

A STUDY OF

'FP-200' (LOCAL & ORAL)

**IN PATIENTS WITH HAEMORRHOIDS (PILES)
AND ANAL FISSURES**

(Report of 18 Cases with brief Review)

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SUMMARY

The results of an open, non comparative trial with 'FP-200' a homoeopathic formulation in patients of piles, anal fissures and associated diseases of anorectal region are reported. This drug trial of 'FP-200' (as the name suggests) was undertaken on eighteen patients suffering from haemorrhoids or piles and anal fissures. Most of the patients were relieved of their symptoms within 5 days in cases of anal fissures and by second week in cases of piles with the treatment. No adverse effect of 'FP-200' (Local or oral) were seen. As pregnancy is the commonest predisposing context for the development of piles and fissures, the response of local FP-200 formulation was dramatic in pregnancy and post delivery cases without any side effects. Thus this study indicates that 'FP-200' is very effective in treatment of piles, fissures and also in diseases of anorectal regions.

PATHOPHYSIOLOGY OF PILES AND FISSURES

The piles and Fissures are commonest diseases of anorectal region.

Piles is a common name given for the medical term haemorrhoids. Piles is the varicose veins occurring in the anorectum. The veins around the anal canal become swollen and give rise to pain and bleeding, usually hereditary¹ weakness of venous walls along with the straining accompanying constipation or induced by over purgation is the commonest cause for piles. There are two types of piles external and internal.

Anal Fissures : (Fissure in Ano)

This is an elongated ulcer in the anal canal over sphincters due to passage of hard faeces. This is more common in women who have born children. Pain is main symptom, during defaecation, stools are streaked with blood.

Introduction

Haemorrhoids/Piles, Anal Fissures are common ailments of anorectal region. Patients with piles and fissures suffer from bleeding, pain, irritation which lead to anaemia and

chronic ill health. Charak advocates fourfold treatment of Piles. It is as follows :

- i) Excision of piles (Shastra Karma)
- ii) Cauterisation using chemicals (Kshar Karma)
- iii) Cauterisation diathermy (Agni Karma)
- iv) Conservative medical treatment (Bheshja-Chikitsa)

Of these, medical treatment is advised for first and second degree of internal piles and anal fissures specially in acute cases. Unlike conservative therapy given by modern medicine, the homoeopathic treatment does not treat only the symptoms but also cures the root cause of haemorrhoids.

Therefore 'FP-200' a homoeopathic formulation (both local and oral) is selected for study of its effects in haemorrhoids and fissure patients. The patients who suffered from painful defaecation due to passing of hard stools were also treated.

TABLE - 1

Composition of 'FP-200' Local Application.			
Hamamelis virginica	∅	2.5%	V/W
Hydrastis canadensis	∅	1.5%	V/W
Aesculus hippocastanum	∅	2.5%	V/W
Ratanhia peruviana	∅	1.0%	V/W
Paeonia officinalis	∅	1.0%	V/W
Viburnum prunifolium	∅	1.5%	V/W
Paraffinum molle album q.s. To 100 gm.			

TABLE - 2

Composition of Tablet 'FP-200'	
Ratanhia peruviana	200
Hamamelis virginica	200
Aesculus hippocastanum	200
Aloe socotrina	200
In equal proportion	
Excipients q.s. To 1 tablet of 250 mg.	

MATERIAL & METHODS

Eighteen patients of both sexes and from different age groups attending OPDs and Indoor Patients in SMNH Palam, SV Hospital Mehrauli, and Phoolwat Jain Hospital were included in this study.

TABLE - 3

NO. OF PATIENTS ACCORDING TO AGE GROUP			
Age Group (Years)	Haemorrhoids	Fissures	Haem/Fissure
10-20		1	
21-30	3	2	
31-40	4	4	2
41-50	1	1	
51-60	2		

Out of 18 patients, there were 6 female patients.

Detailed history, clinical examination and other relevant observation on the patients were recorded in the proforma specially designed for the purpose. The diagnosis of piles and fissures was made by inspection, digital examination and by direct vision through proctoscope.

Piles caused by tumour of colon-rectum, ovarian tumour, enlarged prostate, inflammation of the lower bowel and rectum, were excluded from study.

The design of study was totally non-operative.

LAB INVESTIGATIONS:

- I) Complete Haemogram;
- li) Stool Examination (Routine test)

These investigations were done in the beginning and on the completion of treatment.

- I) Application of 'FP-200' ointment twice daily;
- li) 2 tabs. of 'F.P-200' three hourly daily.
- li) Sitz Bath advised daily.

Diet : Non-constipatory diet.

Duration : The total duration of treatment was maximum for one week in cases of fissures during which the patient was examined daily, and one to two weeks with biweekly examination with protoscopy in cases of piles.

Assessment of Trial Efficacy: The efficacy of trial drug was assessed on basis of the following criterion;

Changes in baseline- Signs and symptoms along with biweekly proctoscopic examination.

Results

Eighteen patients with Piles and Fissures completed the trial. Out of which twelve were having Piles and six were of fissures. Two of the patients were having piles and fissures both.

Haemorrhoids are more below 20 yrs. of age and an equally distributed in both the sexes.

The history is usually long.

Fissure in ano is a simple condition that causes considerable 'discomfort. The acute forms should be treated by conservative non surgical regimens initially.

Pregnancy and post delivery period is most vulnerable for the formation of piles and fissures.

Results of the study are shown in Tale Nos. 4 & 5.

FISSURES : (Table - 4)

Signs & Symptoms	No. of parients with a complaint on			
	0 Day	3rd Day	5th Day	7th Day
Stool with blood	6	2	0	
Stool with mucous	4	0	0	
Constipation	6	1	0	
Constant Pain	6	2	0	
Pain while passing stools	6	3	1	
Something coming out of anus	2	2	1	1
Pain on P/R examination	6	3	1	
Itching	4	1	0	

PILES (TABLE - 5)

Signs & Symptoms	No. of patients with a complaint on					
	0 Day	5th day	1 week	10th day	2nd week	3rd week
Constipation	12	6	0			
Stool with blood	12	7	2	1	0	
Something coming out of anus	6	4	2	1	1	1
Frank red bleeding	8	6	4	2	1	
Pain with passing stool	4	2	1	0		
Proctoscopic Examination :						
i) No reduction	12	8	4	3	2	1
ii) Slight reduction		4	6	5	2	1
lii) Considerable		0	2	4	6	4
iv) Marked					2	6

The results of FP-200 in piles and fissures are very encouraging as it relieves symptoms in 5-7 days in fissures and maximum upto 2 weeks in piles. There is considerable shrinkage of pile mass. Only one patient showed no reduction of pile mass. No adverse effect of FP-200 were reported by patients.

DISCUSSION

Present trial shows that the symptoms of piles and fissures like constipation, constant pain and bleeding while passing stools are relieved by 'FP-200'. Aloe socotrina, Aesculus hippocastanum, Hamamelis and Ratanhia have been described to have pain-relieving anticonstipatory and haemostatic properties which help in curing fissures and piles by reducing pain and venous congestion of the anus. Proctoscopy shows that there is considerable shrinkage of pile mass in 1st and 2nd degree piles with FP-200.

There is a marked improvement in the general health and anaemia of the patients.

In the past the treatment of haemorrhoids was predominantly conservative prior to 1800 they were treated simply by poultice, bedrest, ligation or cauterisation. All these conservative methods aim to interrupt the haemorrhoidal symptoms mainly protrusion of vascular submucosal cushion through tight anal canal. In a study of Ispghula husk, there was a significant improvement in the fibre treated groups with first and second degree haemorrhoids, but no advantage in advanced cases⁴. This study also shows that constipation is the major predisposing factor which causes descent and swelling of anal cushions, leading to prolonged congestion in rectal veins. FP-200 is found to be useful in reducing congestion thereby relieving the symptoms of pain, bleeding and size of pile mass

without any complication.

In present study, FP-200 application is quite safe in female patients during pregnancy where surgery is not advisable. Present study confirms that treatment must be aimed at symptomatic relief and correction of anatomic deformity without non excisional treatment one preferable to surgical methods. Considering the difficult nature of the disease and its treatment with such short duration though there is considerable reduction in size but with the help of diet restrictions.⁵

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