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A Clinico-Pathological Study on *Amlapitta* w.s.r to Gastroesophageal Reflux Disease (GERD) and its Comparative Management with *Narikela Khanda* and *Kusmanda Khanda*.

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ABSTRACT:

Introduction: *Amlapitta* described in *Ayurveda* classics resembles to the clinical features of GERD. *Amlapitta* is more prevalent disease of *Annavaha Srotasa* (gastrointestinal system) described in various classical *Ayurvedic* texts. *Narikela Khanda* and *Kushmanda Khanda* are the formulations mentioned in *Bhaisajya Ratnavali* indicated for management of *Amlapitta*.

Aims: To evaluate the effect of *Narikela Khanda* and *Kushmanda Khanda* in management of *Amlapitta*.

Materials and methods: A non-randomized, single-armed, open-labeled clinical trial was conducted in 30 patients having classical symptoms of *Amlapitta*, administered with 10gm of *Narikela Khanda* & 10gm of *Kushmanda Khanda* twice a day after food for 30 days respectively. The assessment was done based on subjective parameters, i.e., *Amlodgara* (sourbelching), *Daha* (heartburn), *Gaurava* (heaviness), *Utklesha* (nausea), *A vipaka* (indigestion) and *Aruchi* (loss of appetite) were taken into consideration. The subjective parameters were analysed by Wilcoxon-W test and p-value.

Result- In Group A, 6.67% patients had marked improvement, while 73.33% patients had moderate improvement and 20.00% mildly improved. In Group B, 60.00% patients had moderate improvement and 40% marked improved. In both the Group the result was statistically significant, but improvement was noticed more in Group- B.

Conclusion- On comparison between two groups, *Kushmanda Khanda* have shown more effect than *Narikela Khanda*. No adverse effects were noticed during clinical trial in both groups.

Key words -*Amlapitta*, *Kusmanada Khanda*, *Narikela Khanda*, GERD

INTRODUCTION

Amlapitta is a disease which is commonly found in almost all parts of the world. *Amlapitta* is one of the *Annavaha srotas*^{1,2} gata vyadhi and *Amlapitta* is a classic example of

the lifestyle disorders common in the present scenario. *Madhukosa* explained *Amlapitta* as “*Amlam vidagdham cha tat pittam amlapittam*”³ which denotes the vitiated



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condition of *pitta*, imparts *Amlatvam* and *Vidagdathavam* to the ingested food. *Kasyapa samhita* is the first text which explained *Amlapitta* as a separate entity⁴. In *Madhavanidan*³, *Nidana Panchaka* of *Amlapitta* has been described. When *Pitta* becomes *Vidagdha* changes into *Amla* and *Pitta* which attains *Amla guna* and *Vidagdhata* is called as *Amlapitta*.

There are many uncountable minerals and herbal preparations, which are sure shots to treat *Amlapitta* and remarkable results are found in mild and moderate degree of Gastro-esophageal reflux disease (GERD). Very less remedy is still available in the modern medicine to treat GERD. So, to find out a suitable remedy the present study is carried out. In the excellency of our ancient Ayurveda *Maharsis* of old era also described that *Narikela*, *Kushmanda*, *Amalaki*, *Pippali*, *Twak*, *Ela*, *Patra*, *Nagakesara* etc are very much effective to treat *Amlapitta*. In view of the above fact a clinical trial of *Narikela Khanda*⁵ and *Kushmanda Khanda*⁵ were taken into consideration.

AIMS AND OBJECTIVES

- To establish co-relation between *Amlapitta* and GERD.
- To find out the effective treatment of *Amlapitta* in *Ayurveda*.
- To evaluate the effect of *Narikela Khanda* and *Kushmanda Khanda* in management of *Amlapitta*.

MATERIALS AND METHOD

IEC Number- 1146/G.A.C & H Dated 20/05/2020

CTRI Registration No.- CTRI/2021/05/033525 on dated 09/12/2020

Selection of the patients:

Total 30 Patients of *Amlapitta* (Gastro-esophageal reflux disease) were taken for the present study were selected from OPD and IPD of Govt. Ayurvedic college & Hospital, Balangir and Shardeswari Govt. Ayurvedic Hospital, Balangir. They were screened by a special proforma which included details history taking, physical sign and symptoms and pathological investigation mentioned in classics and modern science. The patient examination proforma is placed in the appendix of this dissertation.

Grouping:

Group-A (Trial Group-1): 15 patients were treated with *Narikela Khanda* 10gm twice daily with *Shitala jala* for 30 days after food.

Group-B (Trial Group-2): 15 patients were treated with *Kushmanda Khanda* 10gm twice daily with *Shitala jala* for 30 days after food.

Diagnostic Criteria

The patients were diagnosed on the basis of subjective parameters for the diagnosis of *Amlapitta*⁶. They are *Avipaka* (Indigestion), *Klama* (Tiredness without exertion), *Utklesha* (Nausea), *Tiktoamlodgar* (Acidic eructations), *Gourav* (Heaviness of abdomen), *Hridkanthadaha* (Heartburn) and *Aruchi* (Anorexia).

Inclusion Criteria

- Both new and previous treated cases were included.
- Patients who fulfill the diagnostic criteria.
- Patients age between 15-70 years.
- Subject willing to follow the procedures as per the study protocol and signing informed consent form.

Exclusion Criteria

- Patient with any greivous systemic illness, Malignancy, Genetic disorder, Tuberculosis, Hepatitis B or C, or HIV.
- Patient having *Parinamashoola* or *Annadravashoola*, Cholelithiasis and Cholecystitis.
- H/O haematemesis, malena, gastric surgery, CKD & CHD.
- Patients below 15 years and above 70 years.
- Patients not willing to participate in the trial.
- Pregnant and lactating females.

Selection of Drugs:

Two medicines *Narikela Khanda* and *Kushmanda Khanda* had been taken for clinical trial. The drugs of both medicines were identified by the experts of Dept. of *Dravyaguna* and *Rashashastra & Bhaisajya Kalpana* which were approved by DRC and IEC of Govt. Ayurvedic College & Hospital, Balangir, and Sambalpur University. Medicines were prepared as per GMP certified method in Mini Pharmacy of College under the supervision of expert of *Rashasashtra & Bhaisajya Kalpana*. The sample of research medicines were sent to Quality control Laboratories of ALN Rao Memorial Ayurvedic Medical College & PG Centre Koppa, Dist. Chikmagalur, Karnataka for Analytical study

Table No.1; Showing the pharmacodynamics of *Narikela Khanda*. Table No.2; Showing the pharmacodynamics of *Kushmanda Khanda*.

Dose and Administration Procedure

Dose of *Narikela Khanda*: - 10gm twice daily after food for 30 days.

***Anupana*:** - *Shitala jala*

Dose of *Kushmanda Khanda*: - 10gm twice daily after food for 30 days.

***Anupana*:** - *Shitala jala*

Dietic Regimen:

Ahara – Advised to Take normal diet except more tea, junk food, spicy food, non-vegetarian items *etc.*

Vihara – Advised for Exercise and Yoga, take food and sleep at right time, avoid stress and anxiety.

ASSESSMENT CRITERIA:

The subjective parameters as per Inclusion Criteria were fixed by grading score from 0 to 3 according to the severity of disease and favourable shift to back. The parameters were followed up 15th and 30th day of medication. The overall assessments were done considering the percentage of relief in both parameters and statistical evaluation was made.

OBSERVATION & RESULT

The clinical study period of 30 patients were from 07/04/2021 to 30/03/2022. Within the aforesaid period the demography (Table no. 3) based on Age, Sex, Religion etc, along with incidence of *Dasavidha pariksha* (Table No. 04) were observed and assessed. The result obtained after completion of the trial were recorded in tabular forms along with graphical presentations. The Subjective Parameters of both Group-A and Group-B were observed during clinical study. The percentage of improvement were also observed and assessed after clinical trial which is placed here as Table No. 05. (Graph 1)

DISSCUSSION

The description of the disease *Amlapitta* is found since Samhita period. The detail of *Amlapitta* was discussed in the form of *Nidana*(Causative factor), *Purvarupa*(Prodermal Symptoms), *Rupa*(symptoms), *Upasaya*(Symptomatic treatment), *Samprapti* (Pathogenesis) and treatment which are described in various classical books. All these features were taken into consideration for this study as well as aetiology, pathogenesis, clinical features and treatment described in Modern science were also followed during research work. The aim of present study was to study the effect of *Narikela Khanda* and *Kushmanda Khanda* on *Amlapitta*. Both the

medicines were selected from *Bhaisajya Ratnavali*. The whole study was performed in two groups i.e., 1. Group-A treated with *Narikela khanda* and 2. Group-B treated with *Kushmanda Khanda* 10gm twice daily after food with *Shitala jala*.

Predominant rasa of *Narikela Khanda* is *Katu*, *Madhura* and *Tikta* rasa having *Katu* and *Madhura vipaka*. *Madhura*, *Tikta* rasa is *Pittashamaka* and *Kaphanashaka* whereas *Madhura* and *Katu Vipaka* helps in alleviation of both *vata* and *Pitta dosha*. In pathogenesis of *Amlapitta*, *Mandagni* leads to *Ama* formation and *Pippali* and *Musta* are the best medicine for *Amapachana* and alleviates the *Srotorodha* by *Ushna Tikshana Guna*. The *Madhura Rasa*, *Sheeta Veerya*, *Mrudu* and *Snigdha Guna* with *Dahahara* and *Hridya* property refers to the soothing action of *Narikela* on *Annavaha Srotas* thus reducing the irritation. *Madhura Vipaka* and *Sheeta Veerya* drugs may counteract the *Tikshana Guna* of *Vitiated Pitta*, which showed the expulsion of *Mutra* and *Purisha*, i.e., *Vatanulomana* and helps in expulsion of the *Vidagdha Pitta*. This drug is predominantly having *Tridosahara* and *Deepana Pachana* properties which improves the *Agni*.

Kushmanda Khanda is having predominance of *Madhura rasa*, acts on the *vitiated pitta dosha*. *Kushmanda* poses *laghu guna* and *sheeta veerya* which alleviates *pitta dosha*. The drug has *Madhura vipaka* as a result of which the *vata* and *pitta dosha* are alleviated. Also, it has *deepan-pachan* property which improves the status of *Agni*. The drug is predominantly *Vata-pitta Shamaka* & help in relieving *Hrid-kanthadaha*, *Amlodgara*, *Tiktodgara* etc. *Tikta-Kashaya* rasa of *Amalaki* also helps in relieving *Amla-Tiktodgara*. This is also rich in gastro-protective tannins. It is potential to correct the *Agni*.

It was observed from demographical study that most of the patients were found from Middle aged i.e 33.3% and 30%, maximum number of females i.e. (56.67%), 93.33% were Hindus, Housewife (33.33%) followed by students (23.33%) all the patients were already taken treatment for this disease, 13.3% were having family history, 90.00% having no history of past illness. married (66.67%), middle class (63.33%). educated (83.3%), all of the patients were taking mixed diet, 90% patients were found to addicted to Tea, Alcohol. 53.33% had less or disturbed sleep, 60.00% were having abnormal bowel habit, having normal micturition pattern i.e 93.33%. 40% female patients had normal Menstrual History.

It was observed that maximum number of patients were having *Vata-pitta prakriti* with the predominance of *Madhyama Satwa-Sara-Samhanana-Satmya-Pramana-*

Jaranashakti-Vyayamashakti and *Madhyama Vaya*.

The overall assessment revealed that In Group A, 3.33% patients had marked improvement, while 73.33% patients had moderate improvement and 20.00% mildly improved and in Group B, 60.00% patients had moderate improvement and 40% were marked improved. Table No.06;(Graph 2) shows Showing clinical assessment of Result in Group-A and Group-B

In assessing overall effect of therapy, it was seen that

- Overall comparison showed that the best results was obtained in Group-B(*Kushmanda Khanda*) in form of better clinical response and statistical significance.
- Present study reveals that *Kushmanda Khanda* has potential effect on *Amlapitta* with the added advantage of being free from side effects.

CONCLUSION

There is an involvement of all the three doshas in *Amlapitta* but the vitiation of *Pitta dosha* is of prime importance. In *Amlapitta*, *Manasika bhava* also plays major role with *Sharirika bhava*. Total 30 patients were registered for the study; and all of them turn up for follow up. Hence clinical study was carried out on 30 patients. The outcome of clinical study was significant statistically in intergroup comparison. On comparison between two groups, *Kushmanda Khanda* have shown more effect than *Narikela Khanda*. Both the selected drugs showed better results with its *Pitta Shamaka* and *Dipana-Pachana* properties. The positive point observed during the study that, there were no side effects seen during the trail, which is really a good sign to the patients and is of vital importance in view of the global acceptance of *Ayurveda*. Encourage all to avoid spicy, junk food, and develops good eating habits time to time. Recommend for Practicing the *Yoga, Pranayam, Meditation & Exercise* regularly. As the saying goes “Prevention is better than cure” it is better to avoid all the causative factors of *Amlapitta* and thus lead to healthy life.

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Table No.1; Showing the pharmacodynamics of *Narikela Khanda*.

<i>Name</i>	<i>Rasa</i>	<i>Guna</i>	<i>Veerya</i>	<i>Vipaka</i>	<i>Prabhava</i>
<i>Narikela</i>	<i>Madhura</i>	<i>Guru, Snigdha</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Pittasamaka</i>
<i>Goghrita</i>	<i>Madhura</i>	<i>Guru, Snigdha, Mridu</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vata-pittahara</i>
<i>Sita</i>	<i>Madhura</i>	<i>Snigdha, Laghu</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vata-pittahara</i>
<i>Pippali</i>	<i>Katu</i>	<i>Laghu, Snigdha, Tikshna</i>	<i>Anusnas heeta</i>	<i>Katu</i>	<i>KaphaVatashamaka</i>
<i>Maricha</i>	<i>Katu</i>	<i>Laghu, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphasamaka, Kaphavatahara</i>
<i>Nagaramotha</i>	<i>Laghu, Rukshya</i>	<i>Tikta, Katu, Kasaya</i>	<i>Sheeta</i>	<i>Katu</i>	<i>Kaphapitta samaka</i>
<i>Twak & Patra</i>	<i>Katu, Tikta, Madhura</i>	<i>Laghu, Rukshya, Teekshna</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Kaphavata samaka</i>
<i>Ela</i>	<i>Katu, Madhura</i>	<i>Laghu, Rukshya</i>	<i>Sheeta</i>	<i>Katu</i>	<i>Tridosahara</i>
<i>Nagakeshara</i>	<i>Katu, Madhura</i>	<i>Laghu, Rukshya</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Kaphapittasamaka</i>
<i>Dhanyaka</i>	<i>Kashaya, Tikta</i>	<i>Laghu, Rukshya</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridosahara</i>
<i>Jeeraka</i>	<i>Kashaya, Tikta, Katu</i>	<i>Laghu, Rukshya</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Kaphavatahara</i>
<i>Bamsalochana</i>	<i>Madhura, Kasaya</i>	<i>Rukshya, Laghu, Tikshna</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Kaphapittasamaka</i>

Table No.2; Showing the pharmacodynamics of *Kushmanda Khanda*.

Name	Rasa	Guna	Veerya	Vipaka	Karma
<i>Kushmanda</i>	<i>Madhura, Amla</i>	<i>Laghu</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Tridoshashamaka,</i>
<i>Amalaki</i>	<i>Amla, Madhura, Kashaya, Tikta, Katu</i>	<i>Guru, Ruksha, Sheeta</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Tridoshashamaka,</i>
<i>Goghrita</i>	<i>Madhura</i>	<i>Guru, Snigdha, Mridu</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vata-pittahara</i>
<i>Godugdha</i>	<i>Madhura</i>	<i>Snigdha, Guru, Mridu, Pichhila, Manda, Prassana</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vata-pittashamaka</i>
<i>Sita</i>	<i>Madhura</i>	<i>Snigdha, Laghu</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vata-pittahara</i>

Table No. 03; Demography incidence of Registered Patients. (n=30)

Sl. No.	Criteria	Maximum Percentage	Category
01	Age	10(33.33%) and 9(30.00%)	21-30 years & 31-40 yrs
02	Sex	56.67%	Female
03	Religion	28 (93.33%)	Hindu
04	Occupation	33.33%, 23.33%	Housewife, Students
05	Treatment History	100%	Taken
06	Family history	86.67%	No family history
07	History of past illness	90.00%	No past history
08	Marital status	66.67%	Married
09	Socio- Economical status	63.33%	Middle class family
10	Education status	83.33%	Literate
11	Dietary habit	100%	Both veg & nonveg
12	Addiction	90.00%	Tea
13	Sleeping habit	53.33%	Less Sleep
14	Bowel habit	60.00%	Constipation
15	Urine habit	93.33%	Normal
16	Menstrual History	40.00%	Regular
17	Mode of onset	73.33%	Gradual

Table No. 04; Incidence of *Dasavidha Pariksha*⁷ of Registered patients. (n=30)

Sl. No.	Criteria	Maximum Percentage	Category
01	<i>Prakriti</i>	56.67%	<i>Vatapittaja</i>
02	<i>Vikriti</i>	76.67%	<i>Madhyam vala Vyadhi</i>
03	<i>Sara</i>	93.33%	<i>Madhyam Sara</i>
04	<i>Samhanan</i>	96.67%	<i>Madhyam</i>
05	<i>Pramana</i>	100%	<i>Madhyam</i>
06	<i>Satwa</i>	100%	<i>Madhyam</i>
07	<i>Satmya</i>	100%	<i>Madhyam</i>
08	<i>Ahara Shakti</i>	50.0%	<i>Madhyam</i>
09	<i>Vyayama Shakti</i>	43.33%, 43.33%	<i>Madhyam, Uttama</i>
10	<i>Vaya</i>	96.67%	<i>Madhyavasta</i>

Table 5: Showing the observation of total patients as per disease and percentage of improvement in Group-A and Group-B

Subjective Parameters	Group A		Group B		Group A % Effect	Group B % Effect
	N	%	N	%		
TIKTOAMLODGARA	15	100.00%	15	100.00%	65.71	87.10
HRIDKNTHADAHA	15	100.00%	15	100.00%	65.52	87.10
AVIPAKA	15	100.00%	15	100.00%	54.55	66.67
ARUCHI	14	93.33%	13	86.67%	48.00	53.85
KLAMA	9	60.00%	9	60.00%	86.67	68.75
UTKLESHA	14	93.33%	14	93.33%	78.26	80.65
GURU KOSTHA	15	100.00%	14	93.33%	52.00	62.50

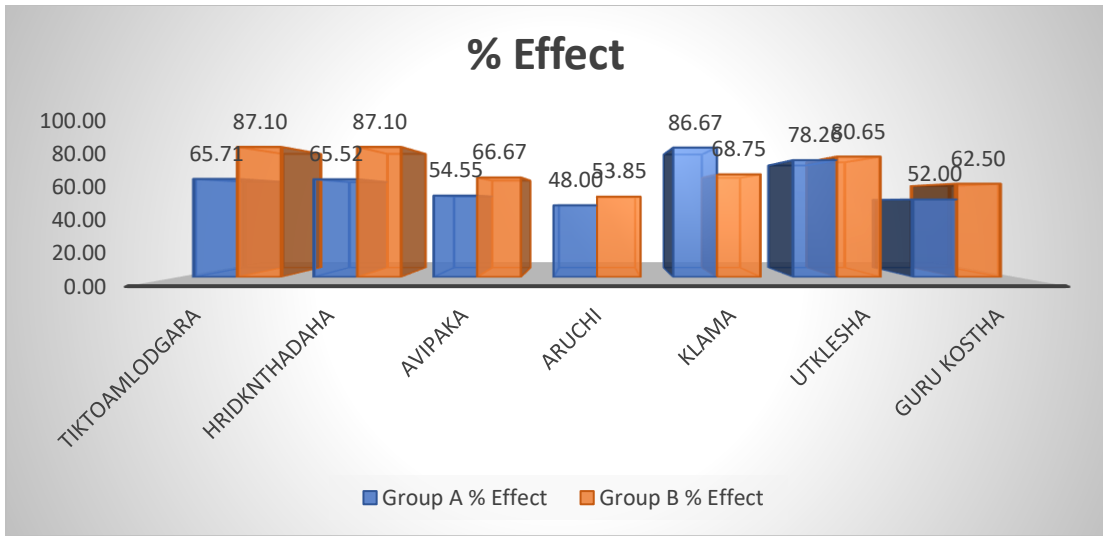


Table No.06; Showing clinical assessment of Result in Group-A and Group-B

OVERALL EFFECT	GROUP A		GROUP B	
	N	%	N	%
MARKED IMPROVEMENT	1	6.67%	6	40.00%
MODERATE IMPROVEMENT	11	73.33%	9	60.00%
MILD IMPROVEEMNT	3	20.00%	0	0.00%
NO CHANGE	0	0.00%	0	0.00%
TOTAL	15	100.00%	15	100.00%

