

**How to Cite:**

Dhakite, S. K., & Wajpeyi, S. M. (2022). Study of the efficacy of Tryushanadigudika in the management of Prameha with special reference to diabetes mellitus type II. *International Journal of Health Sciences*, 6(S2), 882–896. <https://doi.org/10.53730/ijhs.v6nS2.5052>

## **Study of the Efficacy of Tryushanadigudika in the Management of Prameha with Special Reference to Diabetes Mellitus Type II**

**Sneha K. Dhakite**

PG Scholar, Department of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha, India

**Sadhana Misar Wajpeyi**

Professor, Department of Kayachikitsa, Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha, India

**Abstract**---Background: *Prameha* is a *Tridoshaj*, *Kapha* predominant disease. There are twenty kinds of *Pramehas* in Ayurveda. Out of these *Madhumeha* is one of the types of *Vataja Pramehas*. Due to similarities of signs and symptoms, *Madhumeha* can be correlated with Diabetes mellitus type II. In Ayurveda, *Nidanparivarjana*, *Shodhana* and *Shamana Chikitsa* are described for *Prameha*. In Chakradatta, *Tryushanadigudika* is indicated in the management of *Prameha* (Diabetes mellitus type II). So, this study was conducted to compare the effectiveness of *Tryushanadigudika* in the management of *Prameha* with special reference to Diabetes mellitus type II. Methodology: Total 40 patients were enrolled and randomly divided into two equal groups. Group A was treated with *Tryushanadigudika* and Group B with Tab. Metformin for 30 days. Patients were assessed for *Kshudhadhikya*, *Naktamutrata*, *Kar-Pada Suptata*, *Hasta Pada Tala Daha*, Fasting and Postprandial blood sugar level on 0 and 30<sup>th</sup> day. Results: Significant improvement was observed in Subjective and Objective parameters like *Kshudhadhikya*, *Naktamutrata*, *Kara Pada Suptata*, *Hasta Pada Tala Daha* and blood sugar level (Fasting and Postprandial) in both groups.

**Keywords**---diabetes mellitus, madhumeha, prameha, tab. metformin, tryushanadigudika.

## Introduction

The term 'Prameha' is made from 'Pra' and 'Meha'. The term *Meha* has its origin from "MihSechane" by the addition of 'Lue' pratyaya. In Sanskrit literature, it means to eliminate. 'Prameha' means *Prabhutmutrata* (Polyuria) or *Avilmutrata* (Turbid urine). *Prameha* is a *Tridoshaj*, *Kapha* predominant disease.<sup>1</sup> It is included under *Ashtamahagada* by Acharya Charak, *Sushrutand Vagbhata*.<sup>2</sup> Ayurveda has mentioned twenty kinds of *Pramehas*. As per the dominance of *Dosha*, they are classified as four *VatajaPramehas*, six *PittajaPramehas* and ten *KaphajaPramehas*. Out of these *Madhumeha* is one of the types of *VatajaPramehas*.<sup>3,4</sup>

The word 'Madhumeha' means a disease in which *Mutra* attains similar property like *Madhu* (Honey). It is a disease of *MedovahaStrotas* and is mainly caused due to *Medodushti*. This *Medodushtivitiates* *Mansa*, *Rakta*, *Kleda* and *Ojas*. Thus *Rasa*, *Mansa*, *Meda* *Dhatu*s, *Mutra*, *Sweda* and all three *Doshas* are involved in the *Samprapti* of *Prameha*.<sup>5</sup> As per Acharya Charak *Asyaasukha* (a habit of sitting always), *Swapnasukha* (a habit of sleeping), *Dadhivarga* (curd preparations), *Mansa sevana* of *Gramya*, *Audaka* and *Anoopa* (kind of flesh aggravating *Kapha*), *Navaanna* (newly harvested food grains less than 1 year) and *Navapana* and other factors causing aggravation of *Kapha* *Dosha* having dominance of *mahabhuta* like *Prithvi* and *Jala*.<sup>6</sup>

Due to similarities of signs and symptoms, *Madhumeha* can be correlated with Diabetes mellitus type II. It can be defined as an increased blood sugar level due to a lack of insulin or resistance to insulin.<sup>7</sup> Changing lifestyle, no any exercise, improper diet and sedentary life are predisposing factors of it.<sup>8</sup> Diabetes mellitus is a major health problem in the 21<sup>st</sup> century. India is one of the five countries which have the highest sufferers of Diabetes mellitus; hence India is stated as the "Capital of Diabetes" now. Diabetes is called a "silent killer". This disease and its consequences have a great risk to all population as well as health resources all over the globe if remain untreated can lead to various health complication and at times death.

Presently above 62 million population suffering from Diabetes and is rapidly gaining the status of the epidemic in India.<sup>9,10</sup> As per the IFD (International Federation of Diabetes) about 415 million grown-ups around the globe have Diabetes and it is predicted to reach around 642 million population by 2040.<sup>11</sup> Some 415 million population around the globe, or 8.8% of grownups, are predicted to be Diabetic.<sup>12</sup>

As per modern science, Diabetes mellitus is a disorder related to impairment in the metabolism of carbohydrates (*Kapha*), fat (*Meda*), and protein (*Mansa*). In Ayurveda, *Agni* is considered to be responsible factor for all the metabolic processes in the body. So, all types of *Prameha* having physical abnormality in urine can be considered as metabolic disorders. In Ayurveda, *Nidanparivarjana* (avoiding causative factors), *Shodhana* (purification procedure) and *ShamanaChikitsa* (Internal medication) are described for *Prameha*.

In *ShamanaChikitsa*, many herbal formulations are described which are effective in the management of *Prameha*. *Tryushanadi gudika*<sup>13</sup> is one of them described in *Chakradatta*. It contains *Amalaki*(*Emblca officinalis*. Burm), *Bibhitaki*(*Terminalia bellerica*. Roxb.), *Haritaki*(*Terminalia chebula*. Retz.), *Pippali*(*Piper longum*. Linn.), *Marich*(*Piper nigrum*. Linn.), *Sunthi*(*Zinziber officinalis*. Roxb.), *Guggul* (*Commiphoramukul*) and *Gokshur*(*Tribulus terrestris*. Linn.).

### **Need of study**

*Madhumeha* is a rapidly spreading global issue with significant social, health, and economic outcome. The occurrence of *Madhumeha* is rising due to unhealthy dietary habits and sedentary lifestyles. Ultimately it affects the kidneys, the eyes, the heart, the blood vessels & the nerves. So, to overcome such complications it is essential to maintain the blood glucose level within the normal level. Despite incredible advancements in contemporary medicine, such as oral hypoglycemic agents and insulin, no such curative therapies have been developed to date due to its complexity, and scientists are currently searching for a successful and safe cure. Patients who are not willing or contraindicated for *ShodhanaChikitsa* can be managed effectively with *ShamanaChikitsa*. Hence there is a need to search the effective and safe herbal medicine. All the ingredients of *Tryushanadigudika* have *Katu*, *Tikta rasa*, *Vatakaphashamaka* and *Medohar* properties which can help break the *Samprapti* of *Prameha*. Metformin is a biguanide-based antihyperglycemic medication, used as the first drug of choice for the management of Diabetes mellitus type II.<sup>14</sup> So, this comparative study is planned to evaluate the efficacy of *Tryushanadigudika* with the drug Metformin on blood glucose levels.

### **Aim and Objectives**

- Aim  
Evaluation of efficacy of *Tryushanadigudika* in the management of *Prameha* with special reference to Diabetes mellitus type II.
- Objectives
  - To assess the efficacy of *Tryushanadigudika* on Subjective and Objective parameters of *Prameha*.
  - To assess the efficacy of Metformin on Subjective and Objective parameters of *Prameha*.
  - To compare the efficacy of *Tryushanadigudika* with Metformin on Subjective and Objective parameters of *Prameha*.

### **Material and Methods**

Source of Data: Total 40 patients, divided into Group A & Group B (20 patients in each group) reported to OPD and IPD of Kayachikitsa department, MGACH & RC and also from peripheral camps were enrolled for this study.

Study design: Randomized Standard controlled Double arm Open label Study.

Study Type: Interventional Clinical Study.

### Inclusion criteria

- Age between 30-70 years of either sex and any *SharirikPrakruti*
- Patient with Fasting blood sugar level  $\geq 126$  mg/dl and /or
- Postprandial blood sugar level  $\geq 200$  mg/dl<sup>15</sup>
- Newly diagnosed patients.

### Exclusion criteria

- Insulin Dependent Diabetes Mellitus (IDDM) and those who are under insulin therapy.
- Pregnant and lactating women.
- Patient with Cirrhosis of liver, Pancreatitis, HIV, Hepatitis.
- Patients with acute complications like Hyperglycemia and Hypoglycemic Coma.
- Patient with chronic Diabetic complications like Nephropathy, Neuropathy and Retinopathy.

### Intervention

Group A- Treated internally with *Tryushanadigudika*

Group B- Treated internally with Tab. Metformin

### Posology

Group A - *Tryushanadigudika* 500 mg Two times a day 40 min before a meal with water.

Group B – Tab. Metformin 500 mg Two times a day 40 min before meal with water.

### Composition of material

Table 1  
Showing Ingredients of *Tryushanadi gudika*<sup>16</sup>

Sr.no.	Drug	Latin Name	Part used	Quantity
1.	<i>Sunthi</i>	( <i>Zingiber officinale</i> . Roxb)	Rhizome	1 part
2.	<i>Marich</i>	( <i>Piper nigrum</i> . Linn.)	Dry Fruit pulp	1 part
3.	<i>Pippali</i>	( <i>Piper longum</i> . Linn.)	Dry Fruit pulp	1 part
4.	<i>Haritaki</i>	( <i>Terminalia chebula</i> . Retz.)	Dry Fruit	1 part
5.	<i>Amalaki</i>	( <i>Emblica officinalis</i> . Burm.)	Fruit pulp	1 part
6.	<i>Bibhitaki</i>	( <i>Terminalia belerica</i> . Roxb.)	Dry Fruit	1 part
7.	<i>Guggul</i>	( <i>Commiphoramukul</i> )	Gum (Resin)	6 parts
8.	<i>Gokshur</i>	( <i>Tribulus terrestris</i> . Linn.)	Fruit	Q. S

### Preparation of material

Preparation of *Tryushanadigudika*

- In a stainless-steel container, 200gms of *Gokshurbharad* was taken and mixed with 16-part water (3200 ml). Mild heat was applied continuously until the quantity was decreased to 1/8<sup>th</sup> of the original (400 ml). As shown in Table no. 1, the remaining authenticated raw drugs (*Triphala*, *Trikatu*) were crushed to a fine powder and small pieces of dried *Guggul* mixed with *Gokshur* decoction in a grinder for *Bhavana* procedure for at least 4-5 hrs, till it became dried and kept overnight.
- On the next day, 150gms fresh *Gokshur* were coarsely crushed in *khalvayantra* and mixed with 16 parts of water (2400ml) and reduced to 1/8<sup>th</sup> (300ml). Then prepared *Kwath* was added to the dried material and again *Bhavana* was given for 4-5 hrs. till it became dried. The same procedure was repeated for the next day.
- The completely dried material was crushed in a small bolus and kept in a tray applied with *ghrita* and kept in a drier on 50<sup>o</sup> C for 6-7 hrs. On the next day, the same procedure was done.
- After this procedure, the bolus was finely powdered and added with Gum acacia, starch, magnesium stearate and sodium benzoate for binding the tablets. Lastly, 250 mg tablets of *Tryushanadigudika* were prepared and packed in airtight container.

Study Duration: 30 days.

Follow Up Period: On 0 day and 30<sup>th</sup>day (after treatment)

Investigation: Blood sugar level (Fasting & Postprandial) – before and after treatment.

### Assessment criteria

- Subjective parameters:
  - *Kshudhadhikya*(Increased appetite)
  - *Naktamutrata* (Nocturnal micturition)
  - *Kar-Pada Suptata*(Numbness palms and soles)
  - *Hasta Pada Tala Daha* (Burning palms and soles)
- Objective Criteria:
  - Fasting blood sugar level
  - Postprandial blood sugar level

### Gradation of Assessment criteria

Table 2  
Showing Gradation Subjective parameters<sup>17</sup>

Sr.no	Gradations	During Treatment (0 day)	After Treatment (30 <sup>th</sup> day)
1	<i>Kshudhadhikya</i> (Increased appetite)	Present / Absent	
2	<i>Naktamutrata</i> (Nocturnal micturition)	Present / Absent	
3	<i>Kar-Pada Suptata</i>	Present /	

	(Numbness palms and soles)	Absent
4	<i>Hasta Pada Tala Daha</i> (Burning palms and soles)	Present / Absent

### Statistical analysis

Data was analyzed Statistically for which descriptive and inferential statistics were used by applying chi-square test, the student's paired and unpaired t-test. SPSS 24.0 version and Graph Pad Prism 7.0 version software was used for the analysis and the value of p for the level of significance is considered as  $p < 0.05$ .

### Observation and Results

Demographic data showed that the maximum number of patients 15(37.5%) were in the age group between 50-59 years, followed by 10(25%) in the age group 40-49years, out of 40 patients. From this result it is evident that the disease is prevalent in middle and old age. In this study, the number of males 21(52.5%) and females 19 (47.5%) are equal and there was

no significant difference observed regarding sex. Majority of the patients in the present study 38(95%) were Hindu. In the present study, the majority of patients were married 35(87.5%). Regarding occupation this study showed that the greater number of the subjects 11(27.5%) were housewives followed by 8(20%) govt. servants followed by 5(12.5%) retired or engaged in private jobs. Majority of patients 29(72.5%) belonged to the urban areas. In this study, it was observed that the disease was more prevalent in patients belonged to middle 23(57.5%) and higher socioeconomic class 14(35%). Regarding addiction, it was observed that the majority of the patients had a habit of tea, tobacco and cigarette smoking. In the present study family history was absent in 28 (70%) patients. In this study, the majority of patients had *KaphaVatajaPrakruti* and *Pitta KaphajPrakruti* which indicates more incidence of disease in the *Kapha* dominant *Prakruti*. In this study, the mean BMI was 25.04 kg/m<sup>2</sup> and 23.88 kg/m<sup>2</sup> in Group A and Group B respectively. Also, the majority of patients 24(60%) were having *MadhyamAkru*ti and 15(37.5%) having *SthulaAkru*ti which suggests that Diabetes was prevalent in an overweight and obese person. In this study, the mode of detection was accidental in the majority of 24(60%) patients and the remaining it was detected on basis of suspicion. Majority of patients had a habit of *Diwaswap* 24(60%) and sound sleep 31(77.5%). In this study, *Adhyashana* and *Vishamashana* were found in the majority of patients. In this study majority of patients had the habit of consuming *Madhura Rasa* dominant food and 29(72.5%) patients had Mixed diet. In the present study, the maximum number of patients had *Tikshnagni* and *Vishamagni*. Most of the patients 27(67.5%) had *MruduKoshta*. In this study majority of 24(60%) patients had Normal bowel habits while 16(40%) patients had Constipation and 27(67.5%) patients had *SaamJivha*.

Statistically, significant improvement was observed in both groups in reduction of Fasting and Postprandial blood sugar levels after treatment. Comparison of both

groups was statistically not significant after treatment that is both groups are equally efficient in decreasing blood sugar ranges, fasting as well as post meal. Regarding the comparison of overall improvement in both groups, it was observed that in both groups most of the patients showed Moderate (51-75%) to Mild Improvement (25-50%).

Table 3  
Showing Comparison of *Kshudhadhikya* at day 0 and day 30 in two groups

	Day 0	Day 30	x <sup>2</sup> -value	p-value
Group A				
Present	19(95%)	3(15%)	25.86	0.0001, S
Absent	1(5%)	17(85%)		
Group B				
Present	17(85%)	3(15%)	19.60	0.0001, S
Absent	3(15%)	17(85%)		
Comparison between group A and Group B				
x <sup>2</sup> -value	1.11	0.00		
p-value	0.29, NS	1.00, NS		

Table 4  
Showing Comparison of *Naktamutrata* at day 0 and day 30 in two groups

	Day 0	Day 30	x <sup>2</sup> -value	p-value
Group A				
Present	13(65%)	1(5%)	15.82	0.0001, S
Absent	7(35%)	19(95%)		
Group B				
Present	8(40%)	0(0%)	10	0.0016, S
Absent	12(60%)	20(100%)		
Comparison between group A and Group B				
x <sup>2</sup> -value	2.50	1.02		
p-value	0.11, NS	0.31, NS		

Table 5  
Showing Comparison of *Kar -Pada Suptata* at day 0 and day 30 in two groups

	Day 0	Day 30	x <sup>2</sup> -value	p-value
Group A				
Present	18(90%)	0(0%)	32.73	0.0001, S
Absent	2(10%)	20(100%)		
Group B				
Present	14(70%)	0(0%)	21.54	0.0001, S
Absent	6(30%)	20(100%)		
Comparison between group A and Group B				
x <sup>2</sup> -value	2.50	-		
p-value	0.11, NS	-		

Table 6  
Showing Comparison of *Hasta Pada Tala Daha* at day 0 and day 30 in two groups

	Day 0	Day 30	x <sup>2</sup> -value	p-value
Group A				
Present	9(45%)	0(0%)	11.61	0.0007, S
Absent	11(55%)	20(100%)		
Group B				
Present	12(60%)	5(25%)	5.01	0.025, S
Absent	8(40%)	15(75%)		
Comparison between group A and Group B				
x <sup>2</sup> -value	0.90	5.71		
p-value	0.34, NS	0.016, S		

Table 7  
Showing Comparison of Fasting blood Sugar at day 0 and day 30 in two groups  
Student's paired t-test

		Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	Day 0	157.90	20	46.23	10.33	17.55±5.77	13.59 p=0.0001, S
	Day 30	140.35	20	44.21	9.88		
Group B	Day 0	159.80	20	44.93	10.04	20.35±7.19	12.64 p=0.0001, S
	Day 30	139.45	20	43.34	9.69		

Table 8  
Showing Comparison of Postprandial blood sugar at day 0 and day 30 in two groups  
Student's paired t-test

		Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value
Group A	Day 0	269.85	20	59.20	13.23	30.05±12.78	10.50 p=0.0001, S
	Day 30	239.80	20	58.59	13.10		
Group B	Day 0	265.80	20	85.08	19.02	36.50±25.47	6.40 p=0.0001, S
	Day 30	229.30	20	77.99	17.44		

Table 9  
Showing Relief in Subjective parameters in overall patients

Symptoms	Before Treatment Score	After Treatment Score	Relief Score	% Relief
<i>Kshudhadrhikya</i>	36	6	30	83.33%
<i>Naktamutrata</i>	21	1	20	95.23%
<i>Kar - Pada Suptata</i>	32	0	32	100%
<i>Hasta Pada Tala Daha</i>	21	5	16	76.19%

Table 10  
Showing Comparison of group-wise and overall percentage improvement in patients

Assessment	Group A	Group B	Total
Complete Remission	0(0%)	0(0%)	0(0%)
Markedly Improvement (>75%)	2(10%)	3(15%)	5(12.5%)
Moderate Improvement (51-75%)	11(55%)	9(45%)	20(50%)
Mild Improvement (25-50%)	7(35%)	8(40%)	15(37.5%)
Unchanged (<25%)	0(0%)	0(0%)	0(0%)
Total	20(100%)	20(100%)	40(100%)

## Discussion

The aim of this study was to determine the efficacy of *Tryushanadigudika* in the treatment of *Prameha*, with a reference to Diabetes mellitus type II. It was designed to search out a safe and effective herbal remedy in the management of *Prameha*. This is a randomized clinical study in which 40 patients of *Prameha* were selected and classified into two equal groups. The study commenced after getting approval from the Institutional Ethical Committee and clinical trial registry. Patients in Group A were treated with *Tryushanadigudika* 500mg twice a day before a meal with water and patients in Group B were treated with Tablet Metformin 500mg twice a day before a meal with water for 30 days. Patients were assessed for Subjective parameters like *Kshudhadhikya* (Increased appetite), *Naktamutrata* (Nocturnal micturition), *Kar Pada Suptata* (Numbness of palms and soles) and *Hasta Pada Tala Daha* (Burning palms and soles) shown in Table no. 2 and Objective parameters like Fasting and Postprandial blood sugar level. This trial enrolled a total of 40 patients, all of whom finished the treatment.

As shown in Table no. 3, significant improvement in *Kshudhadhikya* was observed in both groups and the comparison of both the groups was statistically not significant ( $p=1.00$ , NS) after completion of treatment that is both groups are equally effective in reducing *Kshudhadhikya*. *Kshudhadhikya* (polyphagia) is caused by *Tikshna Ushnaguna* of *Pitta*. It also occurs due to deranged *Agni* like *Tikshnagni* and *Vishmagni*. As per the pathology of Diabetes mellitus explained in modern science, glucose expenditure in muscle tissues is reduced due to a lack of insulin utilization, which is an important requirement for energy.

Polyphagia is a term used to describe when muscle tissue does not receive glucose but needs it.<sup>18</sup> *Deepana* and *Pachana* properties of *Triphala*, *Trikatu*<sup>19</sup> help in improving the digestive process by normalizing deranged *Agni*, resulting in the normal digestion process and also help in the prevention of further *Medovridhi*. *Vatashamaka* property of *Guggul*<sup>20</sup>, *Haritaki*<sup>21</sup> causes alleviation of aggravated *Vata Dosha* responsible for *Vishmagni*. Thus, help in reducing the *Kshudhadhikya*.

As shown in Table no. 4, significant improvement in *Naktamutrata* was observed in both groups and the comparison of both groups was statistically not significant with (0.31, NS)  $p$ -value in *Naktamutrata* that is both groups are equally effective in

reducing *Naktamutrata*. *Naktamutrata* was present due to an increase in *Kleda* and *abdhatu* in the body. As per modern pathology, when the glucose level increases in the body it stimulates the body to excrete excess glucose through the urine. In such a case, to eliminate extra sugar from the body extra volumes of urine are produced thus causes polyuria. *Lekhan*, *Kledshoshan* and *Shodhana* properties of ingredients present in the trial drug help in reducing the excessive *Kleda* and *abdhatu*. This helps in reducing excessive urination at night.

As shown in Table no. 5, significant improvement in *Kar - Pada Suptata* was observed in both groups and comparison of both groups was statistically not significant with (0.11, NS) p-value in *Kar - Pada Suptata* that is both groups are equally effective in reducing *Kar - Pada Suptata*. As shown in Table no. 6, significant improvement in *Hasta Pada Tala Daha* was observed in both groups and comparison of both groups was statistically significant with (0.016, S) p-value in *Hasta Pada Tala Daha* that is group A (100%) treated with *Tryushanadigudika* is more effective in reducing *Hasta Pada Tala Daha* than group B treated with Metformin.

*Kara Pada Tala Suptata* is caused due to *ashayapkarshagati* of *Kapha*. By the *vyanvayusanga*, *Kapha* gets dislocated to another place that may lead to the state of *Hasta Pada Suptata*. *Kara Pada Tala Daha* is caused due to *ashayapkarshagati* of *Pitta* and due to loss of *Ambu* content from the body. *Tridoshashamaka* property of *Tryushanadigudika* helps in alleviating *Vata*, *Pitta* and *Kapha* *Dosha*. *Strotoshodhana* and *Lekhana* properties help in removing the obstruction. Thus reduces *Kara Pada Tala Suptata* and *Kara Pada Tala Daha* (burning sensation and numbness in the palm and soles). Both these symptoms are caused due to peripheral neuropathy caused by Diabetes. Antidiabetic activity of *Amalaki*,<sup>22</sup> *Sunthi*,<sup>23</sup> *Pippali*,<sup>24</sup> ingredients of *Tryushanadigudika*, help in normalizing blood sugar levels. *Amalaki*, *Haritaki*,<sup>25</sup> *Sunthi*, *Marich*,<sup>26</sup> and *Guggul*,<sup>27</sup> are *Nadibalya* and are useful in symptoms related to neurology by giving strength to peripheral nerves. This helps in reducing these symptoms.

Statistically, significant improvement was observed in both groups in reduction of Fasting and Postprandial blood sugar levels after treatment. As shown in Table no.7 and 8, significant improvement was observed in reduction of Fasting and Postprandial blood sugar levels in both groups and comparison of both groups was statistically not significant after treatment that is both groups are equally efficient in decreasing blood sugar ranges, fasting as well as post meal. As shown in Table no.9, Overall improvement in both groups, it was observed that 83.33% patients got relief in *Kshudhadhikya*, 95.23% patients got relief in *Naktamutrata*, 100% patients got relief in *Kar - Pada Suptata* and 76.19% patients got relief in *Hasta Pada Tala Daha*.

As shown in Table no. 10, comparison of overall improvement in both groups, it was observed that in both groups most of the patients showed Moderate (51-75%) to Mild Improvement (25-50%). Markedly Improvement (>75%) was found in a smaller number of patients in both groups which might be due to the short duration of study that is of 30 days.

### **Probable mode of action of *Triphala***

*Triphala* is a combination of *Haritaki*, *Amalaki* and *Bibhitaki* in equal quantity. *Triphala* has *Kashaya* dominance *Madhur*, *Amla*, *Tikta*, *Katu rasa*, *Lagu*, *Rukshaguna*, *Ushnavirya*, *Madhur vipak* and *Tridosaharprabhava*. It helps in balancing *Tridosha*. *Kashaya rasa*, *Laghu*, *Rukshaguna* of *Triphala* causes *Vatanulomana*. *Tikta*, *Katu rasa*, *Lagu*, *Rukshaguna*, *Ushnavirya* help in clearing the obstruction from *strotas* by removing *Kapha* and *Kleda*.<sup>28</sup> *Lekhana* and *Kaphamedahar* properties help in reducing excessive *Kapha*, *Meda* and *Kleda* thus help in breaking *Samprapti*. *Triphala* has *Tridoshashamak*, *Pramehahara* and *Rasayanaproperty*.<sup>29</sup>

Tannins, gallic acid, chebulinic acid, ellagic acid, and other bioactive substances such as flavonoids, saponins, anthraquinones, amino acids, fatty acids, and different carbohydrates are found in *Triphala*. Due to which it has hypoglycemic, antihyperglycemic, hypolipidemic, hypocholesterolemia, insulin-releasing, anti-stress, antioxidant and immunomodulatory activities. It enhances free radicals and reduces oxidative stress.<sup>30</sup>

### **Probable mode of action of *Trikatu***

*Trikatu* comprises *Sunthi*, *Marich* and *Pippali*. Ingredients of *Trikatu* possess *Katu* (Pungent) *rasa*, *Laghu* (Light), *Ruksha* (Dry), *Tikshna* (Pungent), *Ushna* (Hot) *guna*, *Ushnavirya* (Hot potency). It possesses *Vatakaphaghna*, *Agnideepana*, *Amapachana*, *Kledashoshana*, *Lekhana*, *Chedana* and *Strotoshodhana* properties. *Vatakaphagnaproperty* help in alleviating aggravated *Vata* and *Kapha Dosha*. *Agnideepana* (appetizer) property helps in normalizing deranged *Agni* and *amapachana* (digestive) properties help in digestion of *Ama*. *Kledashoshana*, property aids in the absorption of excessive *Kleda* and *abadhatu*. *Strotoshodhana* (Cleaning), *Lekhana* (Scrapping) and *Chedana* (Removing) properties help in eliminating *Kapha*, *Meda*, *Kleda* and *abdhatu* thus help in clearing the obstruction of *strotas* and removing the *Avarana* by promoting *anulomana* of *Vyana* and *Pranavayu*. Due to all these properties, *Trikatuchurna* helps in breaking the *Samprapti* of *Prameha* thus causes a reduction of symptoms.

### **Probable mode of action of *Guggul***

*Guggul* possesses *Tikta*, *Katu rasa*, *Laghu*, *Ruksha*, *Vishada*, *Sukshma*, *guna*, *Ushnavirya*, *Tridosahar*, *Medohar*, *Amapachana*, *Lekhana* and *Rasayanaproperties*. *Guggul* stimulates the functions of the *Vyanavayu* and helps in the digestion of *Ama*.<sup>31</sup> *Guggul* having *Ushnavirya* helps in pacifying the *Vata Dosha*, and *Lekhana* property helps in reducing *Kapha-Meda*.<sup>32</sup> It is one of the most effective medications for *Mutravahastrotas*, *Meda*, and *Kapha Dosha*.<sup>33</sup> Hence it is indicated in *Prameha*, *Kleda*, *Sthaulya* and *Agnimandya*. *Apatarpana Chikitsa* is indicated in *Prameha*. According to *Dalhana* administration of *TiktaKatu rasa* is also caused *Apatarpana* by reducing *Kapha* and *Meda*. It also causes *Shoshana* of excess *Kleda* and *abadhatu* from the body. Thus, helps in breaking the *Samprapti* of *Prameha* and reduces the symptoms.

### **Probable mode of action of Gokshur**

*Gokshura* possesses *Madhura rasa and vipak, Sheetavirya, and Guru Snigdha* properties. It has *Vatapittahara, Mutral, Balya, Rakta-Prasadak, Basti-Shodhak, Kledaghna, Medoghna, Shothaghna, Lekhan and Rasayanaproperties*. It is indicated in *Prameha, Mutravikarand Shotha*. It reduces excess *Kleda, Meda, and abdhatu* from the body. *MutravahaStrotodushtinashakand Lekhan* properties help in removing blockage from *strotas*. Thus, it corrects *strotorodha* in *Mutravaha*, as well as *Medovahasrotas* in *Prameha*, caused due to vitiated *Kaphadi Doshas*.<sup>34</sup>*Rasayana* property nourishes *Sapta Dhatu* and also improves metabolic processes. All these properties help in breaking *Samprapti* and reducing symptoms of the disease.

All the ingredients of *Tryushanadigudika* by their properties balance all three *Doshas, Dushyas* and *Agni* responsible for causing disease. It reduces obstruction from *strotas* and absorbed excess *Meda, Kleda* and *abdhatu* from the body. This causes breaking of *Samprapti* and reduction in symptoms. Two protocol and case study of *Madhumeha* are reviewed<sup>35-45</sup>.

### **Conclusion**

Comparison of improvement in all Subjective, as well as Objective parameters, was statistically non-significant that is both groups are equally effective in reducing all symptoms except *Hasta Pada Tala Daha* in which group A treated with *Tryushanadigudika* showed better improvement than group B treated with Tab. Metformin. No adverse effect of *Tryushanadigudika* was observed in the study. Hence, it can be a good option for reducing symptoms of Diabetes mellitus type II.

### **Acknowledgment**

I am very thankful to Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha, a constituent unit of Datta Meghe Institute of Medical Sciences (DU), Nagpur, Maharashtra, India for giving me the opportunity and environment to conduct such this study.

Funding support: Nil

Conflict of interest:None

### **References**

1. Shukla Vidyadhared, Charak Samhita of AgniveshaChikitsaShtana(Hindi), Chapter no.6,Verse no.7, ChaukhambaSanskritaPrakashana, Reprinted:2013, p.168.
2. Tripathi Brahmananded, AshtangHridayam(Hindi), NidanSthana, Chapter no.10, Verse no. 4,5, Chaukhambha Sanskrit Prakashan Delhi, 2011, p.493.
3. Prof. K.R. Srikantha Murthy, Bhavaprakasa of Bhavamisra, PurvakhandDvitiyabhaga, Section I, Part II, Chapter 7 (III), Krishnadas Academy, Varanasi - 2<sup>nd</sup> edition 2001-p.551.

4. Basavaraju NK. MeharogaNidanaLaksanaChikitsadyayah (9<sup>th</sup> Chapter). In: Basavarajeeyam. Hyderabad: Published by NIIHM; 2013, p.328-331.
5. Sharma Bhawana, Goyal Dinesh Kumar, et.al - A Comparative Clinical Evaluation of the Efficacy of MadhumehaNashiniGutika&DarvyadiKwath in Madhumehaw.s.r. to Diabetes mellitus, IJAPR, Vol 3, Issue 8, August 2015, p.11-18,
6. Y.T. Acharya and Narayana Ram Acharya KavyatirthaSushruta Samhita, repr., Uttartantra, Chapter no.1, Sutra 15, ChaukhambhaSurabharatiPrakashana, Varanasi, 2008.
7. Davidson's Principles and Practice of Medicine, Churchill Livingstone, Edinburgh, London, New York, Philadelphia ST Louis Sydney Toronto, 21<sup>st</sup> edition: 2010, p.798
8. Chaudhary Vijay, Johri Sharad, et.al. - Evaluation of Comparative efficacy of Neelkanthi (*Ajuga bracteosa*), Tejapatra (*Cinnamomum tamala*) and Methikabeeja (*Trigonella foenumgraecum*) Churna in the management of Diabetes mellitus, IJAPR, Vol 3, Issue 2, 2015, p.80-85.
9. Joshi SR, Parikh RM. India- diabetes capital of the world: now heading towards hypertension. J Assoc Physicians India. 2007; 55:323- 4. [PubMed].
10. Kumar A, Goel MK, Jain RB, Khanna P, Chaudhary V. India towards diabetes control; key issues, Australas Med J.2013, Vol 6, Issue 10, p.524-31. [PMC free article] [Pub Med]
11. International Diabetes Federation. IDF Diabetes Atlas, 8th edition. Brussels, Belgium: International Diabetes Federation, 2017. (Cited 2018 march 10<sup>th</sup> time: 10.30 am)
12. IDF Diabetes Atlas, Seventh Edition, 2015.
13. Chakradatta, Pramehaadhikar, Chapter no.35, Verse - 52 - 53, Shlok no.47-48, p.216
14. Harrison's Principles of Internal Medicine, Dennis L. Kasper, Anthony S. Fauci, Stephen L. Hauser, et.al., 19<sup>th</sup> edition, Vol 2, 2015, p. 2413.
15. American Diabetes Association. Classification and Diagnosis of Diabetes mellitus Standards of Medical Care in Diabetes Care 2019; 42(Suppl. 1): S13-S28.
16. Deshpande A.P., Ranade Subhas, Textbook of Dravyagunavijnanya (English), A.R. Nandurkar Proficient Publishing House 535, Shanivarpeth, Pune, 2007
17. Sonalika Jena, B.B.Khuntia et.al - A comparative placebo, control clinical evaluation of PhalatrikadiKwath in Madhumeha with special reference to Diabetes mellitus type 2, Int. J. Ayur. Pharma Research, Vol 3, Issue 10, 2015, p. 71-79
18. Tannalla, et al., Clinical efficacy of *Mehamudgaravati* in type 2 diabetes mellitus Ayu, Vol 32, Issue 1, Jan-Mar 2011
19. Database on Medicinal plants used in Ayurveda. Vol. 2. New Delhi: Central Council of Research in Ayurveda & Siddha; 2001. Anonymous; p. 177.
20. Ibid, Database on Medicinal plants used in Ayurveda. 2: p.223.
21. Ibid, Database on Medicinal plants used in Ayurveda. 3: p.282.
22. Ibid, Database on Medicinal plants used in Ayurveda. 3: p.11.
23. Ibid, Database on Medicinal plants used in Ayurveda. 5: p.315.
24. Ibid, Database on Medicinal plants used in Ayurveda. 3: p.472.
25. Ibid, Database on Medicinal plants used in Ayurveda. 3: p.282.
26. Ibid, Database on Medicinal plants used in Ayurveda. 5: p.187.

27. Ibid, Database on Medicinal plants used in Ayurveda. 2: p.223.
28. PC Sharma, M B Yelne, T J Dennis, Database on medicinal plants used in Ayurveda, Vol 3, published by Central Council Research in Ayurveda and Siddha, New Delhi, year of publication 2001, p.283-284
29. Anam K, Widharna RM, Kusurini D,  $\alpha$ -Glucosidase Inhibitor activity of Terminalia species, International Journal of Pharmacology, 2009, p.277-280
30. Peterson CT, Denniston K, Chopra D. Therapeutic uses of Trip hala in Ayurvedic medicine. The Journal of Alternative and Complementary Medicine. 2017 Aug 1, Vol 23, Issue 8, p.607-614.
31. Karda Rinku R., Wankhade Vaishali, et.al - A Comparative study of efficacy of Bhudhatrayadiyog and metformin in the management of Madhumehaw.s.r to type-2 diabetes mellitus, Wjpmr, Vol 4, Issue 10, 09/2018, p. 88-94.
32. Rangarajan B, Murlidhara, et.al - Ayurvedic approach to management of madhumehaw.s.r to type 2 diabetes mellitus – a single case report, IAMJ, Vol 5, Issue 1, January- 2017
33. Stohr JR, Xiao PG, Bauer R. Constituents of Chinese Piper species and their inhibitory activity on prostaglandin and leukotrienes biosynthesis in vitro. J Ethnopharmacol, 2001;75, p.133-9
34. Anonymous 4. The Ayurvedic Pharmacopoeia of India, 1 sted, Ministry of Health and Family Welfare, Govt. of India, Part I, 11999, Appendix - 214(2.2.7).
35. Deshpande D, Shilpa B, Parwe S, Patil M, Belsare A. Evaluation of effect of Argwadha kwatha Nitya virechana and Nishakathkadi kwatha in Madhumeha (Diabetes mellitus II). European Journal of Molecular & Clinical Medicine. 2020 Dec 22;7(7):1846-55.
36. Belsare, Anuja, Gaurav Sawarkar, and Pratiksha Mahure. "An Observational Study Protocol For The Prevalence Of Non-Insulin Dependent Diabetes Mellitus In Different Types Of Prakruti In Wardha City." International Journal Of Modern Agriculture 9, No. 3 (2020): 96–99.
37. Ashfaque, Aaliya Rukhsar Mohammad, Najnin Khanam, Farhan Khan, Rutuj Narendra Waghmare, and Shobha Kanhaiyalal Joshi. "Assessment of Self-Care Practices among Type 2 Diabetes Patients at a Tertiary Care Hospital - A Cross-Sectional Study." JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS 9, no. 36 (September 7, 2020): 2630–35. <https://doi.org/10.14260/jemds/2020/572>.
38. Ashtankar, Poonam, V, and Punam Sawarkar. "Role of Panchatikta Panchaprasutik Niruha Vasti in Prediabetes A Case Report." INTERNATIONAL JOURNAL OF AYURVEDIC MEDICINE 11, no. 3 (September 2020): 588–93.
39. Deshpande SB, Parwe S, Nisargandha M. Role of Argwadha Nitya Virechana in Madhumeha (Diabetes Mellitus-II): A Case Study. JOURNAL OF PHARMACEUTICAL RESEARCH INTERNATIONAL. 2021;33(33B):170-6.
40. Jankar, Jayshri Sadashiv, Kumud Namdeorao Harley, Kanchan Manoharrao Mohod, and Vijay Yashwantrao Babar. "Association of Urinary Albumin with HbA1c Levels in Subjects of Type 2 Diabetes Mellitus in Central India." JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS 9, no. 52 (December 28, 2020): 3921–25. <https://doi.org/10.14260/jemds/2020/859>.

41. Shrivastava, Priyal, Mahalaqua Nazli Khatib, Shilpa Gaidhane, Dipti Shrivastava, Abhay M. Gaidhane, and Zahiruddin Quazi Syed. "Assessment of Mean Platelet Volume (MPV) in Subjects with Type 2 Diabetes Mellitus (T2DM) in a Rural Backdrop of Central India." *MEDICAL SCIENCE* 24, no. 101 (February 2020): 12-21.
42. Behere PB, Das A, Yadav R, Behere AP. Religion and mental health. *Indian journal of psychiatry*. 2013 Jan;55(Suppl 2):S187.
43. Khatib N, Gaidhane S, Gaidhane AM, Khatib M, Simkhada P, Gode D, Zahiruddin QS. Ghrelin: ghrelin as a regulatory Peptide in growth hormone secretion. *Journal of clinical and diagnostic research: JCDR*. 2014 Aug;8(8):MC13.
44. Agrawal A, Timothy J, Cincu R, Agarwal T, Waghmare LB. Bradycardia in neurosurgery. *Clinical neurology and neurosurgery*. 2008 Apr 1;110(4):321-7.
45. Nagrale AV, Herd CR, Ganvir S, Ramteke G. Cyriax physiotherapy versus phonophoresis with supervised exercise in subjects with lateral epicondylalgia: a randomized clinical trial. *Journal of Manual & Manipulative Therapy*. 2009 Jul 1;17(3):171-8.