



Research Article

**A CLINICAL STUDY ON AMLAPITTA AND ITS MANAGEMENT WITH CHHINNODBHAVADI GHANAVATI**

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**ABSTRACT**

*Amlapitta* is a disease prevalent all over the world. The increasing prevalence rate is a constant challenge to the research workers. The disease *Amlapitta* is a common functional disease of *Annavaha srotas*. Materialistic life style provokes people to run behind a busy, stressful life with least concern towards proper food habit. The aim of the present study was to find out efficacy of *Chhinnodbhavadi Ghanavati* in comparison to modern PPI. In present study total 40 patients were taken, divided into 2 equal groups. In group-I: 20 patients were treated with oral administration of trial drug that is *Chhinnodbhavadi ghanavati 500mg 2 tab twice a day for 45 days* and in group-II: 20 patients were treated with control drug that is pantoprazole 40mg 1 tab once a day orally for 45 days. After conducting clinical trial on 40 patients, observation and results were obtained. Statistical analysis shows that both trial and control drug were significantly effective to reduce the cardinal symptoms. As compared to trial drug the effect of control drug is better to reduce symptoms. However as compared to side effects and contra-indications of the control drug, it is advisable to use *Chhinnodbhavadi Ghanavati* for the treatment of *Amlapitta* for a long period.

**KEYWORDS:** *Amlapitta, Chhinnodbhavadi Ghanavati, Pantoprazole, GERD, Gastritis, APD.*

**INTRODUCTION**

*Ayurveda*, the most ancient science of the world, considered as *Upaveda* (subsidiary) of *Atharva Veda*, has taken rapid stride over the last few decades in realizing people probe into basics of physical and psychological health related problems of fast changing life styles. Change is the unchanged law of the universe. Theory of evolution talks about the Survival for the fittest. Human being need to go for short term or long term adaptation to survive in this world. Irregular and improper food habits, busy stressful lifestyle and westernization are the main culprits of an Obstinate disorder escalating in its prevalence i.e. *Amlapitta*<sup>1</sup>. This is a burning problem of the society.

As the new era is progressing, human needs are rising proportionately in a higher ratio due to introduction of newer technology through research. But in this fast food era human being forgets everything to achieve their goal. No gain without pain, for that he need a faceoff with hurry, worry, stress, strain, anxiety, improper food habit<sup>2</sup>. All of them accelerate the vitiation of *dosha* by disturbing action of *Agni*<sup>3</sup>.

Change in function of *Agni* leads to various diseases. It is common for many of us to face a burning sensation in stomach and chest at times. This is in most

cases due to excessive secretion of acidic material in the stomach. In *Ayurvedic* terminology, this is referred as *Amlapitta*, where vitiation of *Pitta Dosha* occurs along with *Kapha Dosha*<sup>3</sup>.

This disease was not described in any text of the *Brihatrayi* but a condition named as "*Vidagdha Jirna*" can be compared with *Amlapitta*. The *Amlapitta* is an established entity from the time of Madhav the famous writer of the book "*Madhav Nidan*" (*Rogavinischaya*)<sup>1</sup>. Among the three *Doshas*, *Pitta* plays a key role for the genesis of *Amlapitta*. Improper digestion of *Amla rasa* gives rise to *Amlapitta*. This is a *mohakari*<sup>4</sup> (confusing) disease, which gives up different sign and symptoms in various persons. If we can treat *Agni* we can do a great favour to society.

In a demographic survey, its prevalence range observed is about 11% to 38.8% of world population. Malaysia, Mexico, Spain and Yemen reported figures on the top quartile of prevalence, whereas the Asian countries reported prevalence rates in the lowest quartile. It is reported that 7.6% of Indian subjects have significant GERD symptoms<sup>5</sup>. Rapid socioeconomic development and the westernization of Asian lifestyles, including changes in diet and an increase in average

body mass index, are likely to be the key factors in change in epidemiology.

### NEED OF STUDY

Hence taking into consideration of its severity and rampant occurrences a combination named as “*Chhinnodbhavadi Ghanavati*” was taken to prove its efficacy for the satisfactory management of *Amlapitta*. *Chhinnodbhavadi kwath*<sup>6</sup> (decoction) consists of equal proportion of *Terminalia chebula* Retz, *Terminalia bellerica* Roxb, *Emblica officinalis* Gaertn, *Tinospora cordifolia* (Willd), *Azadirachta indica* A juss and *Trichosanthes dioica* Roxb. Coarse powder of these drugs will be converted to *Ghanavati* form from the decoction for enteral administration (of the drug) with honey with special reference to *Chakradutta* (52/17) and *Bhaisajya ratnavali* (56/17). *Guduchi*<sup>7</sup> has antiulcer and antioxidant activity. *Neem*<sup>8</sup> is regularly taken to correct problems with in the stomach and bowels. It promotes a healthy digestive system by protecting the stomach, aiding in the elimination and removal of toxins and harmful bacteria. *Haritaki*<sup>9</sup> maintains the gut transit time. *Bhibhitaki*<sup>10</sup> is a stomachic and cholagogue by nature. *Amalaki*<sup>11</sup> is a cholagogue, antioxidant and protective by nature. *Patol*<sup>12</sup> Leaves are cholagogue, aperients, tonic, febrifuge, expectorant, alterative and used in cases of enlarged liver and spleen, hemorrhoids, fistula-in-ano, intrinsic hemorrhage, Erysipelas diseases of mouth,

inflammations and wounds. As it consists of six drugs and all of them will full fill the requirement to treat the *Amlapitta* (GERD) which will give relief to the patient that’s why the drug has been selected for this research work.

### Aims and Objectives

The study was conducted with the following objectives.

1. To compare the efficacy of the trial drug with control drug.
2. To compare the trend of recovery of both the groups.

### DRUG REVIEW

#### Criteria for selection of “*Chhinnodbhavadi ghanavati*” as the trial drug

- A) The drug is purely herbal.
- B) All the ingredients are easily available and cheap.
- C) It is suitable for oral administration.
- D) All the drugs are *Pittasamaka* in nature and *Guduchi* is an immunomodulator.

### Physical Analysis of trial drug

**Colour** – Black

**Odor** – Aromatic

**Taste** – Astringent, Sweet, Sour, Salty and Bitter

**Table 1: Ingredients of *Chhinnodbhavadi ghanavati*<sup>6</sup>:**

S.No	Drug	Botanical name	Part used	Quantity
1	<i>Guduchi</i>	<i>Tinospora cordifolia</i> wild	Stem	1 part
2	<i>Nimba</i>	<i>Azadirachta indica</i> A juss	Bark	1 part
3	<i>Patola</i>	<i>Trichosanthes dioica</i> Roxb	Whole plant	1 part
4	<i>Amalaki</i>	<i>Emblica officinalis</i> Gaertn	Fruit	1 part
5	<i>Vibhitaki</i>	<i>Terminalia bellerica</i> Roxb	Fruit	1 part
6	<i>Haritaki</i>	<i>Terminalia chebula</i> Retz	Fruit	1 part

### Method of preparation of *Chhinnodbhavadi ghanavati*

All the above 6 drugs were taken in equal quantity in Coarse powder form (*Yavakuta churna*) and mixed thoroughly. Then the drugs were cooked in about 16 times of water. The resulting solution was then sieved through a cloth again brewed until it became thick. The thick solution then dried in sunlight. The dried solution was then made into *Ghanavati* form.

### MATERIALS AND METHODS

The present clinical study was conducted in P.G Dept. of Kayachikitsa, G.A.M Puri. In this study total number of 47 patients was registered for the research work and the patients were collected from both O.P.D and I.P.D of hospital attached to the G.A.M Puri based on the criteria of selection.

#### Source of Data

Literary Data: Taken from various Ayurvedic Samhitas, Text books, Journals, magazine’s articles and also from various conferences.

**Clinical Data:** were taken from O.P.D and I.P.D of G.A.M Puri irrespective of age, sex, religion, socioeconomic status etc.

### STUDY DESIGN

Patients diagnosed with *Amlapitta* were selected from the O.P.D. & I.P.D. of GAM&H , Puri in a random manner. Basing on the screening, investigation and taking consent from them, the diagnosed cases were registered for the study in a prescribed case sheet. Out of 47 registered patients, Forty (40) patients (20 patients in Grade- 1 and 20 patients in Grade-2) completed therapy and 7 patients left the treatment schedule between the therapies, which were counted as dropout cases. The study was carried out from May 2013 to October 2013.

#### The case selection for trial was according to the following criteria

#### INCLUSION CRITERIA

1. Age-20 to 60 yrs
2. Both sexes
3. Mentally stressed and strained
4. Spicy and oily food in takers

5. Patients with classical symptoms of *Amlapitta*.
6. Patients who were co-operative and ready give written consent.

**EXCLUSION CRITERIA**

1. Below 20yrs and above 60 yrs
2. Pregnant and lactating
3. Intestinal Koch's
4. Ca stomach
5. Cholecystitis
6. Addicted to alcohol
7. Barrett's oesophagus

**LABORATORY INVESTIGATION-**

1. TLC
2. Hb%
3. FBS
4. Stool test (RE, ME, OBT)
5. Gastric juice base line pH (early morning)
6. Endoscopy

**Table 2: Showing Grouping and Management**

Group	Trial (20 cases)	Control (20 cases)
Drug	<i>Chhinnodbhavadi ghanavati</i>	pantoprazole
Dose	500mg 2 tab bd	40 mg 1 tab OD
Duration	45 days	45 days

The trial drug was prepared in the Department of *Rasasastra* and *Bhaisajya Kalpana*, G.A.M. Puri with the approval of IEC (Institutional Ethical Committee).

**DIET TO ADVICE** – Strictly advised to avoid salty, spicy and stale food.

**Study design-** TG<sub>1</sub> (BT) Vs TG<sub>1</sub> (AT) –effectiveness of treatment group-1 will be assessed.

TG<sub>2</sub> (BT) Vs TG<sub>2</sub> (AT) –effectiveness of treatment group-2 will be assessed.

**N.B.** - BT – Before treatment AT – After treatment

**Follow up**

- Patients were followed up after 15 days, 30 days and 45 days.
- All the investigations were done in empty stomach.
- Improvements and other effects were noted down.
- No side effects were reported by any individual during trial.

**ASSESSMENT**

The assessment progress was noted after 15 days based on the subjective and objective criteria. Grade points considering the severity of the sign and symptoms are

Severity	Gradation	Grade point	
Normal	G <sub>0</sub>	-	0
Mild	G <sub>1</sub>	+	1
Moderate	G <sub>2</sub>	++	2
Severe	G <sub>3</sub>	+++	3

**Subjective Parameters**

- 1) *Avipaka Klama*
- 2) *Utklesha*
- 3) *Vamana*
- 4) *Tiktoamlodgara*
- 5) *Hritkanthadaha*
- 6) *Aruchi*
- 7) *Udarashoola*

**Objective Parameters**

- 1) Gastric juice baseline pH
- 2) Endoscopic findings

**Assessment scale:**

The symptoms were recorded in terms of clinical grades as per the statement of the patients. The different gradations were done for different complains as follows:

**1. Avipaka**

- G<sub>0</sub> - natural appetite for food after 5- 6 hrs of ingestion of mixed Indian food
- G<sub>1</sub> -appetite for food after 7- 8 hrs of taking food
- G<sub>2</sub> - appetite for food after 9 – 10 hrs of taking food
- G<sub>3</sub> - appetite for food after 10 – 12 hrs of taking food

**2. Klama**

- G<sub>0</sub> - no tiredness on routine physical work
- G<sub>1</sub> - feeling tiredness on routine physical work
- G<sub>2</sub> - feeling tiredness to do normal routine work
- G<sub>3</sub> - feeling of tiredness to do any work or no interest in work

**3. Utklesha**

- G<sub>0</sub> - no sensation of vomiting
- G<sub>1</sub> - nausea 1 – 3 times a wk
- G<sub>2</sub>- nausea 4 – 7 times a wk
- G<sub>3</sub> - frequent feeling of nausea with or without food

**4. Vamana**

- G<sub>0</sub> - no vomiting
- G<sub>1</sub> - occasional
- G<sub>2</sub>- 2-3 times a wk
- G<sub>3</sub> - every day

**5. Tiktaamlodgara**

- G<sub>0</sub> - no regurgitation of gastric content in to the mouth
- G<sub>1</sub> - rare regurgitation of gastric content in to the mouth
- G<sub>2</sub> - often regurgitation of undigested food in to the mouth
- G<sub>3</sub> - frequent regurgitation of gastric content in to the mouth

**6. Aruchi**

- G<sub>0</sub> - having good appetite
- G<sub>1</sub> - loss of appetite for breakfast and snacks
- G<sub>2</sub>- loss of appetite for breakfast, lunch , dinner

G<sub>3</sub> - aversion of any food

### 7. *Hritkantha daha*

G<sub>0</sub> - no pyrosis

G<sub>1</sub> - pyrosis in empty stomach

G<sub>2</sub> - pyrosis in empty stomach as well as after 3-4 hrs of taking meal

G<sub>3</sub> - constant or frequent pyrosis

### 8. *Udarashoola*

G<sub>0</sub> - no pain in the abdomen

G<sub>1</sub> - mild pain in the abdomen of low intensity

G<sub>2</sub> - moderate pain causing partial interruption in the work

G<sub>3</sub> - severe pain complete interruption of work

### Gastric juice baseline pH

G<sub>0</sub> - in a range of >6

G<sub>1</sub> - in a range of 4-5.9

G<sub>2</sub> - in a range of 2-3.9

G<sub>3</sub> - in a range of 0-1.9

### Endoscopy

The severity of esophagitis is commonly classified into four grades according to the Los Angeles Classification:

- **Grade A**---One or more mucosal breaks < 5 mm in maximal length
- **Grade B**---One or more mucosal breaks > 5mm, but without continuity across mucosal folds
- **Grade C**---Mucosal breaks continuous between > 2 mucosal folds, but involving less than 75% of the esophageal circumference
- **Grade D**---Mucosal breaks involving more than 75% of esophageal circumference

### Assessment of Result

**Statistical assessment of results** The sign and symptoms observed for the study among trial and control groups were carefully recorded. The sign and symptoms before and after treatment are also recorded. The mean ± SD before treatment of each sign and symptoms was compared with after 15days, 30 days and 45 days of treatment in each group. Then the paired t-test was used for the purpose of test of significance. The effectiveness of the trial and control drug to different sign and symptoms of each group were assessed through p- value.

### Observation

Table No: 3- Demographic Observation

Geographic observation	Predominance	Percentage	No. of patients
Age	50-60 yrs	32.5%	13
Sex	Females	57.5%	23
Socio-economic status	Middle class	85%	34
Onset of disease	Gradual	65%	26
Incidence of aggravation factors	Hunger	62.5%	25
Incidence of relieving factors	Medicines	50%	20
Addiction	Tea	55%	22
Agni(Digestion capacity)	<i>Mandagni</i> (less)	52.5%	21
Mental status	Stressed	37.5%	15
<i>Prakruti</i> (nature of patient)	<i>Pitta Kaphaja</i>	37.5%	15
Site of <i>Udarashoola</i>	Epigastrium	60%	21
Chronicity	<2 year	60%	24
Nature of <i>Udarashoola</i>	Recurrently burning	40%	14
Family history	Present	77.5%	31
Habitat	<i>Anupa</i>	77.5%	31
Nature of work	Service	37.5%	15

### RESULTS:

Table 4: Showing the percentage of relief in different sign/ symptoms with the cases of trial and control drug (after 45 days of treatment)

S.No.	Sign and Symptoms	Trial Group Degree of Severity				P*	Control Group Degree of Severity				P*
		G0	G1	G2	G3		G0	G1	G2	G3	
1	<i>Avipaka</i>	8	4	0	0	80	14	0	1	0	93.1
2	<i>Klama</i>	12	2	0	0	88.25	7	2	0	0	83.33
3	<i>Utklesha</i>	7	6	0	0	76	13	3	1	0	82.75
4	<i>Vamana</i>	3	2	2	0	53.84	8	2	0	0	88.88
5	<i>Aruchi</i>	12	2	0	0	87.5	8	1	0	0	90.9
6	<i>Hritkanthadaha</i>	8	3	0	0	72.72	11	0	0	0	100
7	<i>Tiktoamlodgara</i>	6	4	1	0	75	17	1	0	0	96.55
8	<i>Udarashoola</i>	8	9	0	0	75	18	0	0	0	100

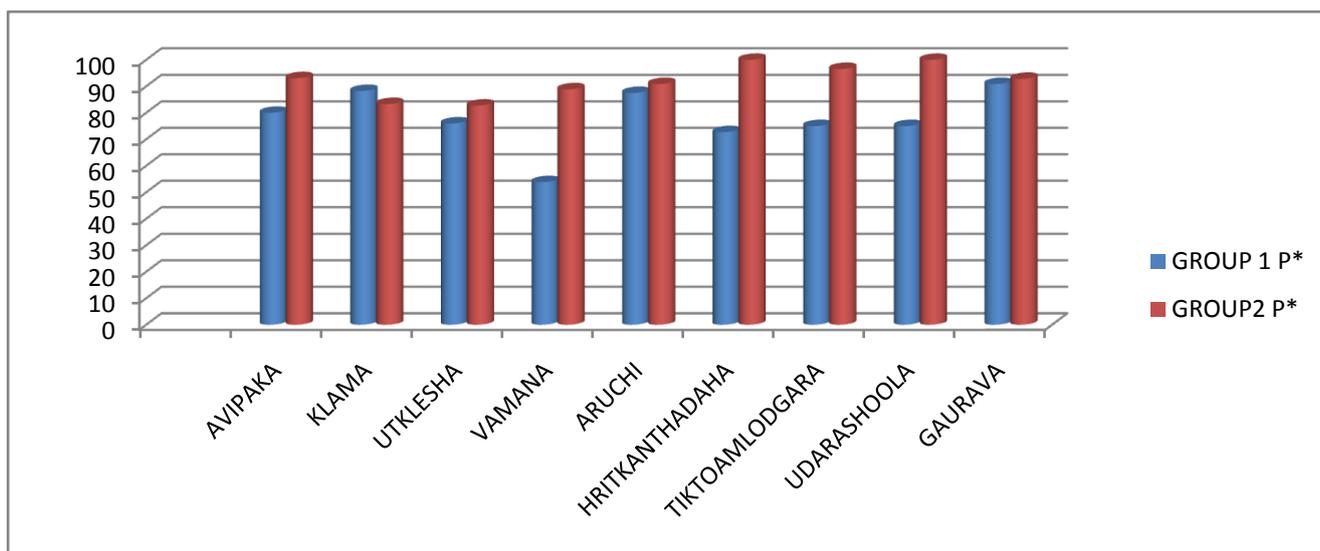


Table 5: Showing the percentage of change in pH with the cases of trial and control drug (after 45 days of treatment)

S.No.	Range	Trial Group		P*	Control Group		P*
		BT	AT		BT	AT	
1	4 to 5.9	0	2	20.4	0	5	27.65
2	2 to 3.9	11	17		13	15	
3	0 to 1.9	9	1		7	0	

The percentage of relief in trial group was 20.4% while in control group it is 27.65% after 45 days.

Table 6: Showing the percentage change of the patients got improvement after treatment with respect to different sign and symptoms (group 1)

S. No.	Sign and Symptoms	Group 1 ( n1= 20)					
		AT (15)		AT(30)		AT(45)	
		f	%	f	%	F	%
1	Avipaka	1	9.09	7	63.63	11	100
2	Klama	5	38.38	10	76.92	13	100
3	Utklesha	4	30.76	7	53.84	12	92.3
4	Tiktoamlodgara	4	36.36	9	81.81	11	100
5	Hritkanthadaha	3	42.85	5	71.42	6	85.71
6	Aruchi	2	14.28	7	50	12	85.71
7	Vamana	1	14.28	3	42.85	7	100
8	Udarashoola	3	17.64	14	82.35	17	100
9	pH	-	-	-	-	9	45
10	Endoscopy	-	-	-	-	6	60

Table 7: Showing the percentage change of the patients got improvement after treatment with respect to different sign and symptoms (group2)

S. No.	Sign and Symptoms	Group 2 n2=20					
		AT(15)		AT(30)		AT(45)	
		f	%	f	%	f	%
1	Avipaka	8	53.53	13	86.86	15	100
2	Klama	3	33.33	6	66.66	8	88.88
3	Utklesha	13	76.47	16	94.11	16	94.11
4	Tiktoamlodgara	13	72.22	16	88.88	16	88.88
5	Hritkanthadaha	9	81.81	10	90.9	11	100
6	Aruchi	2	22.22	8	88.88	9	100
7	Vamana	4	40	10	100	10	100
8	Udarashoola	14	77.77	18	100	18	100
9	pH	-	-	-	-	11	100
10	Endoscopy	-	-	-	-	10	100

N:B – Clinical assessment is calculated considering the clinical relief in the severity grade details of the grade described in the clinical profile.

**Table No: 8- Showing the clinical assessment of results after treatment in different groups**

S.No.	Clinical Assessment	AT (15 DAYS)				AT (30 DAYS)				AT (45 DAYS)			
		Group1		Group2		Group 1		Group 2		Group 1		Group 2	
		f	%	f	%	f	%	F	%	f	%	f	%
1	Cure	-	-	-	-	-	-	3	15%	-	-	-	-
2	Maximum Improvement	-	-	1	5%	2	10%	10	50%	8	40%	17	85%
3	Moderate Improvement	1	5%	6	30%	8	40%	5	25%	11	55%	3	15%
4	Mild Improvement	3	15%	10	50%	6	30%	2	10%	1	5%	-	-
5	Unsatisfactory	16	80%	3	15%	4	20%	-	-	-	-	-	-

## DISSCUSION

Though various medicaments are available to treat this disease but result is unsatisfactory on long term use, due to their adverse effect. Review of research work shows that no such clinical research had been carried on this typical disease with respect to the present trial drug that is “*Chhinnodbhavadi ghanavati*”. Experimental study of this particular trial drug had been carried on stress induced ulcer on Albino rats and no toxicity was reported in the study (MB Nariya et al) which inspires the researcher to conduct a clinical study on this particular drug. Hence in this study “*Chhinnodbhavadi ghanavati*” (ref- *Chakradutta Amlapitta prakarana*) has been selected as the trial drug consisting of six different drugs in equal amount. All the six drugs are *Pittasamaka* and *Deepan* in nature. In various studies it was reported that *Guduchi* acts as an antacid, *Medhya* (anti stress activity) and also immunomodulator which strengthens the mucosal defence mechanism. About *Nimba*, it has direct impact on H+K+ ATPase inhibition. *Patola patra* is stomachic and cholagogue in nature, while *Triphala* increases gut transit time or gastric motility. *Madhu*<sup>13</sup> (honey) is taken as *Anupana* which is *Madhura* in rasa and *Kasaya* in *Anurasa*, *Anushnasheeta veerya* and *Pittasamaka* in nature. It also creates coating on the mucosal surface.

*Acharya* Madhav<sup>1</sup> described this disease as a separate chapter and *Acharya* Kashyap<sup>14</sup> described it with its management. *Amlapitta* is a *Pitta* predominant *Vata*, *Kapha* disease. The cardinal features of *Amlapitta* are *Avipaka*, *Klama*, *Utklesha*, *Tiktoamlodgara*, *Gaurava*, *Aruchi*, *Hritkanthadaha*. With the trial drug, there was a symptomatic relief in the patients i.e. improvement in *Avipaka*, *Tikta Amla Udgara*, *Hridakanthadaha*, *Utklesha*, *Aruchi*, *Vamana* and *Udarashoola*. A comparative gastric pH and endoscopy before and after the treatment showed that the trial drug increases the base line pH of the gastric juice as well as strengthen the mucosal defense mechanism.

Out of 20 patients of *Amlapitta* (GERD) treated with trial drug, 40 % patients had shown maximum improvement and 55% patients were moderately improved. This implies that *Chhinnodbhavadi ghanavati* may be considered as an effective drug for *Amlapitta* (GERD). As *Amlapitta* (GERD) is a chronic condition it

needs a long period study. Statistically it has been observed that the trial drug is significantly effective to reduce all the sign and symptoms of *Amlapitta*.

## CONCLUSION

From this study it is revealed that though both the drugs are significantly effective in *Amlapitta* but control drug is highly significant in comparison to trial drug.

## Scope of further study

- This trial was a time bound limited study of 45 days so an extended long term trial is required comparing both the drugs for better comparison.
- The cost of trial drug can brought down by massive production.
- Since the recurrence rate of GERD after PPI treatment is significant so an extension of trial to include the recurrence rate may show better efficacy of trial drug.
- The mode of action of the drug is not clear as such. It needs a further study.

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**Cite this article as:**

Mohapatra Nibedita, Biswal Debasis, Murthy Seema Krishna, Sharma Vishnu Dutt, Arawatti Siddaram. A Clinical Study on Amlapitta and its Management with Chhinnodbhavadi Ghanavati. International Journal of Ayurveda and Pharma Research. 2015;3(12):43-49.

**Source of support: Nil, Conflict of interest: None Declared**

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