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EFFICACY OF JAMBU BEEJA CHURNA IN STHULA MADHUMEHI W.S.R. TO TYPE 2 DIABETES MELLITUS – A CLINICAL STUDY

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ABSTRACT

Background: Madhumeha is one among the type of Vataja Prameha explained by Acharya Charaka. Madhumeha is a disease of Bastigata vikara. Jambu Beeja churna is mentioned in Adarsha Nighantu for Madhumeha. Diabetes is a metabolic disease which costs our dearly in terms of morbidity and mortality. The management of diabetes and its complications is not possible with one way approach. Due to multifactorial involvement of metabolism, people living with diabetes face many daily challenges including diet, exercise, treatment taking, psychological stress, illness and disability. **Objective:** There is a need for simple and effective medicine for the management thus the clinical study was taken up and to evaluate the efficacy of Jambu Beeja Churna in Sthula Madhumehi w.s.r. to Type II Diabetes Mellitus. Material & Method: A total of 20 patients who fulfilled the inclusion criteria were selected, and were administered with Jambu Beeja Churna 6gm twice daily before food with Sukhoshnajala for 45 days. The assessment parameters were Bahuashi, Swapnasheelata, Prabhuta mutrata, Avila mutrata, Pipasaadhikya ,Karapada Suptata , Karapada daha, Swedapradhurbhava, Sthoulyata, Dourbalya, FBS, PPBS, FUS and PPUS. Discussion and conclusion: The total duration of the study group was 45 days. To infer the clinical study and to draw conclusion paired 't' test was applied for within the group analysis and unpaired 't' test was applied for between the group analysis. Jambu Beeja Churna showed highly significant results before treatment to after treatment, was found to be effective in parameters like Swapnasheela, Dourbalya, Karapadasuptata, Swedapradhurbhava, Sthoulyata, FBS, PPBS, and FUS.

Keywords: Diabetes Mellitus, Madhumeha, Sthula Madhumehi, Jambu Beeja churna, Bastigata vikara.

INTRODUCTION

In an attempt to reveal the secrets of healing within the spectrum of diseases; the therapeutic pearls of wisdom in the form of aphorisms delivered by our Ancient *Ayurvedic* Seers several thousand decades ago is now still on the verge of great discoveries and achievements, under the sacred healing hands of the present day Ayurvedic Professionals of varied specialties. Madhumeha is one among the type of Vataja Prameha explained by Acharya Charaka¹. Madhumeha is a disease of Bastigata vikara. Jambu Beeja churna is mentioned in Adarsha Nighantu for Madhumeha². The samanya lakshanas are Prabhuta

- Avila mutrata and that of Sthula Madhumeha are Bahuashi, sthoulvata, Swapnasheela, shavana Sheela, snigdha shareera, Dourbalya³. The present era is full of chaos, stress & strain due to life style modifications, change in dietary habits, urbanization and industrialization. This has lead in the upsurge of many diseases and one of them is Madhumeha. Though Madhumeha is a disease known since ancient times to the mankind, its upsurge is quiet alarming. On the basis of its symptomatology Madhumeha can be correlated to the features of Type II Diabetes mellitus.DM is one of the most common diseases of the modern world. It is a disorder which is sparing neither the developing nor the developed nations. Irregular food habits, lack of exercise, stress and strain is some of the causative factors that make an individual more prone to develop diabetes at an early age. India has been projected by the W.H.O. as the country with the fastest growing population of Diabetics⁴. Recent studies have estimated that in the year 2000, 171 million people had Diabetes and are expected to be double by 2030⁵. Thus, in this present study, Jambu Beeja churna are selected to evaluate its efficacy on Sthula Madhumeha.

AIM & OBJECTIVES OF THE STUDY:

To evaluate the efficacy of *Jambu Beeja Churna* in *Sthula Madhumehi* w.s.r. to Type II Diabetes Mellitus.

MATERIALS AND METHODS:

20 patients with clinical features of Srhula *Madhumeha* fulfilling the inclusion criteria approaching the OPD and IPD of SKAMCH&RC, Bangalore were selected for the study.

Medicine source:

The identified raw drug required for the study were purchased from approved vendors and post purchase of raw drug was authenticated by the faculty of Dravyaguna department, SKAMCH & RC, Bengaluru.

Sampling technique

The subjects who fulfil the inclusion criteria and complying with the informed consent (IC) were se-

lected for the study. A special case proforma was prepared with details of history taking, physical signs, symptoms and lab-investigations.

The data obtained were recorded, tabulated & statistically analyzed using statistical methods i.e., Paired t-test within the group and unpaired t-test in between the groups.

Diagnostic Criteria:

The patients were diagnosed based on the following ters^{6, 7}.

parame-

- FBS >126 mg/dl
- PPBS > 200 mg/dl
- BMI $> 25 \text{ kg/m}^2$

Inclusion Criteria:

- Patients presenting with *Lakshanas* of *Sthula Madhumeha*.
- Patients with signs and symptoms of obese NIDDM
- Patients of either sex from 21 to 90 years of age.
- Blood sugar Fasting>126 mg/dl or PPBS
 >200 mg/dl

Exclusion Criteria:

- Patients on any immunosuppressant drugs or corticosteroid therapy.
- Patients with juvenile diabetes, gestational diabetes.
- Pregnant & lactating women.
- Any other systemic disorders interfering with the course of the treatment.
- Type I Diabetes Mellitus.
- Madhumeha patients with complications like diabetic gangrene

& carbuncles will be excluded from the study.

Investigations:

Blood: FBS and PPBS

Urine: FUS, PPUS, Urine routine and micro.

Assessment Criteria:

Assessment of the study was done based on subjective and objective parameters as per the proforma.

Table 1: Showing subjective and objective para	nmeters:	
Subjective parameters :	Objective parameters :	
1. Bahuashi	11. FBS	
2. Swapnasheelata	12. PPBS	
3. Prabhuta mutrata	13. FUS	
4. Avila mutrata	14. PPUS	
5. Pipasaadhikya		
6. Karapada Suptata		
7. Karapada daha		
8. Swedapradhurbhava		
9. Sthoulya		
10. Dourbalya		

Duration of the study – 45 Days

Assessment was done before treatment (BT), on 16^{th} day (DT 1), 31^{st} day (DT 2), and 46^{th} (AT) day.

Table 2: Showing gradings of Bahuashi:		
Parameters	Gradation	score
Bahuaashi	Normal appetite, 1-3 meals/day	0
	Slightly increased, 4-6	1
	meals/day	1
	Moderately increased, 7-8	2
	meals/day	2
	Markedly increased, >9	2
	meals/day	3

Table 3: Showing gradings of Prabhutamutrata:		
Parameters	Gradation	score
Prabhuta	3-4 times/day and one time	0
mootrata	or occasionally at night	U
	5-6 times/day and two	1
	times at night	1
	7-10 times/day and 3-4	2
	times at night	∠
	11-12 times/day and 5	2
	times at night	3

ASSESSMENT CRITERIA

The following subjective and objective parameters were assessed using different grading before treatment and during the course of treatment.

Table 4: Showing gradings of Pipasadhikya :		
Parameters	Gradation	score
Pipasadhikya	Normal, 1.5-2litres	0
	Increased, 2-2.5litres but fre-	
	quency is more volume of drink-	1
	ing can be controlled	
	Increased, 2.5-3litres with in-	
	creased excessive amount fre-	2
	quency (approx. once in 2 hours)	
	Very much increased with exces-	
	sive amount and very frequent	3
	intake > 3litres	

Table 5: Showing gradings of Swapnasheela:			
Parameters	Gradation	score	
Swapnasheela	No day sleep, can get up early, Night sleep upto 6-8 hours.	0	
	Can avoid day nap easily, bit drowsy, night sleep 6-8 hours or more.	1	
	Can't avoid day nap of about 0.5 hour at least, night sleep 6-8 hours or more.	2	

Always drowsy, sleepy, day sleep 1-2 hours, night sleep	3
6-8 hours.	

Table 6: Showing gradings of Karpadadaha			
Parameters	Gradation	score	
Karpadadaha	No daha	0	
	Karpada daha occasionally	1	
	Karpada daha moderate and		
	daily activity is not ham-	2	
	pered.		
	Karpada daha continues,	2	
	severe and unbearable.	3	

Table 7: Showing gradings of Aavila mootrata		
Parameters	Gradation	score
Aavila mootrata	Crystal clear fluid	0
	Faintly cloudy or hazy with slight turbidity	1
	Turbidity clearly present but news print can be read through the tube.	2
	More turbidity and news print can't be read	3

Table 8: Showing gradings of Sveda pradhurbhava		
Parameters	Gradation	score
Sveda prad- hurbhava	No sweating	0
	Sweating while doing routine work	1
	Excessive sweating while walking for a short distance	2
	Excessive sweating by slight exertion like standing, walking	3

Table 9: Showing gradings of Daurbalya		
Parameters	Gradation	score
Daurbalya	Can do routine work and exercise	0
	Can do moderate work and exercise	1

Can do mild routine work and exercise	2
Can do mild routine work and exercise with difficulty	3

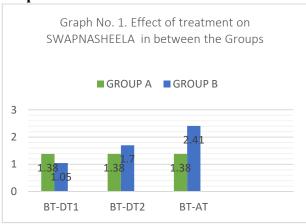
Table 10: Showing gradings of <i>Sthoulya</i> - BMI (Meas-				
ured according to	ured according to BMI Kg / Height in m ²)			
Parameters	Gradation	score		
Sthoulya	Normal	0		
	Overweight	1		
	Obese	2		
	Very Obese	3		
Table 11: Showing FBS & PPBS				
FBS ≥126 mg/dL	(7.0 mmol/L). Fasting is defin	ed as no		
caloric intake for at least 8 h.				
2-h PG or PPBS	≥200 mg/dL (11.1 mmol/L)			

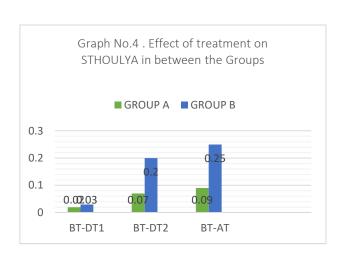
Table 12: Showing gradings of FUS (mg/dl)							
Mutramadhurya							
Parameters	Gradation score						
FUS	Negative	0					
	Traces	1					
	1 + / 0.5 %	2					
	2 + / 1 %	3					
	3 + / 1.5 %	4					
	4 + / 2 %	5					

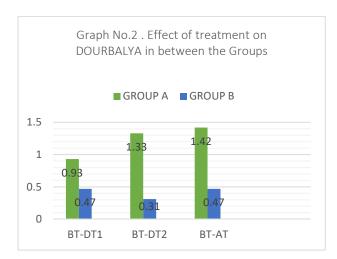
Table 13: Sho Mutramadhurya	owing gradings of PP	US (mg/dl)	
Parameters	Gradation	score	
PPUS	Negative	0	
	Traces	1	
	1 + / 0.5 %	2	
	2 + / 1 %	3	
	3 + / 1.5 %	4	
	4 + / 2 %	5	

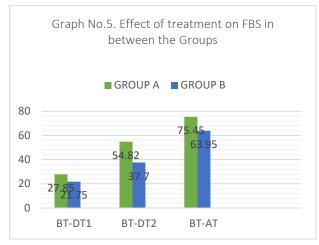
Table 14: Showing The RoSYMPTOMS	Phase	MD	SD	SE	't' VALUE	'p' VALUE	Re
STML LOMP	BT-DT1	0.66	0.49	0.14	4.69	<0.001	HS
Bahuashi	BT-DT1	1.16	0.49	0.14	7	<0.001	HS
	BT-AT	1.58	0.57	0.10	8.20	<0.001	HS
	BT-DT1		0.00	0.19	3.80	<0.001	HS
Pipasadhikya Swapnsheela	BT-DT1	0.66		0.20	4.78	<0.01	HS
			1.05				
	BT-AT	1.22	1.09	0.31	4.60	<0.001	HS
	BT-DT1	1.05	0.24	0.05	17.98	<0.001	HS
	BT-DT2	1.70	0.58	0.14	11.95	<0.001	HS
	BT-AT	2.41	0.71	0.17	13.95	<0.001	HS
Prabhutamutra	BT-DT1	1.0	0.64	0.14	6.89	<0.001	HS
	BT-DT2	1.35	0.81	0.18	7.42	<0.001	HS
	BT-AT	2.2	0.89	0.2	11.00	<0.001	HS
Avilamutrata	BT-DT1	0.81	0.40	0.12	6.70	< 0.001	HS
	BT-DT2	1.36	0.67	0.20	6.70	<0.001	HS
	BT-AT	1.45	0.52	0.15	9.23	< 0.001	HS
	BT-DT1	0.47	0.71	0.10	8.19	< 0.001	HS
Dourbalya	BT-DT2	0.31	0.85	0.07	13.54	< 0.001	HS
	BT-AT	0.47	0.80	0.10	13.63	< 0.001	HS
	BT-DT1	0.82	0.68	0.16	5.33	< 0.001	HS
Karapada Suptaha	BT-DT2	1.58	0.51	0.12	6.96	< 0.001	HS
	BT-AT	1.82	0.46	0.11	5.63	< 0.001	HS
	BT-DT1	1	0.83	0.34	3.45	< 0.01	HS
Karapadaha	BT-DT2	1	0.44	0.18	5.52	< 0.001	HS
	BT-AT	1.2	0.54	0.22	2.92	< 0.01	HS
	BT-DT1	0.64	0.78	0.19	3.39	< 0.01	HS
Swedapradhurbhava	BT-DT2	1.64	0.86	0.20	7.87	< 0.001	HS
•	BT-AT	2.05	0.82	0.20	10.25	< 0.001	HS
Sthoulya	BT-DT1	0.03	0.06	0.01	1.75	>0.05	NS
	BT-DT2	0.20	0.42	0.09	2.18	< 0.05	S
	BT-AT	0.25	0.48	0.11	2.35	< 0.05	S
FBS	BT-DT1	21.75	21.31	4.76	4.50	< 0.001	HS
	BT-DT2	37.7	27.25	6.09	6.01	< 0.001	HS
	BT-AT	63.95	40.27	9.0	7.10	< 0.001	HS
	BT-DT1	20.55	16.83	3.76	5.46	< 0.001	HS
PPBS	BT-DT2	47.40	42.88	9.59	4.94	<0.001	HS
	BT-AT	88.95	55.38	12.38	7.18	<0.001	HS
	BT-DT1	1.2	0.63	0.22	6	< 0.001	HS
FUS	BT-DT2	1.4	0.69	0.22	6.33	<0.001	HS
100	BT-AT	2	0.66	0.21	9.48	<0.001	HS
	BT-DT1	0.86	0.86	0.23	3.71	<0.001	HS
PPUS	BT-DT2	1.78	1.12	0.29	5.96	<0.001	HS
1100	BT-AT	2	1.12	0.23	6.03	<0.001	HS

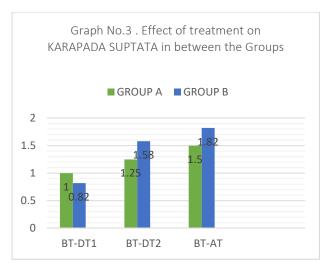
Graphs

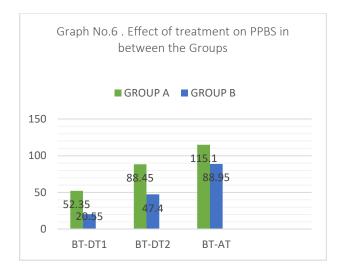


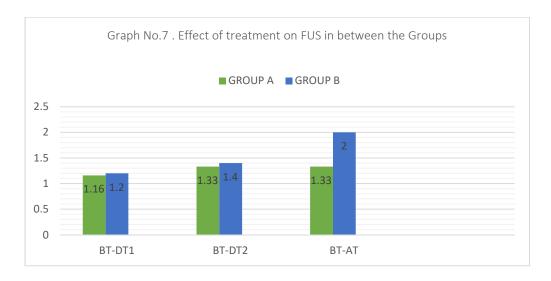












DISCUSSION

Probable mode of action of Jambu Beeja churna:

1. EFFECT OF TREATMENT ON BAHUASHI:

'Bahuashitvam Pitta Teekshna-Ushna Gunataha.'Bahuashi is caused due to vitiation of Vata in Koshta as a resultant causing Agni Sandhukshana leading to Atikshuda manifesting as Bahuashi.

Jambu Beeja churna is having Kashaya-Tikta Rasa, Laghu-Ruksha Guna which does Kaphaharana and Kleda Shoshana; this may further help in Vatanulomana thereby reducing Bahuashi. This might have helped in reducing the Bahuashi in a better way.

2. EFFECT OF TREATMENT ON PI-PASAADHIKYA:

Pipasaadhikya is caused by Pitta Vriddhi and udaka kshaya. The Prakrutha Karma of Mutra is Kledavaahanam, when there is Atipravrutti beyond the normal threshold, it leads to Shoshana of Ap Dhaatu manifesting as Pipasadhikyatha.

Jambu Beeja Churna has Tikta, Kashaya rasa pacifies Pitta and by its Sthambhana property checks Mutratipravritti thereby alleviating Pipasaadhikya.

3. EFFECT OF TREATMENT ON SWAP-NASHEELA:

The Lakshana Swapnasheela, seen in Madhumehi is due to excessively vitiated Kapha and Dushyas like Meda, Mamsa and Shareeraja Kleda. Acharya

Sushrutha states Panchavida Kriya-Ashraya Linga – 'Sa Chaapi Gamanath Sthanam, Sthanad Asanam Ichchanti, Aasanat Vrunute Shayyam, Shayyanat Swapanam Ichcchanti.' (Su.Ni 4/25)

Jambu Beeja Churna is having Tikta, Kashaya Rasa, Laghu and Ruksha Guna which pacifies Kapha and does Kleda Shoshana which helps in reducing Swapnasheelata.

However, Jambu Beeja churna was better than Nisha-Amalaki Churna in reducing Swapnasheelata.

4. EFFECT OF TREATMENT ON PRABHUTAMUTRATA:

Prabhutamutrata is seen in Madhumehi due to the Avayava Mishribhavatwa of Dushyas like Meda, Rakta, Mamsa, Majja, Shukra, Udaka, Vasa, Lasika, Ojas and there after the Draveekarana of these dushyas happens and they are brought to the Basti and excreted through Mutra.

Jambu Beeja churna by its Kashaya Tikta Rasa, Sangrahi Guna and Sthambhana property does Mootra Sangrahana and helps in reducing Prabhuta Mootrata.

5. EFFECT OF TREATMENT ON AVILA MUTRATRA:

Avila mutrata in Prameha is due to the presence of dooshyas mootra in , which is in accordance with explanation in our Shastra as 'kwachiteva Prameha, kasychiteva dooshya avayava mishribhava.'-(Su. Ni. 6/6)

Jambu Beeja churna by its virtue of Tikta - Kashaya Rasa, Rooksha Guna acts in Avila mutrata.

6. EFFECT OF TREATMENT ON *DOURBA-LYA*:

In Madhumehi, Dourbalya is because of 'Asamathvat Dhatoonam' (ch.su.21/3). The Bahuabadha Mamsa, Meda and increased Shareera Kleda is expelled as mootra causing Dourbalya seen as Shaithilyata in Mamsa, Medas. Dourbalyata is also due to kapha- meda avarana which leads to uttarothara dhathu kshaya.

Jambu Beeja churna by its Tikta - Kashaya Rasa, Laghu- Ruksha, Grahi, Guna, Kleda Shoshana Karma, removes Avarana of Kapha effectively brings about Sthitikarana of the dhatus thereby exhibits the action of Dhatuprasadana, increases Prakrutha karma of Dhathu and alleviates Dourbalya effectively.

7. EFFECT OF TREATMENT ON KARA-PADASUPTATAH:

Karapada Suptata is explained as 'Supti Padayoh Nishkriyatvam Sparshjnata Va' and is one of the samanya Purvaroopa of Prameha. (ch.ni.4/47). It is caused by Rakta Margavarana by Kapha Dosha and resulting in vata prakopa manifesting as karapada Suptata.

Jambu Beeja churna by its Kashaya - Tikta Rasa, Rooksha - Lekhana Guna, Kapha Pittahara Karma removes the Kapha-Vata Avarana thereby improving the circulation to Tiryakgata Dhamanis, by which it nourishes the Dhamanis and reduces Karapadasuptata.

8. EFFECT OF TREATMENT ON KARAPADA DAHA:

Karapadadaha can be understood as 'Padayoho Kurute Daham, Pitasruk Sahite Anilaha' and 'Hastapadatala Daha Iti Pitta Ushna Gunataha.' (Nidana – Lakshanayo Sambandha).

The Tikta Rasa, Rooksha Guna, Kapha-Pittahara Karma of Jambu Beeja Churna reduces Karapada-Daha more in Avaranajanya Madhumeha. Even though both drugs reveal statistically significant result, the t value of Nishaamalaki has an edge over

Jambu Beeja churna in reducing Karapadadaha.

9. EFFECT OF TREATMENT ON SWEDA PRADURBHAVA:

Swedapradhurbhava is caused due to Bahu Abadha Medas formed due to increase mala of medo dhatu. This is in accordance to the explanation in our shasthra 'Kakshamedradijam Medomalam' told by Acharya sharangadhara. (sha.pu.5/13). As the dooshyas involved are Medas and Mamsa, Medovruddi leads to Swedhadhikyata in the Shareera.

Jambu Beeja churna by its Kashaya, tikta rasa, rooksha guna, kapha pittahara karma removes Bahu Abaddha Medas, and does the shoshana of kleda thereby reducing swedapradhurbhava.

10. EFFECT OF TREATMENT ON STHOULYA (B.M.I):

Medoroga is said to be platform for Prameha. Obesity particularly truncal obesity is closely related to prevalence of diabetes and cardio-vascular disease. Plasma leptin, tumor necrosis factor α and nonesterified fatty acids levels are elevated in obesity and play role in causing insulin resistance. Glycemic control and insulin resistance improve with reductions in obesity.

Jambu Beeja churna by its Kashaya, Tikta Rasa, Rooksha, Lekhana Guna, Kapha - Pittahara Karma removes Bahu Abaddha Meda and reduces Sthoulya.

11. EFFECT OF TREATMENT ON FBS:

FBS can be understood as the increased *Shareeraja Kleda* which is *Sarva Deha Vayptam*. Further it is understood as increased *Abaddata of dhatu* as a result of *Dhatwagni Mandhya* which is exhibited in *Rasa* and *Rakta*. In type 2 diabetes, beta cells of pancreas failure leads to reduced basal insulin secretion in fasting state.

Jambu Beeja churna by its Kashaya, tikta rasa, rooksha guna, kapha pittahara karma removes bahu abaddha medas, and does the shoshana of kleda. Jambu seed contains jamboline, anathocyanins, glucoside, ellagic acid, iso-quercetin, kamferol and alkaloids. The glucoside jambolin prevents the conversion of starch into sugar and these benefits by

controlling blood sugar levels. Also it contains calcium, potassium, carotene m magnesium. Calcium directly enhances response for glucose transport and indirectly essential for insulin – mediated intracellular process in insulin responsive tissues such as skeletal muscle and adipose tissues.

This improves the *guna* of *rasa* & *rakta* thereby reducing FBS.

Variations are seen in the blood sugar ranges as there will be changes in *Dosha avastha* which is clearly explained in our *shasthra* as – 'kshnaatth ksheenam, kshanath poornam' in Avaranajanya Madhumeha.

12. EFFECT OF TREATMENT ON PPBS:

PPBS can be understood as the increased *Shareeraja Kleda* which is *Sarva Deha Vyaptam*.

In modern it occurs due to insulin resistance and in altered metabolism of glucose.

The Kashaya-Tikta Rasa, Rooksha-lekhana guna, Kapha Pittahara Karma, Ushna veerya of jambu Beeja churna does the kapha, kleda shoshsana and hence reduces PPBS more effectively showed HS reduction in PPBS level this may be by virtue of carbohydrate absorption from intestines and improvement in peripheral utilization of glucose. But variations is seen in the blood sugar ranges as there will be changes in Dosha avastha which is clearly explained in our shasthra as – 'kshnaatth ksheenam, kshanath poornam' in Avaranajanya Madhumeha.

13. EFFECT OF TREATMENT ON FUS:

FUS is seen due to metabolic derangement and lower renal threshold point. It can be understood as mootramdhuryata explained in our classics seen due to production of amadosha in urine. The normal function of mootra is 'mootrasya kleda vahaanam' which is hampered here.

The Kashaya-tikta rasa, Rooksha guna, Ushna veerya, mootra sangrahi karma, kapha-pittahara karma of Jambu Beeja churna does the kapha, kleda shoshsana and hence reduces FUS more effectively.

14. EFFECT OF TREATMENT ON PPUS:

PPUS is seen due to increase in the renal threshold for glucose (= < 7 mmol/l) at proximal tubules of

kidney. Glycosuria leads to excessive water loss into the urine with resultant dehydration, a process called osmotic diuresis.

It can be understood as *mootramdhuryata* explained in our classics. The normal function of mootra is 'mootrasya kleda vahaanam' which is hampered here.

In Jambu Beeja churna Kashaya, tikta rasa, rooksha guna, mootra sangrahi karma, kapha pittahara karma of Jambu Beeja churna does the kapha- kleda shoshsana and hence reduces PPUS.

CONCLUSION

Madhumeha is one among the 20 types of Prameha. Madhumeha is a tridoshaja vyadhi, predominant with vata dosha and with much emphasis on Medo Dhatvaghni Mandhyata due to excess intake of guru, siddha, Madhura, Sheetha Ahara and simultaneously Avyayama, Diwaswapna. Asvasukham etc. Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial riskreduction strategies beyond glycaemic control and lifestyle has a major impact on disease. (Standards of Medical Care in Diabetes -2018). The prevalence of diabetes as per WHO reports in India is at 31.7 million by 2017.

In this present clinical study, where 20 patients of Sthula Madhumeha were administered Jambu Beeja churna for 45 days. Jambu Beeja Churna was found effective in parameters like Swapnasheela, Dourbalya, Karapadasuptata, Swedapradhurbhava, Sthoulyata, FBS, PPBS, and FUS, But fluctuations were seen in blood sugar ranges which is in accordance with explanation in our Shastra - 'Kshnaatth Ksheenam, Kshanath Poornam' in Avaranajanya Madhumeha. (A.H Ni 10/19) which is said to be krichra sadhya and is evident in this study.

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