PARIPEX - INDIAN JOURNAL OF RESEARCH | Volume - 12 | Issue - 05 | May - 2023 | PRINT ISSN No. 2250 - 1991 | DOI : 10.36106/paripex

ORIGINAL RESEARCH PAPER

THE EFFECT OF KAIDARYADI GULIKA IN DIARRHEA DOMINANT IRRITABLE BOWEL SYNDROME

KEY WORDS: Irritable bowel syndrome, Kaidaryadi gulika, Rome III criteria ,Grahani

Ayurveda

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Irritable bowel syndrome is one of the most common functional gastrointestinal disorder. It has 3 major subtypes based on the predominant symptom. Patients with diarrhea-predominant IBS (IBS-D) comprise a substantial proportion of the overall IBS population. Across the IBS subtypes, the presentation of symptoms may vary among patients and change over time. There is no structural impairment and the pathophysiology is not well understood. IBS can significantly impact patient function and quality of life. It can be diagnosed easily with Rome criteria after a careful history and examination without extensive diagnostic tests. There is currently no treatment that cures IBS, the treatments are often symptom specific. In ayurveda classics there is no single equivalent to IBS, but the symptoms are more similar to grahani roga. The study drug Kaidaryadi gulika contains five drugs, of which kaidarya, deepyaka, ambhoda, samanga, athivisha are having antidiarrheal effect which is proven scientifically. Athivisha and deepyaka has analgesic properties. All the drugs are deepana and pachana also. Twenty four consecutive cases eligible and willing for the study were selected from OP and IP section of Department of Kayachikitsa, Government Ayurveda College, Thiruvananthapuram as per inclusion and exclusion criteria. After collecting the base line data, the patients were subjected to thorough physical examination and primary laboratory investigations. Study was conducted in a single group and study design was quasi-experimental study, one group pre and post-test design. The trial drug Kaidaryadi gulika was given to the study subject for a period of l month. Dose of the drug was 2 tablets thrice daily before food, with luke warm water. Periodic evaluation was conducted on 0th, 30th and 60th day. Changes in symptoms were assessed after treatment and after follow up. Statistical analysis revealed significant reduction in all symptoms except mucus with stool with a p value<0.001

INTRODUCTION

ABSTRACT

Irritable bowel syndrome is a functional bowel disorder in which abdominal pain or discomfort is associated with defecation or a change in bowel habit, and with features of abnormal defecation¹. This occurs in the absence of organic disease. It is the most common functional bowel disorder, with a prevalence in the range 5-25% and accounts for 36% of all visits to gastroenterologists². According to World Gastroenterology Organisation it is prevalent in 7.5% of the population in India. Women are affected more than men globally. However studies conducted in India have reported a higher male or equal gender prevalence of IBS. IBS severely impairs the quality of life . the inability to predict symptoms places significant burden on daily living. IBS limits productivity and performance at work, has a negative effect on the quality of relationships and limits participation in the routine social activity. The chronic nature of the condition carries a psychological burden. Abnormal psychiatric features are recorded in up to 80% of patients with IBS. No single psychiatric diagnosis predominates. The lifetime incidences for major depression, somatization disorder, generalised anxiety disorder, panic disorder, and phobias are higher in patients with IBS than in healthy controls.

In Ayurveda, there is no direct reference of a single disease entity that can be directly correlated with the IBS, but the symptoms are more similar to Grahani roga. The major etiological components include factors causing vitiation of jataragni²(pachaka pitha), samana vayu, apana vayu, and pureesha vaha srotas. The derangement of jataragni will lead to diseases of abhyantara rogamarga. The samprapthi and samprapthi vighatana of annavaha srotas largely depend on the pathological states of agni¹. While explaining the ajeerna lakshanas Acharya Charaka has mentioned both vibandha and atisara⁵ and this concept is largely applicable to IBS.

Objective

To evaluate the effect of Kaidaryadi gulika in reducing the

signs and symptoms of diarrhoea dominant irritable bowel syndrome.

METHODOLOGY

Study design

Interventional study -pre and post study without control group

Study setting

OPD & IPD of Department of Kayachikitsa, Govt. Ayurveda college, Thiruvananthapuram.

Study population

Patients having the symptoms of IBS with Diarrhea predominance satisfying Rome 3 criteria, of age group 20-60 years of both sexes attending the study setting.

Inclusion criteria

- IBS with diarrhoea predominance satisfying Rome 3 criteria⁶
- Age between 20-60 years

Exclusion criteria

- Diagnosed cases of haemorrhoids.
- $\bullet \quad {Patients\,with\,bleeding\,per\,rectum}.$

Sample size

24 cases

Sampling technique

Consecutive cases satisfying inclusion and exclusion criteria till attaining sample size

Data collection

Data was collected through clinical research proforma and laboratory investigations.

Study tools

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- Clinical research proforma
- Visual analogue scale for pain and abdominal distension
- Bristol stool form scale

PREPARATION OF MEDICINE

The study drug Kaidaryadi gulika is mentioned in Athisara chikitsa adikara in Arogyakalpadrumam⁷. It consists of 5 drugs.They are

- 1.Kaidarya
- 2.Samanga
- 3.Ambhoda
- 4.Deepyaka
- 5. Athivisha

Method of preparation

Ativisha is purified by dola yantra sweadana for 3 hours in cow dung juice. Then it is washed in water and is dried well in sun light. All the five drugs will be mixed in equal quantity ground well in deepyaka kashaya and rolled in to pills of 1.3 g each.

Dose of the drug

2 Kaidaryadi gulika thrice daily half an hour before food with luke warm water as anupana for a period of 30 days.

Procedure

Patients as per the inclusion criteria was selected from the study setting as per Rome 3 criteria. Detailed clinical evaluation was done and they were explained about the study. Then written consent was obtained from them. The selected patients were given Kaidaryadi gulika for 30 days as explained above with specific dietary advices. Periodical evaluation will be conducted on day 0, day 31, and day 60 from the starting of the study. Changes were recorded. The result obtained was statistically analyzed.

OUTCOME VARIABLE

a) Change in abdominal pain or discomfort – was assessed using Visual Analogue Scale method.

b) Change in frequency of stools – the frequency of stool per day was taken for assessment.

c) Change in consistency of stools – was assessed using Bristol stool form chart.

d) Change in feeling of incomplete evacuation –change in presence of incomplete evacuation per day was assessed.

e) Change in presence of mucus in stools – was assessed subjectively per day.

f) Change in abdominal distension – was measured with a measuring tape at the level of umbilicus.

ASSESSMENT

DATA RELATED TO RESPONSE TO TREATMENT

The data related to various symptoms before treatment (BT), after treatment (AT) and after follow-up (FU) period were collected from patients and statistically analyzed using paired sample Wilicoxon signed rank test. The details of the analysis is given in the following sections.

a. Effect of Kaidaryadi gulika on the severity of abdominal pain/discomfort:

Table (1): Effect of Kaidaryadi gulika on the severity of abdominal pain/discomfort

Abdominal pain or	Ν	Median	Inter quartile range		
discomfort			25th	75th	
			percentile	percentile	
вт	24	5	5	7.8	
AT	24	3	2	5	
AF	24	3	2	5	
Paired compa	arison	Wilco	Wilcoxon signed rank test		
		Z		Р	
BT-AT	4.322		<0.001		

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AT-AF	1.857	0.063						
BT-AF	4.244	< 0.001						





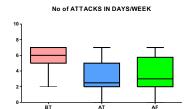
a. Effect of Kaidaryadi gulika on number of attacks in days/week

The statistical analysis of data related to the effect of Kaidaryadi gulika on number of attacks in days/week is as given in table (2)

Table (2): Effect of Kaidaryadi gulika on number of attacks in days/week

FREQUENCY OF STOOLS	Ν	Median	Inter quarti 25th percentile		le range
OF STOOLS					75th percentile
BT	24	5.0	4.0		6.0
AT	24	2.0	2.0		3.0
AF	24	3.0	2.0		4.0
Paired compar	rison	Wilcoxon signed rank test			test
		z		Р	
BT-AT		3.852		<0.001	
AT-AF		2.81		0.005	
BT-AF		3.64		<0.001	

Graph(2)



a. Effect of Kaidaryadi gulika on frequency of stools/day

Table (3): Effect of Kaidaryadi gulika on frequency of stools/day

z	Ν	Median	Inter quartile range		
STOOLS			25th		75th
			percentile)	percentile
BT	24	5.0	4.0		6.0
AT	24	2.0	2.0		3.0
AF	24	3.0	2.0		4.0
Paired compariso	on	Wilcoxon signed rank test			test
		z P		Ρ	
BT-AT		4.335		<(0.001
AT-AF		2.877	7 0		004
BT-AF		4.154		<(0.001
-					

Graph(3)



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 $d.\,Effect\,of\,Kaidaryadi\,gulika\,on\,consistency\,of\,stools.$

Table (4): Effect of Kaidaryadi gulika on the consistency of stools

CONSISTENCY OF STOOLS	N			Inter quartile range		
				25th percentile		75th percentile
BT	24	6.0		5.0		6.0
AT	24	4.0		4.0		4.8
AF	24	4.0		4.0		5.0
Paired comparison				Wilcoxon signed rank test		
			z		Ρ	
BT-AT			4.005		<0	.001
AT-AF		1.	.732 0.0		83	
BT-AF		4.		.028	<0	.001
Graph (4)						

Graph (4)



e. Effect of Kaidaryadi gulika on feeling of incomplete evacuation

Table (5): Effect of Kaidaryadi gulika on incomplete evacuation

INCOMPLETE EVACUATION	Ν	Median		Inter quartile	e range	
				25th percentile	75th percentile	
ВТ	24	4.5		0.0	7.0	
AT	24	0.	0	0.0	3.0	
AF	24	0.0		0.0	3.8	
Paired compar		Wilcoxon signed rank test				
			z P		P	
BT-AT			3.241 0.001			

Graph (5)

AT-AF

BT-AF

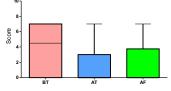
INCOMPLETE EVACUATION

1.732

3.225

0.083

0.001



f. Effect of Kaidaryadi gulika on mucus in stool:

Table (6): Effect of Kaidaryadi gulika on mucus in stools

MUCUS IN	Ν	Median	Inter quartile ra	ange				
STOOLS			25th percentile	75th percentile				
вт	24	0.0	0.0	0.0				
AT	24	0.0	0.0	0.0				
AF	24	0.0	0.0	0.0				
Paired con	Paired comparison Wilcoxon signed rank test							
			Z	Р				
BT-AT		1	0.317					
AT-AF		0	1.000					

BT-AF	1	0.317
From the table Wilicove	n signod rank tos	t showed that there

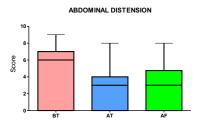
From the table, Wilicoxon signed rank test showed that there is no significant reduction in the presence of mucus from before treatment to after treatment (p>0.05) and also no significant reduction in the presence of mucus while comparing before treatment and after follow up (p>0.05) and no significant change between after treatment and after follow up scores (p>0.05).

g. Effect of Kaidaryadi gulika on abdominal distension:

Table (7): Effect of Kaidaryadi gulika on abdominal distension

ABDOMINAL	N	Μ	ledian	Inter quartile range		
DISTENSION			25th percentile		e	75th percentile
ВТ	24	6.	.0	0.0		7.0
AT	24	3.	.0	0.0		4.0
AF	24	3.	8.0 0.0			4.8
Paired compar	ison	ľ	Wilcoxon signed rank test			nk test
			Z		Р	
BT-AT			3.592		<0	.001
AT-AF			1.414		0.157	
BT-AF			3.558		<0.001	

Graph(6)



DISCUSSION

Most of the symptom presentations in samgraha grahani as explained in Madhavanidana like watery stools, day time aggravation and no night symptoms could be seen in the patients⁸. Second disorder to be considered is bhayathisara⁹ which is vata pitha dominant On analyzing doshas, symptoms of vatika and pithaja grahani and kaphaja atisara could be seen in patients. Incomplete evacuation was an invariable presentation which has been included in kaphaja atisara lakshanas¹⁰. Hence diarrhea dominant irritable bowel syndrome can be considered in lines of sannipatha grahani with vata pitta predominance ie. vata pittadhika sannipataja grahani.

The statistical analysis of the assessment variables showed that there is significant improvement in the symptoms like abdominal pain/discomfort, frequency of stools, consistency of stools, feeling of incomplete evacuation and abdominal distension showed highly significant response. The study drug created massive response in patients with chronicity less than 3 years but did not show much result in patients with chronicity of greater than 5 years. There is no significant changes in values of after treatment – after follow up assessment.

PROBABLE MODE OF ACTION OF DRUG

The study drug is an excellent and unique combination of deepana, pachana and grahi drugs. All of them are katu in vipaka. Grahani being the sthana of agni¹¹ is also hampered in the disease. So the drugs with katu vipaka, ushna veerya, deepana and pachana properties have helped in attaining the samyavastha of agni.

The impairment of apana vayu is important in the pathology of the disease. Hence vatanulomana should be one of the

principle in the treatment. Here no drugs are having anulomana properties. But the anupana given is hot water which is anulomana. This might have helped to reduce the symptoms of abdominal distension.

Also the dosha samanatwa of the synergestic action of all the drugs in the gulika is sannipata dosha samana. Hence it has been found effective in vatapittadhika sannipataja grahani.

Therefore the study drug, Kaidaryadi gulika can be used safely as a drug of choice for Diarrhea dominant Irritable bowel syndrome as most of the signs and symptoms of the disease reduced.

CONCLUSION

After the study it can be concluded that: IBS is a disease which affects all age groups of both sexes with a male predominance. Stress factors in life had an association with the disease because the complaints aggravated on stress. There was aggravation of symptoms on intake of any food. Defecation gave relief to symptoms. The drug was very effective in cases with less years of chronicity. The study drug was effective in reducing almost all symptoms and signs except presence of mucus with stool. The complaint of heart burn persisted in patients and hence the drug may be administered with a better anupana for even more better results. Kaidaryadi gulika is an effective drug in the management of IBS-D and easy to use and carry but it is not much palatable due to its bitter taste. Hence may be administered in capsules for easy intake. The patients if given psychological interventions as counseling or meditation, yoga etc. would yield better and long standing results.

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