https://doi.org/10.47552/ijam.v16i2.5115 ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 16 (2), 2025; 398-410

Comparative evaluation of the efficacy of Hydrocortisone suppository and *Durvadi Gudavarti* in *Raktarsha* – A randomized controlled clinical trial

Research Article

Nitin Biswas[1*], Reena Jaiswal[2]

1. PhD Scholar, 2. Associate Professor, Department of Shalya-Tantra,
Mahatma Gandhi Ayurveda College, Hospital and Research Centre, DMIHER, Wardha, Maharashtra, India.

Abstract

Background: *Arsha*, which is correlated to Hemorrhoids according to contemporary sciences, is a disease of yore. It is one of the most prevalent illnesses nowadays. It is the most common cause of bleeding per rectum in adults and the fourth leading diagnosis made in the gastrointestinal outpatient department. Aim and Objectives: This study aimed to compare the efficacy of *Durvadi Gudavarti* and Hydrocortisone acetate-based suppository in the management of *Raktarsha* (Bleeding Piles). Methods- A randomized active-controlled double-blind superiority clinical trial that involved 130 subjects between the age group of 20 to 60 years of *Raktarsha*, were assigned into two groups with equal allocation. The Control group (Group C) received Hydrocortisone suppository and the Experimental group (Group E) received *Durvadi Gudavarti* for rectal administration twice daily (12 hourly) after the proper evacuation of the bowel, for 2 weeks. Clinical evaluations were performed at Baseline, 5th, 10th, 15th day post-inclusion. The main endpoint was the proportion of subjects with complete clinical response and reduction in the size of pile mass measured using a transparent millimeter ruler on the 15th day. Results- Groups were homogeneous in terms of demographic and baseline characteristics. The *Durvadi Gudavarti* was found to be 34% and 32% more efficacious than the Hydrocortisone acetate-based suppository in terms of reduction in the size of pile mass and bleeding PR respectively. Interpretation & conclusions- *Durvadi Gudavarti* as rectal administration showed a significant advantage over a widely used standard treatment in the management of *Raktarsha.*

Keywords: *Raktarsha,* Bleeding Piles*, Durvadi Gudavarti,* Haemorrhoids, Hydrocortisone suppository, Ayurvedic suppository.

Introduction

It is estimated that one in two people over the age of 50 years in the West has some degree of Hemorrhoid formation (1,2). It is more prevalent in Western Europeans, Black and White Americans, and Africans and it appears to be three times more common in rural Indians than in Africans. As a more Western way of life was gradually adopted in India, it became increasingly commonplace (2). There are only a few articles on Hemorrhoid epidemiology, so the prevalence of Hemorrhoids is not well known, but it is estimated to be 4.4 to 5% around the world. The peak age for both genders is estimated to be between 45-65 years (3).

The treatment options available in contemporary science for the management of hemorrhoids are classified into conservative and surgical. According to contemporary surgery, conservative treatment is the first line of treatment for symptomatic hemorrhoids, regardless of the grade. It includes general steps including lifestyle modifications, dietetics, hygiene, and symptomatic medicines. Only a small percentage of patients with severe symptoms and advanced grades may have to be considered for surgery (4). Sclerotherapy, Infrared Photocoagulation, Rubber band ligation, and Surgery are examples of more intrusive treatment modalities that are only used on individuals with severe manifestations of the condition or those whose symptoms persist after several months of conservative therapy (5, 6).

Conservative treatment for symptomatic Hemorrhoids includes Lifestyle modification, oral medicines for symptomatic relief like Laxatives, Anti-inflammatory, Venotonics and flavonoids, high fiber diet, sitz baths, topical application of corticosteroids (example- Hydrocortisone), anesthetics (example- Lidocaine), astringents (example- Policresulene), emollient (example- Allantoin), and antiseptics (example- Zinc oxide) containing ointments and suppositories. These ointments and suppositories are indicated in all stages of the disease. It relieves local pain, discomfort, itching, and bleeding. They are recommended according to international guidelines. They are used particularly in local inflammation and swelling (5, 6, 7).

According to Ayurveda parlance, *Arsha* (Hemorrhoids) is one of the Anorectal illnesses which occur in *Guda Pradesh* (Anal region) and *Guda* (Anus) is said to be one of the *Sadyapraanhara Marma* (8). It is

*** Corresponding Author:**
Nitin Biswas
Professor and HOD, Department of Shalya-Tantra,
SVAMCH, Wandhari,
Chandrapur, Maharashtra, India.
Email Id: dr.biswas84@gmail.com

one of the *Pranayatana* and requires delicate management. Even though the illness is not lethal, it obstructs the Anorectal passage and tortures the sufferer like an enemy (9). Due to the chronic nature, difficulty in treating it by medical methods, involvement of *Tridosha*, and occurrence at a *Marma Sthana*, this illness is regarded as one of the *Ashta Mahagada* in Ayurveda (10). Sushruta narrates *Arsha*, as a disease which when associated with *Upadrava* (complications) becomes *Yapya* or *Asadhya* (Difficult to cure or incurable) (11).

It is manifested due to multifold factors like *Adhyashana, Vishamashana, Virruddhahara*, and *Vihara* (unhealthy, improper, and irregular dietary habits and lifestyle), prolonged standing or sitting conditions, irregular bowel habits resulting in derangement of *Jatharagni* (*Mandagni*) causing vitiation of *Tridosha* (predominantly *Vata Dosha*) (12). These vitiated *Dosha* travel through *Pradhana Dhamani* towards *Guda* and get localized in the *Gudavali*. The involvement of *Meda, Mansa*, and *Twak* in the *Guda* region causes the fleshy mass to develop called *Arsha* (13). These masses, when they bleed, are called *Raktarsha*.

The management of *Arsha* according to Ayurveda is of four kinds namely *Bheshaj Chikitsa, Ksharakarma, Agnikarma,* and *Shastrakarma.* Among these treatment modalities, *Bheshaj Chikitsa* (conservative treatment) is primarily given. If it fails then the other treatment modalities are tried (14). *Raktarsha* is a disease in which *Shaman Chikitsa* is primarily given. Ayurveda advocates equal importance to *Sthanik Chikitsa* (local measures) along with *Abhyantar Aushadh* (internal medications). *Lepa* is one such therapy that is mentioned for local application in *Raktarsha*. It gives relief from anal pain, burning sensation, bleeding, protrusion, and mucous soiling. It has a greater emphasis. So, the medicinal herbs described for *Lepa* and *Pratisarana* (Paint or Ointment application) in *Raktarsha* could be transformed into *Gudavarti* (Suppository) so that the patient can administer it at their place instead of visiting each time to the Proctologist for the application of *Lepa* over hemorrhoids. The patient will comply with it more readily.

Therefore, *Durvadi Gudavarti* was developed using the native medicinal herbs mentioned in Charaka Samhita as an alternative to the *Lepa* and *Pratisaran* formulations from the texts. It was intended to be administered rectally to patients suffering from *Raktarsha* and would be effective with less noticeable side effects.

A randomized active control double blind superiority clinical trial was conducted to assess its efficacy. Using the appropriate statistical values and tools, the results were evaluated based on clinical assessment criteria.

Aim and Objectives: -

Aim: - To compare the efficacy of *Durvadi Gudavarti* and Hydrocortisone suppository in the management of *Raktarsha*.

Objectives

Primary Objectives

- To evaluate the efficacy of Hydrocortisone suppository in *Raktarsha* with respect to bleeding per rectum and size of pile mass.
- To evaluate the efficacy of *Durvadi Gudavarti* in *Raktarsha* with respect to bleeding per rectum and size of pile mass.
- To compare the efficacy of Hydrocortisone Suppository and *Durvadi Gudavarti* in *Raktarsha* with respect to bleeding per rectum and size of pile mass.

Secondary Objectives

- To evaluate the efficacy of Hydrocortisone suppository in *Raktarsha* with respect to *Guda Shool, Guda Kandu, Mansankur Prachiti, Gudagata Pichillata,* and *Vibandha*.
- To evaluate the efficacy of *Durvadi Gudavarti* in *Raktarsha* with respect to *Guda Shool, Guda Kandu, Mansankur Prachiti, Gudagata Pichillata,* and *Vibandha*.
- To compare the efficacy of Hydrocortisone suppository and *Durvadi Gudavarti* in *Raktarsha* with respect to *Guda Shool, Guda Kandu, Mansankur Prachiti, Gudagata Pichillata,* and *Vibandha*.

Material & Methods

A single-centric, randomized, active-controlled, double-blind superiority clinical trial was carried out at the Department of Shalya-Tantra, Mahatma Gandhi Ayurveda College, Hospital and Research Center, DMIHER, Salod, Wardha, Maharashtra.

After getting ethical clearance from institutional IEC the study was initiated by enrollment of subjects. A total of 130 patients between the age group of 20 to 60 years were enrolled with the clinical features of *Raktarsha* as per classical Ayurveda text and verified by clinical examination (Anoscopy). Simple randomization using computer generated table method was done and divided into two groups as follows

- Group C - Control Group, treated with Hydrocortisone suppository and
- Group E - Experimental Group, treated with *Durvadi Gudavarti*.

As no proper reference article was found, so, before initiating work a pilot study was carried out in 24 patients (12 patients in each group) and the sample size was calculated on that basis using mean difference pre and post of the size of the pile mass (mm).

- Primary Variable: Size of pile mass in mm.
- Mean Pile mass size in mm (pre) = 20.58 ± 3.00 (As per pilot study)
- Mean Pile mass size in mm (post) = 15.00 ± 2.07
- Mean Difference = 5.58
- Considering 30% superiority with mean difference = 1.67
- Pooled Standard Deviation = (3.00 + 2.07)/2 = 2.54

https://doi.org/10.47552/ijam.v16i2.5115 ISSN No: 0976-5921

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- Minimum sample size required;
- Sample size N= Considering 10 % drop out (60*10)/ 100 = 6, Total samples = 59+6 = 65 per group

Subjects with Clinical features as follows were scrutinized for the study:-

- *Gudagata Raktastrava* (Bleeding PR),
- *Guda Shool* (Anal pain),
- *Guda Mansankur Prachiti* (Protrusion of pile mass),
- *Guda Kandu* (Anal pruritus),
- *Guda Pichillata* (Mucous soiling),
- *Vibandha* (Constipation).

Inclusive criteria

Diagnosed case of Internal grade II Hemorrhoids (Goligher classification) patient (characterized by bleeding PR, anal pain, pile mass of variable size and appearance possibly red-violet/blue color, anal pruritus, mucous soiling, and constipation). The patients with hemoglobin more than or equal to 10 g/dl and patients who didn't want to undergo surgery and were ready to follow *Pathya* (dietary and lifestyle regulations) according to Ayurveda.

Exclusion criteria

Subjects with Grade I, III, and IV Hemorrhoids (Goligher classification), external hemorrhoids, and hemorrhoids associated with acute Fissure-in-Ano, Fistula-in-Ano, Ulcerative colitis, Crohn's disease, Malignancy, Intestinal Polyps, and Diverticulitis. TB, Diabetes mellitus and uncontrolled hypertension, portal hypertension, sepsis or severe hemorrhagic complications, bleeding disorders, acute diarrhoea in the last 12 hours, and allergy to corticosteroids or any other component of the medicament. Patients on corticosteroid therapy, anticoagulant medications, other anti-hemorrhoidal medicines, or planning to undergo any surgical procedure for hemorrhoids. Pregnant and nursing female patients, and HIV and HBsAg positive patients.

Drug source

The raw drugs to prepare *Durvadi Gudavarti* containing *Durva* (*Cynodon dactylon* L. Pers.), *Yashtimadhu* (*Glycyrrhiza glabra* L), *Daruharidra* (*Berberis aristata* DC), *Sarjarasa* (*Vateria indica* Linn), *Nimba* (*Azadirachta indica* A. Juss), *Manjishtha* (*Rubia cordifolia* L.), *Goghrita* (Clarified butter), *Guda* (*Saccharum officinarum* L.), were collected from the local market vendor. They were authenticated from Department of *Dravyaguna*, DMIHER, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod, Wardha, Maharashtra, India (Figure 1). These raw drugs are used to prepare *Durvadi Gudavarti* by the *Paka* method mentioned in classical texts at Dattatraya Ayurveda Pharmacy, DMIHER, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod, Wardha, Maharashtra, India and provided to the patients (Figure 2,3 and Table 1).

Figure 1. Authentication Certificate of the Raw Herbs

Datta Meghe Institute of Higher Education and Research (Deemed University)
Mahatma Gandhi Ayurved College, Hospital & Research Centre
Salod (H) Wardha
QUALITY CONTROL PROFORMA
Dattatraya Ayurveda Rasashala : Analytical Lab Lic.No:-NG/AYU/002/14

Ref No.AC/23-24 Date:- 24/10/2023

Authentication Certificate

This is to certify that the plant specimen brought by Dr. Nitin Biswas, PhD scholar in the department of Shalyatantra .The plant specimen is identified and authenticated of Durva (Cynodon dactylon L.Pers.), Yastimadhu (Glycyrrhiza glabra L.), Daruharidra (Berberis aristata DC), Sarjarasa (Vateria indica Linn), Neem (Azadirachta indica A. Juss), Manjistha (Rubia cordifolia L.), Guda (Jaggery)(Saccharum officinarum L.), Ghrita (Clarified Butter)

HOD

Department Of Dravyaguna:-

Figure 2. Preparation of *Durvadi Gudavarti*

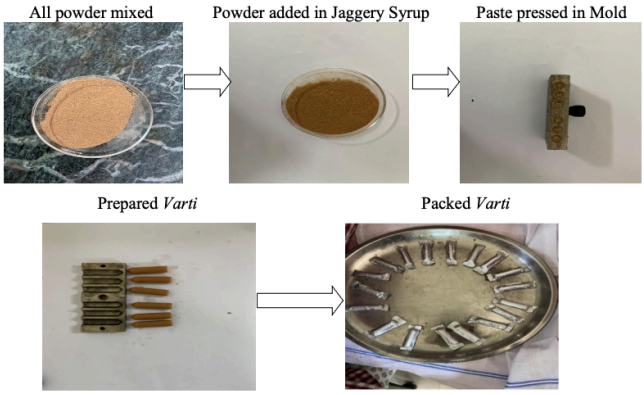


Figure 3. Quality Control Proforma of *Durvadi Gudavarti*

Datta Meghe Institute of Higher Education and Research (Deemed University)
Mahatma Gandhi Ayurved College, Hospital & Research Centre
Salod (H) Wardha
QUALITY CONTROL PROFORMA
Dattatraya Ayurveda Rasashala : Analytical Lab

Sample Received Date:- 07/12/2023 Lic.No:-NG/AYU/002/14

Issued To : Dr. Nitin Vishwas	Sample Particulars/ Details: Durvadi Gud Varti	Quantity Received:- 15 Nos

Test Required :- Colour , Texture , Melting Point(°c), pH, Liquification Point , Refractive index , Microbiological Parameter.

Sr. No.	Test parameter	Test Result
1.	Colour	Brownish
2.	Texture	Smooth
3.	Melting Point(°c)	39 °C
4.	pH	8.8
5.	Liquification Point	60 °C
6.	Refractive index	1.385
	Microbiological Parameter	
7.	Total viable count	Absent
8.	Enterobacteriaceae	Absent
9.	Total fungus count	Absent
10.	E-coli	Absent
11.	Salmonella	Absent
12.	Staphylococcus aureus	Absent
13.	Pseudomonas aueruginosa	Absent

Analyzed by:- Verified by :-

Table 1: Quality Control Proforma of *Durvadi Gudavarti*

Sr. No	Test Parameter	Test Result
1	Color	Brownish
2	Texture	Smooth
3	Melting Point (°c)	39°c
4	pH	8.8
5	Liquification Point	60°c
6	Refractive index	1.385
	Microbiological Parameter	
7	Total viable count	Absent
8	Enterobacteriaceae	Absent
9	Total fungus count	Absent
10	E-coli	Absent
11	Salmonella	Absent
12	Staphylococcus aureus	Absent
13	Pseudomonas aueruginosa	Absent

Hydrocortisone-based suppository containing Hydrocortisone (0.25% w/w) + Zinc oxide (5% w/w) + Lidocaine/Lignocaine (3% w/w) + Allantoin (0.5% w/w) (Anomex- Bliss GVS Pharma) available in local medical stores was purchased and provided to the patient.

Intervention procedure

After obtaining written informed consent from all the patients selected for the study, on the 1st day of the intervention, a demonstration of the administration of the medicament was shown to the patient. From the 2nd day up to the end of the intervention period (2 weeks), patients were advised to administer it similarly by themself at home after proper evacuation of the bowel, twice daily (At morning after defecation and at night before going for sleep). The *Varti* was kept in the anal canal till the next defecation of the patient. To ensure the proper use of the *Varti* by the patients, they were asked to collect the empty packaging cover of the *Varti* after use and bring to show it at follow ups.

Dietary regimen

All the patients were directed to follow dietary restrictions and lifestyle regulations according to Ayurveda and were advised to a take high-fiber diet and an adequate quantity of water every day.

Withdrawal criteria

Subjects were withdrawn if they developed any drug reactions, profuse bleeding, or occurrence of any other serious illness.

Laboratory investigations

Hemoglobin, Random blood sugar, Bleeding and Clotting time, HIV, and HBsAg.

Criteria for Assessment

Objective Criteria: -

- Size of pile mass (length in mm).
- Hemoglobin (g/dl).

Subjective Criteria: -

- *Gudagata Raktastrava* (PR Bleeding),
- *Guda Shool* (Anal pain),
- *Mansankur Prachiti* (Protrusion of pile mass),
- *Guda Kandu* (Itching),
- *Gudagata Pichillata* (Mucous soiling),
- *Vibandha* (Constipation).

These subjective parameters were assessed

I. Qualitatively as Yes/No and

II. The frequency of bleeding per rectum was measured quantitatively as: -

a) Never (Score 0)
b) 1-2 times weekly (Score 1)
c) Daily or Alternate day. (Score 2)

III. The severity of PR Bleeding was assessed subjectively as: -

a) No bleeding (Score 0)
b) Mild bleeding (Score 1) - Found in toilet paper/ Fingers,
c) Moderate bleeding (Score 2) - Few (~01-10) drops/ Drippings,
d) Severe (Score 3) - Splash of blood/Sluice.

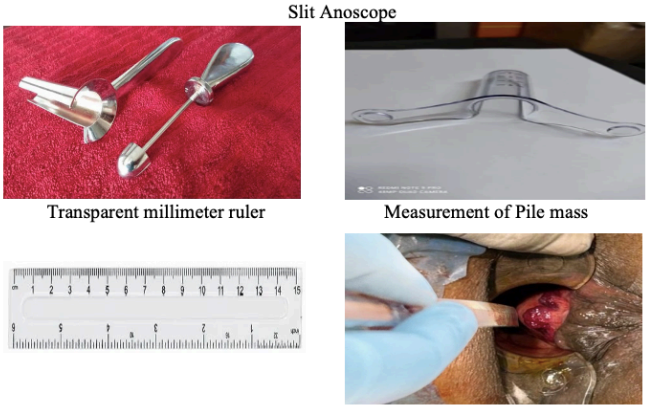
IV. The severity of Anal pain was assessed using a linear Visual Analogue Scale (VAS): -

Range 0-10 (0- no pain and 10- worst pain) however it is regrouped as

a) 1-3 as mild pain,
b) 4-6 as moderate pain and
c) 7-10 as severe pain.

Clinical evaluation was carried out via outpatient visits on BT (Before treatment), 5th, 10th, and 15th day-AT (After treatment). The main endpoint was the proportion of patients with a complete clinical response on the 15th day (After treatment) determined via the disappearance of the symptoms and reduction in the size of pile mass (measured using a transparent millimeter ruler) (Figure 2). A follow-up was taken on 1 month after treatment. Side effects (type, duration, severity, and outcome) were registered carefully. Data was analyzed based on 'Intension to Treat' the patients with the application of suitable statistical methods. Results were reported as per CONSORT guidelines.

Figure 4. Instruments for measurement of the size (length) of Pile mass.



https://doi.org/10.47552/ijam.v16i2.5115 ISSN No: 0976-5921

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Ethical Clearance

Clearance from the Institutional Ethical Committee of DMIHER (DU), Sawangi (M), Wardha, Maharashtra, India was taken.

Source of Funding

Intramural Funding as per policy of DMIHER (DU).

Statistical Analysis

Statistical analysis was done by using descriptive and inferential statistics using the Chi-square test, unpaired t-test, and Confidence interval, the observations were depicted in the form of a Forest Plot. The software for analysis was SPSS 26.0 Version and $P < 0.05$ is considered as the level of significance. Results were reported as per CONSORT guidelines.

Results

From June 2021 to December 2023, a total of 130 patients were included and enrolled in the study after screening. Treatment was completed by all the patients without dropout of any patient. No adverse effect was noted in any of the patients in either group.

Demographic data

Age-wise distribution of patients showed that the maximum numbers of patients (38.46 % in Group C and 30.77% in Group E) were in the age group of 41-50 years. The mean age was found to be 40 years in Group C and 39 years in Group E. Gender-wise distribution of patients showed that Males were more affected, 64.62% in Group C and 76.92% in Group E, whereas females were affected 35.38 % in Group C and 23.08 % in Group E. Habitat-wise distribution showed that most of the patients 58.46% in group C and 69.23% from group E were from urban habitats while 41.54% in group C and 30.77% in group E were from rural regions. Because of the Hindu dominant population, Religion-wise distribution showed 83.08% of patients in Group C and 73.85% in Group E belong to the Hindu religion. Buddhist religion accounts for 12.31% and 16.92%, followed by the Muslim religion at 3.08% and 6.15%, followed by the Jain religion at 1.54% and 3.08% in Group C and Group E respectively. The maximum numbers of patients were married with a frequency of 81.54% in Group C and 72.31% in Group E. Whereas 18.46% and 27.69% of frequency were unmarried in Group C and Group E respectively. Occupation-wise distribution showed that the maximum numbers of patients were officials having a frequency of 30.77% and 23.08% in Group C and Group E respectively. The long-time sitting nature of the job of these officials might have contributed to the pathogenesis of hemorrhoids. This was followed by Business work with 18.46% and 23.08% while Housewives with a frequency of 23.08% and 18.46% in Group C and Group E respectively. Prolonged sitting or prolonged standing both can contribute to the formation of hemorrhoids. In the present study, maximum patients 64.61% in Group C and 70.76 % of patients of Group E had a sitting nature of work while 35.38% and 29.23% of Group C and Group E respectively had a standing nature of work. In the present study 15.38%, 44.62%, and 40% of patients had predominantly Veg, Non-Veg, and mixed-type diets respectively in Group C and in Group E 29.23%, 40%, and 30.77% had predominantly Veg, Non-Veg and Mixed type of diet respectively. Frequency distribution according to bowel habits showed that the maximum number of patients in the present study had irregular bowel habits with a frequency of 69.23% and 73.85% in Group C and Group E respectively (Table 2).

Table 2: Comparison of Group C and Group E with demographic characteristics using Chi-square test.

Characteristic	Group C		Group E		Total		Chi-Square	P-Value
	n	%	n	%	n	%		
Age groups								
20-30	18	27.69	23	35.38	41	31.53	1.17	0.76
31-40	13	20	13	20	26	20		
41-50	25	38.46	20	30.77	45	34.61		
51-60	9	13.85	9	13.85	18	13.84		
Gender								
Male	42	64.62	50	76.92	92	70.76	2.38	0.12
Female	23	35.38	15	23.08	38	29.23		
Habitat								
Urban	38	58.46	45	69.23	83	63.85	1.63	0.20
Rural	27	41.54	20	30.77	47	36.15		
Religion								
Hindu	54	83.08	48	73.85	102	78.46	1.83	0.61
Muslim	2	3.08	4	6.15	6	4.61		
Buddhist	8	12.31	11	16.92	19	14.61		
Jain	1	1.54	2	3.08	3	2.30		
Marital Status								
Married	53	81.54	47	72.31	100	76.92	1.56	0.21
Unmarried	12	18.46	18	27.69	30	23.07		

Habitat								
Urban	38	58.46	45	69.23	83	63.84	1.63	0.20
Rural	27	41.54	20	30.77	47	36.15		
Occupation								
Business	12	18.46	15	23.08	27	20.76	3.82	0.70
Official	20	30.77	15	23.08	35	26.92		
Housewife	15	23.08	12	18.46	27	20.76		
Student	8	12.31	15	23.08	23	17.69		
Teacher	5	7.69	4	6.15	9	6.92		
Labor	2	3.08	2	3.08	4	3.07		
Driver	3	4.62	2	3.08	5	3.84		
Nature of work								
Sitting	42	64.62	46	70.77	88	67.69	0.56	0.45
Standing	23	35.38	19	29.23	42	32.30		
Diet Type								
Veg	10	15.38	19	29.23	29	22.31	1.85	0.40
Non-Veg	29	44.62	26	40	55	42.31		
Mixed	26	40	20	30.77	46	35.38		
Bowel Habits								
Regular	20	30.77	17	26.15	37	28.46	0.34	0.56
Irregular	45	69.23	48	73.85	93	71.54		

Comparison of Group C and Group E with demographic characteristics using Chi-square test was done to ensure that both the groups were homogenous in terns of demographics before intervention.

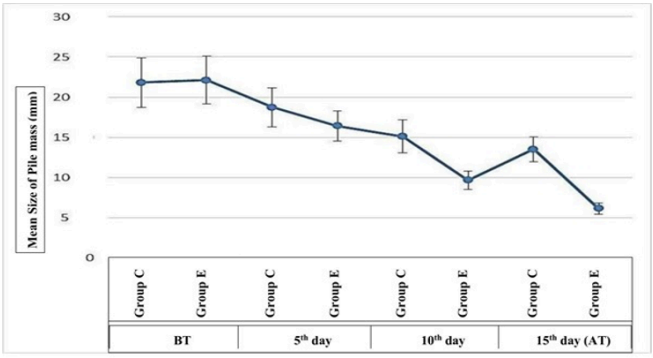
Effect on Size of pile mass (length in mm)

The statistical evaluation by unpaired "t-test" to find out the difference between both groups, it was observed that at BT mean size of pile mass in Group C was 21.82 with SD of 3.09 while in Group E it was 22.12 with SD of 2.99 and this mean difference in pile mass size between the group was statistically not significant (P-value - 0.58). After treatment mean size of pile mass in Group C was 13.54 with SD of 1.54 while in Group E it was 6.14 with SD of 0.70 and this mean difference in the size of the pile between the groups was statistically highly significant (P-value<0.01) (Table 3 and Graph 1).

Table 3: Comparative evaluation of the mean size of pile mass (mm) between the groups (Group C vs. Group E).

		Mean size of Pile mass (mm)	Std. Deviation	Std. Error Mean	Mean Diff.	Lower	Upper	t-test	P-value
BT	**Group C**	21.82	3.09	0.38	-0.31	-1.36	0.75	-0.58	0.57 NS
	Group E	22.12	2.99	0.37					
15th Day (AT)	**Group C**	13.54	1.54	0.19	0.74	6.98	7.82	35.19	<0.01 HS
	Group E	6.14	0.70	0.87					

Graph 1. Mean size of the pile mass (mm) between the groups (Group C vs. Group E)



Effect on Hemoglobin (g/dl): -

The statistical evaluation by unpaired "t-test" to find out the difference between both groups, it was observed that before intervention the mean hemoglobin levels between the Group C (11.35) and the Group E (11.23) were relatively close. The standard deviations are also relatively similar between Group C (0.61) and Group E (0.46). The t-test value is 1.29, suggesting a slight difference in means, but the p-value (0.12) is greater than the conventional significance level of 0.05. Therefore, there is no statistically significant difference in hemoglobin levels between Group C and Group E before the intervention.

After the intervention, the mean hemoglobin level for Group C (11.82) is lower compared to Group E (12.60). The standard deviations for Group C (0.59) and Group E (0.46) are relatively similar. The t-test value was -8.48, indicating a substantial difference in means between the two groups. The p-value is reported as "<0.01", indicating that it is less than 0.01 (highly significant), which suggests a statistically significant difference in hemoglobin levels between Group C and Group E after the intervention (Table 4).

https://doi.org/10.47552/ijam.v16i2.5115 ISSN No: 0976-5921

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Table 4: Comparative evaluation of the mean Hemoglobin (g/dl) level between the groups (Group C vs. Group E) before and after treatment

Hb (g/dl)		N	Mean	Std. Deviation	Std. Error Mean	t-test	P-value
BT	Group C	65	11.35	0.61	0.08	1.29	0.20 NS
	Group E	65	11.23	0.46	0.06		
15th day (AT)	Group C	65	11.82	0.59	0.07	-8.48	<0.01 HS
	Group E	65	12.60	0.46	0.06		

Effect on *Gudagata Raktastrava* (Bleeding PR)

Frequency distribution of *Gudagata Raktastrava* (Bleeding PR) between Group C and Group E, it was observed that at BT Bleeding PR was present in both the groups among all the patients and after treatment among 38(58.5%) patients bleeding PR was not observed in Group C, while in Group E it was not observed among 59(90.8%) of the patients and this difference between the groups was statistically highly significant (P-value <0.01).

Effect on *Gudagata Raktastrava* (Bleeding PR)-Frequency (Times)

Frequency distribution of *Gudagata Raktastrava* (Bleeding PR) between Group C and Group E, it was observed that at BT among 11(16.9%) of the patients it was found for one time in Group C while 12(18.5%) in Group E, among 54(83.1%) of the patients it was found for two times in Group C while 53(81.5%) in Group E, and this difference in the frequency of bleeding among Group C and Group E was found statistically not significant (p-value=0.82). After treatment among 36(55.4%) of the patients it was found for 0 times in Group C while 60(92.3%) in Group E. Among 29(44.6%) it was found for 1 time in Group C while 5(7.7%) in Group E. This difference between Group C and Group E was statistically highly significant (p-value<0.01).

Effect on *Gudagata Raktastrava* (Bleeding PR) (severity)

Frequency of Gudagata Raktastrava, at BT we have observed that among 19(29.2%) of the patients it was found with mild bleeding, 16(24.6%) with moderate bleeding, and 30(46.2%) with severe bleeding in Group C while 21(32.2%) with mild bleeding, 12(18.5%) with moderate bleeding, and 32(49.2%) with severe bleeding in Group E. This difference in the severity of bleeding between Group C and Group E was found statistically not significant (p-value=0.69). After treatment, we observed that, among 34(52.3%) of the patients it was found with no bleeding and 31(47.7%) with mild bleeding in Group C while 58(89.2%) with no bleeding and 7(10.8%) with mild bleeding in Group E. This difference in the severity of bleeding between Group C and Group E was found statistically highly significant (p-value=0.015) (Table 5).

Table 5: Comparative Evaluation of the Frequency distribution of *Gudagata Raktastrava* (Bleeding PR) between groups (Group C vs. Group E)

Gudagata Raktastrava (Bleeding PR) Presence		Group				Total		Chi-Square	P-value
		Group C		Group E					
		Frequency	%	Frequency	%	Frequency	%		
BT	Yes	65	100	65	100	130	100	NA	NA
	Total	65	100	65	100	130	100		
15th day (AT)	No	38	58.5	59	90.8	97	74.6	17.91	<0.01 HS
	Yes	27	41.5	6	9.2	33	25.4		
	Total	65	100	65	100	130	100		
***Gudagata Raktastrava* (Bleeding PR) Number of times**									
BT	1.0	11	16.9	12	18.5	23	17.7	0.05	0.82 NS
	2.0	54	83.1	53	81.5	107	82.3		
	Total	65	100	65	100	130	100		
15th day (AT)	0	36	55.4	60	92.3	96	73.8	22.94	<0.01 HS
	1.0	29	44.6	5	7.7	34	26.2		
	Total	65	100	65	100	130	100		
***Gudagata Raktastrava* (Bleeding PR) Severity**									
BT	Mild	19	29.2	21	32.3	40	30.8	0.74	0.69 NS
	Moderate	16	24.6	12	18.5	28	21.5		
	Severe	30	46.2	32	49.2	62	47.7		
	Total	65	100	65	100	130	100		
15th day (AT)	No	34	52.3	58	89.2	92	70.8	21.42	<0.01 HS
	Mild	31	47.7	7	10.8	38	29.2		
	Total	65	100	65	100	130	100		

Effect on *Guda Shool* (Anal pain): VAS scale

Visual Analogue scale called the Pain scale was used to assess the pain. Before treatment among 18(27.7%) patients there was mild pain and among 47(72.3%) there was moderate pain in Group C, while 20(30%) of the patients had mild pain and 45(69.2%) had moderate pain in Group E and this difference in pain scale was found statistically not significant (p-value=0.7). After treatment 52(80%) of the patients had no pain and 13(20%) had mild pain in Group C, while 62(95.4%) of the patients had no pain and 3(4.6%) of the patients had mild pain in Group E and this difference in the pain scale was found statistically not significant (P-value=0.08) (Table 6).

Table 6: Comparative Evaluation of the Frequency distribution of *Guda Shool* (Anal Pain- Visual Analogue Scale) between groups (Group C vs. Group E).

Guda Shool (Anal Pain-VAS)			Group		Total	Chi-Square	P-value
			Group C	Group E			
BT	Mild	Frequency	18	20	38	0.15	0.7 NS
		%	27.7	30.8	29.2		
	Moderate	Frequency	47	45	92		
		%	72.3	69.2	70.8		
Total		Frequency	65	65	130		
		%	100.0	100.0	100.0		
15th day (AT)	No	Frequency	52	62	114	7.13	0.08 NS
		%	80.0	95.4	87.7		
	Mild	Frequency	13	3	16		
		%	20.0	4.6	12.3		
Total		Frequency	65	65	130		
		%	100.0	100.0	100.0		

Effect on *Mansankur Prachiti* (Mass Protrusion)

Before treatment, it was observed that anal mass protrusion was present in both groups among all the patients. After treatment among 31(47.7%) patients mass protrusion was not observed in Group C, while in Group E it was not observed among 58(89.2%) of the patients and this difference between the groups was statistically highly significant (P-value <0.01) (Table 7).

Table 7: Comparative Evaluation of the Frequency Distribution of *Mansankur Prachiti* (Mass Protrusion) between Groups (Group C vs. Group E)

Mansankur Prachiti (Anal Mass Protrusion)			Group		Total	Chi-Square	P-value
			Group C	Group E			
BT	Yes	Frequency	65	65	130	NA	NA
		%	100.0	100.0	100.0		
	Total	Frequency	65	65	130		
		%	100	100	100		
15th day (AT)	No	Frequency	31	58	89	25.97	<0.01 HS
		%	47.7	89.2	68.5		
	Yes	Frequency	34	7	41		
		%	52.3	10.8	31.5		
	Total	Frequency	65	65	130		
		%	100.0	100.0	100.0		

Effect on *Guda Kandu* (Anal Pruritus): -

Before treatment among 3(4.6%) patients Anal Pruritus was not observed in Group C, while in Group E it was not observed among 6(9.2%) of the patients and this difference between the group was statistically not significant (P-value = 0.3). After treatment among 55(84.6%) patients Anal Pruritus was not observed in Group C, while in Group E it was not observed among 64(98.5%) of the patients and this difference between the groups was statistically highly significant (P-value <0.01) (Table 8).

https://doi.org/10.47552/ijam.v16i2.5115 ISSN No: 0976-5921

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Table 8: Comparative Evaluation of the Frequency distribution of *Guda Kandu* (Anal Pruritus) between groups (Group C vs. Group E).

***Guda Kandu* (Anal Pruritus)**			**Group**		**Total**	**Chi-Square**	**P-value**
			Group C	**Group E**			
BT	No	Frequency	3	6	9	1.07	0.3 NS
		%	4.6	9.2	6.9		
	Yes	Frequency	62	59	121		
		%	95.4	90.8	93.1		
	Total	Frequency	65	65	130		
		%	100.0	100.0	100.0		
15th day (AT)	No	Frequency	55	64	119	8.04	< 0.01 HS
		%	84.6	98.5	91.5		
	Yes	Frequency	10	1	11		
		%	15.4	1.5	8.5		
	Total	Frequency	65	65	130		
		%	100.0	100.0	100.0		

Effect on *Guda Pichillata* (Mucous discharge):-

Before treatment among 13(20.6%) patients Anal Pruritus was not observed in Group C, while in Group E it was not observed among 19(29.2%) of the patients and this difference between the group was statistically not significant (P-value = 0.22). After treatment among 33(50.8%) patients Mucous discharge was not observed in Group C, while in Group E it was not observed among 57(87.7%) of the patients and this difference between the groups was statistically highly significant (P-value <0.01) (Table 9).

Table 9: Comparative Evaluation of the Frequency distribution of *Gudagata Pichillata* (Mucous soiling) between groups (Group C vs. Group E).

***Guda Pichillata* (Mucous soiling)**			**Group**		**Total**	**Chi-Square**	**P-value**
			Group C	**Group E**			
BT	No	Frequency	13	19	32	1.49	0.22 NS
		%	20.0	29.2	24.6		
	Yes	Frequency	52	46	98		
		%	80.0	70.8	75.4		
	Total	Frequency	65	65	130		
		%	100.0	100.0	100.0		
15th day (AT)	No	Frequency	33	57	90	20.8	<0.01 HS
		%	50.8	87.7	69.2		
	Yes	Frequency	32	8	40		
		%	49.2	12.3	30.8		
	Total	Frequency	65	65	130		
		%	100.0	100.0	100.0		

Effect on *Vibandha* (Constipation)

Before treatment among 10(15.4%) patients Anal Pruritus was not observed in Group C, while in Group E it was not observed among 13(20%) of the patients and this difference between the group was statistically not significant (P-value = 0.49). After treatment among 37(59.9%) patients Constipation was not observed in Group C, while in Group E it was not observed among 57(87.7%) of the patients and this difference between the groups was statistically highly significant (P-value <0.01) (Table 10).

Table 10: Comparative Evaluation of the Frequency distribution of *Vibandha* (Constipation) between groups (Group C vs. Group E).

***Vibandha* (Constipation).**			**Group**		**Total**	**Chi-Square**	**P-value**
			Group C	**Group E**			
BT	No	Frequency	10	13	23	0.48	0.49 NS
		%	15.4	20.0	17.7		
	Yes	Frequency	55	52	107		
		%	84.6	80.0	82.3		
Total		Frequency	65	65	130		
		%	100.0	100.0	100.0		
15th day (AT)	No	Frequency	37	63	100	29.92	<0.01 HS
		%	56.9	96.9	76.9		
	Yes	Frequency	28	2	30		
		%	43.1	3.1	23.1		
Total		Frequency	65	65	130		
		%	100.0	100.0	100.0		

The overall effect of treatment on objective and subjective parameters

After evaluating the objective and subjective parameters in Group C and Group E and after calculating the percentage of improvement, it is found that changes are more significant in Group E as compared to Group C. The overall effect of the treatment was calculated according to a 95% confidence interval- Group C vs. Group E. It was assessed by a reduction in the size of pile mass and a reduction in the frequency of patients with complete clinical response. The improvement was assessed after 2 weeks of treatment.

In group C, where patients received hydrocortisone suppository significant change was observed in objective and all subjective parameters. After treatment, there was 37.94% reduction in pile mass size, Hemoglobin level by 4.10%, frequency of patients with bleeding PR (presence) improved by 58.50%, frequency of bleeding PR (times) improved by 55.40%, the severity of bleeding PR improved by 52.30%, protrusion of mass improved by 47.70%, Anal pruritus improved by 80%, mucous soiling improved by 30.80%, constipation improved by 41.50%, and anal pain improved by 80%.

In group E where patients received *Durvadi Gudavarti* significant change was observed in objective and all subjective parameters. After treatment, there was 72.25% reduction in pile mass size, Hemoglobin level by 12.23%, frequency of patients with bleeding PR (presence) improved by 90.80%, frequency of bleeding PR (times) improved by 92.30%, severity of bleeding PR improved by 89.20%, protrusion of mass improved by 89.20%, Anal pruritus improved by 89.30%, mucous soiling improved by 58.50%, constipation improved by 67.70%, and anal pain improved by 95.4%.

In an intergroup comparison of objective and all subjective parameters it was observed that Group E had shown a highly significant percentage improvement as compared to Group C. Percent of superiority was calculated with the formula % improvement in Group E - % improvement in Group C. Data revealed that after treatment Group E was 34.31% superior in reducing the size of pile mass as compared to Group C. After treatment in improvement of HB% Group E was 8.14% superior as compared to Group C. After treatment in bleeding PR Group E was 32.30% superior, in the frequency of bleeding PR Group E was 36.90% superior, in the severity of bleeding PR Group E was 36.90% superior, in mass protrusion Group E was 41.50% superior, in anal pruritus Group E was 9.30% superior, in mucous soiling Group E was 27.70% superior, in constipation Group E was 26.20% superior, and in anal pain calculated in VAS scale Group E was 15.4% superior to Group C (Table 11,12,13). The effect size is demonstrated in the Forest plot diagram (Figures 3 and 4).

Table 11: Comparative results of the mean size of pile mass between the Groups (Group C vs. Group E) with superiority in each timeline

Mean size of Pile Mass (mm)		BT	At timeline	% Change	% Superiority
5th day	Group C	21.82	18.74	14.10	11.70
	Group E	22.12	16.42	25.80	
10th day	Group C	21.82	15.11	30.75	25.51
	Group E	22.12	9.68	56.26	
15th day (AT)	Group C	21.82	13.54	37.94	34.31
	Group E	22.12	6.14	72.25	

Table 12. Overall percent improvement results and superiority outcomes in each timeline

Parameter		Group C			Group E			
	Time- line	Before	After	% Change	Before	After	% Change	% Superiority
Bleeding PR (Presence)	5th day	0	17	26.20	0	15	23.10	-3.10
		0%	26.20%		0%	23.10%		
	10th day	0	34	52.30%	0	53	81.50	29.20
		0%	52.30%		0%	81.50%		
	15th day (AT)	0	38	58.50	0	59	90.80	32.30
		0%	58.50%		0%	90.80%		
Bleeding PR (No of Times)	5th day	0	15	23.10	0	5	7.70	-15.40
		0%	23.10%		0%	7.70%		
	10th day	0	31	47.70	0	49	75.40	27.70
		0%	47.70%		0%	75.40%		
	15th day (AT)	0	36	55.40	0	60	92.30	36.90
		0%	55.40%		0%	92.30%		
Bleeding PR (Severity)	5th day	0	29	44.60	0	34	52.30	7.70
		0%	44.60%		0%	52.30%		
	10th day	0	32	49.20	0	48	73.80	24.60
		0%	49.20%		0%	73.80%		
	15th day (AT)	0	34	52.30	0	58	89.20	36.90
		0%	52.30%		0%	89.20%		

https://doi.org/10.47552/ijam.v16i2.5115 ISSN No: 0976-5921

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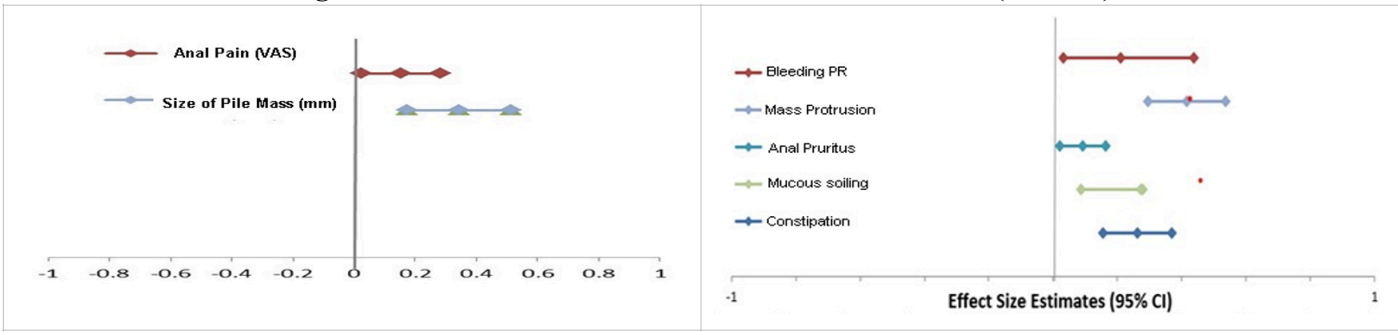
Mass Protrusion	5th day	0	3	4.60	0	6	9.20	4.60
		0%	4.60%		0%	9.20%		
	10th day	0	31	47.70	0	51	78.50	30.80
		0%	47.70%		0%	78.50%		
	15th day (AT)	0	31	47.70	0	58	89.20	41.50
		0%	47.70%		0%	89.20%		
Anal Pruritus	5th day	3	44	63.10	6	47	63.10	0.00
		4.60%	67.70%		9.20%	72.30%		
	10th day	3	48	69.20	6	57	78.50	9.30
		4.60%	73.80%		9.20%	87.70%		
	15th day (AT)	3	55	80.00	6	64	89.30	9.30
		4.60%	84.60%		9.20%	98.50%		
Mucus Soiling	5th day	13	22	13.80	19	31	18.50	4.70
		20.00%	33.80%		29.20%	47.70%		
	10th day	13	33	30.80	19	57	58.50	27.70
		20.00%	50.80%		29.20%	87.70%		
	15th day (AT)	13	33	30.80	19	57	58.50	27.70
		20.00%	50.80%		29.20%	87.70%		
Constipation	At 5th day	10	18	12.30	13	44	47.70	35.40
		15.40%	27.70%		20.00%	67.70%		
	At 10th day	10	35	38.40	19	63	67.70	29.30
		15.40%	53.80%		29.20%	96.90%		
	At 15th day (AT)	10	37	41.50	19	63	67.70	26.20
		15.40%	56.90%		29.20%	96.90%		
Anal Pain (VAS)	At 5th day	0	9	13.8	0	2	3.1	10.7
		0%	13.8%		0%	3.1%		
	At 10th day	0	52	80	0	52	80	0
		0%	80%		0%	80%		
	At 15th day (AT)	0	52	80	0	62	95.4	15.4
		0%	80%		0%	95.4%		

Table 13: Comparative results of the mean Hb (g/dl) between the groups (Group C vs. Group E) with superiority after treatment

Group	BT	15th day (AT)	% Change	% Superiority
Group C	11.35	11.82	4.10	8.14
Group E	11.23	12.60	12.23	

Figure 3 and 4: FOREST PLOT OVER EFFECT SIZE (95% CI)



Discussion

Ayurveda procedures like *Abhyanga, Swedana, Dhoopana, Raktamokshana, Basti, Pichu, Lepa, Pratisarana* are referenced in Ayurveda classical writings and are effective in the management of *Raktarsha* due to their *Shothaghna, Vranashodhan, Vranaropana, Raktaprasadana, Raktasthambhana, Kandughna* effects according to the drug used in it. However, they have limitations because most of the procedures are clinician-dependent (self-administration not possible), require daily visits for treatment, have less contact time of medicine, need instruments or applicators for administration, and need to prepare fresh every time before application.

Several *Pralepa* and *Pratisarana* formulations, such as *Haridradi Lepa, Pipalyadi Lepa, Shuranadi Lepa,* and *Shirishbijadi Lepa*, are referenced for application over *Arsha* (Hemorrhoids). These formulations have greater emphasis. The medicinal herbs described for *Pralepa* and *Pratisaran* in *Raktarsha* could be transformed into *Gudavarti* (Suppository) so that the patient himself can administer

it at home instead of the proctologist applying the *Lepa* in the clinic. The patient will comply with it more readily.

Therefore, *Durvadi Gudavarti* was developed using the native medicinal herbs mentioned in Charaka Samhita as an alternative to the *Lepa* and *Pratisaran* formulations from the texts. It was intended to be administered rectally to patients suffering from *Raktarsha* and would be effective with less noticeable side effects. A randomized active-controlled double-blind superiority clinical trial was conducted to assess its efficacy.

In the present study, a total of 130 patients were treated in two individual Groups. In Group C (Control group) - received a Hydrocortisone suppository and in Group E (Experimental group) - received a *Durvadi Gudavarti* BD for 2 weeks. The results were observed and evaluated for Objective parameters and Subjective parameters at the end of treatment. The clinical efficacy of the drug was analyzed statistically on all parameters mentioned in the Assessment criteria. A scoring system was employed to evaluate the effectiveness of therapy. Scoring of chief clinical features of *Raktarsha (Gudagata Raktastrava and Guda shool)* was done before, at follow-ups, and after treatment. Appropriate statistical tests were adopted to assess the level of significance.

Data revealed that after treatment *Durvadi Gudavarti* was 34.31% superior in reducing the size of pile mass, in the improvement of HB% it was 8.14% superior, in bleeding PR it was 32.30% superior, in the frequency of bleeding PR it was 36.90% superior, in the severity of bleeding PR it was 36.90% superior, in mass protrusion it was 41.50% superior, in anal pruritus, it was 9.30% superior, in mucous soiling it was 27.70% superior, in constipation it was 26.20% superior, and in anal pain calculated in VAS scale it was 15.4% superior to Hydrocortisone suppository**.**

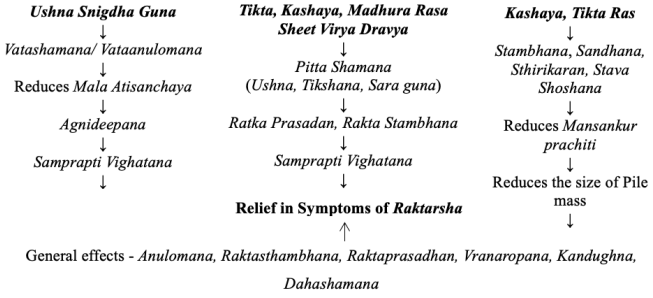
Probable mode of action: Since the classics do not provide an adequate description of *Durvadi Varti's* pharmacodynamics, an attempt is made to do so based on the symptomatic alleviation observed in clinical trials. In the Charaka Samhita, *Durvadi Yoga* is mentioned for the management of *Raktarsha* for *Pralepa* and *Pratisarana*.

The reduction in the size of pile mass could be because of *Kashaya Rasa* in the herbs *Durva, Daruharidra, Sarjarasa, Nimba*, and *Manjistha*. As *Kashaya Rasa* is Astringent in the property they reduce the size of pile mass. The *Anulomana* property of *Yastimadhu* and *Guda* reduces the straining while defecating thereby reducing the protrusion and size of pile mass. Also, the *Shothaghna* property of *Yashtimadhu* decreases the swelling and congestion of the pile mass causing a reduction in its size.

An increase in the Pitta Dosha and its combination with Rakta Dhatu causes a bleeding tendency. Tikta, Kashaya, and Madhura Rasa have the property of reducing Pitta Dosha. Therefore Durva, Yashtimadhu, Daruharidra, Sarjarasa, Nimba, and Manjistha in Durvadi Gudavarti reduce Pitta Dosha and arrest the bleeding PR in Raktarsha. The Sheet Guna of Durva, Yashtimadhu, Sarjarasa, Nimba, and Guda also help in arresting the bleeding PR in Raktarsha.

Ushna, Tikshana, and *Snigdha Guna* of *Durvadi Varti* may correct the *Vata Dushti* and regulate the function of *Apana Vayu* which breaks *Samprapti* and cures the disease *Arsha*.

Figure 6: Flow chart of the probable mode of action of *Durvadi Gudavarti*



Conclusion

It was concluded from the study that Hydrocortisone suppository and *Durvadi Gudavarti* both have significant clinical efficacy in the management of *Raktarsha*. However, *Durvadi Gudavarti* is more effective than the Hydrocortisone suppository in its management.

Acknowledgment

The authors are thankful to the staff of DMIHER, Mahatma Gandhi Ayurveda College, Hospital, and Research Centre for their support in completing this study.

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