

REPORT ON CLINICAL TRIAL OF PIRRHOIDS

Sponsored By:
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**REPORT ON THE CLINICAL TRIAL
OF
“PIRRHOIDS TABLETS” IN PILES DISORDERS**

Arsa or Haemorrhoids (Greek; Haima = Blood, Rhoo = Flowing) commonly known as Arsa or Piles (Latin Pila = a ball) are dilated veins occurring in relation to anus. It may be external or internal, i.e. external or internal to anal orifice. The external variety is covered by skin, while internal variety lies beneath anal mucous membrane. When the two varieties are associated, called ENTEROEXTERNAL haemorrhoids or piles.

Haemorrhoids are very common in male and female. About half of the population have haemorrhoids by age of 50 years. Haemorrhoids are also common among pregnant women. The pressure of the foetus in the abdomen, as well as hormonal changes cause haemorrhoidal vessels to enlarge. Anorectal varices are commonly found in patients with portal hypertension also.

Haemorrhoids or piles arises from congestion of the internal or external venous plexus around and anal canal. They are extremely common in adult. The exact aetiology is unknown. Although they are associated with constipation and straining and may develop for the first time in pregnancy.

The first degree piles bleeds, while second degree piles prolapse, but retract spontaneously. The third degree piles are those which requires manual placements after prolapsing. Other symptoms includes pain, pruritus-ani and mucous discharge.

Haemorrhoids (piles) may be the symptom of some other conditions and this important fact must be remembered as Carcinoma of rectum, piles during pregnancy, from straining at micturition and from chronic constipation. The common symptoms of Haemorrhoids or piles are bright red painless bleeding, mucous discharge, rectal prolapse, pain only on prolapse, pain in rectum, anaemia and weakness etc.

Modern medicine prefers surgery for treatment of piles. But in ayurvedic classics there are so many medicine useful to cure piles or haemorrhoids successfully as well as with no/least side effects. PIRRHOIDS is an ayurvedic formulation, prepared by Shree BAIDYANATH Ayurved Bhawan Pvt. Ltd, 1 Gupta Lane, Kolkata - 700006, was trialed in patients of piles disorders to know the efficacy of the durg clinically.

AIMS AND OBJECTS :

To evaluate the therapeutic value of “PIRRHOIDS” tablets in the patients of piles disorders, the present clinical trial was undertaken. Total 44 cases have been included in this study, who were studied in different groups viz. trial group and control group. Trial group included 32 patients to whom PIRRHOIDS, trial drug was administered. Control group included 12 patients to whom PLACEBO was administered in the similar way.

MATERIAL AND METHOD :

44 Patients of piles disorder were registered during the course of trial. The study consisted clinical patterns in piles disorder and the management of the particular conditions with "PIRRHOIDS" tablets.

Out of 32 patients of the trial group 28 cases had completed the full treatment schedule (i.e. 60 days) and remaining 4 cases had discontinued the course of treatment.

The control group included 12 patients, out of which 10 patients, followed the full term treatment (i.e. 60 days) and rest 2 patients had discontinued the course of treatment.

The clinical pattern were studied in all the 44 cases for incidence of age, sex (male and female) religion, occupation, economic status, educational status, social status and symptoms of piles disorders following routine blood test and stool etc. examination.

Selection of Cases:

All patients selected for study were interrogated and the details history was recorded in the prescribed case history sheet. All patients were thoroughly examined and findings were also recorded. To establish the final diagnosis, the routine examination of blood, stool and urine etc. were also done, in additional to the observation of subjective features, clinically.

Criteria for Final Diagnosis:

All the patients included in clinical study were carefully examined physically and records were maintained with detail clinical history. The individual who have symptoms of piles disorders with or without rectal bleeding were subjected to clinical trial.

Method of Drug Administration:

The drug "PIRRHOIDS" was administered orally to the patients of the trial group in the form of tablets prepared and supplied by Shree BAIDYANATH Ayurved Bhawan Pvt. Ltd, 1 Gupta Lane, Kolkata - 700006. The patients of piles disorders taken for the study, were administered 2 tablets twice daily morning and evening with water for a period of 60 days.

PLACEBO tablets were administered orally to the patients of control group in the similar way which was also prepared and supplied by Shree BAIDYANATH Ayurved Bhawan Pvt. Ltd, 1 Gupta Lane, Kolkata - 700006.

Diet:

All the patients selected for trial were advised to avoid spicy foods.

Follow Up:

Follow up study was conducted in all the cases at interval of 15 days for 2 months (60 days), routine blood, stool and occult blood test were done before treatment and after 2 months (60 days) of treatment.

Clinical Pattern:

The present study consists of total 44 cases who have symptoms of piles disorders and out of the total cases, 38 cases could be followed up. But the clinical pattern will be discussed on 44 cases. The result will be analysed on observation of the findings of 38 cases (i.e. 28 patients in trial group and 10 patients in control groups).

Age Incidence:

Patients of the present study were from 20 to 60 years of age. Patients of different age group are given in Table No. 1.

Table No. 1 : Showing the incidence of different Age Group

Sl.No.	Age Group (years)	No. of patients	Percentage
1.	20 - 35	15 - 14	31.82
2.	36 - 50	24	54.55
3.	51 and above	06	13.63
	Total	44	100

Sex Incidence:

Patients of both sexes were registered for the present study. The sex groups are given in Table No. 2

Table No. 2 : Showing the incidence of Sex

Sl.No.	Sex	No. of patients	Percentage
1.	Male	34	77.27
2.	Female	10	22.73
	Total	44	100

Religion Incidence:

Patients of various religions were included in this study. Patients belonging to different religion are shown in Table No. 3.

Table No. 3 : Showing the incidence of Religion

Sl.No.	Religion	No. of patients	Percentage
1.	Muslim	30	68.18
2.	Hindu	10	22.73
3.	Christian	04	9.09
	Total	44	100

Occupation Incidence:

In this study patients belonging to various occupations were included and shown in Table No. 4

Table No. 4 : Showing the incidence of Occupation

Sl.No.	Occupation	No. of patients	Percentage
1.	Service	10	22.72
2.	Hosue wives	05	11.37
3.	Labour	07	15.90
4.	Businessmen	10	22.72
5.	Student	05	11.37
6.	Cultivator	04	9.10
7.	Retired	03	6.82
	Total	44	100

Economic Status:

In this study patients of different income groups were recorded and shown in Table No. 5.

Table No. 5 : Showing the incidence of Income Status

Sl.No.	Income Status	No. of patients	Percentage
1.	L.I.G	26	59.09
2.	M.I.G	18	40.91
	Total	44	100

Educational Status:

When educational status was enquired, patients of both literate and illiterate were found in the series. The educational status as found are given in Table No. 6.

Table No. 6 : Showing the incidence of Educational Status

Sl.No.	Educational Status	No. of patients	Percentage
1.	Illiterate	4	09.10
2.	Primary	15	34.10
3.	Madhyamik	05	11.36
4.	Higher Secondary	07	15.90
5.	Graduate	10	22.72
6.	Post Graduate	03	06.82
	Total	44	100

Rural and Urban Incidence:

This study included patients from urban and rural areas and shown in Table No. 7

Table No. 7: Showing the incidence of Rural and Urban

Sl.No.	Rural / Urban	No. of patients	Percentage
1.	Rural	14	31.82
2.	Urban	30	68.18
	Total	44	100

Incidence of Diet Habits:

Patients included in the present study were found to have both types of diet habits (vegetarian & non-vegetarian), which are presented in Table No. 8.

Table No. 8: Showing the incidence of Diet Habits

Sl.No.	Diet Habits	No. of patients	Percentage
1.	Non-Vegetarian	35	79.54
2.	Vegetarian	09	20.46
	Total	44	100

Incidence of Nature of Work:

In this trial study nature of work were studied which are presented in Table No. 9.

Table No. 9: Showing the incidence of Nature of Work

Sl.No.	Nature of Work	No. of patients	Percentage
1.	Sedentary	26	59.10
2.	Moderate	11	25.00
3.	Hardworker	07	15.90
	Total	44	100

Incidence of Marital Status:

In this study married and unmarried both patients are included which are presented in Table No. 10.

Table No. 10: Showing the incidence of Marital Status

Sl.No.	Marital Status	No. of patients	Percentage
1.	Unmarried	06	13.64
2.	Married	38	86.36
	Total	44	100

Incidence of Piles Position:

In this study rectum was examined in each individual. It was observed that pile mass was present in different position of the rectum. Our observation is presented below in Table No. 11.

Table No. 11: Showing the incidence of Position of Piles

Sl.No.	Position of Piles	No. of patients	Percentage
1.	3 O'clock	16	36.37
2.	5 O'clock	14	31.81
3.	7 O'clock	18	40.91
4.	9 O'clock	30	68.18
5.	11 O'clock	36	81.82

Incidence of Rectal Prolapse:

In this study rectum was examined in each individual. It was observed that pile mass was present in different position of the rectum. Our observation is presented below in Table No. 12.

Table No.12: Showing the incidence of Rectal Prolapse

Sl.No.	Rectal Prolapse	No. of patients	Percentage
1.	Rectal Prolapse with piles	10	27.73
2.	Piles without Rectal Prolapse	34	77.27
	Total	44	100

Incidence of Rectal Bleeding:

In this series the status of rectal bleeding was observed in each individual by interrogation and oral examination. The observation is presented below in Table No. 13.

Table No. 13: Showing the incidence of Bleeding in Patients of Piles

Sl.No.	Bleeding Status	No. of patients	Percentage
1.	Non bleeding Piles	10	22.73
2.	Bleeding Piles		
	A. Active Bleeding	12	27.27
	B. Non-Active Bleeding	22	50.00

RESULT AND OBSERVATION :

Response of Treatment in Group A (Trial Group):

Group A or Trial Group consisted of 32 patients, out of which 4 patients had discontinued and 28 cases had completed the treatment schedule of 60 days. Patients were observed in terms of subjective criterias before treatment, during treatment and after treatment. The response of treatment on subjective criterias as observed before treatment and after treatment are presented below in Table No. 14.

Table No. 14: Showing the response of treatment on subjective features of piles disorders in trial group (group A, N=28)

Sl. No.	Symptoms	No.of patients B.T	No. of patients Relieved A.T	Percentage of Relief
1.	Pain in Rectum	21	18	85.71
2.	Bleeding P/R	25	24	96.00
3.	Rectal Pruritus	28	20	71.42
4.	Rectal Prolapse	10	4	40.00
5.	Constipation	28	22	78.58
6.	Heaviness of abdomen	24	17	70.84
7.	Flatulence	26	19	73.08
8.	Vertigo	21	15	71.42
9.	Loss of Weight	18	10	55.56
10.	Weakness	27	18	66.67
11.	Rectal growth	15	11	73.33

It is revealed from the above table that more than 70% of relief was observed in symptoms like pain in rectum, rectal pruritus, constipation, flatulence and vertigo. More than 60% of relief was observed in symptoms like rectal bleeding, discharge of pus and mucous and weakness. Less than 60% relief was found in other symptoms.

Response of treatment in Group B (Control Group)

Group B or Control Group consisted of 12 patients out of which 2 patients had discontinued the treatment and 10 patients had completed the treatment schedule of 60 days. Patients were observed in terms of subjective features (as in trial Group A) before treatment, during treatment

and after treatment. The response of the treatment on subjective criterias as observed before the treatment and after the treatment are presented below in Table No. 15.

Table No. 15: Showing the response of treatment on subjective features of piles disorders in control group (group B, N=10)

Sl. No.	Symptoms	No.of patients B.T	No. of patients Relieved A.T	Percentage of Relief
1.	Pain in Rectum	9	9	0.00
2.	Bleeding P/R	6	6	0.00
3.	Rectal Pruritus	7	8	-14.28
4.	Rectal Prolapse	4	4	0.00
5.	Constipation	9	9	0.00
6.	Heaviness of abdomen	10	10	0.00
7.	Flatulence	8	9	-12.5
8.	Vertigo	6	8	-33.33
9.	Loss of Weight	9	9	0.00
10.	Weakness	8	9	-12.5
11.	Rectal growth	5	5	0.00

The responses of treatment on subjective features in patients of Group B (control group) as revealed from the above table, it is found that there was no relief in subjective features. Moreover, negative relief, was observed in some of the subjective features like rectal pruritus, flatulence, vertigo and weakness.

DISCUSSION :

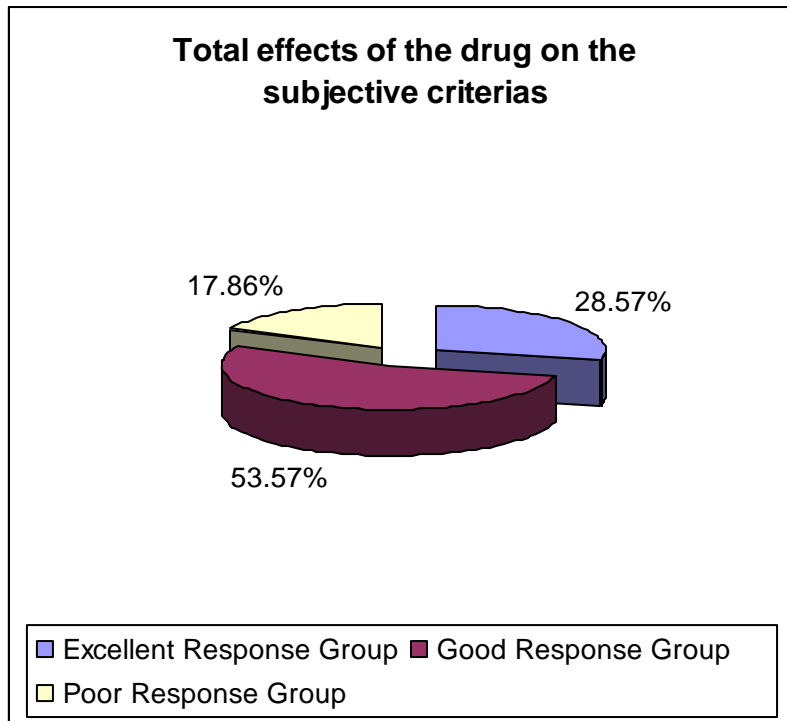
In the present clinical study 44 patients suffering from Arsha or Haemorrhoids disorders were included. The total cases were randomly divided into 2 groups viz. (1) Group A (Trial Group) consisted of 32 patients to whom PIRRHoids the trial drug was given for a period of 60 days, (2) Group B (Control Group) consisted of 12 cases to whom Placebo was given for a period of 60 days. Out of these cases, 4 cases could not be followed in Group A (Trial Group) and 2 cases in Group B (Control Group), 28 cases in Group A (Trial Group) and 10 cases in Group B (Control Group) could be followed up properly.

In trial group, to all the patients "PIRRHOIDS" tablets were given in the dose of 2 tablets twice daily orally, morning and evening with water for a period of 60 days. Similarly in Control Group, to all the cases "PLACEBO" tablets was given in the dose of 2 tablets twice daily morning and evening with water.

The effect of treatment of both the group of patients were assessed at the end of the treatment. The response of the treatment was observed mainly on subjective improvements. At the end of the treatment, the result was assessed in terms of excellent improvement, good improvement and poor improvement. The patients were included under excellent response group when they showed more than 70% relief of subjective features. The patients were included under good response group when they showed more than 50% relief of subjective features and patients showing relief of subjective features below 50% were leveled under poor response group. In consideration to the effects of the drug in Trial Group 28.57% cases were included under

excellent response group, 53.57% under good response groups and 17.86% under poor response group.

In the trial group in most of the cases subjective features were found to be reduced. The effects of the treatment on subjective features in patients of group A (Trial Group) have been analysed and found highly significant. Any improvement in patients of Control Group (Group B) was not found when the effect of the treatment on subjective criterias were analysed.

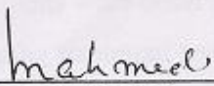
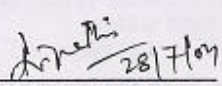
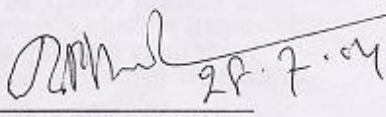


CONCLUSION :

The drug "PIRRHOIDS" tablet has been found to be an effective drug in piles disorders. The result in the trial group has shown encouraging results after 4 weeks of treatment. After 60 days of treatment along with the improvements of the subjective criterias significant response was also noticed. The active bleeding was found to be controlled by two weeks and there was prompt response in constipation, pain in rectum and rectal pruritus. In any cases, the size of the piles mass was found reduced. Hence, "PIRRHOIDS" can safely be prescribed in bleeding/ non bleeding haemorrhoids.

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