ISSN: 2277–4998



International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS) 'A Bridge Between Laboratory and Reader'

<u>www.ijbpas.com</u>

ANTIPYRETIC EFFECT OF AMRITTOTTAR KASHAYA GHAN VATI IN THE MANAGEMENT OF FEVER –A PILOT CLINICAL STUDY

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Received 12th Dec. 2021; Revised 14th Jan. 2022; Accepted 7th Feb. 2022; Available online 5th March 2022

https://doi.org/10.31032/IJBPAS/2022/11.3.1103

ABSTRACT

Background: Fever is one of the most common presenting signs of illness in officebased pediatric practice, and is present in 19% to 30% of encounters.¹ Because of immature immune system of children, they are more prone to infections in which fever is one of the symptoms. It's the very initial symptoms force the patients to visit clinician. Although established paracetamol has good antipyretic effect but it does not correct cause of fever, where as in *shastra* or *samhitas* mentioned that properties of *Amruttotar kashaya* are not only *jwarghna* but also has properties that may affect the cause of *jwara*. In present pilot clinical study *Amrutottar kashaya ghan vati* was prepared and used as symptomatic antipyretic agent. **Materials and Methods**: *Amrutottar kashaya ghan vati* were prepared in Late Kedari Redekar Ayurveda pharmacy and was used in patients having fever. 31 Patients were enrolled from all different nearby hospitals of Sankeshwar city. Special case record proforma were used for collection of data. **Results**: In subjective parameters Significant antipyretic activity of *Amrutottar kashaya ghan vati* was noted 80% of the individual with dose of 2 tablets (500mg each) in TDS. Statistically non-significant results were observed in reduction of fever but significant results were observed in spike and duration of fever. **Discussion and Conclusion**: *Amrutottar kashaya ghan vati* is the combination having the drugs with, *kashaya* possesses the property of *Deepana*, *Paachana*, and *Anulomana* and thereby helps in treating all types of *Jwara* and can be used in day to day clinical Ayurveda practices.

Keywords: Antipyretics, Ayurveda, Amrutottar kashaya ghan vati, Fever INTRODUCTION –

Fever is one of the most common presenting signs of illness in office-based pediatric practice, and is present in 19% to 30% of encounters.¹ There are on average 8 visits for fever per child per year, one quarter of which are for fever 39°C, is a lower bound of the actual rate.² *Ayurvedic* literatures consider fever as disease as well as a symptom. *Jwara* was considered to be the most important of all the diseases because of its attributes to afflict the body, the mind and the senses.³

Fever is the important sign which can't be ignored. Fever causes the feeling of uneasiness and discomfort, along with loss of appetite, tastelessness, irritability as its cardinal subjective feeling.⁴ Apart from this increase in body temperature is alarming physiological sign which should be taken in account on priority basis. Therefore, to reduce the body temperature is the main aim of therapy while treating fever as disease or fever as symptom of other underlying disease. Reduction in body temperature is achieved with different mean in Allopathic medicine aiming mainly as antipyretic effect. Paracetamol, Ibuprofen, mefenamic acid, diclophenac sodium are different antipyretics are in used since long time, and this entire agent are found to be effective and safe in recommended doses. Though this drugs reduces the body temperature readily, but doesn't treat pathology of underlying diseases.

On the contrary *Ayurveda* have large number of multiple drugs combinations known as *Kashaya* for treatment of fever. All the ingredients of different *Kashaya* act on the different systems and organs and help to treat or cure the pathogenesis of underlying disease and to reduce the body temperature as well. In Ayurveda fever is known as *Jwara* and classified in different types. *Sharangdhara Samhita*, one of the legendary ancient Ayurveda drug formulatory describe *Amrutottar kashaya* as a treatment of *Jwara*. In order to increase the palatability, easy administration and potential of medicine; *Kashaya* can be converted to *Ghana Vati*, which is highly effective and potent. With this logic to reduce the dose and to increase the efficacy and palatability *Amrutottar kashaya ghan vati* was selected for this Pilot clinical study.

Fever is the commonest presentation of many diseases of childhood and is of very primary or of utmost concern as children may have chances to get febrile convulsion as one of the deadly complication of fever in paediatric age group. Considering this early intervention for fever in children is highly essential.

AIM:

- To evaluate the anti-pyretic effect of the *Amrutottar kashaya ghan vati* tablets as symptomatic treatment
- To observe safety of *Amrutottar kashaya* ghan vati.

INCLUSIVE CRITERIA:

- Temp between 99- 102° F.
- Fever of acute onset without any complications i.e. dehydration, convulsion, etc. Acute onset fever of 1to 3 days.
- Patient of either sex suffering from fever of age 18-80 years.
- Patients who agree to participate and sign the informed consent

EXCLUSION CRITERIA:

- Chronic fever associated with infective disorder.
- Fever more than 3 days and diagnosed with diarrhea, malaria, dengue, typhoid, pneumonia etc
- If fever exceeds beyond 102° F.
- If CRP > 6
- If fever exceeds beyond 5 days.
- Any febrile condition of patient requiring an immediate intervention depending on history and general condition at the point of examination as found by the investigator will be excluded from study.

ASSESSMENT CRITERIA

Objective parameters:

- Temperature (axillary body temperature in 0 F)
- CBC
- CRP

Subjective parameters:

- 1. Agnimandya
- 2. Angamarda,
- 3. Swedavarodh
- 4. Pindikodwestan
- 5. Shirashoola

MATERIALS AND METHODS:

Amrutottar kashaya ghan vati is the combination Guduchi, shunthi and Haritaki. *Amrutottar kashaya* from Sharangdhar Samhita was taken as the antipyretic medicine. In order to reduce the dose of medicine and to improve its potency, the *Amrutottar kashaya* was make in to Rasa kriya (Ghana Vati). All drug procured from the local market of the Belgaum City and authenticated by dravyguna department of SBSS Krishna Ayurveda medical college and hospital, Sankeshwar.

The finished product was prepared in GMP certified Late Kedari Redekar Ayurveda pharmacy Gadhingalaj with following the SOP for *Ghana Vati* formation. The 31 patients/subjects with fever having 18 to 60 years of age were enrolled in this study in between November 2021 to December 2021. According to age, weight and spike of fever we have given *Amrutottar kashaya ghan vati* in different amount to individual. Data

collected with specially prepared case record form .Data obtained were recorded in Microsoft Excel 2011 and all statistical analyses were performed with Graph Pad Prism software (version4.00). SPSS for Windows version 17.0, Chicago, USA, was also used for data analysis. Descriptive characteristics (mean and standard deviation) and percentage were performed for each parameter separately.

OBSERVATION AND RESULTS:

As it is pilot study all subjects of all age groups 18 to 70 are included in study, the lowest age limit was observed to 24 years while upper range of age was observed 68 years. Among which maximum number of patients are belongs to young adult age group (20-40 years).



Graph No- 1 Number of subjects completed study

31 patients were enrolled for the study, out of them 26 patients completed the study, and 5 were dropout.



Graph No.2: Etiological factors for fever in 26 patients

From 26 patient 95 % having viral fever and 5 % are having other causes

Graph No-3: Time Span taken to get Afebrile by 26 Patients treated with *Amrutottar kashya ghan Vati*



Maximum patients (85%) get afebrile before 2.5 hours suggest significant antipyretic effect of *Amrutottar kashaya ghan vati*.



Graph No: 4 – Number of days to reduce fever

On day 2 of drug administration 6 patients get afebrile, on day 3 of therapy 11 patients get afebrile and on day 4 of therapy 7 patients get afebrile. Maximum patients (80%) get afebrile on day 3 and 4 suggest significant antipyretic effect of *Amrutottar kashaya ghan vati*.



Day by day temperature were getting lower and lower, gives significant result of *Amruttotar* kashaya ghan vati in fever.



Graph No :6 - Subjective parameters score BT and AT

Chart no-1 Statistical analysis of Subjective paramaeters

	Agnimandya		Angamard		Swedavroadh		Pindikodwestan		Shirashool	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Mean	1.89	0.15	1.89	0.04	0.54	0	0.50	0	1.30	0
SD	0.86	0.46	0.59	0.20	0.58	0	0.51	0	0.61	0.20
SE	0.17	0.09	0.12	0.04	0.11	0	0.05	0	0.121	0.04
P value	<0.00	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.00	<0.0001	<0.000
	01							01		1
Statistica	-	Yes	-	Yes	-	Yes	-	Yes	-	Yes
lly S or										
NS										

In all subjective parameters Amrutottar kashyay ghan vati shows significant result in reduction

of lakshanas.





Mean WBC total count were increased from 5196 to 5554



Graph No: 8 - Paracetamol as a rescue medicine given -

Paracetamol is given as a rescue medicine in 4 patients.

Graph No: 9- Loose stool seen in patients



Out of 26 subjects 3 patients observed with loose stools, 2-3 episodes per day for 2 days.

DISCUSSION:

Ayurvedic literatures consider fever as disease as well as a symptom. *Jwara* was considered to be the most important of all the diseases because of its attributes to afflict the body, the mind and the senses.

The *Sanskrit* word "*uttara*" means predominant/later/followed by/ more

powerful/chief/excellent/ superior. Thus the name *Amrutottara Kashaya* suggest a *Kwatha* preparation in which the drug *Amruta* is more powerful, predominant among others, have powerful action and used as chief ingredient.

Amrutottara Kashaya originally mentioned in Sahasrayogam ⁵ and

Chikitsamanjari by the name of Tridosha Jwarahara Kashaya and Nagaradi Kashaya. Fever can be seen because of an infection, infestations, inflammation, infarctions and ischemia. infiltration. immunological, iatrogenic, idiopathic, inherited diseases, granulomatous diseases, endocrine disorders, Metabolic disorders. Though there is various the antipyretic medicines causes are universally used in conventional medicines along with the treatment of underlying disease pathology. Paracetamol is used as an antipyretic, it is use to subside the fever not to cure cause of disease. Paracetamol, especially at high doses, may induce upper GI symptoms such as abdominal pain/discomfort, heartburn. nausea or vomiting.⁶ Although established paracetamol has good antipyretic effect but it does not correct cause of fever, where as in shastra or samhitas mentioned that properties of Amruttotar kashava are not only jwarghna but also has properties that may affect the cause of jwara.

Jwar roag samprati ghatakas tells that Amashaya is udhbhav sthan for jwar, agnidusti is mandagni and strotodusti type is sang.⁷ This kashaya possesses the property of Deepana, Paachana, and Anulomana and thereby may help in treating all types of Jwara.⁸

Demographic profile -

31 patients enrolled in the study out of which 26 has completed the study, 05 were drop out. Majority of patients from 30-40 age group, having *vaat* and *pittaj prakruti*, from Hindu community and rural area.

Clinical profile -

Effect of therapy –*Amruttotar kahsay ghan* vati gives significant results in all subjective criteria p <0.0001. Agnimandya, Angamard and shirashool were major lakshanas found in the patients. It gives the clear direction that amashay is udhbhav sthan of Jwar that's why agnimandva is seen most of the patients. Amruttotar kahsaya ghan vati not statistically significant in reducing fever, may be because of low sample size. But it definitely helps as a antipyretic. On an average 3 to 4 days required to reduce the fever. Among 26 patients 19 patients were afebrile by the end of 3 day. Day by day temperature were lower and lower, form 2 day on ward mean temperature was below 99 F. Maximum patients (85%) get afebrile before 2.5 hours suggest significant antipyretic effect of Amrutottar kashaya ghan vati.

Adverse effects - Out of 26 subjects 3 patients developed loose stool 2-3 episodes per day for 2 days that were subsided without any intervention.

Probable mode of action – *Jwar* is *mandagni janya vyadhi* and *udhbhav sthan* is *aamashay*. This *kashaya* possesses the property of *Deepana*, *Paachana*, and *Anulomana* and thereby may help in treating all types of *Jwara*.⁸ Most of the ingredients having antipyretic, anti-inflammatory and antioxidant properties that may help as antipyretic action.

Hurdles during pilot study-

- Most difficult hurdles was 3rd wave of covid-19 pandemic, we have got many cases of fever but most of the patients does not ready for the RTPCR test. So we are unable to interpret on type of fever.
- Temperature recording during the night time was big challenge, so to overcome on that we have selected patients which are residing nearby to us and of medical background.

CONCLUSION -

- There is definite and potent antipyretic effect of the *Amruttotar kahsay ghan vati* as a symptomatic relief for fever, hence the drug shows antipyretic properties and additionally combating the underlying pathology.
- During the course of pilot study no any major adverse effects were observed.

- However this is only preliminary study as a part of research training, and further clinical and experimental studies of longer duration on larger samples with fever markers are needed.
- It is hope that the observations made in this work will be helpful for future studies and mankind of whole.

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