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CLINICAL EFFICACY OF BAIDYANATHA AYUCID IN MANAGEMENT OF AMLAPITA (GERD): HUMAN SCIENTIFIC TRIAL

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ABSTRACT

Amlapita (GERD) refers to a chronic recurring gastro-intestinal disease, very common nowadays due to improper dietary habits and inactive lifestyle. Ayurveda the glorious proud of India has the potentiality to address Amlapitta. Ayurveda had truly entered the new age with the advent of modern methodologies that allow for Pharmacognosy and clinical research, and Baidyanath since added a new dimension to this ages old science by standardizing old formulations and evolving newer ones In this Human scientific trial, on the basis of subjective parameters 50 patients were selected randomly to assess the efficacy of Baidyanath Ayucid, an ayurvedic proprietary herbal antacid in Amlapita (GERD). At the end of the trial the Baidyanath Ayucid had shown statistically significant results and 82.46% of overall of improvement. Thus it can be concluded that Baidyanath Ayucid is fruitful in.

KEYWORD: Amlapita (GERD), Ayurveda, Baidyanatha, Ayucid, Human scientific trial, statistically significant.

1. INTRODUCTION

In this present era a huge population is highly affected from Amlapita (GERD) due to unhealthy food habits, mental stress and inactive lifestyle. Amlapitta (GERD) refers to the gastrointestinal disease characterized symptoms such as Avipaka (indigestion), Klama (feeling of lassitude), Utklesha (nausea), Gaurava (heaviness), Hritkantha Daha (burning sensation in chest & throat), Tiktamlodgara (sour eructations), and Aruchi (anorexia).

Gastroesophageal reflux disease (GERD) is a chronic condition where stomach acid flows back into the esophagus, leading to symptoms like heartburn, regurgitation, and difficulty swallowing. Lifestyle changes, medications, and sometimes surgery can helps to manage it.

The basic principle of ayurveda is to prevent and treat disease by maintaining balance in the body and mind through proper diet, daily lifestyle and medication. Recognizing the potential of Ayurvedic remedies in addressing common fitness concerns, we endorse to conduct a human scientific trial at the Government Ayurvedic College and Hospital in Guwahati. In this clinical trial, on the basis of subjective parameters 50 patients were selected randomly to assess the efficacy of

Baidyanath Ayucid, an ayurvedic proprietary herbal antacid in Amlapita (GERD).

2. LITERATURE REVIEW A) DISEASE REVIEW

a) Avurvedic Review: The whole Avurveda revolves around the concept of Agni, which has been mentioned from Atharaveda. In today's lifestyle, Amlapitta (GERD) is a very common and major problem due to improper lifestyle. The etiology like excess consumption of viruddha ahaar (incompatible food), dushta (rotten), atiamla (sour) & vidahi aahar (spicy food), pittakarak aahar (pitta aggravating diet & drinks), guru aahar (food which is heavy to digest), Abhishyandi aahar (unctuous diet), Atidrava aahar (excess liquid diet), vegdharan (suppression of natural urges), atimadhyapana (excess alcohol consumption), diwaswap (Day sleep) etc. and stress lead to indigestion and causing the disease Amlapitta (GERD). The undigested food remains in abdomen thus further undergo fermentation. This leads to increased amla guna of pitta dosha and causes Amlapita (GERD). In Ayurveda Acharya has mentioned various pathya and apathya (wholesome & unwholesome) diet and regime for amlapitta (GERD).

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Table 1: Pathya and Apathya: (Wholesome and unwholesome).

	PATHYA (wholesome)	APATHYA (unwholesome)
AHARAJ (Food)	Quality food: light, sweet, cold potency food Cereal: Purana Shali (old rice), yava (wheat) Pluses: Mudga (mung bean), Chana Sattu Veg & fruits: Patola (pointed gourd), Dadima (Pomegranate), Amla, Banana flower, ripe Kapitta (wood apple), Kushmanda (Ash gourd), karvellak (bitter gourd), Narrikal (coconut), Pipali (Piper longum), Sunthi (dried ginger), Draksha (raisin) Shatavari (Asparagus racemosus)	Quality of food: Oily, Spicy, salty, hot potency, fast food, Fermented food. Cereal: Maida based products like pizza, biscuits, burger Dairy products like cheese Pluses: Kulatha (Horse Gram) Beverages: Tea, Coffee, Preservative drinks, Beer, Alcohol Veg & fruits: pitta prakopita veg like Brinjal.
VIHARAJ (Regime)	Follow Dinacharya (proper day routine) Follow Rituacharya (proper night routine) Pranayam: Nadi Sodhana Pranayam, Sheetali Pranayama Yoga: Vajar Asana, Vakrasana Bhujanga asana, Pavan Mukta asana Shava asana	Diwasapana (day sleep) Ratri Jagrana (awake till late night), Vega Dharan (suppress natural urge) Ati kodha(anger), lobha (greedy), irsha (jealousy).

b) Modern Review

Gastroesophageal Reflux Disease (GERD) is a chronic condition characterized by the reflux of stomach contents into the esophagus, leading to symptoms and potential complications.

Pathophysiology

- ★ Lower Esophageal Sphincter (LES) Dysfunction: Weakness or relaxation allows acid to escape from the stomach.
- ★ Increased Intra-abdominal Pressure: Can occur due to obesity, pregnancy, or tight clothing.
- ★ Esophageal Motility Disorders: Impaired peristalsis can contribute to reflux.

Symptoms

- ★ Classic: Heartburn (Pyrosis), regurgitation, chest pain, and dysphagia.
- ★ Atypical: Chronic cough, asthma exacerbations, laryngitis, and dental erosions.

Diagnosis

- ★ Clinical History: Symptom assessment and response to proton pump inhibitors (PPIs).
- ★ Endoscopy: To evaluate esophageal damage and rule out complications.
- ★ Ph Monitoring: 24-hour esophageal pH monitoring for reflux quantification.
- **★** Manometry: Assesses esophageal motility.

Table	2:	Ma	nagement	of	GERD.

1. Lifestyle Modifications	2. Medications	3. Surgical Options
 Weight loss Dietary changes (avoid trigger foods) Elevation of head during sleep 	 Antacids: Neutralize stomach acid. H2-Receptor Antagonists: Reduce acid production (e.g., ranitidine). Proton Pump Inhibitors (PPIs): Strong 	 Fundoplication: Surgical reinforcement of the LES for refractory cases. LINX device: Magnetic device that helps keep the LES closed.
 Smoking cessation 	acid suppression (e.g., omeprazole).	keep the LES closed.

Complications

- Esophagitis
- Barrett's esophagus
- Esophageal stricture
- Increased risk of esophageal adenocarcinoma

B) DRUG REVIEW

More than 5000 years ago, in India originated a science by the name Ayurveda – Ayu meaning life and Veda meaning dealing in essence, for the maintenance of physical, mental, social and spiritual health of an individual. Ayurveda had truly entered the new age with the advent of modern methodologies that allow for Pharmacognosy and clinical research, and Baidyanath since added a new dimension to this ages old science by standardizing old formulations and evolving newer ones. Baidyanath a renowned Ayurvedic company founded in 1917 is a manufacturer of approximately 700 + Ayurvedic products and formulations. Baidyanath Ayucid is an herbal antacid which is specially formulated using Amla (Indian gooseberry) and Mulethi (licorice) mainly to combat hyperacidity and indigestion.

Table 3: Product specification.

Brand	Baidyanath
Item Weight	500 Milligrams
Product Benefits	Acidity Relief
Specific Uses For Product	Indigestion
Age Range (Description)	Adult
Package Type	Bottle

Dosage Form	Tablets
Model Name	Ayucid - 60 Tablets
Manufacturer	Shree Baidyanath Ayurved Bhawan Pvt Ltd
Country of Origin	India

Table 4: Ingredients and their mode of action.

S No	Ingredient	Quantity	Rasa (taste)	Virya (potency)	Vipaka	Doshaghnata	Karma (Mode of Action)
1.	Amlakhi (Emblica officinalis)	163 mg	Amla predominant pancha- rasa (except lavana)	Sheeta	Madhur	Sarvadoshaghan (alleviate all the tri-doshas)	*Rasayana (Rejuvenation Therapy) *Dahahara (subsiding burning sensation) *Vibhandhara (relief constipation) *Chakshuya (good for eyes), *Vrishya (improve sexual health) *Hridya (good for heart), *Pramehahara (cure diabetes) etc.
2.	Mulethi (Glycyrrhiza glabra)	163 mg	Madhur	Sheeta	Madhur	Vata - Pitta Hara (alleviate Vata & pitta)	*Jeevaniya (improve the quality of life), *Sandhaniya (helps in connective tissue health) *Kanthiya (good for throat), *Varniya (enhance lustre)
3	Kapardhak bhasma	163 mg	Katu	Ushna	Katu	Alleviate Kapha - Pitta predominat tridosha	*Dipaniya (helps in digestion)

3. MATERIAL AND METHODOLOGY

- 3.1 Subject Area: Gastroenterology.
- **3.2 Source of data:** Subjects with Amlapitta are selected from the OPD, IPD of Government Ayurvedic College & Hospital, Assam.

3.3. Study Design: The study will involve a single-arm trial where all subjects will be administered Baidyanath Ayucid as part of the intervention. Measures will be taken to ensure blinding in order to minimize any potential bias during the evaluation of treatment outcomes.

Table 5

Aspect	Baidyanath Ayucid
Study Duration	3 months
Drug Dosage	2 tablets (500mg) BD
Patient Population	50 patients
Study Design	Randomized Control Trial (RCT)
Randomization	Yes
Blinding	Double-blind
Outcome Measures	Improvement in symptoms related to gastric acidity

3.4 Selection Criteria

3.4.1. INCLUSION CRITERIA

- 1. Patients having classical features of Amlapitta (GERD) i.e fulfilling the subjective assessment criteria.
- 2. Patients above 18 years and below 80 years of age.
- 3. Patient willing to participate in the study

3.4.2. EXCLUSION CRITERIA

- 1. Age below 18 years and above 70 years.
- 2. Pregnant and lactating women.
- 3. Already diagnosed Patients with major systemic illness including cardiac diseases, hepatobiliary disease, kidney disease, Cancer Patients etc.

- 4. Individuals with recognized allergies to product's ingredients.
- **3.4.3. WITHDRAWAL CRITERIA:** Patient can get withdraw from the trial anytime with following reasons.
- 1. In case patient having any health and safety issues,
- 2. Personal reasons
- 3. Non-compliance
- 4. Lost to follow up
- 5. Randomization error

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3.5. Assessment Criteria Table 6

FEATURES	GRADATION	PARAMETERS
	0	No daha
	1	Burning sensation in one area i.e ura (chest), udara (epigastric region), throat for more than 1/2 hr occasionally.
	2	Burning sensation occasionally in any 2 region or occurs daily for 1/2 an hour to 1 hour.
Dobo (huming consetion)	3	Burning sensation occurs in more than 2 areas daily for 1hr or
Daha (burning sensation)	4	more and relieves after vomiting or digestion of food Burning sensation occurs in most of the areas so that patient may not able to sleep at night and doesn't not get relieve by
	5	any measure. Sever Burning sensation occurs in whole body areas like hands, feet, or Sarvanga (whole body) and doesn't get relieves by any measure.
	0	No sour eructation
	1	Occasionally occurs during day or night time and last for less than 1/2 hr after eating meal.
	2	Sour eructation occurs daily for 2-3 times for 1/2 hrs and relived by sweets, water and antacids.
Amlaudgara (soureructations)	3	Sour eructation occurs after intake of each meal or any food substance for period of 1/2 to 1 hr and get relieved by digestion of food or vomiting.
	4	Sour eructation occurs for more than 1hr not relieved by any measures.
	5	Sour eructation causing disturbance to patient, even small quantity of food regurgitate to patients mouth
	0	No vomiting at all
	1	Frequent salivation
Chardi and Hailland (anniting	2	Feels sense of nausea and vomiting occasionally
Chardi and Hrillasa (vomiting and nausea)	3	Frequency of vomiting is 2-3 times or more per weeks and comes whenever daha or pain gets aggravated.
	4	Frequency of vomiting daily
	5	Frequency of vomiting after every meal or without meal
	0	No pain at all
	1	Mild/ occasionally pain which need no medication
	2	Pain abdomen for less than 1/2 hr and relived after intake of sweets, cold drink, food, antacid, milk etc.
Udarshula (abdominal pain)	3	Abdominal pain due to ingestion of food and relieves after digestion of food or by vomiting
	4	Sever unbearable pain, which does not subside by any measures and the patient awake at mid night.
	5	Unbearable pain associated with frequent vomiting and hematemesis.
	0	Willing for all edible
	1	Unwilling for some specific food but less than normal.
	2	Unwilling for specific rasa i.e madhura/katu/amla/etc.
Aruchi (anorexia)	3	Unwilling towards food but could take the meal.
	4	Unwilling towards disliked foods but can't take even other food.
	5	Completely unwilling towards meal
	0	No Feeling of lasitude at all
	1	Occasionally feels lassitude without work which remains for some time and then vanish
Klama (feeling lassitude)	2	Feeling of lassitude without work daily for sometime
	3	Feeling lassitude without work daily for long duration
	4	Always feel tired and have no enthusiasm
Brama (reeling of head)	0	No reeling of head

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	1	Occasionally feeling of reeling of head	
	2	Frequency of feeling of reeling of head < 3 times a day	
	3	Frequency of feeling of reeling of head > 3 times a day	
	4	Frequently feeling of reeling of head change of posture causes	
		the severe problem.	

3.6. Interventions

- Standards for terminating and changing assigned interferences.
- Patient will be withdrawn during the study if somewhat inconvenient occurs, medication sensitivity or any supplementary illness or problem rises.
- Subject not willing to continue the treatment.
- Rescue medication: if any untoward situation arises patient will be allowed to take treatment of his/her choice.

3.7. Outcome Measures

- Primary outcome measures will consist of the reduced in symptoms of hyperacidity, indigestion and irregular bowel.
- Secondary final results measures will consist of the occurrence of unfavourable occasions and modifications in biochemical markers related to the conditions.

3.8. Safety and Adverse Events Monitoring

- Adverse events could be intently monitored for the duration of the trial duration.
- Any adverse occasions stated through contributors can be documented, assessed for severity, and managed according to conventional operating techniques.

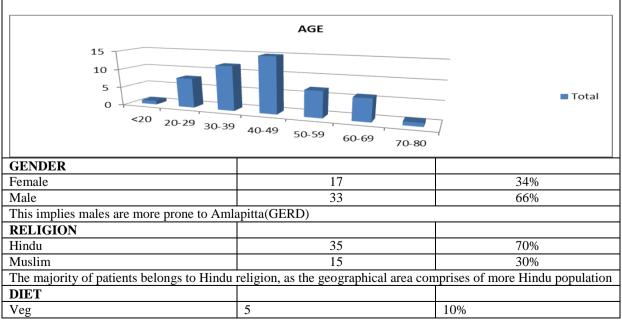
4. OBSERVATION AND RESULT Demographic Profile

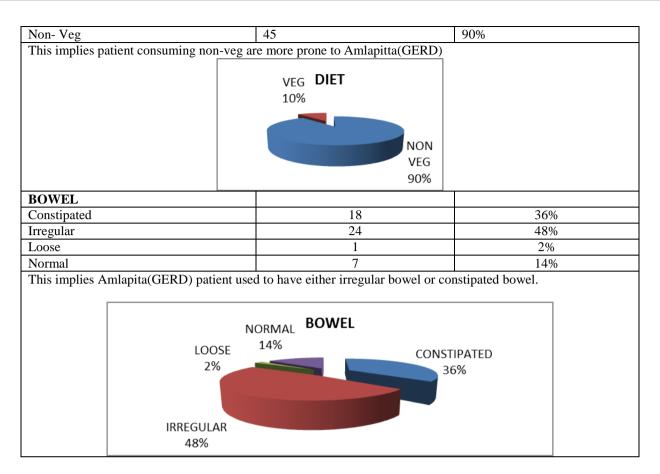
In this study clinical trial was conducted on 50 patients of Amlapitta (GERD) fulfilling the inclusive and exclusive criteria. The patients were randomly selected. Through subjective and objective parameters of patients were noted before the treatment and after treatment, for statistical analysis Pair T- test was applied to all the parameters. The results of assessment of efficacy of Baidyanath Ayucid Tab in Amlapitta(GERD) are presented here.

Table 7

Demographic Profile	No. of Patient	% of Patient
AGE		
<20	1	2%
20 - 29	8	16%
30 – 39	12	24%
40 - 49	15	30%
50 - 59	7	14%
60 – 69	6	12%
70 – 80	1	2%

This implies max Amlapita (GERD) patient belongs to the age group of 40-49 years.





Comparison of before, F1, F2 and after treatment time points Table 8

Tikta Amlaudgara (Sour eructations)		SED	t49	P- value	Remarks
$\bar{x} BT + SD$	2.80+-1.44	0.097	7.82	<0.0001	Extramaly Cianificant
$\bar{x} F1 + SD$	2.04+-1.48	0.097	1.82	< 0.0001	Extremely Significant
$\bar{x} F2 + _SD$	1.24+-1.25	0.104	14.82	< 0.0001	Extremely Significant
$\bar{x} AT + SD$	0.70+-0.79	0.130	15.94	< 0.0001	Extremely Significant
Percentage of improvement		74.99	%		Extremely Significant

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 7.82, 14.82 & 15.94. Hence the result is statistically significant. The percentage of improvement in patients regarding tikta amlaudgara

(sour eructations) was 74.99. It signifies that Baidyanath Ayucid is effective in Tikta Amlaudgara (Sour eructations).

Table 9

Chardi & Hrillasa (vomiting and nausea)		SED	t49	P- value	Remarks
$\bar{x}BT + _SD$	1.44 + -1.09	0.138	3.48	= 0.0010	Very Significant
$\bar{x}F1 + SD$	0.96 + -0.97	0.136	3.48	- 0.0010	very Significant
$\bar{x}F2 + SD$	0.52 + -0.76	0.151	6.10	< 0.0001	Extremely Significant
$\bar{x}AT + SD$	0.18 + -0.44	0.133	9.44	< 0.0001	Extremely Significant
Percentage of improvement	87.50%				Extremely Significant

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 3.48, 6.10 & 9.44. Hence the result is statistically significant. The percentage of improvement in patient regarding Chardi and hrillasa

(vomiting and nausea) was 87.50%. It signifies that Baidyanath Ayucid is effective in Chardi and hrillasa(vomiting and nausea).

Table 10

Daha (burning sensation)		SED	t49	P- value	Remarks
$\bar{x}BT + \underline{SD}$	2.60 + -1.26	0.136	4.69	< 0.0001	Extremely Significant

$\bar{x}F1 + SD$	1.96 + -1.40				
$\bar{x}F2 + SD$	1.24 + -1.24	0.180	7.54	< 0.0001	Extremely Significant
$\bar{x}AT + SD$	0.50 + -0.84	0.177	11.88	< 0.0001	Extremely Significant
Percentage of improvement		80.7	Extremely Significant		

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 4.69, 7.54 & 11.88. Hence the result is statistically significant. The percentage of improvement in patient regarding daha (burning

sensation in epigastric, chest and throat region) was 80.76%. It signifies that Baidyanath Ayucid is effective in Daha (burning sensation).

Table 11

Udarshula (abdominal pain)		SED	t49	P- value	Remarks
$\bar{x}BT + _SD$	1.82 +_ 1.06	0.092	8.51	< 0.0001	Extremely Significant
$\bar{x}F1 + SD$	1.04 + -1.07	0.092	8.31	<0.0001	Extremely Significant
$\bar{x}F2 + SD$	0.48 + -0.71	0.113	11.87	< 0.0001	Extremely Significant
$\bar{x}AT + SD$	0.24 + -0.48	0.118	13.37	< 0.0001	Extremely Significant
Percentage of improvement		Extremely Significant			

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 8.51, 11.87 & 13.37. Hence the result is statistically significant. The percentage of

improvement in patient regarding udarshula (pain in abdomen) was 86.81%. It signifies that Baidyanath Ayucid is effective in Udarshula (pain in abdomen).

Table 12

Aruchi (Anorexia)		SED	t49	P- value	Remarks
$\bar{x}BT+_SD$	1.54+-1.07	0.129	5.08	< 0.0001	Extramaly Significant
$\bar{x}F1 + SD$	0.84+-0.87	0.138	3.08	<0.0001	Extremely Significant
$\bar{x}F2 + SD$	0.28+-0.54	0.130	9.66	< 0.0001	Extremely Significant
$\bar{x}AT + SD$	0.12+-0.39	0.140	10.12	< 0.0001	Extremely Significant
Percentage of improvement		92.20	Extremely Significant		

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 5.08, 9.66 & 10.12. Hence the result is statistically significant. The percentage of

improvement in patient regarding aruchi (anorexia) was 92.20%. It signifies that Baidyanath Ayucid is effective in Aruchi.

Table 13

Klama (feeling of lassitude)		SED	t49	P- value	Remarks
x̄BT+_SD	2.08+-1.19	0.16	4.38	< 0.0001	Extremely Significant
$\bar{x}F1 + SD$	1.38+-0.97	0.10	4.36	<0.0001	Extremely Significant
$\bar{x}F2 + SD$	0.78+-0.79	0.170	7.66	< 0.0001	Extremely Significant
$\bar{x}AT + SD$	0.46+-0.73	0.180	8.97	< 0.0001	Extremely Significant
Percentage of improvement	77.88%				Extremely Significant

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 4.38, 7.66 & 8.97. Hence the result is statistically significant. The percentage of

improvement in patient regarding Klama (feeling of lassitude) was 77.88%. It signifies that Baidyanath Ayucid is effective in Klama (feeling of lassitude).

Table 14

Brama (reeling of head)		SED	t49	P- value	Remarks
x̄BT+_SD	0.62 + -1.50	0.204	2.15	=0.036	Significant
$\bar{x}F1 + SD$	0.18+-0.44			< 0.0001	Extremely Significant
$\bar{x}F2 + SD$	0.08+-0.34	0.074	8.84	< 0.0001	Extremely Significant
$\bar{x}AT + SD$	0.06+-0.24	0.80	4.73	< 0.0001	Extremely Significant
Percentage of improvement	90.32%				Extremely Significant

Note: The t49 value at end of 1 month (F1), 2 month (F2) and after 3 month (AT) was 2.15, 8.84 & 4.73. Hence the result is statistically Significant. The percentage of improvement in patient regarding brama (reeling of head)

was 90.32%. It signifies that Baidyanath Ayucid is effective in Brama (reeling of head).

5. DISCUSSION

Drug Discussion: Baidyanath Ayucid, a herbal formulations mainly containing Amlakhi (Indian gooseberry), Mulethi (licorice) and Kapardhak each 163 mg is proven to be effective in Amlapitta (GERD) cases. Amlakhi and Mulethi with its madhur vipaka and sheeta virya (cold potency) counter act the pitta's ushna (hot) & vidahi guna. Amlakhi is a potent drug for amlapita as it alleviates vata due to amla rasa, pitta by madhura rasa & sheetavirya (cold potency) and kapha by its ruksha guna. Whereas Kapardhak bhasma with its prithvi guna do the shoshan (dry up) of increased dravata (liquidity) of vidhagdh pitta. And by its ushna virya (hot potency) act as deepaniya drava (helps in digestion). Therefore Baidyanath Ayucid gave satisfactory results in clinical trial performed on 50 patients.

DISCUSSION ON RESULT: In this study 50 patients diagnosed with Amlapita (GERD) were randomly selected from GAC&H Kayachikitsa OPD. Paired T- test was done for the statistical analyses. The percentage of improvement in patient regarding tikta amlaudgara (sour eructations), chardi & hrillasa (vomiting & nausea), daha (burning sensation), udarshula (abdominal pain), aruchi (anorexia), Klama (feeling of lassitude) and brama (reeling of head) was 74.99%, 87.50%, 80.76%, 86.81%, 92.20%, 77.88% and 90.32% respectively. Overall improvement of 82.46% was noted in patients with amlapita (GERD) after consumption of Baidyanath Ayucid. Hence Baidyanath Ayucid is potent in subsiding the symptoms of Amlapitta (GERD) and fruitful in curing Amlapitta (GERD).

6. CONCLUSION

In today's world majority of disease are due to faulty dietary habits, high intake of fast food, and lack of physical activity, long sedentary hours and mental stress. Amlapitta (GERD) is one of the gastrointestinal disorder, primarily characterized by aruchi (anorexia), utklesh(nausea), tikta amla udhar (acid eructation) etc due to agnimandya (indigestion). Baidyanath Ayucid, a herbal proprietary formulations has been proved potent in mitigating the symptoms of Amlapitta (GERD) and improving the quality of life.

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