

## Standardization and Clinical effectiveness of monotherapy with *Kutaj Parpati* on *Grahani roga*- A pilot case series

V. K. Kasle<sup>1</sup>, Manjiri Ranade<sup>2</sup>

<sup>1</sup>Department of shalyatantra Government Ayurvedic College, Osmanabad

<sup>2</sup>Department of Rasa shastra and BK, Sri Sai Ayurvedic Medical College, Aligarh

**Corresponding Author:**

**Manjiri Ranade**

E-mail : dr.maanjiri@yahoo.co.in

### Abstract :

Irritable bowel syndrome (IBS) is a functional gastrointestinal condition characterised by stomach pain, discomfort, and changes in bowel patterns in absence of organic disorder. *Grahani roga* is mentioned in classical ayurvedic texts which can be correlated with IBS. The current study seeks to prepare and standardise *Kutaj parpati*, as well as conduct a pilot study to evaluate its efficacy in *Grahani roga* (IBS) patients. Assessment of the influence of *kutaj parpati* on patient-related attributes is challenging because to non-standardized methods of preparation, and this study intends to address this gap.

### Materials and Methods:

The *kutaj parpati* was prepared in Rasa shashtra and Bhaishajya kalpana department of ayurvedic Medical college. The standardization was done according to ancient *ayurvedic* parameters. The total loss during preparation of *kutaj parpati* was 12 grams. The reasons for loss might be ignition leading to oxidation. The same *kutaj parpati* was used in *Grahani roga* (Irritable bowel syndrome) patients who satisfied inclusion criteria. The symptoms of the patients were assessed on a numeric rating scale and the changes in parameters were noted and analysed.

### Results :

The physiochemical characteristics of *kutaj parpati* were noted and it as it was brownish black in colour and passed all ayurvedic tests for standardization mentioned in classical texts. Total 4 patients participated in study, who took *kutaj parpati* as a monotherapy. Base line symptomatology of the patient ranged from NRS of 6 to 7 and it reduced to 4 to 5 after 3 months of continuous monotherapy of *kutaj parpati*. All parameters observed showed reduction in symptom severity after *kutaj parpati* monotherapy.

### Conclusion:

Ayurvedic principles were followed in the manufacturing of *kutaj parpati*, including raw material standardisation, process standardisation, and final product standardisation. The same *Kutaj parpati* was administered on *grahani roga* patients which was shown to be favourable in terms of the metrics investigated. To corroborate the findings, more research with a larger sample size is required.

**Keywords:** *Kutaj Parpati*, *Grahani Roga*, Standardization,

### Introduction:

Irritable bowel syndrome (IBS) is a functional gastrointestinal condition characterised by stomach pain, discomfort, and changes in bowel patterns in absence of organic disorder<sup>[1]</sup>. Therapeutic approaches in modern medicine are more essentially preventive, lifestyle modification, and symptomatic therapy<sup>[2]</sup>. *Grahani roga* is mentioned in classical ayurvedic texts which can be correlated with IBS<sup>[3]</sup>. Because of its holistic approach, *Ayurveda* may provide therapy, and some of the therapies have been proven to be helpful, but not through the lens of current medical statistical methods. *Kutaj parpati*, a therapy that has repeatedly proven effective since ancient times, is referenced in various ancient books, and some of its benefits have been found using contemporary methods.<sup>[4]</sup>

Mercury and Sulphur are combined in *Parpati*, a thin flake-like preparation. *Parpati* is a type of preparation that is made

using a variety of specific processing procedures. It is thought that when Mercury is combined with Sulphur, it loses its flaws and poisonous nature and transforms into a black, lustrous powder, known as *Murchana*. When mercury is transformed into *murchhita*, it acquires a variety of medicinal properties. These medicinal properties can be enhanced by the use of additional materials such as gold, silver, copper, iron, other metal *bhasmas* as well as combination with herbs. *Agni samskara* is the result of the inclusion of various ingredients and the heating process is responsible for producing numerous medicinal characteristics.<sup>[5]</sup>

The current study seeks to prepare and standardise *Kutaj parpati*, as well as conduct a pilot study to evaluate its efficacy in *Grahani* (Irritable bowel syndrome). Assessment of the influence of *kutaj parpati* on patient-related attributes is challenging because to non-standardized methods of preparation, and this study intends to address this gap as same is intended to use on patients.

Materials and Methods:

### Preparation of *Kutaj parpati*:

The ingredients used for preparation of *kutaj parpati* were *Shodhit parada*, *Shodhit gandhaka*, *Kutaja twak churna* and *Ghrita*.

The raw material is procured from Rasa Shastra and Bhaishajya kalpana department of Government Ayurvedic College, Osmanabad and Shodhan process of *parada* and *gandhaka* was done. *Kutaj twak churna* was procured from local market and identified and standardized in *dravayaguna* department on the basis of morphological characteristics of the plant. The quantity used was *Shodhit Parada* 100 gm, *shodhit Gandhaka* 100 gm, *Kutaja twak churna* 100 gm and *Ghrita* QS<sup>(67)</sup>.

### Process of Preparation of *kutaj parpati*:

*Shodhit parada* and *gandhaka* were used to make *Kajjali*. *Kajjali* and *kutaj twak churna* are placed in an iron ladle greased with a little ghee and heated over a low heat until the *kajjali* melts, the temperature was maintained around 125 degree celcius, the contents were mixed periodically. After about 5 minutes, the mixture transformed into a shiny black colour semisolid form, with fumes pouring out of it. This was poured over a *kutaj* leaf put over a uniform fresh cow dung cake, which is then covered with another *kutaj* leaf and gently pressed with a *pottali* containing cow dung cake. After cooling, the mixture developed in the shape of a solidified flake, which is *kutaj parpati*. It was pounded into a powder form and stored in an airtight container. The method is as described in Table 1. This *kutaj parpati* such prepared was standardised according to *ayurvedic* standards and the results were recorded.<sup>(7)</sup>

Different parameters for standardization of *kutaj parpati*-

**Table 1: preparation of kajjali**

Ingredients	Initial weight(gm)	<i>Kajjali</i> (gm)	Loss (gm)
<i>Shodhit Parada+shodhit gandhaka</i>	100+100	197	3

Initial weight of *shodhit parada* and *shodhit gandhaka* was 200 grams in total, while 197 grams of *kajjali* was prepared. There was a loss of 3 grams in this process

**Table 2: Preparation of *Kutaj parpati***

Ingredients	Initial weight(gm)	<i>Kutaj parpati</i> (gm)	Loss (gm)
<i>Kajjali+kutaj twak churna+ghrita</i>	197 +100 +2	287	12

The Initial weight and final weight after preparation is as mentioned in Table 2. The loss during preparation was 12 grams. The reasons for loss might be ignition leading to oxidation.

**Table 3: organoleptic and physical properties of *kutaj parpati* for standardization**

Name of parameter		Results
Organoleptic characters	Appearance	Brownish black powder
	Odour	Odour of so 2 on grinding
	Taste	Tasteless
Classical characters	<i>Nirdhoomatwa</i>	Brownish, yellow blackish sublimate at the top of tube, smell like sulphur, taste-positive
	<i>Jwala pariksha</i>	Burns in open air with violet flame
	<i>Varitaratwa</i>	Floats on water

The prepared *kutaj parpati* was brownish black in color, and was tasteless. All ayurvedic standard tests for *parpati* was passed as mentioned in Table 3

### Clinical assessment of efficacy of *kutaj parpati*:

Participants were enrolled from the outpatient department of the Govt. *Ayurvedic* College's *Shalyatantra* department. The patients who were diagnosed with *Grahani roga* and met with following inclusion criteria were enrolled. Patients with *grahani* symptoms and in age group of 18 to 75 years initially diagnosed with ROME 3 criteria, consenting for primary ayurvedic treatment. The exclusion criteria were patients who did not wish to stop other modalities of treatment or having alarming symptoms (significant weight loss, gastrointestinal surgery, co morbid conditions like diabetes, hypertension and other endocrine abnormalities, and females who are expecting child birth.)

Participants' demographic details were recorded at the commencement of the study. On a numeric rating range of 1-10, the patient scored the intensity of stomach discomfort, frequency of abdominal discomfort, severity of abdominal bloating, interference with daily activities, and satisfaction with bowel habits.

The enrolled patients were given *kutaj parpati* prepared by above method.

Dose of medication: the patients received *kutaj parpati* in dose of 250 mg thrice a day for 3 months in the form of powder.

Dietary advice: A good nutritional advice was given because dietary advice plays such a significant role in this condition. Junk foods, foods that induce allergies and foods that are difficult to digest were instructed to avoid during the preparation and consumption of unhygienic food items, they were advised to avoid Abhojanat, Ajeernabhojanat, Attibhojanaat, Visamasanat, Asatmya, and Sandusta Bhojanat. The adoption of diets with a well-balanced nutritional content was requested.

Primary end point: The primary end point was a change in the severity of irritable bowel syndrome symptoms. Adverse drug responses to the trial medication were the secondary end point. The study was conducted over a period of three months.

Observations and results:

As it is a pilot study, total 4 participants consented for the study. The demographic data of participants is as presented in Table 4. All patients were young, literate and in mid socio economic range according to kuppuswamy classification.

**Table 4. Demographic characteristics of participants**

Variable	
Age	
Patient 1	22 years ( Male)
Patient 2	32 years (Male)
Patient 3	43 years( Female)
Patient 4	56 years (male)
Literacy status	All were literate more than higher secondary school
Socio economic status	All patients were in mid socio economic status (kuppuswamy)

**Table 5 : Baseline symptom severity according to NRS pre and post treatment at the end of 3 months**

IBS NRS	Pre treatment NRS	Post treatment NRS
Abdominal pain Severity (0-10)		
	P1 7	6
	P2 8	7
	P3 7	5
	P4 6	5
Abdominal pain Frequency(0-10)		
	P1 8	7
	P2 9	8
	P3 8	6
	P4 7	6
Abdominal bloating severity(0-10)		
	P1 6	5
	P2 7	6
	P3 7	6
	P4 7	5

Interference with daily activities	P1 6	5
	P2 6	6
	P3 5	5
	P4 7	6
Satisfaction with bowel habits(0-10)	P1 5	5
	P2 4	4
	P3 5	6
	P4 6	5

P1-patient 1, P2- patient 2, P3- patient 3,P4-patient 4

There was a change in the symptom profile of *Grahani roga*(Irritable bowel syndrome )during a three-month period, as seen in Table 5. Most metrics have decreased by at least one scale on a neumeric rating scale, while bowel habits have improved in individuals treated with *Kutaj parpati*.

Discussion: *Kutaj* is derived from the Sanskrit term *Kutaj*, which signifies growth in mountainous or steep areas. The term *kutaj* is given to the plant because it thrives in mountainous locations<sup>9</sup>. The tree is thorny and grows in the wild. The therapeutic benefit of the *kutaj* plant may be found in all sections of the plant. *Kutaj* contains the properties of *pachana* (digestion) and *deepana* (appetiser), hence it aids digestion. It contains *grahi guna*(absorbent property of drug), which aids in the management of loose watery stools and the treatment of diarrhoea and dysentery. Some of the alkaloids found in *kutaj* have astringent qualities and have antibacterial and antisecretory activities<sup>10</sup>.

*Grahani roga* is a condition in which Agni, the digestive power, is blamed; when Agni is depressed, *Ama Dosha* (undigested waste material) builds up and travels via the stool. Due to vitiation of *Pachakagni*, *Saman Vayu*, and *Kledaka Kapha*, *Grahani roga* is a *Tridoshatmaka* digestive system illness. It is associated with symptoms such as *Muhurbaddha-Muhurdrava Malapravritti* (huge amounts of solid or liquid faeces, i.e. *Pakwa* or *Apakwa Avastha*), *Udarshoola* (abdominal pain), *Antrakujan*(gurgling sound in abdomens), *Arochaka*(loss of taste), *Klama*(fatigue), and others. The treatment's goal is to increase *Agni*'s power, which will reduce the development of *Ama*.<sup>10</sup>

*Parpati kalp/Kalpana* is that type of form of medicine which is consist of *Parad* and *Gandhak* along with other herbs. The *parpati* which contains Sulphur is called *Sagandha* and *parpati* which does not contains Sulphur / *Gandhak* is called *Nirgandh* type of *parpati* . *Parpati* is *Agnisthayi murchita Parad Bandha*, where *kajjali* is the base material which is *Guru* (heavy)in nature.After *agni samakar*(explosure to heat)

it attains *laghuta and shape like a flake*, hence name as Parpati, which indicate lightness. Because of this property it is useful in most of the disorder from paediatric to geriatric. In *kutaj parpati*, *kutaj twak churna* is used as herbal ingredient along with *parada* and *gandhaka*. Incorporation of specific herb in particular *parpati* further enhances the therapeutic properties mentioned in texts. As *parpati kalpana* in mentioned in *grahani roga*, incorporation of *kutaj* herb having *grahi*, *deepan* and *pachana* property will help to reduce the disorder more effectively as *Kutaj* has *Tikta & Kashaya Rasa*, *Sheeta Veerya*, *Katu Vipaka* and *Deepan*, *Stamabhan*, *Pittakapha Shamaka* properties. According to *Charak Kutaj* is considered as best (*Agraya Dravya*) in *Sangraahik* and *Upshoshan Dravya*.<sup>[12,13]</sup>

There are limited studies on this topic, with only a few case reports and case series<sup>[12,13]</sup>. The production of *kutaj parpati* is also not standardised, therefore most research are inconclusive since the substance and dose of *kutaj* are unknown. There is a disconnect between standardised *kutaj parpati* preparation and patient use of the same *kutaj parpati*. The investigations are either standardisation or non-standardized usage of *Kutaj* in patients. So, in this pilot trial, *kutaj parpati* is prepared at the *Rasa shastra* department and the same is utilised on the patients. The subjects willingly ceased using contemporary medication, reducing the bias of utilising concurrent treatment modalities.

In this study, the discrepancy between the patient's pretreatment NRS and several study parameters is demonstrated. Because just four patients took part in the study, statistical analysis was not possible. The results reveal a difference of 1 to 2 on a scale of 1 to 2 in various symptomatology. The findings suggest that *kutaj parpati* may be used for therapeutic purposes, that it has a positive effect on *Grahani roga* (IBS), and that it has no negative side effects, as revealed by our research.

#### Limitation of study:

Because this is a single-centre study with a small sample size, future research should focus on a multicenter study with a large sample size and long-term patient follow-up. Any delay in the reappearance of symptoms following the aforesaid therapy should also be investigated. Since this sample size is less, generalising the findings is challenging. Due to a lack of resources, *Kutaj parpati* was not studied using current modern characteristics such as x-ray diffraction.

#### Conclusion:

Ayurvedic principles were followed in the manufacturing of *kutaj parpati*, including raw material standardisation,

process standardisation, and final product standardisation. The same *Kutaj parpati* was administered on *grahani roga* patients which has shown to be favourable in terms of the metrics investigated. To corroborate the findings, more research with a larger sample size is required.

#### References:

1. Saha L. Irritable bowel syndrome: pathogenesis, diagnosis, treatment, and evidence-based medicine. *World J Gastroenterol*. 2014 Jun 14;20(22):6759-73. doi: 10.3748/wjg.v20.i22.6759. PMID: 24944467; PMCID: PMC4051916.
2. Masuy I, Pannemans J, Tack J. Irritable bowel syndrome: diagnosis and management. *Minerva Gastroenterol Dietol*. 2020 Jun;66(2):136-150. doi: 10.23736/S1121-421X.19.02640-0. Epub 2019 Dec 9. PMID: 31820883.
3. Shete AS, Nakel MP. An Observational Study of *Grahani Roga* as a Lifestyle Disease and its Hetus with Special Reference to Role of Agni. *IJ-RIM [Internet]*. 2019 Sep. 14 [cited 2022 Feb. 8];3(04).
4. Patel MV, Patel KB, Gupta SN. Effects of Ayurvedic treatment on forty-three patients of ulcerative colitis. *Ayu*. 2010 Oct;31(4):478-81. doi: 10.4103/0974-8520.82046. PMID: 22048543; PMCID: PMC3202252.
5. Rakheja Shefali, Bajaj N, K Thakur S. A REVIEW OF PARPATI KALPANA W.S.R. TO RASA PARPATI. *Int J Ayu Pharm Res [Internet]*. 2018 Oct. 28 [cited 2022 Feb. 8];6(9). Available from: <https://ijapr.in/index.php/ijapr/article/view/1048>
6. Chikitsa Pradeep – Vaidya Vasker Biswanath Gikhale 1st Edition 1954
7. Mohammad Yaseen Hullur, Prashanth AS, Anjaikannan CR. A Clinical Study on Pravahika through Vasti and Kutaja Parpati. *J Ayurveda Integr Med Sci* 2017;6:11-20. <http://dx.doi.org/10.21760/jaims.v2i06.10921>
8. Jamadagni PS, Pawar SD, Jamadagni SB, Chougule S, Gaidhani SN, Murthy SN. Review of *Holarrhena antidysenterica* (L.) Wall. ex A. DC.: Pharmacognostic, Pharmacological, and Toxicological Perspective. *Pharmacogn Rev*. 2017 Jul-Dec;11(22):141-144. doi: 10.4103/phrev.phrev\_31\_16. PMID: 28989249; PMCID: PMC5628520.
9. Kavitha D, Shilpa PN, Devaraj SN. Antibacterial and anti-diarrhoeal effects of alkaloids of *Holarrhena antidysenterica* WALL. *Indian J Exp Biol*. 2004 Jun;42(6):589-94. PMID: 15260110.

10. Shirolkar SG, Tripathi RK, Rege NN. Evaluation of prak[ti and quality-of-life in patients with irritable bowel syndrome. *Anc Sci Life*. 2015 Apr-Jun;34(4):210-5. doi: 10.4103/0257-7941.160865. PMID: 26283806; PMCID: PMC4535069.
11. Ankitha ,jain S, Ram Yadav, c., 2019. Grahani(Irritable Bowel Syndrome)-A case report. *Indian Journal Of Applied Research*, [online] 9(3), pp.5-6. Available at: <[https://www.worldwidejournals.com/indian-journal-of-applied-research-\(IJAR\) / fileview / March\\_2019\\_1551427888\\_\\_03.pdf](https://www.worldwidejournals.com/indian-journal-of-applied-research-(IJAR) / fileview / March_2019_1551427888__03.pdf)> [Accessed 9 February 2022].
12. Kohakade P,Vitonde Y,Burley A. Ayurvedic Management Of Grahani ( Irritable Bowel Syndrome)- A Case Study. *Aayushi International Interdisciplinary Research Journal*.2020:7(12);38-40.
13. Bahatkar G,Jadao M,Kamadi P. Standardization And Evaluation Of Kutaj Leaves (Holarrhena Antidysenterica).2021:8(8);482-488.