

A Randomized, Controlled Clinical Pilot Study to Evaluate the Efficacy of *Pushkaramoola (Inula racemosa Hook. f.)* as a Monotherapy in Reducing Fever in Pediatric Patients

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ABSTRACT

Background: Fever is a common and distressing symptom in children, requiring prompt and effective management. To address this, a randomized, controlled clinical pilot study was conducted to investigate the efficacy and safety of Pushkaramoola Vati, a traditional Ayurvedic medicine mentioned in Arogya kalpa druma, in reducing fever in pediatric patients. The study enrolled 20 pediatric patients with mild to moderate fever, who were randomly assigned to receive either Pushkaramoola Vati or Paracetamol.

Objectives: The primary objectives of the study were to evaluate the efficacy of Pushkaramoola Vati in reducing fever and associated symptoms, assess its safety in pediatric patients, and compare its effects with those of Paracetamol. The study's expected outcomes are to provide preliminary data on the efficacy and safety of Pushkaramoola Vati as a potential treatment option for fever in pediatric patients.

Result: The results will help determine whether Pushkaramoola Vati is a viable alternative to conventional antipyretics like Paracetamol. Overall assessment of the trial drug shows a Moderate improvement in

improvement was found in 50%-75% of signs and symptoms.

Conclusion: This research has the potential to contribute significantly to the management of fever in children, offering a natural and safe treatment option for parents and healthcare providers.

Keywords: Pushkaramoola vati, Fever

INTRODUCTION

Balyaawastha is more prone to infection because of its low immunity level and poor hygienic condition. Children need more care for better physical, mental and social development during this period. Children are more likely to get fever than adults. Fever is one of the most common reasons why children are brought to the doctor or to the hospital for out-of-hours medical advice. Although it is a distinct condition, it is also expressed as a premonitory symptom and causal component in a variety of diseases.

Jwara is first among the diseases explained in Ayurvedic classics, which needs immediate care and cure; otherwise, it leads to complications. It is said that each and every individual suffers from *Jwara* at the time of birth and death. In 2019-20, a new pandemic known as Corona virus (COVID-19) with negative health consequences

emerged. In comparison to the large range of illnesses, viral vaccines are scarce, and those that do exist have negative side effects. As a result, there is an urgent demand in the current context for the most promising indigenous medications with antipyretic and antiviral action.⁽¹⁾

Herbal plants, plant preparations, and phytoconstituents have been shown to be effective in reducing infectious diseases and were the only treatments accessible prior to the introduction of antibiotics. Antipyretic and Anti-inflammatory action of a range of phytoconstituents produced from medicinal plants has been widely researched. *Pushkaramoola* (*Inula racemosa* Hook. f.) is a well-known stout herb from the Asteraceae family often referred to as the “potent among cardio-pulmonary medicinal species”. Nowadays it is a highly recommended and much favoured medicinal herb in folk and traditional medicine. Its multitherapeutic effect has been established through years of traditional and scientific use and research.

MATERIALS & METHODS

- 1) **Collection and identification of sample drug:** The root of *pushkarmoola* in dry form were collected from Joshi muth Parsari Village-Mandal-Gopeshwar, and was authenticated in the Department of Dravyaguna, BHU, Varanasi.
- 2) **Method of prepration:** Pushkaramoola Vati was manufactured in the Pharmacy of Rasa Shastra, Department of Rasa Shastra and Bhaishajya, Faculty of Ayurveda, IMS, BHU. The drugs were powdered and taken for granulation formation. These granules were further compressed for tablet formation. Water was used as bhavana drava, then superfine powder of ingredients was taken in a mortar and triturated for 2 hours till a well-grounded mass was obtained. This mass was easily rolled down into vatis (tablets), which were later dried in sunlight and stored in a sterile container. (Figure 1)



Patients Grouping:

The study was registered in CTRI with register ID- CTRI/2022/07/ 04397

Patient was screened according to the inclusion and exclusion criteria and those who with fulfilled criteria, were randomly distributed into two treatment groups. Total

number of patients was 20, enrolled in the month of Feb 2022 to October 2022. Patients, suffering from the fever as a symptom of different diseases was randomly selected for the study and recorded on the pre-designed Performa from the *Kaumarbhritya*/Balroga OPD and IPD.

1. Group 1(n=10): - Pushkar moola Vati (50mg/kg/dose) (According to ayurvedic text the adult dose of *Pushkaramoola choorna* is (2g-3g/kg/dose), when its converting to a pediatric dose according to the young's formulae its 50mg/kg/dose.)
2. Group 2(n=10): -Paracetamol (15 mg/kg/dose)

Patients who were given the medication were assessed before and after the treatment to know the effect of therapy after a written consent.

Inclusion Criteria:

- Age: 5 to 12 years
- Sex: Irrespective to sex
- Disease: All, except Acute gastroenteritis, persistent vomiting, and life-threatening disorders
- Fever: Mild to Moderate fever(100-103F)

Exclusion Criteria:

- Severe Fever
- Fever associated with neurological impairment

Diagnostic Criteria:

- Axillary Temperature ranging from (37.2°C-38.8°C or 99°F-102°F)

3. Head ache (The faces pain scale revised)⁽⁴⁾

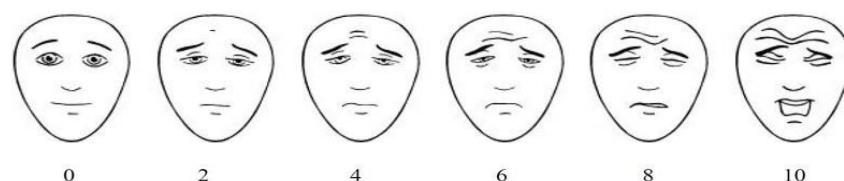


Fig. 2: Head ache (The faces pain scale revised)

4. Dyspnoea scale (MRC SCALE)⁽⁵⁾

Grade	Degree of breathlessness related to activities
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
4	Stops for breath after walking about 100m or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

Parameters for assessments:

Objective Parameter:

- Axillary Temperature
- Headache
- Thirst
- Uneasy breathing/ Dyspnoea
- Myalgia/Arthralgia
- Sweating

Grading/Scoring pattern:

1. Fever grading⁽²⁾

- Low-grade: 37.3 to 38.0 C (99.1 to 100.4 F)
- Moderate-grade: 38.1 to 39.0 C (100.6 to 102.2 F)
- High-grade: 39.1 to 41 C (102.4 to 105.8 F)
- Hyperthermia: Greater than 41 C (105.8 F)

2. Thirst scale (Categorical scale)⁽³⁾

Table 1: Showing Thirst scale (Categorical scale)

GRADING	Score
Not thirsty at all	1
Not thirsty	2
Not very thirsty	3
Neutral	4
Thirsty	5
Very thirsty	6
Very very thirsty	7

Distribution based on grade of fever

Table: 7 Distribution based on grade of fever

Grade of fever	No of Cases	Percentage
Mild	2	10%
Moderate	16	80%
Severe	2	10%

(Table 7) shows the percentage distribution of cases based on the grade of fever. 16% of cases were moderate grade and 2% with mild and severe grade was observed.

Mean difference of temperature

Table 8: Mean difference of temperature at registration and 15min, 30min, 1hour, 2hour

Groups	Temperature				
	R0	F1	F2	F3	F4
Group 1(Trial group)	101.240±1.1443	101.020 ± 1.2968	100.1± 1.1249	99.4±.9983	98.780±.4077
Group 2 (Control group)	101.250± .9046	101.200 ±.6976	100.650±.8209	100.130±.9019	99.390±.5507
Between the group comparison Unpaired t test	t=.022 P=.983	t=.387 P=.704	t=1.045 P=.310	t=1.692 P=.108	t=2.815 P=.011

The mean difference in temperature between the trial and control groups is shown in this table and bar graph during registration and at intervals of 15 minutes, 30 minutes, 1 hour and two hours.

The mean temperatures for the trial and control drugs at registration are around 101.240 and 101.250 respectively. The mean temperature for both groups decreases to 98.780 and 99.390 at the fourth follow-up.

The intergroup comparison was not significant at 0 hours, 15minutes,

30minutes, 1hours as ($P > 0.05$), however it is significant at F4 ($P < 0.05$).

In this study, it is found that both the Group 1 and Group 2 significantly reduce the fever of patient at 15, 30min and 1hour and 2-hour intervals. This shows that the trial drug is as effective as Standard drug. (Table 8)

Comparing mean change in temperature at each time interval with initial temperature

Table:9 Comparing mean change in temperature at each time interval with initial temperature

Group			Mean	Std. Deviation	t	P
1	Pair 1	S_R0 - S_F1	.2200	.4709	1.477	.174
	Pair 2	S_R0 - S_F2	1.0500	.5911	5.617	.000
	Pair 3	S_R0 - S_F3	1.8300	.6800	8.511	.000
	Pair 4	S_R0 - S_F4	2.4600	.8235	9.446	.000
2	Pair 1	S_R0 - S_F1	.0500	.3567	.443	.668
	Pair 2	S_R0 - S_F2	.6000	.5077	3.737	.005
	Pair 3	S_R0 - S_F3	1.1200	.6408	5.527	.000
	Pair 4	S_R0 - S_F4	1.8600	.6059	9.708	.000

The table 9 shows the Variation in temperature at each time interval with initial temperature. Group 1 shows significant variation at the time interval of R0-F2, R0-F3, R0-F4 with $P < 0.05$, at R0-F1 there is no significant variation ($P > 0.05$).

Group2 shows significant variation in temperature at the time interval of R0-F2, R0-F3, R0-F4 with $P < 0.05$, at R0-F1 there is no significant variation ($P > 0.05$).

Inter group correlation of the change in headache in each follow up

Table 10: Inter group correlation of the change in headache in each follow up

Groups	Headache				
	R0	F1	F2	F3	F4
Group 1	3.80 ± 3.190	3.80 ± 3.190	3.20 ± 2.860	2.80 ± 2.530	2.00 ± 2.108
Group 2	2.80 ± 2.348	2.60 ± 2.319	2.00 ± 1.886	1.40 ± 1.350	.80 ± 1.033
Between the group comparison	Z=.738	Z=.853	Z=.944	Z=1.201	Z=1.325
Mann Whitney test	P=.461	P=.394	P=.345	P=.230	P=.185

Table 10 shows distribution of subjects at initial level and subsequent follow up according to improvement in headache among the study groups. At each follow up change in overall means score of headache

in patients of both groups were found, statistically insignificant with (P>0.05)

Inter group correlation of the change in Pain in each follow up

Table 11: Inter group correlation of the change in Pain in each follow up

Groups	Pain				
	F0	F1	F2	F3	F4
Group 1	2.90 ± 1.101	2.90 ± 1.101	2.90 ± 1.101	1.50 ± 1.269	1.40 ± 1.350
Group 2	1.40 ± 1.265	1.40 ± 1.265	1.20 ± .919	.20 ± .632	.20 ± .632
Between the group comparison	Z=2.518	Z=2.518	Z=3.046	Z=2.614	Z=2.316
Mann Whitney test	P=.011	P=.011	P=.002	P=.019	P=.052

Table 11 shows distribution of subjects at initial level and subsequent follow up according to improvement in Pain among the study groups. At each follow up change in means score of pain in patients of both groups were found, statistically highly

significant with (P<0.05) except at F4 Were P>0.05.

Inter group correlation of the change in thirst in each follow up

Table 12: Inter group correlation of the change in thirst in each follow up

Groups	Thirst				
	F0	F1	F2	F3	F4
Group 1	4.70 ± .823	4.70 ± .738	4.10 ± .738	4.00 ± .471	4.00 ± .000
Group 2	4.30 ± .675	4.30 ± .632	4.20 ± .632	4.10 ± .316	4.00 ± .000
Between the group comparison	t=.755	t=.755	t=.757	t=.899	t=.782
Unpaired t test	P=.250	P=.250	P=.749	P=.584	p=.645

Table 12 shows distribution of subjects at initial level and subsequent follow up according to improvement in thirst among the study groups. At each follow up change in overall means score of thirst in patients of

both groups were found, statistically, highly insignificant with (P>0.05)

Inter group correlation of the change in dyspnoea in each follow up

Table 13: Inter group correlation of the change in dyspnoea in each follow up

Groups	Grade	Dyspnoea				
		No. and percent				
		F0	F1	F2	F3	F4
Group 1	1	8(80.0%)	8(80%)	9(90%)	10(100%)	9(90%)
	2	2(20.0%)	2(20%)	1(10%)	0(0.0%)	1(10%)
Group 2	1	9(90%)	9(90%)	9(90%)	9(90%)	9(90%)
	2	1(10%)	1(10%)	1(10%)	1(10%)	1(10%)
Between the group comparison Chi-square test		χ ² =.392 P=.531	χ ² =.392 P=.531	χ ² =.000 P=1.000	χ ² =1.053 P=.305	χ ² =.000 P=1.000

Table no 13 shows distribution of subjects at initial level and subsequent follow up according to improvement in dyspnoea among the study groups.

In group 1, 80% % of cases were observed under grade-1 (Not troubled by breathlessness except on strenuous exercise) 20% cases under grade-2 (Short of breath when hurrying or walking up) at the time of registration. After 2 hours of therapy, the maximum number of patients belonged to grade-1 (90%).

In group 2, 90% of cases were observed under grade-1, 10% cases under grade-2 at the time of registration. After 2 hours of therapy, the maximum number of patients belonged to grade 1 (90%).

After applying Chi square test, the change in dyspnoea was seen as not significant in any follow up.

Inter group correlation of the change in Sweating in each follow up

Table 14: Inter group correlation of the change in Sweating in each follow up

Groups	Grade	Sweating No. and percent				
		F0	F1	F2	F3	F4
Group 1	0	10(100%)	9(90%)	9(90%)	8(80%)	9(90%)
	1	0	1(10%)	1(10%)	2(20%)	1(10%)
Group 2	0	8(80%)	7(70%)	3(30%)	3(30%)	3(30%)
	1	2(20%)	3(30%)	7(70%)	7(70%)	7(70%)
Between the group comparison Chi square test		$\chi^2 = 2.222$ P = .136	$\chi^2 = 1.250$ P = .264	$\chi^2 = 7.500$ P = .006	$\chi^2 = 5.051$ P = .025	$\chi^2 = 7.500$ P = .006

Table 14 shows distribution of subjects at initial level and subsequent follow up according to improvement in sweating among the study groups

In group 1, 100% of cases were observed under grade-0 (No feeling of sweating) 0% cases under grade-1 (Slightly feeling of sweating) at the time of registration. After 2 hours of therapy, the maximum number of patients belonged to grade-1 (No feeling of sweating (90%).

In group 2, 80% of cases were observed under grade-0 (No feeling of sweating) 20% cases under grade-1 (Slightly feeling of sweating) at the time of registration. After 2 hours of therapy, the maximum number of patients belonged to grade 1 (Slightly feeling of sweating) (70%).

After applying Chi square test, the change in sweating was seen as significant in patient at 30min, 1 hour and 2 hours.

DISCUSSION

Jwara is a prevalent problem in today's general practice, affecting both sexes at various stages of their life. Even in the Vedas, *Jwara* is mentioned. It is regarded as

the earliest manifestation of an illness. *Jwara* was given a lot of focus by Acharya Charaka, who kept it ahead of all other diseases. *Jwara* is an illness that is quite common and is comparable to pyrexia. Pyrexia is considered a symptom rather than a single disease. It acts as a defense mechanism of our body. Our body temperature is maintained by the thermoregulatory centre present in the hypothalamus. When the rate of production of temperature takes more than the rate of loss the condition is called Pyrexia. Fever is induced pathologically by the production of pyrogen. Inflammation is a common condition linked with several disorders, characterized by localized increases in leukocytes and a wide range of complex mediator molecules. Inflammation is comparable to the illness *Sopham*. A wide range of modern drugs are used to treat inflammation and pyrexia, but their long-term use may have several harmful side effects. As a result, new anti-inflammatory drugs and anti-pyretic derived from plants must be established, and existing therapies must be utilized more effectively.

Pushkaramoola (*Inula racemosa* Hook. f.) is a well-known stout herb from the Asteraceae family often referred to as the “potent among cardio-pulmonary medicinal species.” Nowadays it is a highly recommended and much favoured medicinal herb in folk and traditional medicine. Its multitherapeutic effect on *Hridroga* (Cardiac-diseases), *Kshaya* (Wasting), *Kasa* (Cough), *Svasa* (Respiratory-diseases), and *Rajayakshma* (Tuberculosis) has been established through years of traditional and scientific use and research. Since *Inula* is a rich source of natural products, details on phytoconstituents such as alantolactone, and isoalantolactone as well as their in-vitro and in-vivo pharmacological, biochemical, and clinical studies are included. Furthermore, particular emphasis is given to the aforesaid uses of *Inula* is available and it is found in Ayurvedic literature that it is the most commonly used medicine for fever which has gone unnoticed by researchers and clinicians.

The *swasa kasahara* and *parwasoola hara* properties of pushkaramoola have widely studied were but the antipyretic effect of the drug is not studied yet. Literature review shows that the drug was widely given in different kinds of *jwara* in the form of formulation and single drug. The survey study shows that the *Maha Sudarsana ghana vati* was given by many pediatricians in their clinical practice, and it contains *Pushkaramoola* as one of the key ingredients. Whereas the use of *Pushkaramoola* as a single drug is not mentioned by any of them due to insufficient data against the antipyretic activity yet done.

This study mainly aims to evaluate the antipyretic effect of the *Pushkaramoola*, so

that it can advise in the conditions of different fever.

The mean temperatures for the trial and control drugs at registration are around 101.240 and 101.250 respectively. The mean temperature for both groups decreased to 98.780 and 99.390 at the fourth follow-up. The intergroup comparison was not significant at 0 hours, 15 minutes, 30 minutes, 1 hour however it was significant at the 2nd hour. The intergroup comparison suggests that the trial drugs significantly reduced fever at 2 hours of therapy.

This study shows the trial drug *Pushkaramoola* when compare to the standard drug (Paracetamol) was almost equally effective in lowering the temperature in patients.

The distribution of subjects at the initial level and subsequent follow-up according to improvement in Pain among the study groups were found, statistically significant with ($P < 0.05$) except at F4 Were $P > 0.05$.

In the present study change in the overall mean score of headache, thirst, and dyspnoea in patients of both groups was found, statistically insignificant ($P > 0.05$). In our study, it was observed that while temperature gets down, sweating occurs in both groups equally.

In vitro, study of *Pushkaramoola* shows Antibacterial, Antifungal, Anti-Inflammatory Activity and Antioxidant Activity.

Overall assessment of the trial drug shows a Moderate improvement ie improvement was found in 50%-75% of signs and symptoms.

Probable Action of Drug According to Rasa Panchaka

According to different nighantus, *Pushkaramoola* possesses *Katu Tikta rasa*, *Ushna veerya* and *Laghu*, *Tikshna guna*, and *katu vipaka*.^{8,9}(Figure 4)

Tikta Rasa	Katu vipaka	Usna virya	Karma
•Vishagna •Krimighna •Trsna-daha Prasamana •Jwaraghna •Deepana •Pacana •Upasoshana Of Kleda,mutra,swe da,puya,lasika •Kapha Pittaghna •Laghu,hima,rook sha •Arochaghna	•laghu	•Sveda janana •Vata Kaphaghna	•Jwarahara, •Sothahaera •Swasa–Kasahara •Hridya •Parswa soolahara

Figure 4: Probable Action of Drug According to Rasa Panchaka (Self-generated image)

Sothahara property of pushkarmoola

The disease *Shotha* mentioned in Ayurvedic classics can be compared to that of inflammation. All the *Shotha* are considered *tridoshaja*. But they differ in predominantly vitiated dosha. As per the *samprapti* of *shotha* *tridosha* and *rakta* get vitiated by various *nidana*. The vitiated *vata* brings the

vitiated *pitta*, *kapha*, and *rakta* into the external channels and gets obstructed by them, producing swelling localized in *twak* and *mamsa*, leading to *Shotha*. So the drugs used for treating *shotha* should be *sroto sodhaka* and *vata anulomaka*, *kleda sosaka*, and *kapha pittaghna*.¹⁰

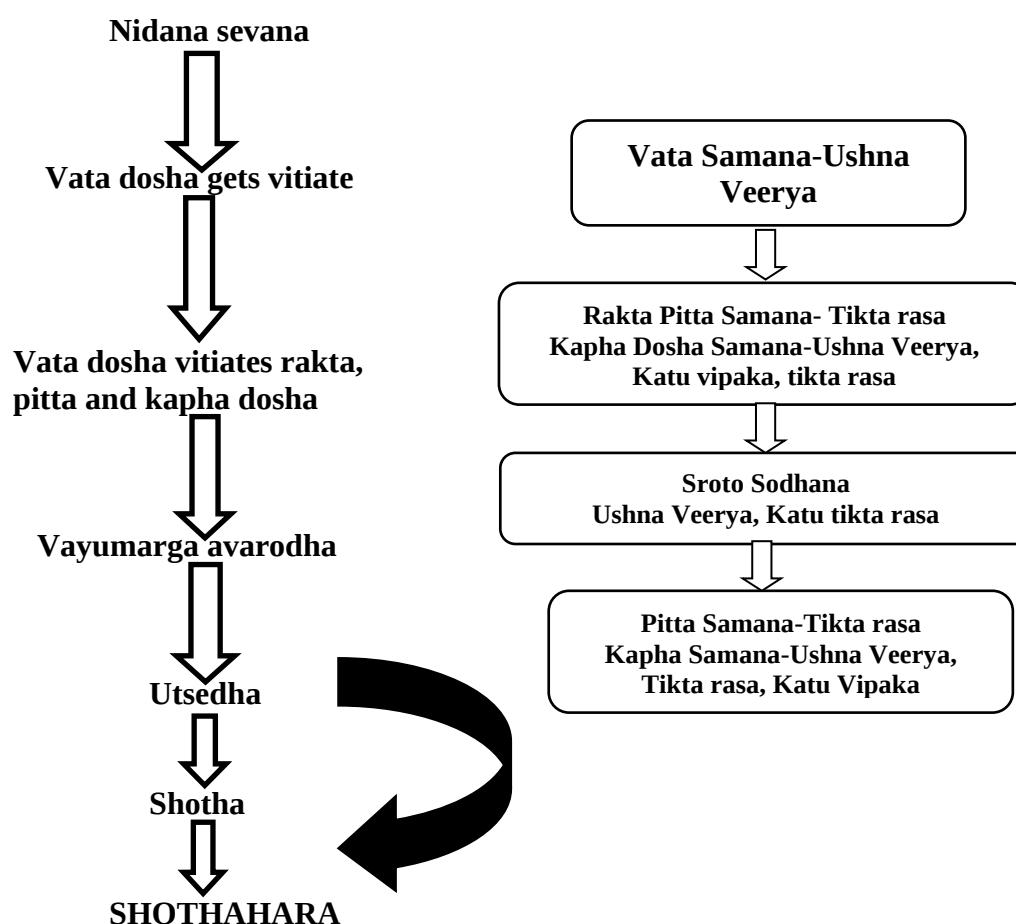


Figure.5 Samprapti Vighatana of The Sopha by the Rasa Panchaka of Pushkarmoola (Self-created diagram)

- As per Acharyas *Katu tikta rasa* alleviates *kapha* and cleanses the *srotas* and produces *sroto sodhana*. *Tikta rasa* is *seeta* and pacifies *pitta* and *kapha*. *Tikta rasa* causes *upasosana* of *kapha*. It also acts as *daha prasamana* which is the main character of *Shotha*.
- *Laghu* and *Ushna* gunas of the drug possess *Sopahara* property. *Laghu* guna has a *panchabhootika* composition of *Agni*, *Vayu*, and *Akasha*. The *dravyas* having this property have *Kapha Shamaka* property.
- *Ushna Veerya* and *Katu vipaka* have *vata kapha hara* property and *sweda janaka* property.
- *Katu vipaka* helps to remove obstructions of the channels.
- Considering all the actions of the drug, It can be said *Pushkarmoola* pacifies *Vata Kaphaja Sopha* (Figure 5)

Jwarahara property of pushkarmoola

The pathophysiology of *Jwara* is due to *vaikruta pitta*, *agnimandya* and *srotorodha*. While going through the literary research it is found that the trial drug are having

antagonistic properties for all the above-mentioned conditions.

In Various *Nighantu* like *Dhanwantara Nighantu*, *Raja Nighantu*, *Madanapala Nighantu*, and *Kaiyadeva Nighantu* the properties ie *rasa panchaka* of *Pushkarmoola* have been given *Katu Tikta rasa*, *Ushna veerya*, *Laghu*, *Tikshna guna* and *katu vipaka* and *Vatapittaghna*, *Jwarahara*, *Shophagna*, *Kasa*, *Swasa*, *Hikkaghna*, *Parswa soola hara* and *Hridya properties*^{11,12}

- *Tikta Rasa* – reduces *pitta*, relieves *daha* and *pippasa* and helps in *ama Pacana*, increases the appetite reduces *Trishna* and act as *vishaghna*
- *Laghu* guna – *ama pachana*, *kapha hara*, helps in *langana* which is the prime treatment of *jwara*
- *Ushna Virya*- helps in *ama pacana*, *kapha hara*, *srotosodhaka*
- *Teekshna guna-sroto sodhaka*, *kaphahara*
- *Katu Vipaka*- *sroto sodhaka*, *kapha hara*
- *Kaphaghna Karma* - *Ama pachana*

Thus by the above said properties *Pushkarmoola* relieves *jwara* by doing the *Samprapti Vighatana* (Figure 6)

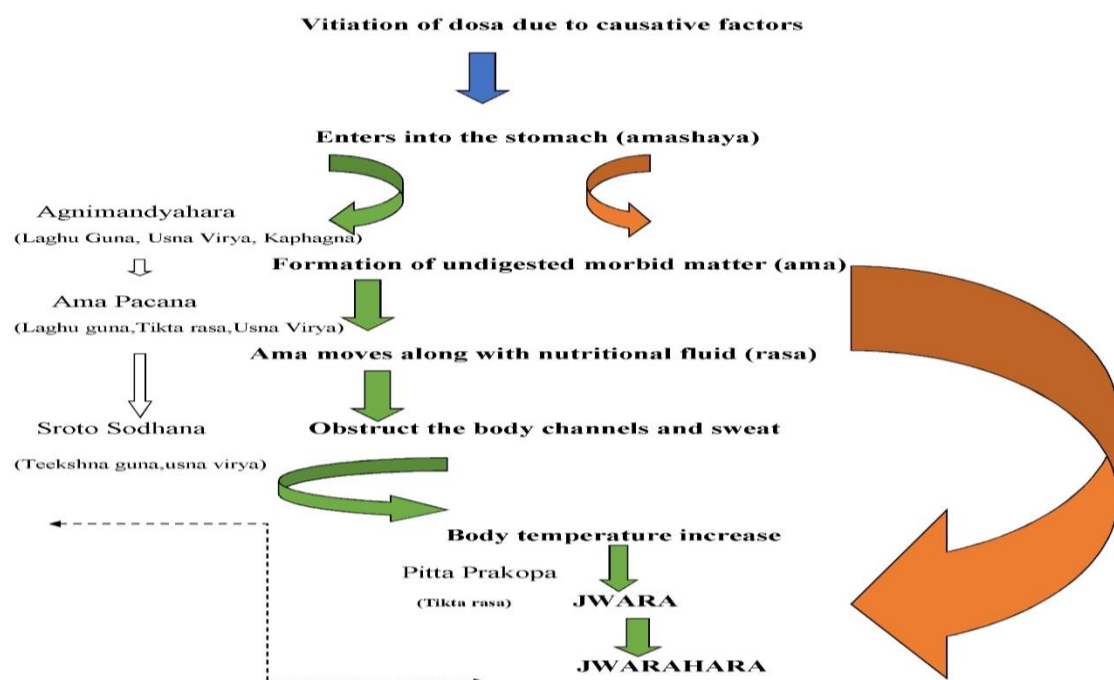


Figure.6 Samprapti Vighatana of the jwara by the Rasa Panchaka of Pushkarmoola (Self-created diagram)

CONCLUSION

Hence, it is established that Pushkaramoola, known for its efficacy in *Swasa Kasa* and *Parshwashula*, also possesses significant antipyretic properties, making it an effective treatment for pediatric patients. This breakthrough highlights the potential of Pushkaramoola as a natural remedy for fever management in children with respiratory infections. The need for alternative treatments that are safe and effective for pediatric populations warrants further investigation into the therapeutic properties of Pushkaramoola. To further substantiate these findings, additional studies involving larger populations and diverse age groups are necessary. These studies will provide valuable insights into the antipyretic efficacy, optimal dosage, and safety profile of Pushkaramoola, ultimately contributing to the development of evidence-based treatments for pediatric patients.

Declaration by Authors

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