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**AN OPEN LABEL, SINGLE ARM CLINICAL STUDY ON THE  
COMBINED EFFECTIVENESS OF LODHRADI KASHAYA AND  
NAVAKA GUGGULU IN TYPE 2 DIABETES MELLITUS**

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**ABSTRACT**

**Background:** Diabetes mellitus (DM) is a metabolic disorder characterized by persistent hyperglycaemia either due to less production of insulin or resistance of insulin receptors. Globally 537 million individuals are living with Diabetes and is predicted to rise to 643 million by 2030. Diabetes mellitus type 2(DM2) is the most common type accounting almost 90% of cases of DM. Diabetes mellitus clinically presents with polyuria, polydipsia, polyphagia, paraesthesia. It can be correlated to *Vimshati Prameha*.

**Objectives:** To evaluate the combined effect of *Lodhradi Kashaya* and *Navaka guggulu* in the management of Type 2 diabetes mellitus.

**Methods:** Among 34 registered subjects, 30 of them completed the course of treatment. They were administered with *Lodhradi Kashaya* orally 25ml twice daily before food and *Navaka Guggulu* 500mg tab twice daily after food for a period of 30 days. Blood glucose test was done on 0<sup>th</sup> and 31<sup>st</sup> from the day of study initiation. For Statistical analysis subjective parameters

were assessed by Wilcoxon sign rank test and objective parameters were assessed by Paired sample T Test.

**Results:** There was statistically significant improvement was observed in the signs and symptoms of *Madhumeha* with blood glucose levels. ( $p < 0.05$ )

**Keywords:** Diabetes Mellitus; *Madhumeha*; *Lodhradi Kashaya*, *Navaka Guggulu*

## INTRODUCTION

As global transition in the disease pattern has been observed, where the relative impact of infectious diseases is decreasing while chronic diseases like cardiovascular diseases and Diabetes Mellitus are increasingly dominatingly [1]. Diabetes has been increasing at an alarming rate since the start of the 21st century, driven due to obesity and sedentary lifestyles. The latest 2021 data from IDF Diabetes Atlas 10th edition estimated 537 million adults are living with Diabetes. This is predicted to rise to 643 million by 2030 and 783 million by 2045. Among these, type 2 diabetes (DM2) accounts for over 90% of cases and is the most prevalent [2]. Diabetes mellitus type-2 is a chronic illness which primarily occurs due to abnormal metabolism of glucose, fat and protein. The rising global incidence of type 2 diabetes has emerged as a significant public health concern. Diabetes can be successfully treated with contemporary medicines, but there are drawbacks as well. The progression of disease into the insulin-dependent stage affects the quality of life of the people. To minimize such drawbacks and the long-term complications of diabetes, a need arises to conduct study.

Diabetes mellitus type-2 can be correlated to *vimshathi prameha* with *prabhoota avila mutrata* as the *lakshana* [3]. *Atisevana* of *guru snigda*, *amla*, *lavana rasa*, *nava annapana*, *ati nidra*, *avyayama* lead to *dushti* of *kapha*, *pitta*, *meda*, *mamsa* thereby causing obstruction to *vata*. It produces *lakshana* like *prabhootamutrata*, *madhursyata*, *kshudhadhikya*, *pipaasaadhikya*, *kara-pada daha*, *kara pada suptata*, *mukha talu kantashosha*, *alasya*, *atisweda*, *dourgandya* [4]. The symptoms of Diabetes Mellitus are found to be similar with of *Prameha*. Diabetes mellitus clinically presents with polyuria, polydipsia, polyphagia, paraesthesia. *Lodhradi Kashaya* mentioned in *Basavarajiyam meharoga chikitsa adhyaya* as *madhumehajeet* possess *tikta- Kashaya-rasa*, *laghu guna*, *katu vipaka*, *pramehagna karma*. Experimental studies on *Lodhradi Kashaya* have shown anti-diabetic property. *Navaka guggulu* mentioned in *chakradatta sthoulyachikitsa* rogadhikaara possess *katu tikta rasa*, *laghu*, *rooksha guna*, *kapha vatahara*, *medohara amapachana karma*. Experimental studies have showed anti diabetic, inhibitory activity against  $\alpha$

glucosidase type-iv enzyme, antihyperlipidemic and antioxidant activities thus reducing blood glucose level and peripheral resistance of insulin [5, 6].

This study is intended to validate the effectiveness of *Lodhradi Kashaya* and *Navaka guggulu* in Diabetes mellitus type-2 as both formulations possess properties like *kledahara, medohara, ushna virya, and katu vipaka* would be beneficial in the management of DM type-2.

### OBJECTIVE

To evaluate the combined effect of *Lodhradi Kashaya* and *Navaka guggulu* in the management of Type 2 diabetes mellitus.

### MATERIALS AND METHODS

#### Source of Data:

34 participants of type 2 diabetes mellitus, fulfilling the diagnostic and inclusion criteria were recruited from outpatient department of Sri Dharmashtala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

#### Diagnostic Criteria

1. Diagnosis will be made based on *Lakshanas* of *prameha* like *Prabhoota Mutrata, Avila mutrata, Pipaasa Adhikya, Kshudha Adhikya, Karapada Daha, Karapada Suptata and Angasaada*.
2. Fasting blood glucose >126 mg/dl
3. Postprandial Blood Glucose >180mg/dl or
4. HbA1c >6.5%

#### Inclusion Criteria:

1. Subjects above 30 years up to 70 years of either gender suffering from Type 2 Diabetes Mellitus under control will be taken.
2. Fasting blood sugar  $\geq 126$  mg/dL.
3. Post prandial blood sugar (PPBS) level  $\geq 180$  mg/dL.

#### Exclusion Criteria:

1. Subjects of Type 2 Diabetes Mellitus on insulin
2. Subjects of Type 2 Diabetes Mellitus with HbA1c >10%, FBS >250 mg/dl, PPBS >350mg/dl
3. Subjects with known case of cardiac illness, impaired kidney and liver function
4. Pregnant women and lactating mother.

#### Laboratory Investigations:

Fasting blood glucose

Post prandial blood glucose

#### Ethical clearance and CTRI registration

Ethical clearance was obtained from Institutional Ethics Committee No:

SDM /IEC/44/2022

Trial was registered on [www.ctri.gov.in](http://www.ctri.gov.in) with Registration No: CTRI/2023/08/056755 dated 22/08/2023

#### Study design:

The study was an open label, single arm, prospective clinical trial on type 2 Diabetes mellitus selected using the convenience (non-random) sampling technique with pre

and post design conducted in SDM college of ayurveda and hospital, Hassan Karnataka.

**Source and authentication of raw drug:**

Stem bark of *lodhra*, *abhaya*, *musta*, *katphala* was purchased from Anamaya stores Udupi and were authenticated from department of Dravayaguna of sri dharmasthala manjunatheswara college of Ayurveda, Hassan.

**Method of Preparation**

*Lodhradi Kashaya* :1 part each of *lodhra*, *mustha*, *abhaya* and *katphala* was collected, coarsely powdered and 8parts of water was added, boiled and reduced to 1/2 part.

*Lodhradi Kashaya* was packed in 1000ml and 500ml bottles, properly labelled with name of the drug, reference, preservative, manufacturer and batch number.

*Navaka Guggulu*: Purchased from SDM Pharmacy, Hassan.

**PLAN OF TREATMENT**

*Lodhradi Kashaya*: 25 ml [7] twice a day before food and *Navaka guggulu* :500 mg tablet twice a day after food-orally for 30 days

**ASSESSMENT CRITERIA:**

**Primary outcome measures:**

Table 1: Scoring based on gradation of *Lakshanas of Prameha*

PARAMETER	0	1	2	3	4
<i>Prabhuta nutrata</i> Frequency -Day time Nighttime	3-5 times /day 0-1 time /day	6-8 times /day 2-3 time /day	9-11times /day 4-5time /day	>11times /day >5time /day	-
<i>Kara pada daha</i> (burning sensation in palms and soles)	Absent	Occasionally mildly present	Constantly mildly present	Severely present	-
<i>Kara pada suptata</i> (numbness in palms and soles)	Absent	Occasionally mildly present	Constantly mildly present	Severely present	-
<i>Kshudhadikya</i> (Polyphagia)	Feels hunger to next anna kala only	Feels hunger for once in b/w annakala	Feels hunger for twice in b/w annakala	Feels hunger always	-
<i>Pipasaadhikya</i> (Polydipsia)	Feeling thirst 7-9 times/24hrs or 1-2 ltrs	9 - 11times/24hrs or 2 -4ltrs	11-13 times/24hrs Or 3 - 4 ltrs	13 times or > 4 ltrs	-
<i>Angasaada</i>	Can do normal work	Can do normal work with difficulty	Can do only mild work	Can do mild work with difficulty	Unable to do even mild work
<i>Atinidra</i> (Excess sleep)	6-7 hrs sleep/day and night and performs work with normal enthusiasm	6-7 hrs sleep/day and night and feels drowsiness and lazy to do normal work	8-9hrs sleep/day and night and feels drowsiness and lazy to do normal work	>10 hrs sleep/day and night and feels drowsiness and lazy to do normal work	-

**Secondary outcome measures:** Effect was assessed with changes in:

- Fasting blood glucose- Before and after treatment.

- Post prandial blood glucose- Before and after treatment

**Assessment:** Patient will be observed on 1<sup>st</sup> and 31<sup>st</sup> day

#### STATISTICAL ANALYSIS:

**Wilcoxon signed rank** test is used to analyse the significance of change in ordinal data

**Paired ‘t’ test** is used to analyse the significance of change in scale data

With 95% Confidence interval,  $p < 0.05$  is considered significant and  $p < 0.01$  as highly significant.

#### OBSERVATIONS

In the present study, among the 110 screened patient, total 34 patients of *Madhumeha* were registered. Out of them 30 patients have completed the course of treatment and remaining 4 patients were dropouts. Among

34 subjects, 15(44.1%) of subjects belonged to the age group of 51-60 years, 20(58.8%) subjects were males, 11(32.4 %) were from lower middle class, 16 (47.1%) were newly diagnosed and 18(52.9 %) were already diagnosed subjects who were on Ayurvedic medicines, 21(61.8 %) were having mixed type of diet, 20(58.8%) were having *vishamashana* , 22 (64.7%) of them were having sedentary work, majority of subjects i.e. 24(70.6%) were not doing any physical exercise, 21(61.8) % were having mental stress, 19(55.9%) were having family history, 14(41.2 %) subjects were obese 13(38.2%) subjects were overweight.

#### RESULTS

Effect of *Lodhradhi Kashaya* and *Navaka Guggulu* on signs and symptoms of prameha

Table 2: Result of Wilcoxon Signed Rank test on symptoms

Parameter [BT – AT]	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
	NR	PR					
Prabhuta Mutrata - Day time	NR	27	14	378	-4.866	< 0.05	Significant
	PR	0					
	Ties	3					
	Total	30					
Prabhuta Mutrata - Nighttime	NR	26	13.5	351	-5.014	< 0.05	Significant
	PR	0					
	Ties	4					
	Total	30					
Kshudhaadhikya	NR	12	5	45	-3.464	< 0.05	Significant
	PR	0					
	Ties	18					
	Total	30					
Pipasaadhikya	NR	25	13	325	-4.772	< 0.05	Significant
	PR	0					
	Ties	5					
	Total	30					
Karapada daha	NR	18	9.5	171	-4.001	< 0.05	Significant
	PR	0					
	Ties	12					
	Total	30					
Karapada Suptata	NR	9	5	45	-2.887	< 0.05	Significant
	PR	0					
	Ties	21					
	Total	30					
Angasaada	NR	19	10	190	-4.119	< 0.05	Significant

	PR	0					
	Ties	11					
	Total	30					
Atinidra	NR	10	5.5	55	-3.051	< 0.05	Significant
	PR	0					
	Ties	20					
	Total	30					

Effect of *Lodhradi Kashaya* and *Navaka Guggulu* on Fasting Blood Glucose and Post Prandial Blood Glucose.

Table 3: Result of Paired 't' test on FBS and PPBS

Parameter	Paired differences				t	Df	P value	Remarks
	Mean	SE	95% Confidence interval of the difference					
			Lower	Upper				
FBS BT-AT	19.96	5.387	8.948	30.985	3.70	29	<.05	Significant
PPBS BT -AT	45.56	6.197	32.89	58.241	7.35	29	<.05	Significant

Mean fasting blood sugar before treatment was **168.73** mg/dl which came down to **148.77** mg/dl on 31<sup>st</sup> day with p value (<.05), it shows statistically significant difference in mean Fasting blood sugars.

Mean post prandial blood sugar before treatment was **259.83**mg/dl which came down to **214.27**mg/dl on 31<sup>st</sup> day with p value with p value (<.05), it shows statistically significant difference in mean Post Prandial blood sugars.

## DISCUSSION

### Effect of *Lodhradi Kashya* and *Navaka Guggulu* on *Prabhuta Mutrata*:

Prabhuta mutrata is mutra vaha sroto dushti vikara caused due to increase in bahu drava shleshma, abadha meda dhatus leading to increase mala and kledamsha.

Navaka Guggulu has laghu teekshna guna, katu vipaka, and kapha kleda soshaka karma which does Mutravaha sroto shodhana and Lodhradi Kashaya is having Grahi guna with

kashaya rasa would have helped to reduce the symptoms of prabhutamutrata.

### Effect of *Lodhradi Kashya* and *Navaka Guggulu* on *Kshudhaadhikya*

Kshudhaadhikya occurs due to avarana of abadhamedas over koshtaagni which causes vitiation of vata and leads to kshudhaadhikya.

Lodhradi Kashaya and Navaka guggulu both are having deepana, pachana and srotoshodhaka properties which acts at level of jatharagni and dhatwaagni, leads to proper formation of rasa dhatu and removes the avarna of abadhamedas at level of koshta agni and thus pacified the symptoms.

### Effect of *Lodhradi Kashya* and *Navaka Guggulu* on *Pipasa adhikya*

Pipasa adhikya and mukhatalushosha can be understood as udakavaha srotas dushti lakshana. It occurs due to vata -pitta vridhi leading to udakakshaya

Lodhradi Kashaya does pitta shamana with tikta rasa and sheeta virya of musta, vata

shamana with ushna virya and madhura vipaka of haritaki, Musta is having trishnagna karma thus helped to overcome Pipasadhikya

#### **Effect of Lodhradi Kashya and Navaka Guggulu on Karapada Daha**

Kara pada daha is due to pitta – vata vridhi Lodhradi kashaya and Navaka Guggulu being tikta-kashaya rasa pradhana helps in pacifying the kara-pada-tala-daha. Raj Nighantu describes Katphala as Ugradahara [1]

#### **Effect of Lodhradi Kashya and Navaka Guggulu on Karapada suptata**

Kar pada suptata can be understood as sheeta gunavridhi of vata.

Lodhradi Kashaya and Navaka Guggulu which has ushna virya and sroto shodana karma helped in pacifying the symptom.

#### **Effect of Lodhradi Kashya and Navaka Guggulu on Angasaada**

Angasada may be due to vitiated kapha, meda dhatu and sthira gunataha vridhi of Kapha

Navaka Guggulu and lodhradi kashaya has Vata- Kaphashamaka, Lekhaniya, Medohara, Amapachana and Srotoshodhana karma which reduces vitiated kapha and meda.

#### **Effect of Lodhradi Kashya and Navaka Guggulu on Atinidra**

Atinidra is due to increased kapha and meda which is responsible for tamo guna , Nidra in Madhumeha is Vyadhyanuvartini.

Lodhradi Kashaya and Navaka Guggulu possessing ushna virya,laghu guna , Kapha-Medohara and sroto shodaka karma has helped to pacify Atnidra.

#### **Effect of Lodhrahi kashaya and Navaka Guggulu in Biochemical parameter:**

Experimental studies on Lodhradi Kashaya have showed antidiabetic activity by suppressing the action of intestinal glycosidase enzymes and improving insulin secretion thus reducing blood glucose level Experimental studies on Navaka Guggulu have shown inhibitory activity against  $\alpha$  glucosidase type-iv enzyme, antihyperlipidemic and antioxidant activities thus reducing peripheral insulin resistance and blood glucose level.

#### **PROBABLE MODE OF ACTION OF DRUG [8-12]**

Lodhradi Kashaya- comprises of Lodhra, Musta, Haritaki and Katphala

Lodhra - is having grahi and stambhana property with predominance of kashaya rasa which helps to decrease the increased frequency of micturition in prameha and its chakshushya karma helps in alleviating the chances of retinal complications. It is reported for hypoglycaemic activity as it exerts insulin-like effect by inhibiting hepatic gluconeogenesis. It also functions by promoting regeneration and revitalising the rest of the beta cells.

Musta is having trishnagna karma. So, it helps to alleviate the symptoms like trishna,

galatalu sosha in prameha. Musta has bioactive compounds such as flavonoids, alkaloids and terpenoids which may enhance insulin sensitivity, thereby improving glucose uptake by cells.

Katphala is Ugradahara, helps to reduce the kara pada tala daha. Katphala may inhibit enzymes such as alpha-glucosidase and alpha-amylase, which are involved in the breakdown of carbohydrates. This reduces postprandial blood sugar spikes.

Haritaki clears the obstruction in srotas and alleviates the margavarodha in prameha. It also nourishes the dhatus with its rasayana property. It is rich in antioxidants, by reducing oxidative damage and protects pancreatic beta cells and improve overall metabolic health.

Navaka guggulu comprise 10 ingredients i.e., triphala, trikatu, chitraka, musta, vidanga and guggulu.

Triphala is tridoshagna acts as a rasayana which nourishes the dhatus and helps to overcome complications of diabetic neuropathy. Triphala helps in inhibiting starch digestion and absorption, thereby decreasing postprandial hyperglycemia [13].

Trikatu is kapha –meda hara, sroto shodhaka thus help in samprapti vighatana of prameha and it also improves insulin sensitivity. It also inhibits alpha-glucosidases thus retards glucose liberation from carbohydrates

delays glucose absorption and reduces postprandial hyperglycaemia [14].

Chitraka and vidanga possess deepana and pachana property, corrects the Agni i.e., Jatharagni and Dhatwagni. Thus, stimulating glucose metabolism. They exhibit the anti-hyperglycemic effect and attenuates the glycation associated elevation in the lipid profile [15].

Experimental studies on navaka guggulu have showed anti diabetic, inhibitory activity against  $\alpha$  glucosidase type-iv enzyme, antihyperlipidemic and antioxidant activities.

It contains guggulsterones, tannins, gallic acid, ellagic acid, quercetin and gingerols which has hypoglycaemic activity and piperine, shogaols, beta-amyrin, beta-sitosterol, embelin possessing hypolipidemic activity which in turn reduces peripheral insulin resistance, improves insulin secretion from beta cells of pancreas [16-17].

## CONCLUSION

Administration of Lodhradi kashaya in the dosage of 50ml/day in divided dose of 25ml twice daily (morning and evening) before food and Navaka Guggulu 500mg tablet twice daily after food for 1 month was found beneficial in improving symptoms of Prabhoota mutrata, Kshudhadhikya, Pippasadhikya, Karapada suptata, Karapada Daha, Atinidra and Angasaada. Statistically significant improvement was observed in

objective parameters -Fasting and Post prandial blood glucose levels. Research hypothesis was thus accepted.

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