

## A CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECT OF KETAKI NIRUHA BASTI IN MADHUMEHA WITH SPECIAL REFERENCE TO DIABETES MELLITUS-II

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### ABSTRACT

**Introduction:** A controlled clinical study to evaluate the effect of *Ketaki Niruha Basti* in *Madhumeha* with special reference to Diabetes mellitus-ii with *Madhutailika Basti* being the controlled group. **Methods:** It was an open-label controlled parallel-group study at a government Ayurveda medical college and hospital in South India. 41 subjects fulfilling inclusion criteria were selected through a convenient sampling method. Group A (study group) 21 subjects were included and 1 dropped out and in Group B (control group) 20 subjects were included. Group A was administered with *Ketaki Niruha Basti* and Group B was administered with *Madhutailika Basti* in *Yoga Basti* pattern. Both the groups were given *Murchita Taila* for *Anuvasana*. **Results:** The effect of the therapy was assessed by analyzing subjective and objective parameters before and after the treatment. While comparing the effect between the groups of *Ketaki Niruha Basti* and *Madhutailika Basti*, it showed no significant statistical difference. **Conclusion:** *Ketaki Niruha Basti* showed marginally better results in polyphagia, polydipsia, FBS and PPBS while *Madhutailika Basti* showed better results in polyuria day, polyuria night, tiredness and BMI.

**Keywords:** *Basti*, Diabetes Melitus-II, *Ketaki Niruha Basti*, *Madhumeha*, *Madhutailika Basti*.

## INTRODUCTION

*Madhumeha* is a multifactorial disease involving all the *Doshas*, *Dhatus*, *Srotas* and *Ojas*. It is one among *Astamahagada*<sup>1a, b, c</sup> and *Agra* in *Anushangi Vyadhi*<sup>2</sup> that shows the dreadfulness of the disease. As *Madhumeha* is *Krichrasadya*[Difficult to cure] or *Yapya*[managable] condition, good control and effective management should be the aim to reduce the risk of the development of further complications.

Diabetes mellitus-2 can be equated with *Madhumeha* as both have similar etiologies, symptoms and complications.

In 2020, according to the International Diabetes Federation (IDF), 463 million people have diabetes in the world and 88 million people in the Southeast Asia region. Of these 88 million people, 77 million belong to India.<sup>3</sup> The prevalence of diabetes in the population is 8.9%, according to the IDF. Its incidence is also increasing at an alarming rate. So, it has become of utmost importance to find ways to combat this disease. Among the *Panchakarma Chikitsa*, *Basti Karma* has its unique importance in treating major diseases. It has a reputation on behalf of the entire treatment.<sup>4</sup> Though *Vamana* and *Virechana* are prime *Samshodhana* modalities for *Prameha* as told in *Samhita*, but non-palatability, *Ushna* and *Kshara* properties of drugs may induce discomfort to the patient.<sup>5</sup> On the other hand *Basti* is a comfortable treatment compared to the other two. Acharya Charaka in *Siddi Sthana* quoted that if a drug is used orally for a particular disease, it can be used for *Basti Karma* in the same disease.

*Ketaki* is one among the wide variety of drugs that have been described in the treatment of *Meha*.<sup>6</sup> It is easily available, cost-effective. Traditionally the roots of *Ketaki* are believed to have antidiabetic, antidiuretic, cardiogenic and aphrodisiac properties.<sup>7</sup> *Madhutailika basti* is one among the few *Bastis* told by *Samhita* in the treatment of *Meha*.<sup>8</sup> A study has been conducted on the effect of *Madhutailika basti* in management of *Madhumeha* by Doddabasayya S Swamy and it found statistically significant results, hence this study, "A controlled clinical study to evaluate the effect of *Ketaki Niruha Basti* in *Madhumeha* with special reference to Diabetes

mellitus-2", aims to assess the *Madhumehahara Karma* of *Kethaki Niruha Basti* and *Madhutailika Basti*, and to find better treatment among these.

### Aim and Objectives:

1. To evaluate the effect of *Ketaki Niruha Basti* in *Madhumeha*.
2. To evaluate the effect of *Madhutailika Basti* in *Madhumeha*.
3. To compare and ascertain the effect of *Ketaki Niruha Basti* and *Madhutailika Basti* in *Madhumeha*.

### Materials and Methods:

**Source of data:** Subjects suffering from *Madhumeha* (Diabetes mellitus type-2) were selected randomly from the OPD and IPD of Jayachamarajendra institute of Indian medicine hospital (Teaching hospital of GAMC), Bengaluru-09

**Diagnostic Criteria:** Among the screened subjects, *Madhumeha* is diagnosed based on,

- Fasting plasma glucose level at or above 126 mg/dL or 7.0mmol/L.
  - Plasma glucose at or above 200 mg/dL or 11.1mmol/L two hours after 75g oral glucose load in glucose tolerance test.
  - Random glucose at or above 200 mg/dL or 11.1mmol/L.
  - HbA1c level at or above 6.5%.
- Subjects fulfilling a minimum of two criteria among the above four, along with HbA1c level at or above 6.5% were diagnosed to have Diabetes mellitus-II

### Inclusion Criteria:

- Subjects between the ages 25 to 75 years of either gender suffering from type 2 Diabetes mellitus were taken for the study.
- Post prandial blood sugar (PPBS) levels between 160-400 mg/dL will be taken for the study.
- HbA1c level between 6.5%-13%.
- Subjects who are fit for *basti* will be taken for the study.

### Exclusion Criteria:

- Subjects with type 2 diabetes mellitus who are insulin dependent.

- Subjects who are diagnosed have complications like diabetic foot, diabetic retinopathy and other secondary complications. Other systemic complications like cardiac, hepatic and renal complications.
- Pregnant and lactating woman.

**Assessment Criteria:** Assessment is made after analyzing subjective parameters and objective parameters before the intervention, after the intervention and after following up.

**Subjective Parameters:** Self-formulated scoring scale was used to assess the subjective symptoms.

Sl.no.	Assessment criteria	0	1	2	3
1.	Polyuria-Day	3-5 times	6-8 times	9-11 times	> 11 times
2.	Polyurea-Night	Does not wake up	Wakes up once	Wakes up twice	Wakes up more than twice
3.	Polyphagia	Feels hunger at <i>Annakala</i>	Feels hunger once in between <i>Annakala</i>	Feels hunger twice between <i>annakala</i>	Feels hunger always
4.	Polydipsia	Normal thirst	Mild increase in thirst(4-6L)	A moderate increase in thirst (6.01-8L)	Severe thirst (8.01-10L)
5.	Tiredness	No tiredness	Mild tiredness	Moderate tiredness	Severe tiredness

### Objective parameters

FBS

PPBS

BMI

### Study design: "Open-label parallel-group controlled clinical study"

An open-label parallel-group controlled clinical study was conducted. The subjects were assigned to two groups.

**Group A (Study group):** Subjects of this group received *Ketaki Niruha Basti* with *Murchita Tilataila* for *Anuvasana Basti* in *Yoga basti* pattern.

This group had 21 subjects, and all received *Ketaki Niruha Basti*. Out of 21 subjects, 20 completed the study and 1 dropped out.

**Group B (Controlled group):** Subjects of this group received *Madhutailika Basti* with *Murchita Tilataila* for *Anuvasana Basti* in *Yoga Basti* pattern.

Group B or the control group had 20 subjects, and all received *Madhutailika Basti*.

**Dosage and drug administration:**

**Drug:**

**Table 1:** Showing ingredients and their quantity used in basti

Ingredients	Ketaki niruha basti	Madhutailika basti
<i>Madhu</i>	136ml	136ml
<i>Saindhava</i>	6g	6g
<i>Murchita tila taila</i>	70ml	136ml
<i>Shatapushpa Kalka</i>	40gm	40g
<i>Ketaki Kwatha</i>	310ml	
<i>Eranda mula kwatha</i>		310ml
<i>Anuvasana basti</i>	40ml	40ml

**Table 2:** Pattern of the *basti*:

Basti	Time	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
<i>Niruha</i>	9-10 am		✓		✓		✓		
<i>Anuvasana</i>	1-2.00pm	✓		✓		✓		✓	✓

**Duration of the study:**

The total duration of intervention: 25 days.

Duration of treatment: 1st -8th day: *yoga basti* pattern *Parihara Kala* for next 16days

Follow up: on 25th day

**Statistical analysis**

Friedman’s test and Repeated measure ANOVA test was used to analyze the significance of the change in subjective and objective parameters respectively.

Mann Whitney U test and Independent T-test was used to comparing the significance of the change between the groups.

**Observation**

Among 41 subjects, 21 subjects were included under Group A (*Ketaki Niruha Basti*). Out of which 20 subjects completed the study and 1 dropped out. 20 subjects were included under Group B (*Madhutailika Basti*), and all the subjects completed the study.

In the present study, out of 40 subjects, a maximum number of subjects (n=31) were from the age group of 46-75 years and a slight predominance of males (n=21) over females was found. Religion wise distribution showed that more patients were Hindus (n=39). The majority (n=38) of patients were married. 18 subjects from this study belonged to middle-class families. The majority (n=15) were of *Pitta Kapha Prikriti*. 26 subjects had *Madhyama Kosta*. A considerable number of cases (n=26) had a positive history of

familial tendency. Maximum (n=31) subjects were k/c/o diabetes mellitus-II and majority (n=26) had average Hba1c >8%. 24 subjects had Polyuria-Day, 22 subjects had polyuria night,16 had polyphagia 16 had polydipsia and 25 subjects had tiredness. Maximum (n=24) had 3 *vegas* after *niruha basti*. The majority (n=19) subjects had a retention period of 5-8 mins after *niruha* and 22 subjects had a retention period of 6-9hours after *anuvasana*.

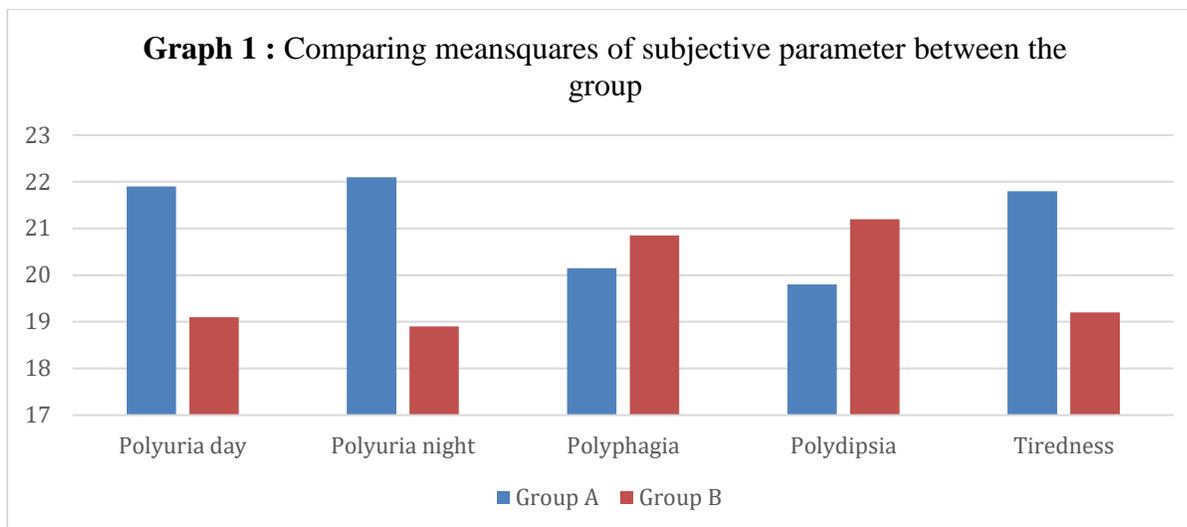
**Results:** The study was registered with 41 subjects of Diabetes mellitus-II in a double group. Out of which 40 subjects completed the study and 1 dropped out. Among 40 subjects, 20 subjects were included under Group A (*Ketaki Niruha Basti*) and 20 were included under Group B (*Madhutailika Basti*)

Friedman's test was run on subjective parameters and both the groups have shown significant improvement in all the symptoms.

Mann Whitney U test was run on subjective parameters between the group, and it was found that there was no significant difference in the action of *Ketaki Niruha Basti* and *Madhutailika Basti* on subjective parameters. However, *Ketaki Niruha Basti* showed marginally better results in Polyphagia and Polydipsia and *Madhutailika Basti* showed slightly better results in Polyuria- Day, Polyuria-Night and tiredness while comparing the mean values. Results are placed in table no.03

**Table 3:** Showing comparative effect of *ketaki niruha basti* and *Madhutailika basti* on subjective parameters

Parameter	Group	N	Mean Rank	Sum of Rank	Z	P	Remarks
Polyuria-day	A	20	21.90	438.00	-.897	.461	NS
	B	20	19.10	382.00			
	Total	40					
Polyuria-night	A	20	22.10	442.00	-.988	.398	NS
	B	20	18.90	378.00			
	Total	40					
Polyphagia	A	20	20.15	403.00	-.244	.862	NS
	B	20	20.85	417.00			
	Total	40					
Polydipsia	A	20	19.80	396.00	-.520	.718	NS
	B	20	21.20	424.00			
	Total	40					
Tiredness	A	20	21.80	436.00	-.799	.495	NS
	B	20	19.20	384.00			
	Total	40					



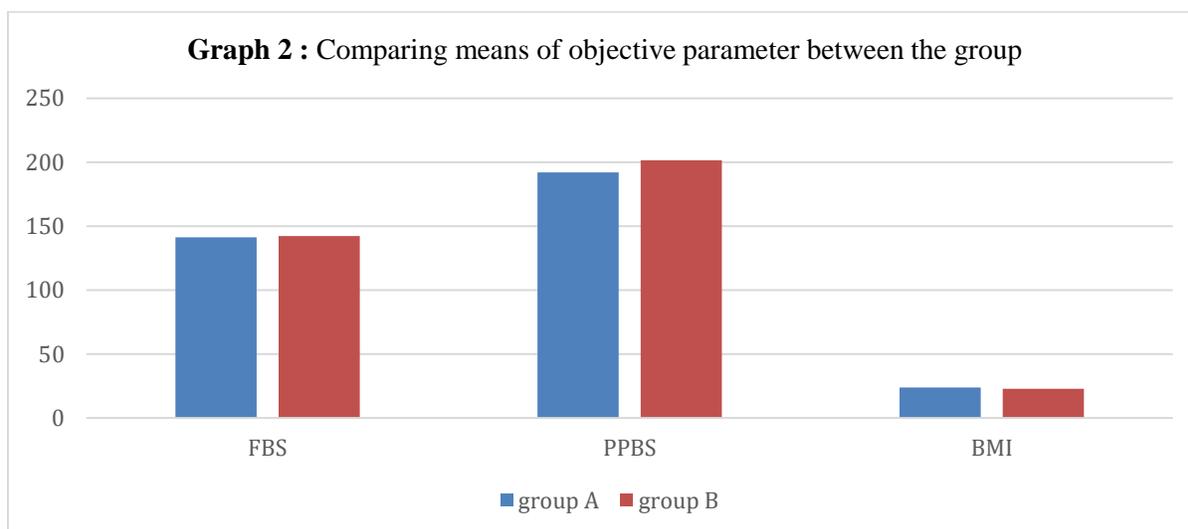
Repeated anova test was run on objective parameters and both the groups have shown significant improvement in all the parameters.

An Independent t-test was run on objective parameters between the group, and it was found that there was no significant difference in the action of *Ketaki Niruha*

*Basti* and *Madhutailika Basti* on objective parameters. However, while comparing the means of objective parameters, FBS and PPBS showed a better reduction in group A or *Ketaki Niruha Basti* group and BMI showed a better reduction in group B or *Madhutailika Basti* group.

**Table 4:** Showing the comparative effect of *Ketaki Niruha Basti* and *Madhutailika Basti* on objective parameters by applying an independent t-test.

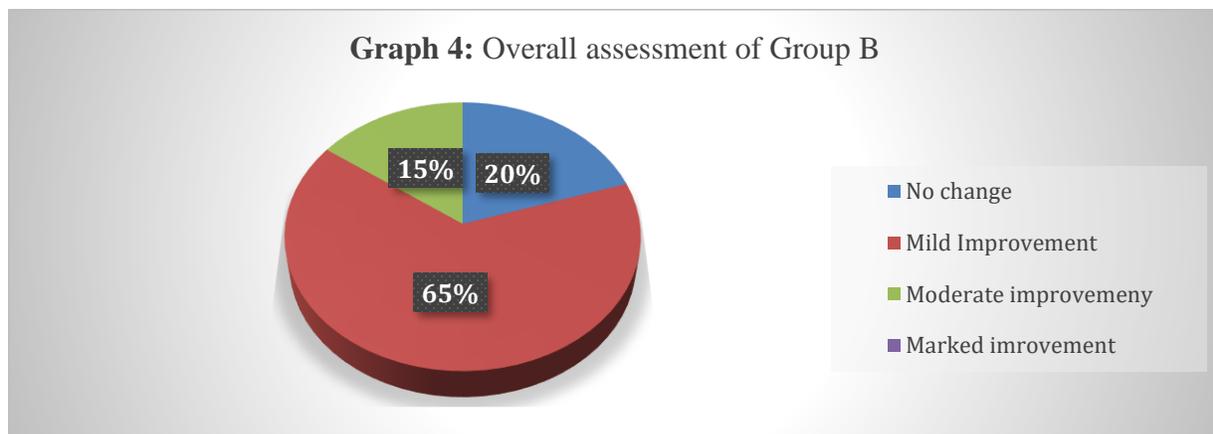
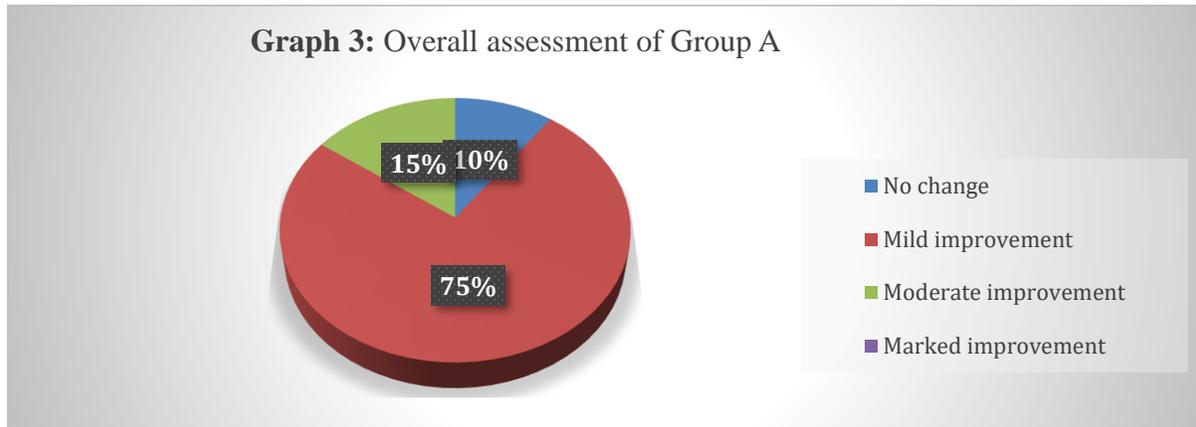
Parameter	Group	N	Mean	Std. Deviation	P-value	Remarks
FBS AT	A	20	141.35	25.1045	.993	NS
	B	20	142.30	43.87914		
PPBS AT	A	20	192.10	35.92814	.606	NS
	B	20	201.500	72.04933		
BMI AT	A	20	23.8435	3.17098	.322	NS
	B	20	22.840	3.15685		



### The overall effect of the intervention:

Among 20 subjects of *Ketaki Niruha Basti* group or group A, 2(10%) subjects had no change, 15(75%) subjects had mild improvement and 3(15%) subjects are moderately improved.

Among 20 subjects of *Madhutailika Basti* group or group B, 4(20%) subjects had no change, 13(65%) subjects had mild improvement and 3(15%) subjects had moderate improvement.



## DISCUSSION

### Discussion on *basti karma*:

**Purvakarma:** The person suitable for *Basti* should be administered with *Snehana*[oleation] and *Swedana*[sudation] but *Abhyanga*[massage] and *Sweda* are contra-indicated in *Santarpanotta Vyadhi*. so only *Sthanika Abhyanga* followed by *Mridu Sthanika Swedana* in the form of *Pata Sweda* is administered specifically to *Kati*, *Vankshana*, *Pakvashaya* to achieve proper *Vatanulomana* and to relax abdominal and local muscles

**Pradhana karma:** *Basti Karma* is the best remedy for morbid *Vata*, but according to Acharya Sushruta it is

beneficial even in *Kaphaja* and *Pittaja* disorders as it contains various combinations of ingredients. This procedure helps in the management of diseases of all the *Roga Margas*.

**Ketaki niruha basti:** Acharya Charaka in *Siddistana* mentioned that whatever medicine is indicated orally for the *Vyadhi*[diseases], can be used for *Basti* in the same *Vyadhi*. This concept is applied while selecting the *Ketaki Niruha Basti*.

**Madhutailika Basti:** it is one among the few *Bastis* mentioned for the treatment of *Prameha*. It is a *Nirapada Nishparihara Basti*, having both *Brahmana* as well as *Lekhana Karma*. This *Basti* is taken as active control group in this study.

### **Time of administration of niruha basti dravya:**

*Niruha Basti* must be administered on empty stomach according to the classics. In this study, light food is advised to prevent diabetic hypoglycemia.

**Basti and madhumeha:** according to Indu commentators of *Astanga Sangraha*, *Prameha* must be treated with *Samshodhana* therapy for the purpose of *Agni Vriddi* and *Kledadi Shamana*. Acharyas mention *Asthapana* therapy for *Prameha* after *Vamana* and *Virechana* therapies. At the same time, acharyas included *Meha* under *Basti* contraindication. Acharya Chakradatta clarifies that *Niruha* can be advised in *Madhumeha* to pacify *Vata*, which is the main dosha involved in *Madhumeha*. He also adds that *Nisneha* Basti mentioned in the quotation can be considered as *Alpa Sneha* not the absolute contraindication of *Sneha*. In this regard, *Ardhamatrika Basti* and *Sneha Basti* in the dose 40ml which is half of *Matra Basti* is taken for the study.

### **Discussion on Drugs:**

**Madhu:** *Madhu* has properties like *Yogavahitva* by which it enhances the properties of the substances with which it is processed. It has *Madhura Kashaya Rasa*, and it does *Karshana* by its *Rukshadi Guna*. It has *Kapha Medohara* action. It is a natural emulsifying agent.

**Saindhava lavana:** *Saindhava* has the property of *Deepana*, *Rochana* and *Teekshna Guna* it is *Sukshma Sroto Gami*.

**Murchita Tilataila:** It is best among *Taila Varga*. It alleviates *Vata* at the same time it does not aggravate *Kapha*. Many acharyas mentioned it in the management of *Shleshmaja* and *Medoja Vikara*. By its *Sukshma Teekshnoshna Gunas*, it enters *Sukshma Srotas*[Minute channels] and does *Kshapana* of *Kapha* and *Medas*.

**Shatapushpa Kalka:** Due to *Ushna Teekshna* property it acts as *Kapha Vata Shamaka*.

**Ketaki quatha:** *Ketaki Quatha* is indicated in *Madhumeha* according to *Bharata Bhaishajya Rathnakara*. It has *Tikta Madhura Katu Rasa*, *Laghu Snigdha Guna Katu Vipaka Ushna Veerya* and *Kapha Pitta Shamaka* property. The root extract of *pandanus odoratissimus* showed anti-diabetic activity and free

radical scavenging activity in male wistar rats.

**Eranda mula quatha:** is told *Agrya* for *Vatahara Guna*, *Ushna Veerya*. The roots of *ricinis cumunis* have free radical scavenging activity by inhibiting lipid peroxidation and helping in fat metabolism.

### **CONCLUSION**

Following conclusions are drawn based on observations and results which were achieved after systematic and appropriate clinical research.

A number of *Vega* after *Basti* administration showed a positive relationship with the type of *Kosta*. Within the groups, all the subjective and objective parameters showed significant results in both the groups. There was a statistically insignificant result seen between *Ketaki Niruha Basti* group and *Madhutailika Basti* group, which proves the null hypothesis. *Ketaki Niruha Basti* showed a better overall percentage of improvement compared to *Madhutailika Basti* group.

The overall percentage of improvement in subjective and objective parameters were only marginal. *Ketaki Niruha Basti* showed better results in polyphagia, polydipsia, FBS and PPBS while *Madhutailika Basti* showed better results in polyuria day, polyuria night, tiredness and BMI

*Ketaki Niruha Basti* group showed the better overall percentage of improvement in *Pitta Kaphaja Prakriti* people as *Ketaki is Pitta Kapha Shamaka* whereas *Madhutailika Basti* group better overall percentage of improvement in *Vata Kaphaja Prakriti* people as *Eranda Mula Quatha* of *Madhutailika Basti* is *Vata-Kapha hara*.

Most subjects had an average retention period within 8-11minutes. The retention period of *Niruha Basti* showed a directly proportional relationship with the overall effect.

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