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Comparative clinical efficacy of Guduchyadi syrup and Guduchyadi Ghanvati in management of Amlapitta

Research Article

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Abstract

Introduction: Amalpitta is most common problem nowadays. Guduchyadi yoga kwatha was indicated in classics in the management of Amlapitta. Kwatha is very effective but it is unpleasant to some patients. So the kwatha was converted into preferable dosage form as requirement of present era. Material and Method: A Clinical trial was carried out on 60 Patients of Amlapitta aged 20 to 60 years with complaints of Aruchi, Avipaka, Tiktodgar, Amlodgar, Urodaha, Kanthadaha etc., who were registered from OPD of Government Ayurved Hospital, Vadodara. They were equally divided into two groups i.e. Group A- Guduchyadi Syrup given in 20ml BD dose and Group B- Guduchyadi Ghanavati given at 500mg2 BD). Each group was treated for 28 days administered empty stomach. The clinical assessment was carried out on the 28th day and 2 weeks after the 28 days of treatment (after follow up period) for the objective & subjective parameters and it was seen that both the dosage form Guduchyadi Syrup and Guduchyadi Ghanavati were very effective and cured or markedly relieved the symptoms of Amlapitta. Results: The study shows the effect of Guduchyadi Syrup and Guduchyadi Ghanavati, which led to cure in 16 patients (53.33%) and 22(73.33%) patients respectively, and markedly improvement in 12(40%) and 8(26.67%) patients affected with Amlapitta disease respectively. Conclusion: Both trial dosage forms of Guduchyadi Yoga, (Group A- Syrup & Group B- Ghanavati) relieved the symptoms of Amlapitta and both the formulation have comparatively similar efficacy in the management of Amlapitta.

Key Words: Amlapitta, Guduchyadi yoga, Guduchyadi syrup, Guduchyadi Ghanavati.

Introduction

Panchvidha kashaya kalpana are very useful and effective but it comes with some drawbacks in usage, so they are less popular and disagreeable to some patients. Safety, Efficacy, Stability and palatability are four basic requirements of a good drug dosage form.

Nowadays, modern life style and food habits of most of the people in the world are suffering from a common disease, Amlapitta. Peculiarities of this disease are, increased prevalence, vast manifestation of symptoms, requires prolonged dietetic control. If not treated in proper time, it may create major problems and relapses are very common. Guduchvadi voga containing Guduchi (Tinospora cordifolia Willd.), Khadira (Acacia catechu Willd.), Yastimadhu (Glycyrrhiza glabra Linn.) and Daruharidra (Berberis aristata DC) is given in the kwatha form in the classical textbook for the management of Amlapitta. The Kwatha is one of the Panchvidha kashaya Kalpana having very short shelf life which leads to its contamination in a short period of

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time. Thus it doesn't fulfill basic requirement of a good dosage form. So it was converted into new dosage form as Guduchyadi syrup and Guduchyadi Ghanavati to fulfill requirement of the present era to make available in the acceptable form to the people globally.

Aims and objectives

Aim: To evaluate efficacy of Guduchyadi yoga in the form of Syrup and Ghanavati.

Objectives:

1.To compare the efficacy of two different dosage forms of Guduchyadi yoga i.e. Guduchyadi Syrup and Guduchyadi Ghanavati in the management of Amlapitta.

Ethical committee clearance and CTRI registration

As this was a clinical research, Institutional Ethics Committee (IEC) approval was taken prior to initiation of research vide its letter No. GAC/VAD/IEC/ 22/2017 dated 22/09/2017. Study was registered in Clinical Trial Registry of India with no CTRI/ 2018/06/1458.

Materials and Methods

Preparation of trial drug

Raw materials of all the drugs were obtained from Govt. Ayurved Pharmacy, Rajpipla and prepared Guduchyadi Syrup and Ghanavati executing SMP by

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Irvee N Solanki et.al., Clinical efficacy of Guduchyadi syrup and Guduchyadi Ghanvati in management of Amlapitta

preparing a standard Pharmaceutical Performa. Then it was preserved in airtight container.

Selection of Patients

70 patients of *Amlapitta* with age 20 to 60 years were enrolled from OPD of Government Ayurved Hospital, Vadodara. Out of which 60 completed the treatment. Total 35 patients were registered in Group A, among them 30 patients were completed and in Group B, total 35 patients were registered among them 30 patients were completed the treatment. Detailed history, complete general and systematic examination was done.

Inclusion criteria

Patients having age between 20-60 yrs, for selection of patients with classical sign and symptoms of Amlapitta Aruchi, Avipaka, Tiktodgar, Amlodgar, Gurukostha, Shiroruja, Urodaha, Kanthadaha, Antrakujan.

Exclusion Criteria:

Patients having age less than 20 years and more than 60 years, Patients Age below 20yrs and above 60yrs., Malignant and accelerated Hypertension, Pregnant women, Lactating mothers, Patients of any other severe illness.

Sixty patients were randomly grouped into two groups. Each group consisted of 30 patients and the groups were named as Group A and B. They were administered with *Guduchyadi* Syrup (group A) and *Guduchyadi* Ghanavati (group B) for 2 times a day (morning and evening) on empty stomach for 28 days. All patients were advised to follow *Pathyapathya*.

Assessment scale

Parameter assessment was carried out by numbering relieves in the symptoms. Evaluation of response in view of the changes in the clinical features, the grading was as below

Result	Criteria				
Cured	100% relief in the signs & symptoms was considered as cured.				
Markedly Improved	70 - 99% relief in the signs & symptoms was considered as markedly improved.				
Improved	36 - 70% relief in the signs & symptoms was considered as (moderate) improved .				
Unimpro ved	< 35% relief in the signs & symptoms was considered as mild improved or Unimproved.				
Severity increases	If the patient have increases the sign and symptoms was considered as Severity increased.				
Dropped out	If the patients hadn't completed course regularly and discontinued treatment during trial for any reason was considered as Dropped out.				

Statistical analysis

The effect of therapy in both the groups is assessed by applying t-test. The results obtained are considered highly significant for P<0.001, significant for P<0.05, and insignificant for P>0.05.

Observations and Results

Table no.1 Total number of patients registered

Trino	No. of Patients Total		%	
Туре	Group A	Group B	70	
Completed	30	30	60	85.71
Discontinued	5	5	10	14.29
Total	35	35	70	100

In this study, total 70 patients were registered. 60 patients had completed the treatment in two groups. (Table 1)

Cardinal Signs	Grou	рА	Group B		
	No. of Patients	%	No. of Patients	%	
Avipaka	26	86.67	29	96.67	
Aruchi	25	83.33	18	60	
Tiktodgar	26	86.67	26	86.67	
Amlodgar	28	93.33	25	83.33	
Gurukostha	27	90	25	83.33	
Shiroruja	20	66.67	26	86.67	
Kanthadaha	21	70	16	53.33	
Antakujana	17	56.67	11	36.36	
Urodaha	27	90	25	83.33	

Table no.2 Percentage wise cardinal signs and symptoms

Table no. 5 Comparison between two groups in ener complaints of Amaquaa								
Sr. No	Chief Complaints of Amlapitta	Relief in %		SD		t value		Group A
		Group A	Group B	Group A	Group B	tt	P value	V/S Group B
1	Avipaka	88.14	98.85	1.135	0.944	0.124	0.902	NS
2	Aruchi	98.77	87.5	0.999	1.258	1.125	0.216	NS
3	Tiktodgar	89.74	95.49	1.145	1.322	-0.313	0.755	NS
4	Amlodgar	81.55	92	0.937	1.281	0.459	0.648	NS
5	Gurukostha	91.36	100	1.053	1.106	1.195	0.237	NS
6	Shiroruja	98.41	100	1.008	1.149	0.597	0.553	NS
7	Kanthadaha	98.81	100	1.02	1.579	-0.389	0.699	NS
8	Antakujna	93.81	90	0.828	0.855	1.534	0.13	NS
10	Urodaha	89.51	96.67	1.094	1.363	-3.239	0.002	S

International Journal of Ayurvedic Medicine, Vol 11 (2), Table no. 3 Comparison between two groups in chief complaints of Amlanitta

Table no. 4 Overall effect of therapy in 60 patients

Result	Group A (no. of patients)	%	Group B (no. of patients)	%
Cured	16	53.33	22	73.33
Markedly Improved	12	40	8	26.67
Moderately Improved	2	6.67	0	0
Unimproved	0	0	0	0
Severity increased	0	0	0	0
Overall		92.41		96.71

Group A

53.33% patients had been cured *Amlapitta* by *Guduchyadi* Syrup when 40% patients had markedly improved and 6.67% had improved moderately symptom of *Amlapitta*.

Group B

Guduchyadi Ghanavati had complete cured *Amlapitta* in 73.33% patients when 26.67% patients had markedly improved and 6.67% had improved moderately.

Overall

Guduchyadi Syrup and *Guduchyadi Ghanavati* had exhibited significant result (Group A-92.41%, Group B-96.71%) in the management of *Amlapitta*. A Comparative efficacy between these two groups is not significant (P>0.05). So both dosage forms of *Guduchyadi Yoga* are merely similar effective in the management of *Amlapitta*.

While evaluating the overall effect of therapy, it was observed that none of the patients remained unimproved or severity increased due to medicine.

Discussion

Nowadays in the modern life style and irregular food habits, many people are suffering from a common disease called *Amlapitta*. If it is not treated in a proper time, it may cause major problems. *Guduchyadi Yoga kwatha* has been mentioned in the management of *Amlapitta* in classics. The *kwatha* form is less preferable to some patients. *Kwatha* doesn't complete these criteria as it has very short shelf life about one day. So, it has to be prepared immediately and daily when they have to consume. Further *kwatha* is nonpalatable because of its bitter and disagreeable taste and patient discontinue medicine. Thus, to overcome these drawbacks the *Guduchyadi yoga kwatha* was converted into further two dosage forms as *Ghanavati* and Syrup which are more palatable amd shelf life of Syrup and



Urvee N Solanki et.al., Clinical efficacy of Guduchyadi syrup and Guduchyadi Ghanvati in management of Amlapitta

Tablet can extend up to 3yrs. *Guduchyadi yoga* having bitter, astringent and Sweet taste and was found very effective in *Amlapiita* clinically. It shows that *Guduchyadi* Syrup and *Guduchyadi Ghanavati* had exhibited significant result (Group A-92.41%, Group B-96.71%) in the management of *Amlapitta*. A Comparative efficacy between these two groups is not significant (P>0.05). So both dosage forms of *Guduchyadi Yoga* are comparatively similar effective in the management of *Amlapitta*.

Conclusion

The dosage forms of *Guduchyadi yoga* that is *Guduchyadi* Syrup and *Guduchyadi Ghanavati* was found very effective in the management of *Amlapitta* individually. Comparative efficacy between *Guduchyadi* Syrup and *Guduchyadi Ghanavati* was found similar in the management of *Amlapitta*.

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