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A CLINICAL STUDY OF THE EFFECTIVENESS OF *ABHAYA PIPPALAYADI YOGA* ON *AMLAPITTA ROGA* (ACIDITY)

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ABSTRACT

Now a days, polluted environment, irregular routine, harmful and improper diet, such as excessive consumption of rich food, soft drinks, tea, coffee, excessive consumption of drugs (Smoking, Alcoholism, Tobacco etc.), day dreaming, night awakening and craving for more pleasures Human physical and mental abilities have greatly decreased, as a result of which diseases and stress surround the body and mind all the time.

The special effect of geographical environment and food habits has also been seen on the origin of acidity disease. In Malvanchal's food and drink, foods made from gram flour, food items containing more chili- spices and rich food items are used in large quantities. The residents of this region who are used to eating sev made of gram flour, salty as well as other spicy things, are more likely to suffer from acidity due to the special food style.

From the priceless treasure of Ayurveda, for the treatment of acidity, the best, easily accessible and low- cost "Abhaya Pippalyadi" Yoga from Bhaishajya Ratnavali with all the components of Abhaya Pippalyadi Yoga (Haritaki, Pippali, Draksha, Sita, Dhanyak, Yavasa) has Pitta virechana and Kostha suddhi effect and it can be inferred from the virtues of being madhura vipaka and Sheetavirya properties that it is a successful and cheap medicine for acidity.

KEYWORDS: *Amlapitta roga, Acidity, Abhaya Pippalyadi Yoga, Ayurveda.*

INTRODUCTION

Now a days, polluted environment, irregular routine, harmful and improper diet, such as excessive consumption of rich food, soft drinks, tea, coffee, excessive consumption of drugs (Smoking, Alcoholism, Tobacco etc.), day dreaming, night awakening and craving for more pleasures Human physical and mental abilities have greatly decreased, as a result of which diseases and stress surround the body and mind all the time.

The special effect of geographical environment and food habits has also been seen on the origin of acidity disease. In Malvanchal's food and drink, foods made from gram flour, food items containing more chili- spices and rich food items are used in large quantities. The residents of this region who are used to eating sev made of gram flour, salty as well as other spicy things, are more likely to suffer from acidity due to the special food style.

Acidic disease has been seen as a side effect of many medicines given in the modern medical system, Non- Steroidal anti-inflammatory drugs (NSAIDS) like Aspirin, Ibuprofen, Nimesulide etc.

Permanent treatment of this disease is not available in modern medical system, use of antacid only gives temporary benefit, but complete solution is not possible. In practice, it has been seen that the best treatment of acidity disease is possible only through Ayurvedic medicine. Although different medical methods are trying to find successful and effective medicines at their own level, still the intensity of patients suffering from this disease is increasing in the present society. Therefore, it is the need of the present time that should be done on such a drug combination, which can be avoided by suppressing acidity disease in a safe way and avoiding the long- term side effects caused by this disease in the body.

From the priceless treasure of Ayurveda, for the treatment of acidity, the best, easily accessible and low- cost "Abhaya Pippalyadi" Yoga from Bhaishajya Ratnavali with all the components of Abhaya Pippalyadi Yoga (Haritaki, Pippali, Draksha, Sita, Dhanyak, Yavasa) has Pitta virechana and Kostha suddhi effect and it can be inferred from the virtues of being madhura vipaka and Sheetavirya properties that it is a successful and cheap medicine for acidity.

AIMS & OBJECTIVES

- Effectiveness of *Abhaya Pippalayadi yoga* on *Amlapitta roga* (Acidity).
- Pharmaceutical study of *Abhaya Pippalyadi Yoga.*

DRUG REVIEW

Medicine is an old as life itself. The survival of the species demands that simultaneously with the appearance of disease, all living things have also evolved the means to combat disease. The higher animals are guided by instinct to seek remedies for illness in plants and herbs, which have extended the scope of this search for remedies.

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In the context of drug *(Aushadhi), Acharya Charaka* said ; There is no available matter (substances) in the world, which has no medicinal values, but it should be used with planning according to need. [2]

According to WHO "A drug is any substance or product that is used or intended to modify or explore physiological or pathological systems for the benefits of the recipient."[3]

The four pillars of treatment in Ayurveda are physician, medicine, attendant, and patient. The wise physician starts treatment after thorough analysis of an ideal therapeutic procedure, thus he never commits mistake in administration of remedial measure.[4]
The comprehensive knowledge of the drug is very important to physician because without knowledge of the drug, the patient cannot be treated properly. In this way, all *Ayurvedic* classics advocate specific formulation for particular disease. While treating a patient the selection of modalities comes after the proper diagnosis of the patient. It should be suitable to the patient and against the ailment as well as *Doshas* involved.

Ayurvedic treatise speak about the importance of drugs as 'Nothing in world exists which does not have the therapeutic utility.' Taking this fact into consideration *Ayurvedic* physicians have formulated single as well as compound drug for cure as well as prevention of various ailments. The theory of *Tridosha* is very special to various concepts of *Ayurvedic*. Drugs and medicinal plants are described for their properties and uses keeping the *Tridoshas* concept in consideration. Thus, the properties of a particular drug may be described as *Vata-hara, Pitta shamak* or *Kapha-Nashak* or vice-versa. According to the predominance of a particular *Dosha* in a disease the symptoms may present. The selection of drug is also to be made according to keeping the three *Doshas* concept in view.

ABHAYA PIPPALYADI YOGA

In the present modern era, due to changing life style and subsequent indulgence in faulty dietary habits and faulty way of life increasing trend of the disease *Amlapitta* is found. This disease has *Chirkarita*, which engenders in to *Dhatugtata Avastha* and its complications like *Amashaya Vrana* (peptic ulcers). The modern medical management of the disease has several shortcomings and various side effects. Due to all these reasons the drug *Abhaya Pippalyadi Yoga* which are mentioned in the *Amlapitta Adhikara* of *Bhaisajya Ratnavali* were selected for the present study.
Abhayapippalidraksha sita dhanyayavaskam,Madhunam kanthdahghnampittashleshmaharam param.

MATERIAL AND METHOD

Material Use
Abhaya Pippalyadi Yoga is prepared by *Churna kalpana* procedure as per mention in *Shadhandhar Samhita Madhyamkhand.*

Method of Preparation of *Abhaya Pippalyadi Yoga***:**
The drug was prepared by *Churna Kalpana* method in mini pharmacy of Vikram University Pharmacy, Ujjain by adopting classical method.

Method of Preparation : (*Sharangadhar Madhyam Khand* 6/1)

Table 1 : Ingredients of *Abhaya Pippalyadi Yoga*

Sr.No.	DRUG NAME	BOTANICAL NAME	FAMILY	PART USED	DOSE
1.	*Abhaya*	*Terminalia chebula*	*Combretaceae*	*Phal*	*1 Part*
2.	*Pippali*	*Piper longum*	*Piperaceae*	*Phal*	*1 Part*
3.	*Draksha*	*Vitis Vinifera*	*Vitaceae*	*Phal*	*1 Part*
4.	*Sita*	*Rock Sugar*	-	-	*1 Part*
5.	*Dhanyak*	*Coriandrum Sativum*	*Umbelliferae*	*Phal*	*1 Part*
6.	*Yavas*	*Alhegi Camelorum*	*Leguminosae*	*Panchang*	*1 Part*
7.	*Madhu*	*Honey*	-	*Madhu*	*Anupana*

Method of Preparation

- All ingredients were taken as mentioned above.
- It was prepared coarse powder form by Udukhala Yantra.
- Then it was grinded by mixer and it prepared fine power form.
- Powder was passed by 60 no BSS sieve.
- *Abhaya Pippalyadi Yoga* was obtained.

Observations

- At the time of pounding and grinding, good smell of ingredients was felt.
- It was easily powdered by mixer.
- *Abhaya Pippalyadi Yoga* was fine powder, gray color with smell.

Precautions

- Ingredients should take genuine.
- Heat should not generate at the time of grinding.
- It should be prepare fine powder.

ANALYTICAL STUDY

INTRODUCTION
Pharmaceutical analysis helps to confirm the quality of finished drug forms.
Though principles of drug standardization at different stages of pharmaceutics (process and finished product) have been highlighted at many instances in *Ayurvedic* treatises it is well known fact that there has been unprecedented technological advancement. It becomes our duty to utilize the same and bring more objectivity to the standardization of *Ayurvedic* formulations. In present study certain parameters of finished drug that is *Abhaya Pippalyadi Yoga* was studied to ascertain

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the qualities.

AIMS AND OBJECTIVES

- To evaluate the organoleptic characters of the test drug.

MATERIALS AND METHODS

1. The drug was prepared by *Churna kalpana* method in pharmacy of Vikram University Pharmacy, Ujjain by adopting classical method.
2. Complete study was carried out in the Pharmaceutical Chemistry Lab, Vikram University, Ujjain. Suitable method was adopted for the study of following parameters as per CCRAS recommendation.

PARAMETERS STUDIED

Organoleptic Parameters

The organoleptic character of *Ayurvedic* drug is very important and give the general idea regarding the genuineness of the sample. Besides quality control measures *Rupa* (colour), *Rasa* (taste), *Gandha* (odour) and *Sparsha* (texture) pertaining to *Panchagyanendriya Pariksha* are noted. These primary parameters are important, the verification of which generates confidence in patient as well as in the physician.

TABLE 2 : Organoleptic Parameters of *Abhaya*

Sr. No.	Parameters	Abhaya
1.	*Roop* (Colour)	Brownish Yellow
2.	*Rasa* (Taste)	Kashayam
3.	*Gandha* (Smell)	Aromatic
4.	*Sparsha* (Touch)	Rough

TABLE 3 : Organoleptic Parameters of *Abhaya Pippalyadi Yoga*

Sr. No.	Parameters	***Abhaya Pippalyadi Yoga***
1.	Colour	Brownish gray
2.	Odour	Smelly
3.	Taste	Kashaya madhura
4.	Texture	Powder
5.	Touch	Rough

The study had been carried out in 20 patients, randomly divided in this group. The standard ***Abhaya Pippalyadi Yoga*** was prepared by classical method in pharmacy of Vikram University, Ujjain and was used to assess its efficacy in *Amlapitta*.

Table 4 - GROUPING AND POSOLOGY

Group	**A**
Name of Therapy/Drug	***Abhaya Pippalyadi Yoga*** *In Amlapitta*
Number of Patients	20
Type of Study	Open RCCS
Duration of therapy/Drug Trial	1 Month
Dose	05 gms
Duration	2 times / day
Anupana	Madhu
Route	Oral
Randomization	Simple random sampling

***** RCCS - Randomized controlled Clinical study.

A special **SCORING PATTERN** was adopted for the symptoms.

- ***Avipak (*Indigestion*)***

Table 5.1 - *Avipak (*Indigestion*)*

Sr. No.	EXPLANATION	GRADE
1.	No Indigestion	0
2.	Digest normal usual diet in 9 hours	1
3.	Digest normal usual diet in 12 hours	2
4.	Digest normal usual diet in 24 hours	3

- ***Klama (*Tiredness*)***

Table 5.2 - Klama (*Tiredness*)

Sr. No.	EXPLANATION	GRADE
1.	No Tiredness	0
2.	Feel tired after exertion work	1
3.	Feel tired after normal work	2
4.	Feel tired after taking rest	3

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- ***Utklesh*** **(Nausea)**

Table 5.3 - Utklesh **(Nausea)**

Sr. No.	EXPLANATION	GRADE
1.	No Nausea	0
2.	Feel nausea after eating some peculiar food	1
3.	Feel nausea after eating all kind of food	2
4.	Full day nausea not related to food	3

- ***Tiktamlaudgar (*****sour and bitter belching*****)***

Table 5.4 - Tiktamlaudgar (**sour and bitter belching*****)***

Sr. No.	EXPLANATION	GRADE
1.	No sour and bitter belching	0
2.	Sour and bitter belching after taking spicy food	1
3.	Feel nausea after eating all kind of food	2
4.	Full day nausea not related to food	3

- ***Guruta*** **(Heaviness)**

Table 5.5 - Guruta **(Heaviness)**

Sr. No.	EXPLANATION	GRADE
1.	No heart and throat burning sensation	0
2.	Burning sensation after taking of spicy food	1
3.	Burning sensation even after taking normal food	2
4.	Burning sensation even on empty stomach	3

- ***Aruchi*** **(Anorexia) :**

Table 5.6 - Aruchi **(Anorexia)**

Sr. No.	EXPLANATION	GRADE
1.	No anorexia	0
2.	Eat food only two times without any snacks in between meals	1
3.	Eat only once	2
4.	Have no feeling of appetite	3

CRITERIA FOR THE ASSESSMENT OF OVERALL EFFECT OF THE THERAPY

The total effect of treatment had been assessed in the terms of complete remission, marked improvement, moderate improvement, mild improvement, and no changes.

Table 6 - CRITERIA FOR THE ASSESSMENT OF OVERALL EFFECT OF THE THERAPY

Sr. No.	CHANGE	EXPLANATION	GRADE	RESULTS
1.	No Change	Up to 25% relief in signs and symptoms	0	Not Significant
2.	Mild Improvement	26-50% relief in the signs and symptoms	1	Quite Significant
3.	Moderate Improvement	51-75% relief in the signs and symptoms	2	Significant
4.	Marked Improvement	Above 76%	3	Very Significant
5.	Complete Remission	100% relief in the signs and symptoms	4	Extremely Significant

RESULTS AND INTERPRETATION

The data obtained in this clinical trial was analysed by adopting statistical tests as mentioned below:

1. Percentage of improvement in each parameter of each scale in both the treated groups was calculated.
2. The Wilcoxon signed-rank test was applied to the non-parametric statistical data for evaluating the difference before and after treatment as well as in weekly interval.

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a) Percentage of improvement in each parameter

To evaluate this, total number of scores observed before treatment (B.T.) and after treatment (A.T.). Average of respective scores was calculated and percentage of change/ improvement was drawn by following formula:

$$\frac{\text{Average BT - Average AT x 100}}{\text{Average BT}}$$

B) Application of Wilcoxon signed-rank test

The Wilcoxon signed-rank test was applied to the data of 20 patients of *Amlapitta* to find the effect of individual therapy. The Wilcoxon signed-rank test is a non-parametric statistical hypothesis test for the case of two related samples or repeated measurements on a single sample (Intra group).

Steps to apply the test are as follow :

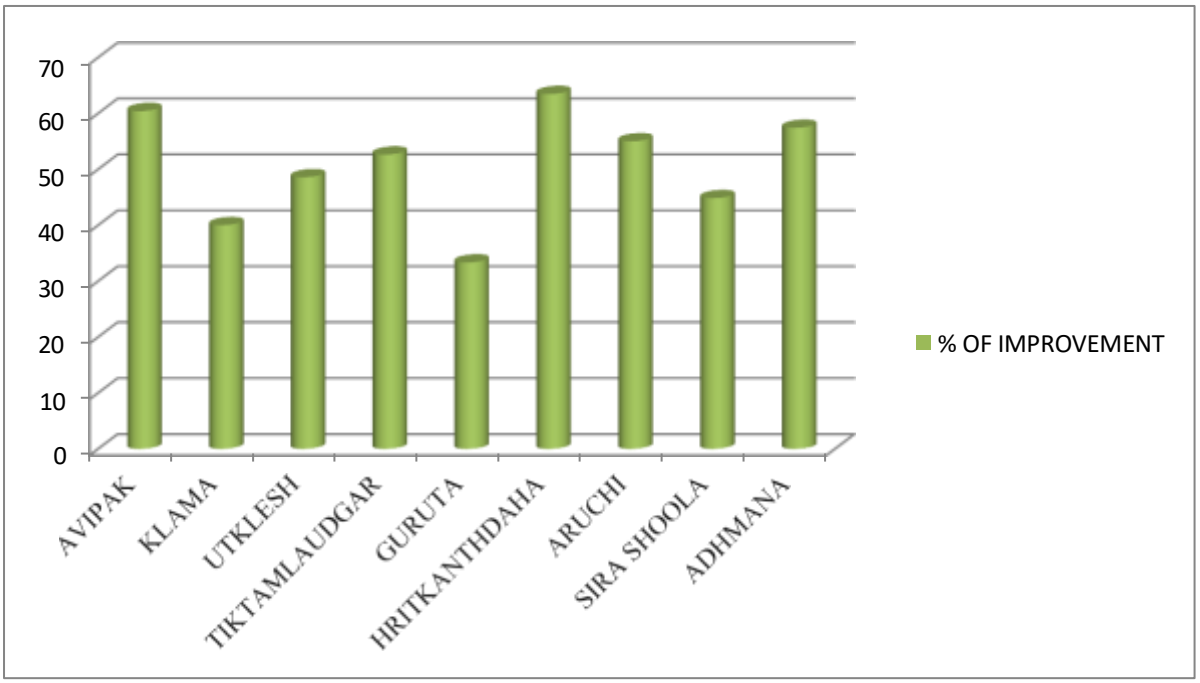
1. The sign of B.T. - A.T. is denoted in the Sign column by either (+) or (-). If B.T. and A.T scores are equal, then the value is thrown out.
2. The values of B.T. - A.T. are given in the next two columns.
3. The last two columns are the ranks. The absolute rank column has no signs, and the signed rank column gives the ranks along with their signs.
4. The data is ranked from the smallest value to the largest value. In the case of a tie, ranks are added together and divided by the number of ties.
5. The test statistic, W+, is given by the sum of all of the positive values in the Signed Rank column. The test statistic, W-, is given by the sum of all the negative values in the Signed Rank column. The minimum of these is considered.
6. Lastly, this test statistic is analysed using a table of critical values. If the test statistic is less than or equal to the critical value based on the number of observations n, then the null hypothesis is rejected for the alternative hypothesis. Otherwise, the null hypothesis is not rejected.

In the present study to make calculations easy & without manual errors GraphPad Instat software (version 3.10,32 bit for win 95/NT created July 10, 2009), was used for statistical analysis.

Table No 7.1 - Showing the Overall response of *Abhaya Pippalyadi Yoga* for 1 Month on 20 Patients of Group A

ASSESSMENT PARAMETER	ON THE BASIS OF SYMPTOMS				CHANGE
	B.T. (+)	A.T. (-)	RELIVED	% OF IMPRO-VEMENT	
AVIPAK	48	19	29	60.41	Significant
KLAMA	15	09	06	40	Quite Significant
UTKLESH	35	18	17	48.57	Quite Significant
TIKTAMLAUDGAR	38	18	20	52.63	Significant
GURUTA	12	08	04	33.33	Quite Significant
HRITKANTHDAHA	52	19	33	63.46	Significant
ARUCHI	40	18	22	55	Significant
SIRASHOOLA	29	16	13	44.83	Quite Significant
ADHMANA	42	18	24	57.41	Significant

Graph 7.2 - Showing the Overall Changes of Group A



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Table No 8 - Showing the Statistical analysis Showing the Overall response of *Abhaya Pippalyadi Yoga* for 1 Month on 20 Patients of Group A

GROUP A	MEAN			% OF IMPRO-VEMENT	S.D.	S.E.	't' Value	'p' Value
	B.T. (+)	A.T. (-)	MEAN DIFF.					
AVIPAK	2.4	0.96	1.45	60.41	0.686	0.153	9.44	<0.001
KLAMA	0.75	0.45	0.3	40	0.470	0.105	2.85	<0.02
UTKLESH	1.75	0.9	0.85	48.57	0.670	0.15	5.66	<0.001
TIKTAMLAUDGAR	1.9	0.9	01	52.63	0.648	0.145	6.89	<0.001
GURUTA	0.6	0.4	0.2	33.33	0.410	0.091	2.17	<0.05
HRITKANTHDAHA	2.6	0.95	1.65	63.46	0.670	0.15	11.0	<0.001
ARUCHI	2.0	0.9	1.1	55	0.788	0.176	6.24	<0.001
SIRASHOOLA	1.45	0.8	0.65	44.83	0.745	0.166	3.90	<0.001
ADHMANA	2.1	0.9	1.2	57.41	0.695	0.155	7.71	<0.001

In this Table showed the Percentage of Avipak Relief was 60.41 % and the effect of the therapy was Significant (S) at 'P' = < 0.001.

In this Table showed the Percentage of Klama Relief was 40 % and the effect of the therapy was Quite Significant (QS) at 'P' = < 0.02.

In this Table showed the Percentage of Utklesh Relief was 48.57 % and the effect of the therapy was Quite Significant (QS) at 'P' = < 0.001.

In this Table showed the Percentage of Tiktamlaudgar Relief was 52.63 % and the effect of the therapy was Significant (S) at 'P' = < 0.001.

In this Table showed the Percentage of Guruta Relief was 33.33 % and the effect of the therapy was Quite Significant (QS) at 'P' = < 0.05.

In this Table showed the Percentage of Hritkanthdaha Relief was 63.46 % and the effect of the therapy was Significant (S) at 'P' = < 0.001.

In this Table showed the Percentage of Aruchi Relief was 55 % and the effect of the therapy was Significant (S) at 'P' = < 0.0101.

In this Table showed the Percentage of Sirashoola Relief was 44.83 % and the effect of the therapy was Quite Significant (QS) at 'P' = < 0.0101.

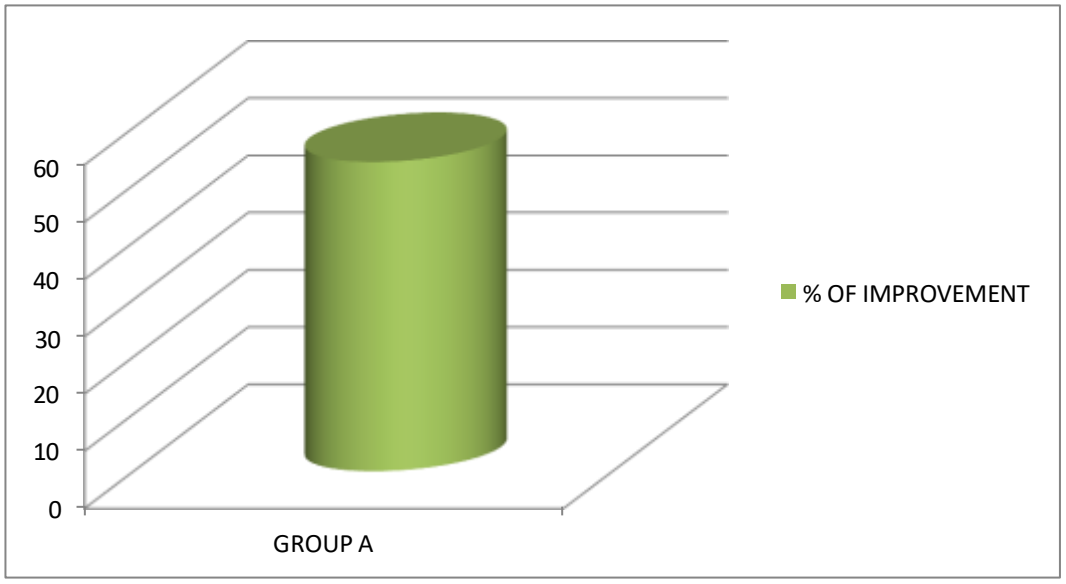
In this Table showed the Percentage of Adhmana Relief was 57.14 % and the effect of the therapy was Quite Significant (QS) at 'P' = < 0.0101.

Table No 9.1 - Showing the Total symptoms Score of % of Improvement in Groups A

Total Symptoms Score	Score – B.T. (+)	Score – A.T. (-)	% of Improvement	Results
Group A	**311**	**143**	**54.01**	**S**

The total symptom score in-group A, before treatment was 311 which was reduced to 143 after treatment thus 54.01 % relief was obtained Result was Significant (S).

Graph 9.2 - Showing the Score of % of Improvement in Groups A

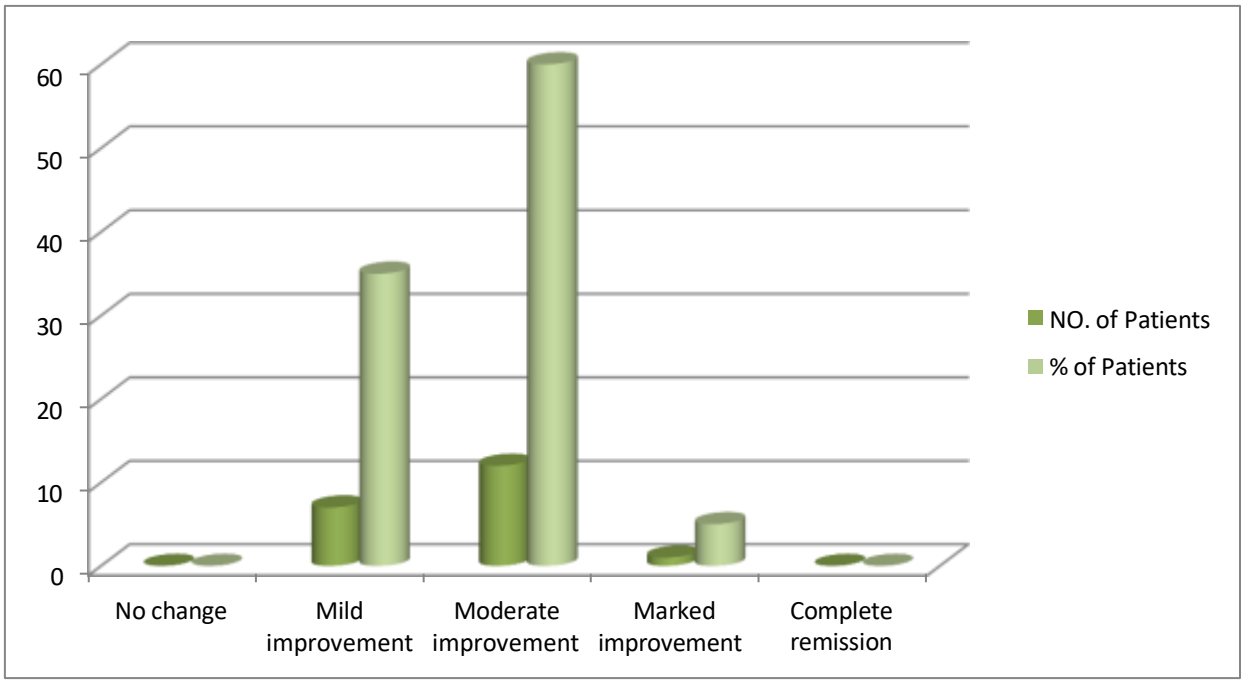


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Table No 10.1 - Showing the Assessment of Overall Effect of the Therapy for Group A

CHANGES	No Change	Mild Improvement	Moderate Improvement	Marked Improvement	Complete Remission
GRADE	0	1	2	3	4
NO. of Patients	00	07	12	01	00
% of Patients	00	35	60	05	00

Graph 10.2 - Showing the Assessment of Overall Effect of the Therapy For Group A



In this table reveals the results of study in 20 patients of *Amlapitta.* It clearly shows that 00 (00 %) patients were No change**,** 07 (35 %) patients were Mild improved, 12 (60 %) patients were Moderately improved while 01 (05 %) patients showed Marked improved and 00 (00 %) patients were Complete Remission.

FOLLOW UP

Follow up was done after one month completion of treatment to see recurrence or complication. On completion of successful follow up of 1 month from complete treated of *Amlapitta* (Hyperacidity), Four patient had reported recurrence of from group-A up to one week after completion of treatment. Hence, this study reveals that these treatments are conservative treatment. Which can relieve pain and increase chances of treated of *Amlapitta* (Hyperacidity). So, for this , advice to patients to drink plenty of water ,take green and leafy vegetables and more fibre diet and taking laxatives even during and after treatment to avoid passing hard stool and Continue following *Yogabhyas*.

DISCUSSION

Probable mode of action of *Abhaya Pippalyadi Yoga*:

Abhaya Pippalyadi Yoga contains *Abhaya, pippali, draksha, sita, dhanya, yavaskam, Madhunam,* having *Tikta, Madhura* and *Kashaya rasa,* as these are *Pittashleshmashamaka rasa* helpful in normalizing the excessive *Ushna, Tikshna* properties of *Pitta and aruchi, Gauravam properties of Shleshma*. These drugs having *Agnideepana*, *Pachana* properties converts S*amapitta* into *Niramavastha*. *Madhu* has been described as *Pathya* in *Amlapitta*. *Madhura rasa.* It increases the potential of drug.

CONCLUSION

It will not become successful in its goals without finding some conclusion on any report. There is certainly some positive conclusion to a scientific discussion on the entire analysis. The following conclusions lead to a near perusal of the observation and inference in this Clinical study following conclusions had been drawn;

- Some GIT disorders like Hyperacidity, Gastritis, Non-ulcer Dyspepsia, GERD can be included under the broad umbrella of *Amlapitta.* It is the common problem of all the age groups. It is the most common cause leading to physicians visits worldwide.
- The knowledge of etiological factors is very important as *Nidana Parivarjana* is the first line of treatment. It plays very important role to cure as well as to prevent its recurrence. If the patient does not follow the *Pathya-Apathya* then there is no importance of drug as *Laulya* is the main etiological factor, also mentioned by *Kashyapa*. The treatment protocol given in the textbooks

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have given more emphasis on life style management.

- In *Amlapitta*, there is involvement of *Annavaha Srotas* along with *Rasavaha Srotas* in most of the patients.
- *Agnimandya* is the main factor responsible for *Amlapitta*.
- In today's pattern of life style as "Hurry,Worry and Curry"GIT disorders are the most common, not only affecting physical health but also Psychological and Social health.
- *Madhavakara* has described the *Amlapitta* as *Swatantra Vyadhi*, due to the
- *Pittaprakopa* which was *sanchita* in its own *sanchayavastha.*
- He describes its *Samprapti* mainly due to *Pittavriddhi* by its own *Ushna*, *Tikshna*, *Drava*, *Sara*, *Amla Guna*.*Acharya Kashyapa* described it as "*Bhishakmohakara*". He describes the *Samprapti* of *Amlapitta* as *Chirakari* in nature, due to *Agnimandya*, *Shuktapaka*, *Laulya*, as this vicious cycle goes on it is *Chirakari* in *Swabhava*. *Acharya Charaka* has described the *Amlapitta* after association of *Pitta* with *Annavisha* or *Amavisha*. This indicates the *Amlapitta* as *Paratantra Vyadhi* as *Pittaprakopa* occurs due to *Ama*, not by its own *Prakopaka* factors.
- Most of the patients having addiction of tea, tobacco, smoking, alcohol which also plays an important role in etiology and aggravating factors also.
- Apart from the above factors, socio-economic status, mental stress and strain, personal habits, also are important causative factors.
- Symptoms of *Amlapitta* aggravate in *Sharada*, *Varsha* and *Grishma Ritu.*
- *Acharya Charaka* has described milk as *Amlapittashamaka*. But it can be useful mainly in the *Swatantra Samprapti* of *Amlapitta* as it has not related with *Ama*.Milk can not relieve the *Partantra* type of *Amlapitta* as it causes increase in *Ama* due to its *Snigdha*, *sheeta*, *Guru Guna*s.
- The *Avipak*, which is main contributing factor for Daha can be relieved effectively by the *Abhaya Pippalyadi Yoga.*
- During treatment period of 1 month as well as follow up period of one week, no adverse effect of any drugs was noticed.
- *Amlapitta* management was achieved effectively by these treatment Protocols.
- *Abhaya Pippalyadi Yoga* showed Significant results on *Avipak*, *Tiktamlaudgar*, *Aruchi*, *Hritkanthadaha* and *Adhmana* and showed Quite significant results on *Klama*, *Utklesh*, *Guruta and Sirashoola.*
- Thus, null hypothesis (H0) is rejected and alternative hypothesis (H1) is accepted that is the intervention *Abhaya Pippalyadi Yoga* have effective in the management of *Amlapitta* (Hyperacidity).

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