

Research article

A randomized clinical trial on *Guduchiyadi gana kwatha* in the management of *amlapitha* (acid peptic disease)

Syyed Mohammed Jalaludheen

Department of Salyatantra, Rajiv Gandhi Ayurveda Medical College, Chalakkara, Mahe-673310, Puducherry, India.

E-mail: smjppt@gmail.com; Tel: +94-9447232573.

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ABSTRACT

Amlapitha (acid peptic disease) has a population prevalence of 6% and a male-female ratio of 1.7:1 in a study population of 10,096 urban dwellers. Two third of which constituted cases of duodenal ulcer and there has been a rapid rise in the 20th century globally. *Amlapitha* is a very common medical condition and the current management available for the same is not comprehensive. The aim of the present study is to assess the efficacy of *guduchiyadi gana kwatha* in the management of *amlapitha*. Ayurveda has a rich tradition in the management of gastroenterological disorders, but, due to reasons unknown, the full potential of Ayurvedic wisdom has not been explored so far in its management. Even the existing management is so trifled considering the plethora of management, principles and practice. So, it is highly essential that simple and cheap but effective formulation should be brought to the fore and the benefits of this great science to be extended to the suffering humanity. This would further help to popularize the system of Ayurveda. Existing treatment modalities available in Ayurveda for *amlapitha* are expensive, time-consuming and results unsatisfying. So, any initiative that would curtail the high cost and enhance the efficacy would be most welcomed. The existing *kalpas* used for *amlapitha* are composed of multiple drugs out of which some drugs are not available today. So, the simple formulation of *guduchiyadi gana kwatha* mentioned in *Ashtanga Hrudaya* would be highly practical considering the low cost and high availability of the drugs. Moreover, *guduchiyadi gana* is the best for the management of *amlapitha*.

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INTRODUCTION

Amlapitha (acid peptic disorders) are the result of distinctive, but overlapping pathogenic mechanisms leading to either excessive acid secretion or diminished mucosal defence. These are common entities present in daily clinical practice that, owing to their chronicity, represent a significant cost to healthcare (Mejia and Kraft, 2009).

The present study has been conducted to identify the merits and demerits of *guduchiyadi gana kwatha* in *amlapitha* management. The results of the study would help in understanding the *amlapitha* with reference to modern clinical aspects. The study would also help in utilizing Ayurveda in the cost-effective management of *amlapitha*.

All relevant classical texts of Ayurveda were studied and the relevant parts were compiled. The description of the *amlapitha* with reference to acid

peptic diseases as well as other selected pathological conditions was also considered. The relevant data regarding the topic was obtained from authentic texts and the internet. Standardization of *guduchiyadi gana kwatha* was done on three different occasions at SGS India private limited on 30.03.2007, 24.08.2007 and 22.08.2008.

These had to be done because there was no existing standardized value for *guduchiyadi gana kwatha*. The selected *guduchiyadi gana* was mentioned in Vagbata's *Ashtanga Hrudaya* (Desai, 1986). Establishment of standard criteria using the best sample as a baseline with a range of standard errors, i.e. 95% confidence limit was done and the report is given in Fig. 1.

Heavy metal analysis of the drug *Guduchiyadi gana kwatha* was done at SGS India private limited. Obtained values are within the permissible limit (AP, 2001). The report obtained has been given in Fig. 2.

Thin layer chromatography of *guduchiyadi gana kwatha choorna* was done at drug standardization unit, Govt. Ayurveda College, Thiruvananthapuram (Rajpal, 2011). Four peak values at areas at 8.05%, 6.75%, 9.32% and 5.89% were found in the HPTLC graph. HPTLC had to be done since no previous data were available for *guduchiyadi gana kwatha*. For authenticity, the resulting process was repeated thrice. The HPTLC chromatogram is shown in Fig. 3.

control group. The trial group (Group A) comprised of 60 patients and was given *guduchiyadi gana kwatha* at the dose of 50 mL twice a day at early morning (6-7 am) and evening (7-8 am) before a meal. Common *pathyapathya ahara viharas* were strictly followed up till the end of the study. On the other hand, the control group (Group B) comprised of 60 patients who were given ranitidine tablets (150 mg/bd), a well-established, researched and published drug used in acid peptic disease, after food with water. Common *pathya ahara viharas* were also strictly followed up similar to Group A.

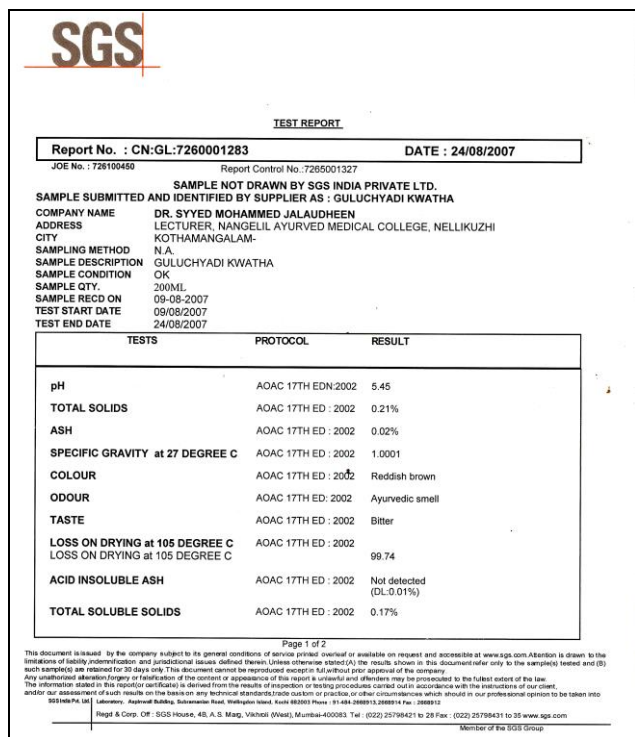


Fig. 1. Standardization report of *guduchiyadi gana kwatha*

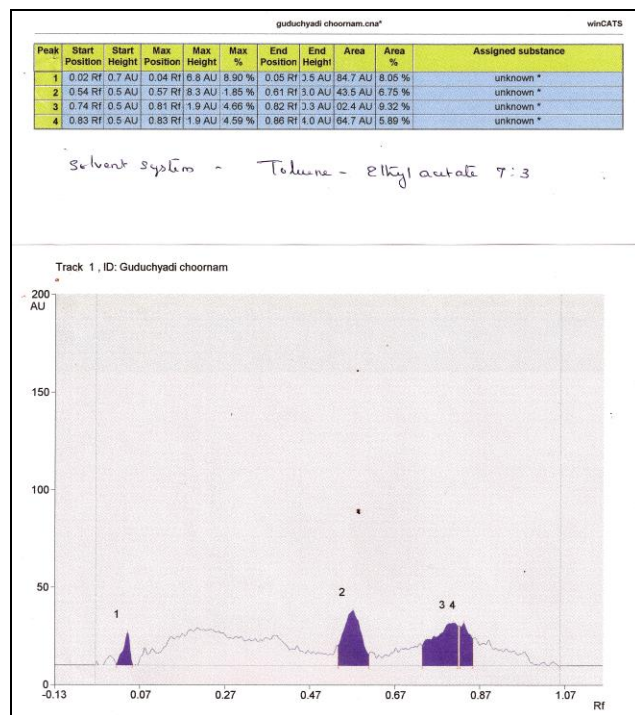


Fig. 3. HPTLC chromatogram

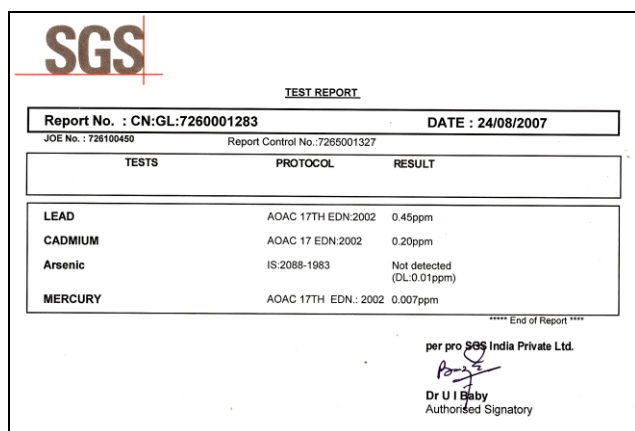


Fig. 2. Heavy metal analysis report

MATERIALS AND METHODS

Clinical study

A randomized clinical trial was conducted on *amlapitha* with *guduchiyadi gana kwatha* as a trial group and H2 receptor blocker (ranitidine) as a

Study population

All patients attended Shalyatantra OPD (out-patient department) with cases of *amlapitha* were considered for the present study.

Sampling method and sample size

All *urdhwaga amlapitha* patients were selected randomly as per exclusion and inclusion criteria. Sixty patients were selected in each group (Group A and B).

Study subjects

Patients with *amlapitha* in the age group of 16 to 60 years as per inclusion and exclusion criteria were selected for the study.

Collection of data

Detailed clinical examination and investigations were done at the time of admission,

during treatment and follow up visits. Endoscopy examination was done only in willing patients and they were not compelled to do the same. Elaborated proforma was prepared on each patient and the data were collected comprehensively.

Inclusion criteria

Only patients with conditions of *pithapradhana kaphanubandhi amlapitha* in the prescribed age group (16-60 years) were included in the study.

Exclusion criteria

Those cases associated with *adhoga amlapitha*, *pitha pradhana vatanubandhi amlapitha*, systemic diseases like CVD, TB, GIT-malignancy, pyloric stenosis, Zollinger Ellison syndrome, pregnant/lactating women were excluded from the study. Consents, mentioning about the various aspects of the study in their own language were signed and obtained from each subject.

Assessment of the research work

The classical, as well as modern references to *amlapitha* in the etio-pathological point of view, were discussed. The available modern understanding of the conditions was studied. From the study, a comprehensive understanding of the condition in a purely Ayurvedic perspective was developed. The study intended to evaluate and compare the existing treatment modalities in Ayurveda and modern system of medicine using the new formula for the management of *amlapitha* without making judgments.

Observations and analysis

The clinical study commenced from 10.02.2007 onwards at Nangelil Ayurveda Medical College and Hospital, Kothamangalam, Kerala and Seth Tarachand Ramnath Charitable Ayurvedic Hospital, Pune. The study population of 150 patients was randomly selected into two groups using lottery methods. 148 patients have admitted during the clinical work and a total of 120 patients completed the study duration as per the protocol of the study. Ten patients had withdrawn from the study and the remaining 18 patients were not willing to participate in the study. After obtaining the permission from the superintendent, clinical works were commenced on April 2007 at Seth Tarachand Ramnath Charitable Ayurvedic Hospital, Pune. For the success of the clinical work, free medical camps were conducted on 23rd and 24th April 2007 at Seth Tarachand Ramnath Charitable Ayurvedic Hospital, Pune. Thirty-four patients were admitted as per the inclusion and exclusion criteria there. The clinical study at Nangelil Ayurveda Medical College, Kothamangalam, Kerala, commenced from 10.02.2007 to 23.04.2008 and 86 patients,

admitted as per the inclusion and exclusion criteria completed the study. All patients were done the laboratory investigations before and after the study. Written consent from all patients was collected and a copy of the same was given to each of them. Out of 120 patients, endoscopy was done in 47 patients before the study and only 33 patients (17 patients in study group and 16 patients in control group) underwent endoscopy at the end of the study.

Abstract of the observations and results obtained during the clinical study revealed that majority of patients belonged to age group of 36-45 years (41%) followed by 29% in the age group 46-55 years, 18% of the patients fell in the age group of 26-35 years while 09% were in the 20-25 years age group. Only 03% of the patients belong to the 56-60 age group (Fig. 4). It has been found that 63% of the patients in the study were males while 57% were females whereas 46% of the patients were professionals followed by 27% belonging to sedentary works, 19% of the patients were engaged in hard manual works while 08% belonged to other fields of work.

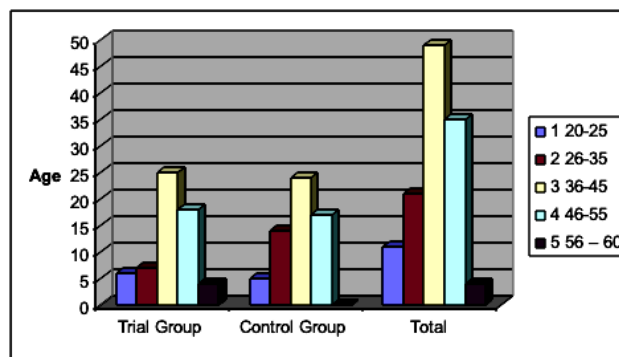


Fig. 4. Age wise distribution of *amlapitha* patients

Out of 120 patients, 41% used to consume spicy food whereas 40% had irregular dietary habits. In addition, 17% of the patients used to eat pungent foods while only 02% had regular dietary habits (Fig. 5). From these findings, it can be observed that spicy and irregular food habits had a major role as a causative factor of *amlapitha* in the majority of the cases.

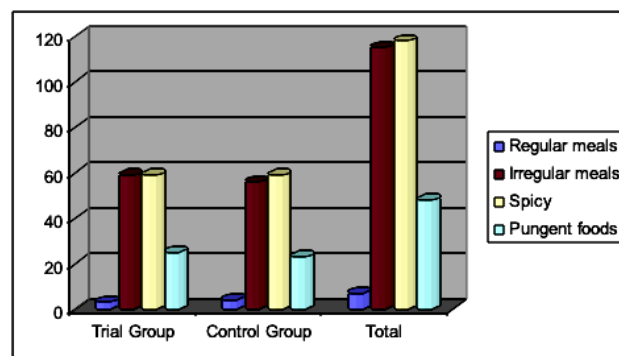


Fig. 5. Food habits of *amlapitha* patients

Among both groups, only 32 patients were vegetarians, the rest of them being predominantly non-vegetarian in food habits. *Amlapitha* was seen not only in non-vegetarian but also in vegetarians.

Comparatively the intake of rice was more common than wheat or ragi among all patients. Most of the patients were not regular non-vegetarians. So, in the study, non-vegetarian food was not found to have a direct impact on the manifestation of *amlapitha*. Intake of milk was observed to be a stronger aggravating factor of *amlapitha* than the curd. Use of red chillies and ginger was commonly found in most of the cases indicating their leading role in the manifestation of *amlapitha*. Regarding the feeling of the stomach in all patients, the pain was the most common complaint (90%) compared to discomfort (59%), heaviness (38%), and fullness (19%). In 105

patients (87%), the pain was reported in relation to the intake of food. In the rest of the patients (15), no relation of pain with intake of food was reported. Pain following the intake of meals was mostly complained off.

Regarding the severity of the pain, only 37 patients (32%) were reported to have been disturbed at sleep in the night waking them up. Remaining 81 patients (68%) had no sleep disturbances. Majority of the patients in both groups had the complaint of vomiting following intake of certain food items (90%). Most of the patients (95%) with the complaint had a spontaneous onset of the same compared to a minority (5%) in whom vomiting had to be induced. In the majority of the patient (92%), the quantity of the vomit was one handful. All the patients had complained of *amlodgara* (acid eructation).

Table 1. The incidence of regurgitation among *amlapitha* patients

S.No.	Regurgitation	Trial Group	Percent	Control Group	Percent	Total	Percent
1	More after food	40	74	39	75	79	75
2	Less after food	06	11	04	08	10	09
3	Doubtful	08	15	09	17	17	16

Out of total patients, 88% had a complaint of regurgitation in relation to a meal. Relation with meals in this study indicated that 75% of the population had a complaint of regurgitation worsening after the intake of food (Table 1). Only 9% had the complaint improving after food and the remaining 16% were doubtful in relation to meals.

In the study, it was found that *aadhmaana* (feeling of abdominal distension) was highly prevalent among *amlapitha* patients (97%). In most of the patients (72%), *aadhmaana* regularly occurred after intake of any food items. Regarding the status of appetite among the *amlapitha* patients, it was observed that the majority of patients (89%) had a very poor appetite and 10% of patients had it less than normal. Nobody had reported black coloured stool in the study. Almost 92% of patients absolutely had no complaint of black coloured stool while the remaining 10 patients were doubtful about it. The bowel habit in 36 patients (30%) were reported to be once daily, while a majority (68%) had it twice or thrice daily. A few patients had a bowel habit of more than three evacuations daily.

Statistical analysis

All data before and after study in each group have been codified, analyzed and statistically tested, with the help of paired ‘t’ test and the efficacy of each group has been analyzed by student ‘t’ test (Syamalan, 2006).

RESULTS AND DISCUSSION

Results observed in the present study were analyzed in 13 categories. Results of 60 patients

with *urdhwaga amlapitha* in the study group and results of other 60 patients with *urdhwaga amlapitha* in control group were analyzed separately. The results were statistically analyzed before and after in both the groups with the help of paired ‘t’ test.

In all the thirteen symptoms considered of both group, the paired ‘t’ test had denoted that both treatments were highly significant (p<0.001) which implied that *guduchiyadi gana kwatha* and ranitidine were effective in the treatment of *urdhwaga amlapitha* while applying student ‘t’ test, p=0.18 (p>0.05) suggestive of the insignificant changes in both modalities of treatment. The follow-up study had denoted that the recurrence rate and complications were less with *guduchiyadi gana kwatha* than with ranitidine.

Out of 120 *urdhwaga amlapitha* patients, 99 patients had severe complaints of acid eructation. In this study, 1.67% patient with mild acid eructation, 15% with moderate and 83.33% with severe acid eructation were taken in the test group. Similarly, 18.33% of patients with moderate and 81.67% patients with severe acid eructation were taken into the control group for the assessment before the treatment (Table 2).

After 2 weeks follow up, 1.67% patients were completely relieved (absent), 15% with mild acid eructation, 58.33% had moderate acid eructation and 25% had severe acid eructation in the study group. Similarly, 1.67% patients were relieved (absent) from acid eructation, 15% patients had mild acid eructation, 61.67% had moderate acid eructation and 21.66% had severe acid eructation in the control group. In study group after 60 days of treatment, only 10% of patients had reported severe acid eructation, 3.3% had moderate,

26.67% had mild acid eructation and remaining 60% had reported complete cure. After 60 days of treatment in control group, 8.33% patient had a complaint of severe acid eructation, 3.33% had

moderate and 36.67% had mild acid eructation at the end of 60 days of treatment whereas 51.67% patients had no complaint with respect of acid eructation after treatment.

Table 2. Percentage distribution of the acid eructation according to the treatment

Acid eructation	Severity	Before treatment		2 nd week of treatment		After treatment	
		Count	Percent	Count	Percent	Count	Percent
Study group	Absent	00	00.00	01	01.67	36	60.00
	Mild	01	01.67	09	15.00	16	26.67
	Moderate	09	15.00	35	58.33	02	03.33
	Severe	50	83.33	15	25.00	06	10.00
Control group	Absent	00	00.00	01	01.67	31	51.67
	Mild	00	00.00	09	15.00	22	36.67
	Moderate	11	18.33	37	61.67	02	03.33
	Severe	49	81.67	13	21.66	05	08.33

Statistically, the gradient of acid eructation treatment in the study group with a mean of 2.17±0.96 and in control group, the gradient of acid eructation with mean value 2.13±0.89 analyzed with paired ‘t’ test (17.52 and 18.55) denotes that both treatments are highly significant (p<0.001). In the contest of relieving acid eructation, both Ayurvedic and modern medicine were the same in the treatment of *urdhwaga amlapitha* (Table 3).

the same in modern medicine was 2.13±0.89 while applying student ‘t’ test, p=0.18 value was greater than 0.05, suggesting that there was no significant change in both modalities of treatment (Fig. 6).

Table 3. Statistical analysis of treatment on acid eructation

Acid eructation	Mean	SD	Paired ‘t’	P value
Ayurveda	2.17	0.96	17.52	0.001
Allopathy	2.13	0.89	18.55	0.001

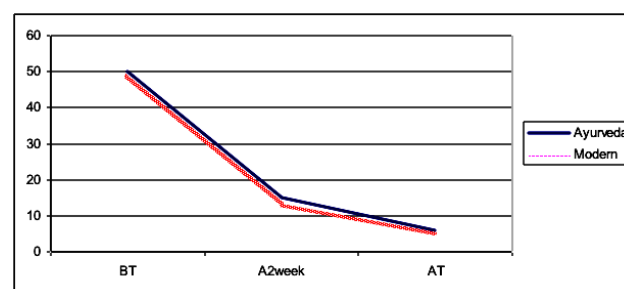


Fig. 6. Comparison of effectiveness of acid eructation treatment in both groups

Evaluation of both groups were done in the treatment of acid eructation in both groups were once more analyzed by using student ‘t’ test for evaluating which modality is highly effective. As far as the acid eructation was concerned, Ayurvedic treatment modality showed a mean of 2.17±0.96,

These observations suggested that both groups had a similar effect on acid eructation treatment. In short, Ayurvedic and modern medicine modalities were the same in the treatment for *amlapitha* with respect to acid eructation.

Table 4. Endoscopic report analysis in both groups

Endoscopy	Severity	Before treatment		After treatment	
		Count	Percent	Count	Percent
Study group	No	0	0	3	17.65
	Mild	0	0	14	82.35
	Moderate	8	47.06	0	0
	Severe	9	52.94	0	0
Control group	No	0	0	3	18.75
	Mild	0	0	11	68.75
	Moderate	10	62.5	1	6.25
	Severe	6	37.5	1	6.25

As shown in Table 4, 47.06% patient with moderate symptoms and 52.94% with severe symptoms were taken into the study group. Similarly, 62.5% of patients with moderate symptoms and 37.5% of patients with severe symptoms were taken into the control group when

the patient was assessed before the treatment. In the study group, 82.35% of patients reported mild symptoms and 17.65% reported complete cure that is normal endoscopy in the study group after 14 days of treatment. In the control group, 68.75% patient complained of mild symptoms whereas

18.75% had no complaint after 14 days of treatment.

The endoscopic analysis of 33 patients, 17 patients in the study group and 16 patients in the control group were compared before and after the study. With the help of paired 't' test, it had been determined that both treatments were statistically significant ($p < 0.001$) and effective in the management of *amlapitha*.

Table 5. Statistical evaluation on endoscopic report

Group	Mean	SD	Paired 't'	P value
Control group	1.375	0.85	06.42	0.001
Study group	1.705	0.68	10.22	0.001

Statistically, the endoscopic results in the study group with a mean value of 1.71 ± 0.69 and in control group with a mean of 1.38 ± 0.86 analyzed with paired t test (6.42 and 10.22) denote that both treatments are highly significant ($p < 0.001$) (Table 5). In this evaluation, both *guduchiyadi gana* and ranitidine were same in the effectiveness of *urdhwaga amlapitha* treatment (Fig. 7).

As far as the endoscopic evaluation was concerned, Ayurvedic treatment modality showed a mean of 1.705 ± 0.68 while the same was 1.375 ± 0.85 in control group. When applying the

student t test, $p = 1.1$ value was found to be greater than $p = 0.05$, suggesting that there was no significant change in both modalities of treatment. This endoscopic evaluation revealed a similar effect with both modalities of the treatment on *amlapitha*.

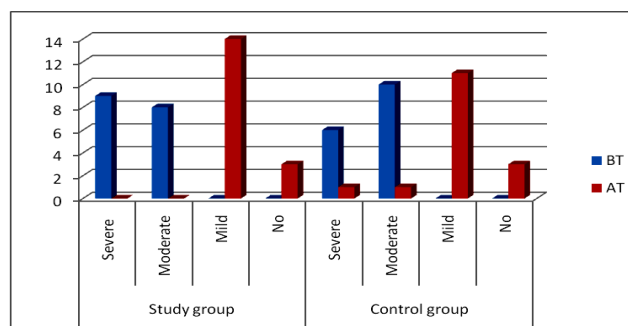


Fig. 7. Effect of treatment in both groups with endoscopic analysis

All laboratory investigations were performed and analyzed before and after with help of paired 't' and the efficacy of both compared with student t test, the analysis showed that both treatments were effective ($p < 0.001$) and same in the management of *amlapitha* (Table 6).

Table 6. Statistical analysis of laboratory investigation

Lab test	Group	Mean	SD	Paired t	Student t
Hb	Study	0.78	0.56	10.99	1.90
	Control	0.74	0.66	7.75	
Total count	Study	30	215.74	1.07	0.74
	Control	8.33	212.56	0.30	
Neutrophil	Study	-0.45	2.65	1.32	0.73
	Control	0.13	3.29	0.31	
Lymphocyte	Study	-0.67	4.34	1.18	-0.29
	Control	0.8	2.83	2.19	
Eosinophil	Study	0.97	0.64	11.75	0
	Control	0.97	0.64	11.75	
Monocyte	Study	0.2	0.48	3.23	0
	Control	0.20	0.48	3.28	
Basophil	Study	0.08	0.28	2.31	0.09
	Control	0	0	0	
ESR	Study	8.25	7.64	8.37	-0.19
	Control	8.39	7.56	8.61	

The impact of the treatment on ESR and lymphocyte on analysis showed statistical significance represented by a lower p-value ($p < 0.05$) suggestive of significant changes with both modalities of treatment. Thus, it can be deduced that *guduchiyadi gana kwatha* was more effective than ranitidine with respect to ESR and lymphocyte management.

In this study, the recurrence rate is less in the study group compared with the control group (Table 7). In control group, 20 patients out of 52

and in study group only 6 out of 53 patients were reported with recurrence of symptoms.

Table 7. The incidence of recurrence in both groups

Recurrence	Yes		No	
	Count	Percent	Count	Percent
Control	20	38.46	32	61.54
Study	6	11.32	47	88.68

Statistically, the gradient of recurrence on treatment in the study group with a mean of 38±0.49 and in control group with 11±0.57 analyzed with paired t test (5.59 and 1.42) denotes that both treatments are highly significant (p<0.001). In this evaluation, both modalities were same in the effectiveness of *urdhwaga amlapitha* treatment.

After completion of 15 days treatment, the recurrence of the symptoms was analyzed with help of Student's 't' which denoted the statistical significance, represented by p-value (-0.254) less than 0.05 (p<0.05). The statistical analysis concluded that Ayurvedic management was more effective than existing modern management with ranitidine as far as recurrence of *amlapitha* after the study period is concerned (Table 8; Fig. 8).

Table 8. Statistical analysis of recurrence rate

Group	Mean	SD	Paired 't'	P value
Control group	0.38	0.49	5.59	0.001
Study group	0.11	0.57	1.42	0.001

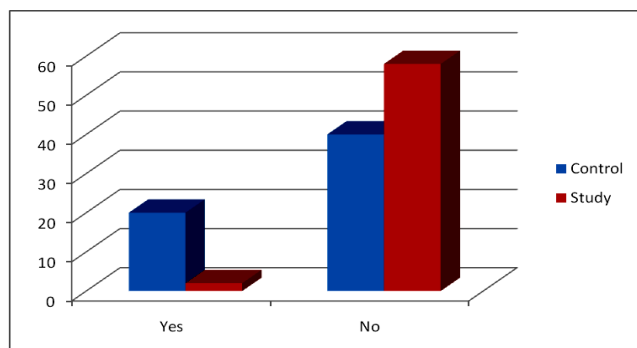


Fig. 8. The incidence of recurrence in both groups

The complications associated with treatment reported during the study period were comparatively lesser in the study group than in the control group (Table 9).

Table 9. The incidence of complication in both groups

Complications	Study group		Control group	
	Count	Percent	Count	Percent
Dizziness	00	0.00	03	05.00
Difficulty in sleeping	00	0.00	15	25.00
Depression	01	0.00	20	33.33
Constipation	00	0.00	04	06.67
Diarrhea	02	3.33	11	18.33

Probable mode of action

The clinical study and statistical analysis had proved the efficacy of *Guduchiyadi gana kwatha* over hyperacidity. *Guduchi* is *Tikta* in *rasa*, *Guru*, *Snigdha* in *guna*, *Madhura vipaka* and has *Tridoshagna* property, which acts against the

Teekshna, *Ushna*, *Laghu guna* of *pitta* and does the *Pittadosha shamana*. It allays thirst, burning sensation, vomiting and acts as antipyretic, anti-allergic, anti-inflammatory. Hence, this *gana* give positive results against hyperacidity.

Dhanyaka is *thiktha*, *kashaya*, *madura* and *kadu rasa*, *laghu* and *snigdha*, *Guna*, *ushna veerya madura vipaka* and *tridoshahara*, *shodhahara*, *shoolahara*, *deepana*, *pachana*, *jwaragna* properties and alleviates *Kapha* and *Pitta* diseases. It allays fever, vomiting, burning sensation and increased thirst.

Padmaka has properties of *kashaya*, *thiktha rasa*, *laghu guna*, *sheetha Veerya*, *katu vipaka* and *vedanasthapana* as *Prabhava*, actions like *kaphapitha samana*, *kushtagna*, *daha prasamana*, *sthambhana*, *chardinigrahana*, *vishaghna*, *jwaraghna*, sedative, astringent, digestive, carminative, antispasmodic and diuretics.

Rakthachandana has the properties of *thiktha*, *madura rasa*; *guru*, *rooksha guna*; *sheetha veerya* and *katu Vipaka*. It acts as *kaphapithasamana*, *dahaprasamana*, *sthambhana*, *sholahara*, *chardi nigrahana*, *thrushna nigrahana*, *raktha shodana*, *kushtagna*, *jwaragna*, mild astringent, cooling and tonic.

Arishta has the properties of *thiktha*, *kashaya Rasa*; *laghu Guna*; *sheetha Veerya*; *kadu Vipaka*. It acts as *Kapha pitha samana*, *vrana pachana*, *vrunashodana*, *ropana*, *dahaprasamana*, *krimigna*, *jwaragana*, *kushtgna*, astringent, anti-peroidic, vermifuge, anti spirochaetal, emmanogogue, purgative and antihelmentic.

Kashaya has *Sthambana*, *Soshana*, *Sheeta*, *Raktapitta prashamana* properties so the gastric juice and pH value are decreased. The *Soshana guna* of *Kashaya* was probably responsible for the *Dravyata kshaya* (decrease in volume) and *Gunata kshaya* (decrease in pH).

Due to anti-infective, anti-helminthes and *krimigna* properties of trial drugs was acted against the *H. pylori* infection.

Guluchyadi gana kwatha mentioned by *Acharya Vagbataa* (Desai, 1986) says that it has the properties of alleviating *pitha kapha*, fever, vomiting, burning sensation in the stomach, thirst and produce *agni deepthi*. Due to the above actions, *amlapitha* shows wonderful relief with this trial medicine. According to *Acharya Sushruta* (Shastri, 2001), it is digestive, alleviating all fevers, hrullasa, arochaka, vomiting, pipasa and burning sensation in the stomach so this *gana* is a very good medicine for *amlapitha* treatment.

After the overall assessment, the *guduchiyadi gana kwatha* was found to be superior to the treatment with ranitidine in the management of *urdhwaga amlapitha* in respect to recurrence and complication.

As per the entire analysis, the null hypothesis "*Guduchiyadi gana kwatha* and ranitidine is equally effective in the management of *amlapitha*" was accepted.

CONCLUSION

The *Guduchiyadi Gana kwatha* administration was found to be effective in the management of *pithapradhana kaphanubanda urdhwaga amlapitha*. The *kaphapitha prasamana* of *Guduchiyadi Gana kwatha* has a superior effect in the management hyperacidity. *Lekhana, Stambhana, shoshana krimigna* and *Ropana* properties of *Guduchiyadi Gana kwatha* bring about symptomatic improvement as well as the reduction of acid secretion. No complications whatsoever were observed during the Ayurvedic management of *amlapitha*, the recurrence rate also being lesser as compared to the treatment with ranitidine.

Ulcer formation in the GI tract commonly occurring as a sequel to *amlapitha* can be prevented by prolonged use of Ayurvedic management. The diet and lifestyle regimen specifically mentioned in Ayurvedic classics were found to be complementary to the management.

CONFLICTS OF INTEREST

The author declares no conflicts of interest.

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