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To,
Director
Herbal Body Cure Pvt Ltd
C-278 1ST Floor, Defence Colony
Delhi.

Dear Sir,
As per your request to conduct a Clinical Trial (A Pilot Study) of Pykure Capsule, Ointment and Kabzkure Powder in the patients of haemorrhoids. A clinical trial was conducted in 22 patients of Haemorrhoids and patients were followed up for 3 months.

The clinical trial was conducted in the patients who attended the OPD of MATA ANANDMAYI HOSPITAL Varanasi. Each patient were registered and their complaints were noted in standard Performa and they asked to take PYKURE Capsule – 2Capsule twice daily and application of PYKURE Ointment before and after defecation locally. Simultaneously, KABZKURE Powder was advised to be taken 1Teaspoon full at bed time.

Follow up of these patients were done at frequent interval.

It has been observed that their symptoms like bleeding, prolapse, pain, constipation, itching is remarkably (80%) improved by this therapy.

The results were satisfactory and none of the case showed any untoward effect.

Hence I recommend that the combination therapy of Pykure Capsule & Ointment and Kabzkure Powder in first, second and early third degree of haemorrhoids cases.
Further it is suggested that the study must be considered in larger number of cases to establish the advantage of above therapy and its acceptance.

Thanks



(Prof. K.R.Sharma)
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A PILOT STUDY OF PYKURE CAPSULE, PYKURE OINTMENT & KABZKURE POWDER IN MANAGEMENT OF HEAMORRHOIDES.

INTRODUCTION:

The anal canal and the lower rectum have a lumen lined by three fibro vascular cushions. In each cushion is a venous plexus fed by arterio-venous communications. The internal haemorrhoidal plexus receives its blood supply exclusively from the terminal branches of the superior rectal artery. There are many factors that contribute to development of pathological haemorrhoidal cushions.

The alteration may be due to * Familiarity, * Environmental factors e.g. Constipation, straining during defecation, low fiber diet, obesity, sedentary life style etc. Further, it may be due to deterioration of connective supportive tissue. Symptoms vary with conditions e.g. pregnancy, repeated straining, constipation, diarrhea and changes in diet or working pattern. These situations may undergo periods of remission and relapse. The commonest symptom is bleeding after going to the toilet. This is bright red colour and is usually noticed in wiping or in the toilet bowl.

Most common cause of Anal bleeding in 54% of the cases is hemorrhoids as confirmed by Nicholls 1985. Internal hemorrhoids are usually painless, however, in grade 3 &4 hemorrhoids there is thrombosis which can form with in the haemorrhoids (it is not so common) and causes intense pain. More over, intense pain is usually associated in cases of Anal fissure, anorectal abscess etc. Prolapses occur with bowel movement and are associated with an uncomfortable sensation of fullness and incomplete evacuation. Larger haemorrhoids may cause mucus discharge, pain, irritation and itching. The discharge may irritate the skin around the anus. This result in fullness in the anus, Fully emptying bowel feeling is not felt by the patient.

Constipation can be caused by lack of exercise, inadequate fluid intake, poor diet and diet lacking in fiber. Certain drugs e.g. narcotic pain medications, iron, diuretics and certain types of antacids, antispasmodics and antidepressants may cause constipation, Irritable bowel syndrome (IBS), Multiple sclerosis, diabetes and thyroid disorders. Problem with rectum and colon including colon cancer with obstruction, anal fissures and haemorrhoids may cause constipation. Pregnancy, traveling, aged persons and life style changes may contribute to the problem of Constipation. Painful or difficult bowel movements or passing less quantities of hard and dry stool, lower abdominal pain and bloating are the common symptoms in majority of cases with constipation. An effective remedy may be required for inducing smooth bowel softening trend in constipation associated with pregnancy, post operative bed ridden patients, Haemorrhoids and fissures cases.

In Ayurvedic classics there are so many medicines useful to cure 1ST, 2nd and early 3RD degree of Haemorrhoids, Fissure and Fistula successfully with no / least side effects.

Thus it was decided to conduct A Pilot Study in 22 cases on Combination therapy of Pykure Capsule, Pykure Ointment and Kabzkure Powder. The Formulation of Pykure Capsule, Pykure Ointment and Kabzkure Powder is given below which is designed as per the Text of Ayurveda.

** PROF. K.R.Sharma , Sr.Consultant in Proctology, Mata Anand Mayi Hospital, Varanasi.
Ex- Prof. & Head, Department of Shalya, IMS.BHU. Varanasi.*

Composition:

Each Pykure Capsule contains the following ingredients:

Mesua ferrea	: 60 mg	Terminalia Chubularetus	: 75 mg
Cuminum cyminum	: 37 mg	Azadirachta indica	: 143 mg
Saraca indica	: 90 mg	Abutilan indicum	: 75 mg
Red ochere	: 37 mg	Alowas	: 173 mg
Picroohiza kurroa	: 60 mg		

Composition:

Each 1gm Pykure Ointment contains extract following ingredients:

Achillea Millefolium	: 1.50mg	Murraya Koenigi	: 1.70mg
Calenduls officinalis	: 2.00mg	Eucalyptus Koenigi	: 1.20mg
Aloe Barbadosensis	: 1.30mg	Lawsonia Inermis	: 1.30mg
Azadirachta indica	: 3.00mg	Rosmarinus officinalis	: 1.50mg
Piper langram	: 1.50mg	Lini Seminalinum	: 2.00mg
Albizzia Labbeck	: 1.20mg	Gloricosa Superba	: 1.20mg
Camphoria	: 1.50mg.	Mentha Arvensis	: 1.50mg
Curcuma longa	: 2.60mg	Petroleum Jelly (BASE)	: 75.00mg

Compositon

Each 1gm Kabz Kure Laxative Powder contains following ingredients:

Cassia Angustifolia	: 28%	Cassia Impoea Turpenthum	: 5%
Cassia fistula	: 20%	Dry Zingiber Officinale	: 5%
Rock salt	: 10%	Terminallia Chebula	: 10%
Trachy spermum ammi	: 5%	Pimpinella awism	: 5%
Terminallia Balerica	: 5%	Cumin cyminum	: 5%

Aim & Objective:

The aim of this study was to evaluate therapeutic value of Pykure Capsule, Pykure Ointment and Kabzkure Powder in the patients of Ano-rectal disorders. Present study was undertaken for 22 cases of Haemorrhoids.

Material & Method:

22 Patients of Haemorrhoidal disorder were registered for management of the particular condition with Pykure Capsule, Pykure Ointment and Kabzkure Powder.

Out of 22 patients, 20 cases completed the full treatment schedule i.e. 90 days while remaining 2 cases left the treatment. However, clinical pattern was studied in all 22 cases for incidence of age, sex, occupation, economical status, educational status, social status and symptoms of piles disorders.

Selection of cases:

All patients selected for study were interrogated and detailed history was recorded on prescribed case history sheet. All patients were thoroughly examined and findings were also recorded for establishing the final diagnosis. Routine examination of blood etc were also done, in addition to the observation of subjective features, clinically.

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

Method of Drug Administration:

The Drug Pykure Capsule was administered orally 2 Capsule twice daily after meal for 60 days and Then,1 Capsule twice daily after meal for 30 days.

Pykure Ointment: suggested to apply before and after passing stool with the help of Nozzle or by finger tips.

Kabxkure Powder : 1 or 2 Teaspoonful with normal or lukewarm water at bed time.

Follow up:

Each case was followed up at the interval of 15 days for 90 days.

Clinical Pattern:

Present study consists of total 22 registered cases, out of which 2 cases did not complete full course of treatment. So clinical pattern will be discussed on 22 cases, however, results will be analyzed on observations of findings of 20 cases.

Age Incidence:

Patients of present study were from 20 to 60 years of age. Details are presented in Table. 1.

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

Sr.No	Age Group (In Years)	Number of Patients	Percentage
1	20 – 35 Years	7	31.8%
2	36 – 50 Years	7	31.8%
3	51 and above	8	36.4%
	Total	22	100.00%

Sex Incidence:

Patients of both sexes were registered for present study. The sex group is given in Table No: 2

Table No: 2: Showing the incidence of sex:

Sr.No	Sex	Number of Patients	Percentage
1	Male	15	68.2%
2	Female	7	31.8%
	Total	22	100.00%

Occupational Incidence:

In present study the patients belonging to various occupations were included and shown in Tab.No.: 3

Table No: 3 showing the breakup of Piles in patients of different Occupation:

Sr.No	Occupation	Number of Patients	Percentage
1	Service	7	31.8%
2	Housewife	5	22.7%
3	Businessman	4	18.1%
4	Student	2	9.1%
5	Cultivator	2	9.1%
6	Retired	2	9.1%
	Total	22	100.00%

Educational Status:

When educational status shows patients of both literate and illiterate group were found in the study as given in Table No: 4

Table No: 4: showing the incidence of Educational status:

Sr.No	Educational Status	Number of Patients	Percentage
1	Illiterate	8	36.3%
2	Primary education	6	27.4%
3	Higher Secondary	4	18.2%
4	Graduate	3	13.6%
5	Post- Graduate	1	4.5%
	Total	22	100.00%

Rural and Urban incidence:

This study includes the patients from Rural & Urban area as shown in Table No: 5

Table No: 5: Showing the incidence of Rural and Urban status:

Sr.No	Rural and Urban	Number of Patients	Percentage
1	Rural	14	63.6%
2	Urban	8	36.4%
	Total	22	100.00%

Incidence of Diet Habits:

Patients included in the present study were found to have both types of diet habits (Veg. & Non-Veg.) which are presented in Table No: 6

Table No: 6 showing distribution according to Diet Habits.

Sr.No	Diet Habits	Number of Patients	Percentage
1	Non-Vegetarian	10	45.4%
2	Vegetarian	12	54.6%
	Total	22	100.00%

Incidence of Marital Status:

In this study married and unmarried both patients are included and details are shown in Table No: 7

Table No: 7: Showing the incidence of Marital Status

Sr.No	Marital Status	Number of Patients	Percentage
1	Unmarried	4	18.2%
2	Married	18	81.8%
	Total	22	100.00%

Incidence of Nature of Work:

In this trial Nature of Work has been presented In Table No: 8

Table No: 8 showing the Nature of work in 22 patients of Haemorrhoids.

Sr.No	Nature of Work	Number of Patients	Percentage
1	Sedentary	10	45.5%
2	Moderate	8	36.3%
3	Hard worker	4	18.2%
	Total	22	100.00%

Incidence of Internal and External Haemorrhoids:

Patients included in this study had both types of hemorrhoids which are presented in Table No: 9

Table No: 9: Showing the incidence of Type of Haemorrhoides.

Sr.No	Type of Hemorrhoids	Number of Patients	Percentage
1	Internal Haemorrhoides	11	50.0%
2	External Haemorrhoides	6	27.3%
3	Both	5	22.7%
	Total	22	100.00%

Other Types of Ano-rectal Disorders:

Patients included in this study found to have different types of ano-rectal disorders as presented in Table No: 10.

Table No: 10: Showing the different associated Ano-rectal Disorders in 22 patients of Haemorrhoids:

Sr.No	Type of Anorectal disorders	Number of Patients
1	Haemorrhoides	11
2	Fistula in ano	2
3	Fissure in ano	7
4	Fistula c Fissure	2

Results and Observation:

In this study 22 patients of haemorrhoids were included, out of which 2 patients discontinued and 20 cases had completed the treatment schedule of 90 days. Patients were observed in terms of subjective criteria before treatment, during treatment and after treatment.

The response of treatment on subjective criteria and observed before and after treatment as presented in Table No: 11.

Table No: 11: Showing the response of treatment on subjective features of Ano-rectal disorders.

Sr.No	Symptoms	No. of Patients Before treatment	No. of Patients After treatment			Percentage
			After 1 Month	After 2 Month	After 3 Month	
1	Pain	15	15	10	nil	100%
2	Bleeding	19	07	08	off & on 04	78%
3	PruritusAnii	02	02	nil	nil	100%
4	Prolapse Pile mass	05	03	02	02	40%
5	Constipation	20	11	05	04	81.8%
6	Mucous discharge	08	02	04	02	75%

It is revealed from above table that more than 80% of relief was observed in symptoms like pain in rectum, rectal pruritus and constipation. More than 65% of relief was observed in symptoms like rectal bleeding, rectal prolapse and itching.

Conclusion:

The drug Pykure capsule, Pykure Ointment has been found to be an effective drug in anorectal disorders. The result in the trial group has shown encouraging results after 6 weeks of treatment. After 90 days of treatment along with the improvements of the subjective criteria's significant response was also noticed. The active bleeding was found to be absolutely control by 8 weeks in 79% of the cases while 21% cases continued bleeding off and on and the size of pile mass was found to be reduced.

The Drug Kabz Kure Powder has been found to be an effective drug for correcting the constipation. There were 80% of the patients noticed for better response in constipation and resulting in reduction of pile mass.

Hence Pykure Capsule, Pykure Ointment and Kabzkure Powder can safely be recommended in bleeding / non bleeding haemorrhoids.

ACKNOWLEDGEMENT:

We are thankful to Herbal Body Care organization (Chhatwal Pharmaceuticals) for arranging the trial drug and necessary support for conducting the study. We are thankful to Mr.A.S.Pandey for his co-operation in the present study. With the results we feel study in larger subjects with long term follow up will be if presented with additional advantage of this combination in patients suffering from various degrees of Haemorrhoids, will be more authentic and paper may be presented in any Anorectal disease conference.