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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF TRIDAX PROCUMBENS IN THE MANAGEMENT OF RAKTARSHA (BLEEDING PILES) UNDER THE INFLUENCE OF CHANDANADI CHOORNA AND INFRA RED COAGULATION (I.R.C)

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ABSTRACT: ABSTRACT

Present article is a clinical research article. This research study was done in the Institute of Ayurveda, an autonomous body of Indian government. Piles are common ailments affecting 45% of patients in anorectal clinics. Symptoms include bleeding, pain and prolapsible mass. Modern science has limited medical treatment for haemorrhoids. This clinical study evaluated Tridax procumbens' efficacy in managing Raktarsha (bleeding piles) using Chandanadi Choorna and I.R.C. on 40 patients. The combination of drugs was found to be the best remedy for treating Raktarsha (bleeding piles) symptoms.

INTRODUCTION

Haemorrhoids are a kind of disease which is most unkind towards mankind. Ever since evolution of its species among all the diseases of the gastrointestinal tract, haemorrhoids is the most common and troublesome disease. Haemorrhoids are called Arsha in Ayurveda. Arsha finds a mention in almost all Ayurvedic literature which deals with diseases and its treatment. Since the time immemorial, efforts have been made all over the

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world to combat the condition through different modalities of treatment, but not all of them have been uniformly successful.

It is one of the eight Mahagada and difficult to cure. Ayurvedic physicians have regarded this disease as a local manifestation of systemic derangement of Dosha or bodily humours. Vitiation of Dosha adversely affects the digestive fire resulting in Mandagni, which in turn leads to constipation. Prolonged contact of accumulated Mala or excretory material taint Gudavali, and thus Arsha develops. Charaka believes involvement of all the three Dosha in the causation of disease.

Present need in the management of Raktarsha are may folds, particularly in a country like India whose major population is devoid of good and well equipped medical care. The therapeutic measures should be such which have clear indications of their applicability and limitations, could be arranged indigenously from local resources, the technique should be simple, the complication must be minimum and easily manageable, it should be acceptable to the patient and convenient for the physician, could be done with minimum interference in patient's day to day activity.

AIM AND OBJECTIVES

1. To evaluate the efficacy of tridax procumbens in the management of raktarsha (bleeding piles).

2. To compare study of chandanadi choorna and infra red coagulation (i.r.c) in the management of raktarsha (bleeding piles).

3. To evaluate the safety and effectiveness Ayurvedic management of bleeding piles.

4. To generate evidence for the validity of the Ayurveda system and its fundamental principles

MATERIALS AND METHODS

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For the present study following material and method had been adopted-

Selection of the patients.

Grouping of the selected patients.

Laboratory investigation.

Method of administration of medicine.

Observation of the patient during treatment.

Assessment criteria.

SELECTION OF THE PATIENTS:

1. Patients were registered from OPD/IPD of Deptt. Of Shalya tantra, N.I.A., Jaipur, irrespective of sex, cast and religion.

2. Scope of this clinical study was to cover all those patients having complaint of bleeding per anum due to haemorrhoids.

3. 40 patients were registered for clinical trial.

4. The studies were conducted only after proper written consent of individual patient explaining the methodology and aim of study.

5. Complete descriptions regarding the details of each research case were recorded in a pre-designed proforma.

INCLUSION CRITERIA -

1. Patient willing to participate in the research trial.

2. Patient aged in between 20-60 years.

3. Patients of Ist and IInd degree internal piles were considered.

EXCLUSION CRITERIA -

1. Patient suffering from systemic disease like diabetes mellitus,

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tuberculosis and Hemophilic disorders.

2. Patients found associated with Hepatitis B and HIV were excluded

from the study.

3. Patient associated with prolapsed rectum, Fistula-in-ano, fissure,

carcinoma of the rectum, ulcerative colitis, crohn's disease, Hepatic disorder, cardiac disorders mentally ill and non-cooperative patients were excluded from the study.

4. If the condition of the patient deteriorated during the trial he/she were

excluded from the study.

GROUPING OF THE SELECTED PATIENTS:

The selected patients were randomly categorized into four groups.

Group A - In this group patients were treated with Chandanadi choorna orally.

Dose- 5 gram twice daily with Luke warm water.

Group B -In this group patients were treated with Infra Red Coagulation.

Group C - In this group patients were treated with local application of swaras of Tridax procumbens.

Group D - In this group patients were treated with Chandanadi choorna orally and local application of swaras of Tridax procumbens.

CHANDANADI CHOORNA

Chandanadi choorna is mentioned in Bhaishajya Ratnavali, StriRogadhikara under Pradara chikitsa. (B.R. 66/20-24)

Chandana, Nalada, Lodhra, Ushira, Padmakesara, Nagapushpa, Bilwa, Bhadramusta, Sharkara, Hrivera, Patha, Kutaja phala and twaka, Sringvera, Ativisha, Dhataki, Rasanjana, Amrasthi, Jambusara and asthi, Mocharasa,

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Neelotpala, Samanga, Sukshmaila and Dadima. Patha was not available so it was excluded from Chandanadi choorna. Rest all the drugs have been taken in equal quantity.

TRIDAX PROCUMBENS

Tridax procumbens L. (Compositae) is a weed found throughout India. The plant is known to local people as “Ghamara” and is dispensed for “Bhringraj” by some of the practitioners of Ayurveda. Tridax having many medicinal properties such as hemostasis or styptic, antiseptic, wound healing, astringent, anti-inflammatory, antimicrobial & allied potentialities.It pacifies vitiated pitta, inflammation, wound, ulcers, anal fistula, and hemorrhoids. Plant is thought to have Kashaya, Amla, Tikta Rasa and sheeta virya. Whole plant was used in the form of swararsa.

INFRA RED COAGULATION (I.R.C.)

Infra Red Photocoagulation also known as Coagulation Therapy is a medical procedure commonly used for hemorrhoid treatment on small and medium sized haemorrhoids. The IRC device creates an intense beam of light which creates a clot to form in the vein. In left lateral position after inserting the proctoscope haemorrhoid was grapsed with forcep and intense infrared beam was passed at the base of haemorrhoid with I.R.C. device.

LABORATORY INVESTIGATIONS

Basic aim of carrying out various investigations of patient was to be access the general health of patient, to check any underlying abnormality or lesions so as to rule out any such suspected case. Following routine laboratorial investigations was performed in patients–

1. Blood Examination

- TLC, DLC, Hb%, ESR, CT, BT, Blood urea, Serum creatinine.
- Blood sugar – Fasting and P.P. (Post Prandial)
- HIV, Hephatis B, HbsAg.

2. Urine Examination

- Routine (physical) and microscopic.

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3. Stool Examination –For ova, cysts and parasites.

4. Sputum – for AFB.

5. X-ray Chest PA View.

6. Plain X-ray of pelvis to exclude bony pathology.

7. ECG

OBSERVATION OF THE PATIENTS DURING TREATMENT:

Condition of the patient was observed under specific assessment criteria every day during oral and local administration of the medicine for 7 days and thereafter follow-up every week up to 4 weeks.

At the end of 7 days assessment were observed and thereafter follow-up at weekly interval was recorded. After completion of 4 weeks all the recorded information was calculated and presented in the form of tables and graphs.

DIAGNOSTIC CRITERIA

It includes Clinical signs & Symptomatology viz

- Character of Bleeding P/R
- Frequency of Bleeding P/R
- Constipation
- Sphincter tone
- Agnimandhya
- Pallor

CLINICAL ASSESSMENT

General observations

Various demographic parameters viz Age, Marital status, Religion, Socio-economic status, Education etc. along with specific features of Dashvidha

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pareeksha & Ashtvidha pareeksha viz prakriti, satva, samshaman, etc. were analyzed in the present trial.

SUBJECTIVE ASSESSMENT

The patients undergone the treatment were assessed on the basis of symptom rating score depicted below for improvement in specific Symptomatology of Raktarsha

Character of bleeding P/R (Raktasrava lakshana) -

No bleeding : 0

Bleeding in the form of streak : 1

Bleeding in the form of drops : 2

Bleeding in the form of splash in the pan : 3

Bleeding in the form of stream : 4

Frequency of bleeding P/R (Raktasrava pravriti) –

No bleeding : 0

Bleeding once in a week : 1

Bleeding twice in a week : 2

Bleeding alternate day : 3

Bleeding once in a day : 4

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Constipation (Kostha baddhata) –

Normal stool is passed regularly : 0

Patient passes irregularly normal stool : 1

Patient passes completely hard stool : 2

Patient takes laxative to pass stool : 3

Patient needs enema to pass stool : 4

Loss of appetite (Agnimandhya) –

Normal : 0

Patient has less interest on food butb intake is normal : 1

Patient has less interest on food, intake is less but regular : 2

Patient has less interest on food, intake is less and not regular : 3

Patient has no interest on food at all : 4

Sphincter tone:

Easy DRE and proctoscopic examination is possible : 0

Easy DRE but painful proctoscopic examination : 1

Easy DRE is possible : 2

Painful DRE

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: 3

DRE is not possible

: 4

Pallor

Normal (>11 gm %)

: 0

Mild (9-11 gm %)

: 1

Moderate (7-9 gm %)

: 2

Severe (<7 gm %)

: 3

OBSERVATION

Effect of the trial drugs of group- A, B, C & D on various subjective symptoms of Raktarsha are described below in table No.1, 2, 3 & 4.

Table no. 1: Effect of the trial drug of group- A on various subjective symptoms:

W=Sum of signed ranks, VS = Very significant, S = significant, NS = Not significant.

S. No.	Symptoms	Mean		Diff.	% of Relief	SD	SE	'w'	p	Results
		BT	AT							
1.	Character of Bleeding P/R	2.3	1	1.3	56.52	0.6749	0.2134	45	0.0039	VS
2.	Frequency of Bleeding P/R	2.3	0.7	1.6	69.56	0.5164	0.1633	55	0.002	VS
3.	Constipation	2.4	0.6	1.8	75	0.4216	0.1333	55	0.002	VS
4.	Loss of appetite	1.5	0.2	1.3	86.67	0.9487	0.3000	36	0.0078	VS

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5.	Sphincter tone	1.5	0.3	1.2	80	0.9189	0.2906	36	0.0078	VS
6.	Pallor	0.9	0.4	0.5	55.56	0.5270	0.1667	15	0.0625	NS

Table no. 2: Effect of the trial drug of group- B on various subjective symptoms:

W=Sum of signed ranks, S = significant, VS = Very significant.

S. No.	Symptoms	Mean		Diff.	% of Relief	SD	SE	'w'	p	Results
		BT	AT							
1.	Character of Bleeding P/R	3	0.5	2.5	83.33	0.7071	0.2236	55	0.002	VS
2.	Frequency of Bleeding P/R	2.7	0.4	2.3	85.18	0.8233	0.2603	55	0.002	VS
3.	Constipation	2.2	1.5	0.7	31.81	0.6749	0.2134	21	0.0313	S
4.	Loss of appetite	2.2	1.3	0.9	40.90	0.5676	0.1795	36	0.0078	VS
5.	Sphincter tone	2.1	0.6	1.5	71.42	0.7071	0.2236	55	0.002	VS
6.	Pallor	2.0	0.7	1.3	65	0.8233	0.2603	45	0.0039	VS

Table no. 3: Effect of the trial drug of group- C on various subjective symptoms:

W=Sum of signed ranks, VS = Very significant.

S. No.	Symptoms	Mean		Diff.	% of Relief	SD	SE	'w'	p	Results
		BT	AT							
1.	Character of Bleeding P/R	2.2	0.8	1.4	63.63	0.6992	0.2211	45	0.0039	VS
2.	Frequency of Bleeding P/R	2.2	0.6	1.6	72.72	0.8433	0.2667	45	0.0039	VS
3.	Constipation	2.2	1.3	0.9	40.90	0.5676	0.1795	36	0.0078	VS
4.	Loss of appetite	2.2	1.1	1.1	50	0.5676	0.1795	45	0.0039	VS

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5.	Sphincter tone	2.1	0.7	1.4	66.67	0.5164	0.1633	55	0.002	VS
6.	Pallor	2.0	0.5	1.5	75	0.8498	0.2687	45	0.0039	VS

Table no. 4: Effect of the trial drug of group- D on various subjective symptoms:

W=Sum of signed ranks, VS = Very significant, S = significant,

Caption

S. No.	Symptoms	Mean		Diff.	% of Relief	SD	SE	'w'	p	Results
		BT	AT							
1.	Character of Bleeding P/R	3.0	0.7	2.3	76.67	0.4830	0.1528	55	0.002	VS
2.	Frequency of Bleeding P/R	2.6	0.6	2.0	76.92	0.6667	0.2108	55	0.002	VS
3.	Constipation	2.4	0.8	1.6	66.67	0.5164	0.1633	55	0.002	VS
4.	Loss of appetite	1.6	0.3	1.3	81.25	0.6749	02134	45	0.0039	VS
5.	Sphincter tone	1.6	0.2	1.4	87.50	0.8433	0.2667	45	0.0039	VS
6.	Pallor	1.2	0.3	0.9	75	0.7379	0.2333	28	0.0156	S

DISCUSSION

Raktarsha is a disease in which majority of human experience certain uncomfortable, physical and psychological symptoms. Here, an attempt has been made to throw some more light on the present knowledge of the subject. As many as one in five people experience some problems with haemorrhoids and are also called ‘piles’. They are common in middle and

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later life, often caused by years of chronic constipation. About 50 per cent of adults have them by the time they turn 50.

Ayurvedic physicians have regarded this disease as a local manifestation of systemic derangement of Dosha or bodily humours. Vitiation of Dosha adversely affects the digestive fire (Agni) resulting in Mandagni, which in turn leads to constipation. Charaka believes involvement of all the three Dosha in the causation of this disease.

Prolonged contact of accumulated Mala or excretory material taint Gudavali and thus Arsha develops. Modern literature also shows the concept of Gudavali as: - There are three fleshy pads inside the anus, also known as anal cushion. These pads, together with the sphincter muscles, keep stools and wind in the rectum until need to release them. When these fleshy pads get damaged and don’t function properly they results in to piles or haemorrhoids.

Charaka described two types of Arshas- Shuska (Dry) and Ardra (Wet or bleeding). Again in Chikitsa-Sthana he described two types of Arsha as- Sahaja (Congenital) Jatasyottarkalaja (Acquired). Sushruta mentioned 6 types of Arshas - Vataja, Pittaja, Kaphaja, Raktaja, Sannipataja and Sahaja. Haemorrhoids that occur in the rectum are called internal haemorrhoids, and those that occur around the anus are called external haemorrhoids.

Increased pressure in the veins around the anus is thought to be the cause of haemorrhoids. The major cause of haemorrhoids is increased abdominal pressure caused by muscle straining and by far the most common reason is constipation.

Our Acharya considered the guda is the sadhyopranahara marma and its origin is mamsaja variety. Therefore every care should be taken meticulously to preserve this marma. Even though the ligation and excision is indicated in prolapsed piles, but certain patients may not like to undergo surgery in inoperable conditions, such as severe anemia, DM & HTN. Under these circumstances we lookout our ancient literature for non-surgical measures which can achieve better results. Chikitsa can be administered by the two methods i.e., externally & internally. The “Chandanadi choorna” for internal (oral) administration & external application with fresh panchang swaras of plant “Tridax procumbens” was

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selected for the present study to achieve the same goal.

As if the physician is not going to treat constipation, lack of digestive fire and operates piles then also there is no cure, because if constipation exists it will cause pressure even after operation and pile mass will not heal and there will be no use of operation.

So this research study was basically to treat the causative factors of piles so that it can be cured by root. The success of operative procedure also depends upon all these factors.

The drug Chandanadi choorna is pitta-kapha shamaka and shodhaka, rakta shodhaka and stambhaka, balya, vatanulomana, deepan-pachana & effective in correcting all the three vitiated dosha and drug Tridax has got mainly rakta stambhaka property, thus the combination of both these drugs gave better result in treatment of Raktarsha.

The effect of drug of Group A reveals that maximum percentage of Relief was observed in the parameter of Loss of appetite (86.67%) followed by Sphincter tone (80%), Constipation (75%), Frequency of Bleeding P/R (69.56%), Character of Bleeding P/R (56.52%), and Pallor showed (55.56%) Relief. Percentage of Relief is statistically very significant in Character of Bleeding P/R, Frequency of Bleeding P/R, Constipation, Loss of appetite and sphincter tone and it is not significant in case of Pallor.

The effect of drug of Group B reveals that maximum percentage of Relief was observed in the parameter of Frequency of Bleeding P/R (85.18%) followed by Character of Bleeding P/R (83.33%), Sphincter tone (71.42%), Pallor (65%), Loss of appetite (40.90%) and Constipation showed only 31.81% of Relief. Percentage of Relief is statistically Very significant in all the symptoms except Constipation in which it is statistically Significant.

The effect of drugs of Group C reveals that maximum percentage of Relief was observed in the parameter of Pallor (75%) followed by Frequency of Bleeding P/R (72.72%), sphincter tone (66.67%), Character of Bleeding P/R (63.63%), Loss of appetite (50%), and Constipation showed 40.90% of Relief. Percentage of Relief is statistically very significant in all the symptoms.

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The effect of drugs of Group D reveals that maximum percentage of Relief was observed in the parameter of Sphincter tone (87.50%) followed by Loss of appetite (81.25%), Frequency of Bleeding P/R (76.92%), Character of Bleeding P/R (76.67%), Pallor (75%), and Constipation showed 66.67% of Relief. Percentage of Relief is statistically very significant in all the symptoms except Pallor in which it is statistically Significant.

Comparative analysis

On the comparative analysis of the four groups on the subjective parameters, in comparison between Group A and Group B- Very significant result was found on the parameter of character of bleeding per rectum & constipation & not significant result was found on rest of the subjective parameters.

In comparison between Group A and Group C- significant result was found on the parameter of constipation & pallor & not significant result was found on rest of the subjective parameters.

In comparison between Group A and Group D- significant result was found on the parameter of character of bleeding per rectum & not significant result was found on rest of the subjective parameters.

In comparison between Group B and Group C- significant result was found on the parameter of character of bleeding per rectum & not significant result was found on rest of the subjective parameters.

In comparison between Group B and Group D- significant result was found on the parameter of constipation & not significant result was found on rest of the subjective parameters.

In comparison between Group C and Group D- significant result was found on the parameter of character of bleeding per rectum & not significant result was found on rest of the subjective parameters.

Overall Effect of therapy

On the basis of criteria of assessment adopted, the total effect of therapy has been carried out, which has shown that in Group A marked improvement was seen in the four patients, moderate improvement in four patients and mild improvement in two patients. In Group B marked

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improvement was seen in two patients, moderate improvement in six cases & mild improvement in two cases. In Group C marked improvement was seen in one patient, moderate improvement in eight cases & mild improvement in one case. In Group D marked improvement was seen in five patients and moderate improvement was also seen in five patients. Mild and no improvement were not seen in any case.

Subjective symptoms are found to be relieved to the maximum in Group D (76.58%), followed by Group A (70.61%) & Group B (64.76%) and lastly Group C (61.25%).

CONCLUSION

1. Urbanization, changing life style, dietary and bowel habits are contributing factors in increasing prevalence of bleeding piles.

2. Further study on evaluation of clinical assessment criteria for Raktarsha is required.

3. Bleeding is the principle & earliest symptoms of haemorrhoids for which patient seeks medical advice.

4. Bheshaja chikitsa (medical therapy) is more effective in early stage of Raktarsha (haemorrhoids) and has greatest advantage of wider acceptability by the medicine patients.

5. The trial medicine of present study was found simple, safe and effective in treating Raktarsha.

6. Arsha is a local manifestation of systemic derangement of Doshas thus it requires both systemic and local medication.

7. Clinical Study shows haemostatic potential (rakta stambhaka action) of all the two drugs and I.R.C in four different groups at varying levels with better results in group D and group A, in correcting the underlying pathology.

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8. Among the four groups, Combination of drugs in group D (Chandanadi choorna with Swaras of Tridax procumbens) proved to be the best remedy for treating the symptoms of Raktarsha as all the six parameters were shown to have better results

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