labour	5	16.66%	0	0%	5	8.33%

Out of 60 pts 43.33% pts belonging to sedentary job. 1.66% were Barbour, 15% were driver, 25% pts were house wife, 6.66% were students & 8.33% patients were labour.

➤ Educational status

Table showing educational status of the 60 pts.

Edu. Status	Group A 30	% of grp A	Group B 30	% of grp B	Total No.of pts	Total %
Literate	22	73.33%	19	63.33%	41	68.33%
Illiterate	8	26.66%	11	36.66%	19	31.66%

Out of 60 patients 68.33% were literate. % 31.66% were Illiteracy

➤ Table showing type of addiction to which the patients are addict:

Addiction	T	S	TA	TS	TAS	No Addict	Total
Group A	5	1	2	1	11	10	30
Group B	10	0	0	2	11	7	30
Total	15	1	2	3	22	17	60

Above table shows the no. of patients addicted to Tobacco chewing, Smoking & Alcohol.

In Group A 20 Patients are addict & 10 pts are non-addict.

In Group B 23 pts are addict & 7 pts are non-addict.

➤ Table showing classification of patients according to bowel habit.

Bowel habit	Regular	Irregular	Total
Group A	6	24	30
Group B	10	20	30
Total	16	44	60

In group A 24 pts had Irregular bowel habit & 6 had regular.

In group B 20 pts had Irregular bowel habit & 10 had regular

➤ Table showing classification of patients according to their nature of sleep.

Nature of sleep	Grp A 30	% of Grp A	Grp B 30	% of Grp B	Total	Total %
Sound	17	56.66%	16	53.33%	33	55%
Disturbed	13	43.33%	14	46.66%	27	45%

➤ Table showing classification of patients according to their diagnosis.

Name of disease	Grp A	%	Grp B	%	Total	%
Acute fissure	7	23.33%	7	23.33%	14	23.33%
Chronic fissure	11	36.66%	6	20%	17	28.33%
Perianal hematoma	0	0%	3	10%	3	5%
Fistula in Ano	4	13.33%	6	20%	10	16.66%
Abscess	4	13.33%	2	6.66%	6	10%
Haemorrhoid	4	13.33%	6	20%	10	16.66%

- Table showing classification of patients according to the result of treatment on 38 th day:

Group	cured	Improved	Relieved	Not cure	complication	Total
Group A	21	9	0	0	0	30
Group B	0	8	22	0	0	30

In the above table in Grp A total 21 patients had complete relief in post-operative pain, Tenderness, Itching and Burning & PR bleeding. While 9 pts improved due to treatment. That means they had more than 50% relief in pain associated other symptoms. None of the case got complication due to the treatment.

In Grp B 0 pts cure means they got 100% result in pain, tenderness but not getting relief in Itching, Burning & PR bleeding. While 8 pts get improver & 22 get relieved. In some cases Itching & burning was observed as to be increased.

Out of 60 pts 21 pts are completely cured, 17 pts improved from previous condition, & 22 pts get relieved.

STASTICAL ANALYSIS AND RESULTS

In present study the patients were specifically observed for post-operative pain, Tenderness, Anal Itching, Anal burning & PR bleeding. The observations were noted from day of operation up to 10 days & follow up taken weekly for one month.

- All the data generated during study is subjected to statistical analysis to reach final result and conclusion. Wilcoxon-Matched-Pair signed-Rank test is applied to assess the effect of therapy as the most of data collected is subjective.
- Comparison of two Groups with respect to data is done by Mann-Whitney test.

1) Table showing Statically analysis of Trial Group

No	Signs & Symptoms	Mean of difference	SD of diff	SE of diff	W	N	P
1	Pain	2.43	0.62	0.11	465.00	30	<0.0001
2	Tenderness	2.46	0.57	0.10	465	30	<0.0001
3	Itching	2.06	0.73	0.13	465	30	<0.0001
4	Burning	2.56	0.56	0.10	465	30	<0.0001
5	PR Bleeding	2.63	0.55	0.10	465	30	<0.0001

Statistical analysis of the effect of treatment on pain (Group A) by Wilcoxon-Matched-pair signed-rank test.

Putting gudavatika from post-operative day 0 up to 10 days & then follow up up to one month i.e. Till 38th day. Mean of difference in pain is 2.43.sum of all signed rank is 465 and no. of pairs is 30. P value is <0.0001, which is statistically extremely significant.

Statistical analysis of the effect of treatment on Tenderness (Group A) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in tenderness is 2.46.sum of all signed rank is 465 and no.of pairs is 30. P value is <0.0001, which is statistically extremely significant.

Statistical analysis of the effect of treatment on Anal Itching (Group A) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in itching is 2.06.sum of all signed rank is 465 and no.of pairs is 30. P value is <0.0001, which is statistically extremely significant.

Statistical analysis of the effect of treatment on Anal burning (Group A) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in burning is 2.56.sum of all signed rank is 465 and no.of pairs is 30. P value is <0.0001, which is statistically extremely significant.

Statistical analysis of the effect of treatment on PR Bleeding (Group A) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in PR bleeding is 2.63.sum of all signed rank is 465 and no.of pairs is 30. P value is <0.0001, which is statistically extremely significant.

2) Table showing Stastical analysis of Control Group.

No	Signs & Symptom	Mean of diff	SD of diff	SE of diff	W	N	P
1	Pain	2.70	0.46	0.08	465	30	<0.0001
2	Tenderness	2.60	0.49	0.09	465	30	<0.0001
3	Itching	0.02	0.76	0.13	34	12	=0.20
4	Burning	0.10	0.30	0.05	6.0	3	=0.25
5	PR Bleeding	0.23	0.56	0.10	15	5	=0.06

Statistical analysis of the effect of treatment on pain (Group B) by Wilcoxon-Matched-pair signed-rank test.

Putting gudavatika from post-operative day 0 up to 10 days & then follow up up to one month i.e. Till 38th day. Mean of difference in pain is 2.70.sum of all signed rank is 465 and no.of pairs is 30. P value is <0.0001 , which is statistically extremely significant.

Statistical analysis of the effect of treatment on Tenderness (Group B) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in tenderness is 2.60.sum of all signed rank is 465 and no.of pairs is 30. P value is <0.0001 , which is statistically extremely significant.

Statistical analysis of the effect of treatment on Anal Itching (Group B) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in itching is 0.20.sum of all signed rank is 34 and no.of pairs is 12. P value is equal to 0.020, which is statistically not significant.

Statistical analysis of the effect of treatment on Anal burning (Group B) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in burning is 0.10.sum of all signed rank is 6.0 and no.of pairs is 3. P value is = 0.25, which is statistically considered not significant.

Statistical analysis of the effect of treatment on PR Bleeding (Group B) by Wilcoxon-Matched-pair signed-rank test.

Mean of difference in PR bleeding is 0.23.sum of all signed rank is 15 and no.of pairs is 5. P value is = 0.06, which is statistically not quite significant.

Table showing comparison between two groups by Mann-Whitney test.

No	Parameters	U	U'	Mean of A & B	SD Of A & B	SE of A & B	P
1	Pain	351	549	2.43 2.70	0.62 0.46	0.11 0.08	=0.13
2	Tenderness	399	501	2.46 2.60	0.57 0.49	0.10 0.09	=0.44
3	Itching	49	851	2.06 0.20	0.73 0.76	0.13 0.13	<0.0001
4	Burning	10	900	2.56 0.10	0.56 0.30	0.10 0.05	<0.0001
5	PR bleeding	12.50	887	2.63 0.23	0.55 0.56	0.10 0.10	<0.0001

Comparison between two groups shows

- 1) P value for pain is =0.13 which is considered not significant.
- 2) P value for Tenderness is = 0.44 which is considered not significant.
- 3) P value for Itching is <0.0001 which is considered to be extremely significant.
- 4) P value for Burning is <0.001 which is considered to be extremely significant.
- 5) P value for PR bleeding is <0.00010001 which is considered to be extremely significant.

Hence, there is no significant difference found between two groups of treatment over pain & Tenderness. But extremely significant difference seen over Anal Itching, Burning & PR bleeding. I.e. Observed good efficacy of polyherbal gadavatika not only on pain & tenderness but also on Itching, burning, & PR bleeding.

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 method.

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*, *Agni*, & *Shastra karma*. 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. But after operation patient feels pain. To relieve pain we use generally IV, Oral analgesics (NSAIDS). still there is need of some locally acting analgesic drug because the severity of pain is so much. Diclofenac suppository used worldwide but having some side effect. While some 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

Total 60 pts were included in the study according to the inclusion and exclusion criteria. After thorough examination, hematological and other laboratory tests, 30 post-operative

patients were treated by putting Polyherbal suppository. Called Group A i.e. Trial group and 30 patients were treated by Diclofenac suppository, called Group B i.e. control group. Patients in each group had put suppository from POD 0 up to 10 days & then follow up taken for 1 month, weekly. During this treatment hot sitz bath, Laxative, Antibiotics & Analgesic drugs as per severity of pains given to the patient.

OBSERVATION AND RESULT are discussed as follows:

- 1) General discussion**
- 2) Clinical parameter**
- 3) Total effect of therapy.**

I) GENERAL DISCUSSION

Age wise distribution shows that patients belonging to age group 31-40 years (50%), age group 21-30 years (25%) and age group 41-50 years (25%). This result shows middle age persons suffering from ano-rectal problems.

Sex wise distribution of disease shows that there are 65% male patient and 35% female patients. This difference may be due to shyness of female patient to discuss the ailment of private organs.

In accordance to the dietary habit all patients are in mixed diet variety but all take spicy, junk foods & had more 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.

In category of addiction 70% patients are addict to alcohol, tobacco chewing and smoking, 30% patients are non-addict. So addict to any, causes Constipation & agnimandya resulting into ano-Rctal diseases.

Occupation also plays an important role in causing diseases. As 43.33% pts had sedentary job. 24% were housewives. 8.33% were labour.

II) CLINICAL PARAMETER

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

A) 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. so Ajmoda & Shirish drug used in Trial group having Anti-inflammatory & Analgesic property, pain is relieved.

B) Tenderness =

Same way Severity of Tenderness equally becomes reduced on using both drug.

C) Itching =

Itching were observed after 7-8 days of surgery due to wound healing phase. In polyherbal gudavatika Daruharidra as an anti-allergic action. Also included in Arshoghna gana. While using Diclo suppo. some patients c/o Itching & few patients are allergic to diclo. Being safer side polyherbal suppository is fruitful in such condition.

D) Burning =

Polyherbal suppository is more effective on anal burning as Raktachandan, Yastimadhu & go-grhut are the ingredients. It acts as a cooling & soothing effect. While diclo had no relief on post op burning.

E) PR bleeding =

Post-operative some patients c/o PR bleeding due to fresh wound. yashimabhu & Ghrut have best healing properties. Lajjalu is included in sandhaniya gana, research work is going on Lajjalu.

Drug worldwide. I found good healing property after using polyherbal suppository. Which is not seen while using diclo suppository.

3) 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.

CONCLUSION

The study entitled.

“A Controlled study of polyherbal gudavatika as a rectal suppository in post-operative ano-rectal diseases.”

Was undertaken. After conducting the clinical trial based upon the clinical study, displayed in form of tables and graphs which is critically discussed in previous chapters. From the study confident conclusion can be drawn as follows =

- ✓ Polyherbal gudavatika & diclofenac suppository both having good efficacy in post-operative pain management of anorectal diseases.
- ✓ Polyherbal gudavatika also cure other associated symptoms like anal itching & burning. Also acts as a cooling & soothing effect as I used Go-Ghrit in it.while using diclo suppository there is no relief observed over itching & burning. In fact some patients complaining of itching over anal region.
- ✓ During study, I did not find any side effects of polyherbal gudavatika whereas urticaria, headache & G.I.problems were observed in the control group.
- ✓ During study, putting polyherbal gudavatika I found in few patients, there is relief up to 10-12 hrs. In pain & burning while after putting diclo suppository, I observed relief in pain up to 3-4 hrs.
- ✓ Apart from pain, Itching& burning, in some cases I found mild laxative effect on using polyherbal gudavatika.
- ✓ There is severe pain & burning in Ksarsutra Application & change of Kshar sutra, so after putting Polyherbal gudavatika, I observed good efficacy in pain management & other associated symptoms
- ✓ Diclofenac suppository needs deep refrigeration, without this it melts & cannot be able to insert. While polyherbal gudavatika remains its consistency without refrigeration.
- ✓ 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.

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