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A randomized controlled comparative clinical trial on *Jwarahara* effect of *Mukkaamukkatukaadi* Syrup with *Kiratatikta* Syrup in Febrile Children

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ABSTRACT

Ayurvedic classics have described many diseases amongst which *Jwara* stands first because of its uniqueness to make everyone suffer, since birth to death. *Jwara* being one of the commonest symptoms which accompanies almost all constitutional diseases has been coined with the term *Rogadhipathi*. Fever is defined as temperature in rectum more than 100.4°F (38°C), in oral cavity above 99.5°F (37.5°C) or in axilla above 99°F (37. 2°C). If we don't treat fever in its earlier stage, there will be more chances of hyperpyrexia which may cause febrile convulsions which leads to brain damage. Therefore, it is necessary to control fever at its earlier stage. One such *Jwarahara* formulation is *Mukkaamukkatukaadi Gulika* and *Kiratatikta* which is converted into syrup form to overcome the palatability issues. A sample size of 30 patients was selected by simple random sampling method and 15 patients were allotted in two groups. It was planned to compare the result between *Mukkaamukkatukaadi* syrup in Group A study group for STG and LTG and *Kiratatikta* syrup in Group B control group for STG and LTG. On STG comparison, the difference in mean in Group A and Group B were 0.49,0.44 before treatment changed to 0.96 and 0.98 after treatment respectively. On LTG comparison, the difference in mean in Group A and Group B were 0.49, 0.44 before treatment changed to 2.02 and 1.96 after follow up respectively. This depicts both the formulations effective when consumed for longer duration. From the results and observations it can be concluded that Group A and Group B are equally effective and equally significant on reducing the temperature in both STG and LTG. No adverse drug reaction was found during the study.

Key words: *Mukkaamukkatukaadi syrup, Kiratatikta syrup, Jwara, Fever*

INTRODUCTION

Jwara is considered to be the king of all diseases. *Jwara* induces *Santapa, Aruchi, Trushna*, *Angamarda* and *Hridivyadha*. *Jwara* is mentioned under *Nidanarthakara Rogas*. If not treated in time, it will lead to complications like *Rakta Pitta* and *Sosha* in children. If neglected it will even lead to death of the child. Children are more prone to infections due to immature immune system in which fever is one of the commonest symptoms. Fever is defined as temperature in rectum more than 100.4°F (38°C), in oral cavity above 99.5°F (37.5°C) or in axilla above 99°F (37. 2°C).[1] If we don't treat fever in its earlier stage, there will be more chances of hyperpyrexia which may cause febrile convulsions which leads to brain damage. Therefore, it is necessary to control fever at its earlier stage.

The formulation selected for present study is *Mukkaamukkatukaadi Gulika* which is converted into syrup form considering the palatability. Most of the ingredients are *Katu* and *Tikta Rasa Pradhana*. They are predominantly *Kaphapittashamak*. This drug is compared to *Kiratatikta* syrup which is proved as antipyretic drug.[2]

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OBJECTIVES OF THE STUDY

1. To evaluate the *Jwarahara* effect of *Mukkamukkatukaadi* syrup in febrile children.
2. To evaluate the *Jwarahara* effect of *Kiratatikta* syrup in febrile children.
3. To compare the *Jwarahara* effect of *Mukkamukkatukaadi* syrup with *Kiratatikta* syrup in febrile children.

MATERIALS AND METHODS

Ingredients of *Mukkamukkatukaadi* Syrup

Table 1: The trial drug contains the following ingredients

Ingredients	Botanical Name	Part used	Quantity
Haritaki	*Terminalia chebula*	Fruit pulp	1 part
Vibhitaki	*Terminalia bellerica*	Fruit pulp	1 part
Amalaki	*Emblica officinalis*	Fruit pulp	1 part
Shunthi	*Zingeber officinale*	Rhizome	1 part
Pippali	*Piper longum*	Fruit	1 part
Maricha	*Piper nigrum*	Fruit	1 part
Kiratatikta	*Swertia chirata*	Plant	1 part
Jiraka	*Cuminum cyminum*	Seed	1 part
Krishna jiraka	*Nigella sativa*	Seed	1 part
Vacha	*Acorus calamus*	Root	1 part
Jatiphala	*Myristica fragrans*	Seed	1 part
Kanyasara	*Aloe Barbedensis*	Extract	1 part
Saindhava	*Rock salt*	___	1 part
Hingu	*Ferula asafoetida*	Resin	1 part
Lavanga	*Syzigium aromaticum*	Flower bud	1 part
Kusta	*Saussurea costus*	Root	1 part
Karpura	*Cinnamomum camphora*	Resin	1 part
Tvak	*Cinnamomum veram*	Bark	1 part
Kankola	*Piper cubeba*	Seed	1 part
Lasuna	*Alium sativum*	Seed	1 part
Ajamoda	*Trychospermum roxburghianum*	Seed	1 part
Nirgundi	*Vitex nirgundo*	Whole plant	1 part
Sharkara	*Saccharum officinarum*	Crystals	1part

Table 2: Ingredients of *Kiratatikta* Syrup

Kiratatikta	*Swertia chirata*	Plant	1 part
Sharkara	*Saccharum officinarum*	crystals	1 part

Method of preparation

The dried drugs were collected, with a quantity 15.72g each. The drugs were soaked in water overnight, next day *Kwatha* of drugs was prepared by adding 48 litres of water, boiled and reduced to ¼ part and filtered, remnant is 12 litres and filtered, to this 3.6 kgs of sugar were added & boiled on mild flame till it is reduced to 6 litres. Total quantity of suspension obtained was 6 litres which is cooled down and bottled, into 200ml each. They were packed in plastic containers which were then sealed. Then the containers were labelled and made ready for distribution.

Source of data

The study was approved by Institutional Ethics Committee (Ref: SDMCAU/ACA -49/ECH45/19-20). 30 patients, diagnosed cases of *Jwara* were selected from the Kaumarabhrithya OPD and IPD of SDMCA&H, Udupi using permuted block randomization. Detailed history was taken based on the Special proforma made for the history taking, examination and assessment.

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Inclusion criteria

1. Children whose temperature is more than 99.5°F to 102°F (axillary).
2. Children between age group of 1-3 years.

Exclusion criteria

1. Children requiring conventional medicine
2. Severely dehydrated patients.
3. Sick child requiring aggressive management.
4. Previous history of convulsions with high-grade fever.
5. Fever with rash and bacterial infection.

Grouping

Group A - Short term - 15 subjects were given with *Mukkaamukkatukaadi* syrup as a single dose. Then temperature was recorded at half an hour interval for 6 hrs. The other symptoms were recorded before treatment and at 6th hour.

Long term - The medicine was given 6th hourly. The temperature and other symptoms were recorded before treatment and every 6th hourly for 5 days.

Group B - Short term - 15 subjects were given with *Kiratatikta* syrup as a single dose. Then temperature was recorded at half an hour interval for 6 hrs. The other symptoms were recorded before treatment and at 6th hour.

Long term - The medicine was given 6th hourly. The temperature and other symptoms were recorded before treatment and every 6th hourly for 5 days.

Plan of intervention

Dosage form (*Kalpana*): *Sharkara* (Syrup)

Dose: 1 year - 2.5ml 6th hourly, 2 year - 5ml 6th hourly, 3year - 7ml 6th hourly.

Duration of Study

Short term - 6hrs

Long term - 5 days

Follow-Up: Follow up was done after 7days of completion of the treatment.

Lab investigations

Routine blood investigations like Hb%, TC, DC, ESR, CRP if necessary.

Assessment criteria

Assessment of treatment quality of Syrup of *Mukkamukkatukaadi* drugs in the management of *Jwara* was done according to signs and symptoms of *Jwara* which were evaluated based on subjective and objective parameters. All these were assessed on the basis of gratings designed according to severity of signs and symptoms.

Subjective parameters

1. *Trushna* (Thirst)
2. *Aruchi* (Anorexia)
3. *Swedavarodha*
4. Activity

Objective parameters

1. Axillary temperature in Fahrenheit.

Observations and Results

In the present study among 30 subjects, 9 (30%) subjects belonged to the age group of 1-2 yrs and 21 (70%) subjects belonged to the age group of 2-3years. Although prevalence of *Jwara* is more at any age but it is more common between the age group of 3 -10yrs as per different texts but 6months to 5yrs are more prone for febrile convulsions.[3] The school going children gets exposed to other sick children in the classroom and develops fever because of overcrowding and weak immunity against infectious diseases. Majority of the subjects 18 (60%) had *Mandagni*, 3 (10%) subjects had *Samagni* and 9 (30%) subjects had *Vishamagni*. *Mandagni* leading to formation of *Ama* stage, responsible for occurrence of *Jwara.*[4]

All of subjects had complaints of *Santapa* irrespective of other associated complaints (Figure 1). *Acharyas* has considered *Santapa* to be one of the cardinal feature for the disease *Jwara*.[5] 22 (73.3%) of subjects had complaints of *Aruchi*. It may be due to *Ama* and *Mandagni* which causes less secretion of digestive

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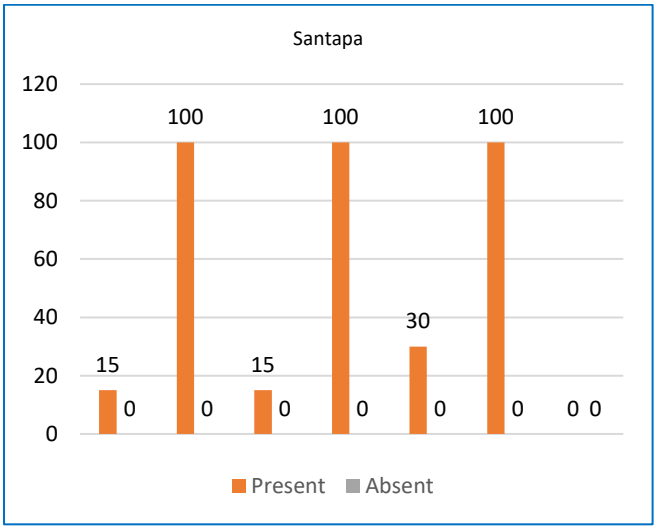
enzymes and obstruction in the channel.[6] 19 (63.3%) of subjects had complaints of *Trushna*. *Trushna* is one among the common character seen relating to *Udakavaha Srotodushti*. Reduction in extracellular fluid releases enzyme Renin which acts on Angiotensinogen and convert it into Angiotensin I and Angiotensin II which causes vasoconstriction and increase in blood pressure and also inhibits Renin release to maintain sodium and water balance in the body.[7] 22 (73.3%) of subjects had complaints of Swedavarodha. Due to *Mandagni, Amotpatti* takes place. The *Snigdha, Picchila* properties of *Ama* obstruct the *Swedavaha Srotas*. 26 subjects (86.6%) had complaints of activity. *Ama* has the tendency to vitiate *Kapha* quickly due to similarity in nature, hence subjects showed decrease in activity.

Figure 1: Showing distribution based on *Santapa*



Effect of therapy

In STG, there was 0.95% of improvement in Group A (Table no. 3) and 0.9% of improvement in Group B (Table no. 5) in temperature after 6hrs. On comparison, the difference in mean in Group A and Group B were 0.49, 0.44 before treatment changed to 0.96 and 0.98 after treatment respectively (Table no. 7). Both Group A and Group B are equally effective and was statistically significant with p value <0.05.

In LTG, there was 2.01% of improvement in Group A (Table no. 4) and 1.95% of improvement in Group B (Table no. 6) after follow up. The improvement before treatment and after treatment in Group A and Group B was statistically highly significant with p value 0.00 within the groups.

On comparison, the difference in mean in Group A and Group B were 0.49, 0.44 before treatment changed to 2.02 and 1.96 after follow up respectively (Table no. 8). This depicts both the formulations equally effective when consumed for longer duration.

Kiratatikta and *Mukkaamukkatukaadi* syrup was not effective in *Aruchi* and *Trushna* in STG. But in LTG, *Kiratatikta* syrup was more effective in reducing *Trushna* and *Aruchi*. *Kiratatikta* syrup and *Mukkaamukkatukaadi* syrup are equally effective in reducing *Swedavarodha*.

Mukkaamukkatukaadi syrup was more effective in increasing daily routine activities in STG and LTG.

Table 3: Showing short term effect of Axillary temperature within Group A.

Mean score		N	S. D.	S.E. M.	M. D.	%	T	P	Interpretation
BT	1H	15	1.47	0.37	0.49	0.48	1.49	0.15	NS
100.41	99.92								
BT	2H	15	1.14	0.29	0.10	0.09	0.43	0.66	NS
100.41	100.30								
BT	3H	15	1.12	0.29	0.16	0.15	0.56	0.58	NS
100.41	100.24								
BT	4H	15	1.51	0.39	0.54	0.53	1.36	0.19	NS
100.41	99.87								
BT	5H	15	1.46	0.37	0.84	0.83	2.24	0.04	S
100.41	99.56								
BT	6H	15	1.49	0.38	0.96	0.95	2.66	0.02	S
100.41	99.44								

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Table 4: Showing long term effect of Axillary temperature within Group A.

Mean score		N	S. D.	S.E. M.	M. D.	%	T	P	Interpretation
BT 100.4	D1 99.44	15	1.49	0.38	0.96	0.95	2.66	0.02	S
BT 100.4	D2 98.9	15	1.49	0.38	1.42	1.41	3.33	0.005	S
BT 100.4	D3 97.96	15	1.12	0.28	2.44	2.43	8.09	.00	HS
BT 100.4	D4 98.12	15	0.69	0.17	2.28	2.27	10.40	.00	HS
BT 100.4	D5 97.9	15	0.38	0.09	2.04	2.03	13.97	.00	HS
BT 100.4	FU 98.3	15	0.24	0.06	2.02	2.01	11.67	.00	HS

Table 5: Showing short term effect of Axillary temperature within Group B.

Mean score		N	S. D.	S.E. M.	M. D.	%	T	P	Interpretation
BT 100.28	1H 99.83	15	1.41	0.36	0.44	0.43	1.49	0.15	NS
BT 100.28	2H 99.40	15	1.49	0.38	0.87	0.86	2.43	0.02	S
BT 100.28	3H 99.16	15	2.00	0.51	1.11	1.10	2.32	0.03	S
BT 100.28	4H 99.5	15	1.81	0.46	0.73	0.72	1.62	0.12	NS
BT 100.28	5H 99.2	15	1.74	0.45	0.98	0.97	2.44	0.02	S
BT 100.28	6H 99.3	15	1.40	0.36	0.98	0.97	2.76	0.01	S

Table 6: Showing long term effect of Axillary temperature within Group B.

Mean score		N	S. D.	S.E. M.	M. D.	%	T	P	Interpretation
BT 100.28	D1 99.36	15	2.76	0.01	0.98	0.97	2.76	0.01	S
BT 100.28	D2 99.06	15	2.95	0.01	1.22	1.21	2.95	0.01	S
BT 100.28	D3 98.48	15	5.05	.00	1.79	1.78	5.01	0.00	HS
BT 100.28	D4 98.85	15	4.23	0.001	1.42	1.41	4.23	0.001	HS
BT 100.28	D5 97.90	15	10.59	.00	2.38	2.37	10.59	0.00	HS
BT 100.28	FU 98.32	15	11.50	.00	1.96	1.95	11.50	0.00	HS

Table 7: Showing short term effect of Axillary temperature between the groups

Axillary temperature	Group	N	M. D.	S. D.	S.E. M.	T	P	Interpretation
BT-1H	A	15	0.49	1.27	0.32	-0.10	0.91	NS
	B	15	0.44	1.15	0.29			NS
BT-2H	A	15	0.10	0.94	0.24	1.77	0.08	NS

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	B	15	0.87	1.38	0.35			NS
BT-3H	A	15	0.16	1.14	0.29	1.68	0.10	NS
	B	15	1.11	1.85	0.47			NS
BT-4H	A	15	0.54	1.53	0.39	0.32	0.75	NS
	B	15	0.73	1.75	0.45			NS
BT-5H	A	15	0.84	1.46	0.37	0.25	0.80	NS
	B	15	0.98	1.56	0.40			NS
BT-6H	A	15	0.96	1.43	0.37	0.26	0.97	NS
	B	15	0.98	1.37	0.35			NS

Table 8: Showing long term effect of Axillary temperature between the groups

Axillary temperature	Group	N	M.D.	S.D.	S.E.M.	T	P	Interpretation
BT-D1	A	15	0.88	1.45	0.37	0.19	0.84	NS
	B	15	0.98	1.37	0.35			NS
BT-D2	A	15	1.42	1.65	0.42	-0.34	0.73	NS
	B	15	1.22	1.59	0.41			NS
BT-D3	A	15	2.44	1.17	0.30	-1.39	0.17	NS
	B	15	1.79	1.38	0.35			NS
BT-D4	A	15	2.28	0.85	0.21	-2.13	0.41	NS
	B	15	1.42	1.30	0.33			NS
BT-D5	A	15	2.04	0.56	0.14	1.26	0.21	NS
	B	15	2.38	0.87	0.22			NS
BT-FU	A	15	2.02	0.67	0.17	-0.27	0.78	NS
	B	15	1.96	0.65	0.17			NS

DISCUSSION

Probable mode of action

Jwara is considered to be *Sarvarogagraja*. It brings miseries to the body none of the other diseases are so serious, so complicated and so difficult to cure as *Jwara*. Drug selected for the present study is *Mukkaamukkatukaadi* syrup and *Kiratatikta* syrup.

Mukkaamukkatukaadi syrup is having *Jwaragna, Deepana, Pachana* properties. *Mukkaamukatukaadi* syrup is having *Katu, Tikta Rasa Pradhana Dravyas*. *Katu, Tikta Rasa* increases *Agni* and treats *Mandagni* (Su.Su.35) and *Agnimandya* is always present in any types of *Jwara*. So ultimately it dissolves *Ama* and increase *Kshudha*. In *Mukkamukkatukaadi* syrup, *Triphala* does *Vatanulomana* by which there will be correction of *Agni* in *Amashaya* leading to *Amapachana* and acts as *Jwarahara*.

Trikatu, Jeeraka Dvaya, Vacha, Jatiphala, Ajamoda, Twak, Lavanga, Hingu, Kankola, Kusta & Karpoora are some of the best *Amapachaka* and *Agnideepaka Dravyas* helping in curing the *Jwara*. *Pippali* has antibacterial and anti oxidant activity. *Pippali* is a good catalyst agent that enhances the absorption and assimilation of drug (S. Chhajed et al. 1990). Alcoholic extract of *Maricha* has antipyretic activity; the underlying mechanism may be inhibition of prostaglandin synthesis within the hypothalamus. *Lashuna* acts as *Deepaka* and *Pachaka* and it also has *Rasayana* property and ginger are effective antibacterial activity. A study on *Vacha* suggested that the active constituents have enough potential to be used as an analgesic, antipyretic.[8] Studies have proved that the various phytoconstituents of *Lavanga* like eugenol exhibit antipyretic, antimicrobial, analgesic effects. *Kusta* drug has immunomodulatory, anticonvulsant, hepatoprotective, antiviral activity.

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Kiratatikta syrup is having *Jwaragna, Swedajanana, Anulomana* and *Dahaprashamana* properties. *Kiratatikta* syrup with its *Tikta Rasa* pacifies the *Pitta* predominanace of *Jwara* as well as initiates *Amapachana* and increase the appetite.

Ushna Veerya of drugs of both groups imparts *Swedana* and *Vilayana* properties to *Ama*, thereby hindering chances of *Srotorodha*. It becomes more effective with the *Laghu, Ruksha*, *Teekshna Guna* and *Katu Vipaka* which enhances the *Agni Deepana* and *Amapachana.* These properties remove obstruction from *Rasa* and *Swedavaha Srotas* and decrease temperature.

Kiratatikta is one of the best *Jwaragna Dravya*. Methanolic extract of *Kiratatikta* possess significant antipyretic effect against elevated rectal temperature induced by yeast suspension in rats, at the dose 200mg/kg at 4hrs and compared to standard drug paracetamol. The presence of alkaloids and flavonoids are responsible for the antipyretic activity.[9]

Jwara is manifested due to *Rasavahasrotoavarodha* and needs a *Deepana, Pachana*, *Srotosodhana* qualities for its relief. Both the formulations are having *Deepana, Pachana* drugs which potentiates the *Agni* thereby facilitating the *Aharapaka* as well as *Dhatupaka* at *Jataragni* and *Dhatwagni* levels. *Deepana Dravya* increases the *Agni* and *Pachana* property improves the digestive action.

Conclusion

Fever in children is one of the most common manifestations of illness, which makes the parents to seek medical attention early. Children between ages of 6 months to 5yrs are at increased risk of benign febrile seizures and irreversible brain damage. *Kiratatikta* syrup and *Mukkaamukkatukaadi* syrup are equally effective in reducing temperature in LTG and STG.

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