A Hospital-based Observational Study of Newly diagnosed Sthula Prameha Subjects with special reference to type 2 Diabetes Mellitus from Maharashtra, India

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The aim of this study is to provide a real picture of the disease burden of Prameha in society. The study was performed in Government Ayurved College and Hospital, Nagpur, Maharashtra during Oct 2015-Mar 2016. Total 60 patients of newly diagnosed type 2 diabetes mellitus attending the Kayachikitsa Opd of GAC Nagpur were included for the study. The subjects details were recorded in case report form. The CRF included many variables such as sociodemographic factors, presenting symptoms, risk factors such as hypertension, obesity and glycaemic status, family history of diabetes and physical activity. Other parameters like BMI, glycosylated haemoglobin, fasting and post prandial blood sugar and fasting lipid profile were documented. Descriptive and bivariate analyses were carried out using the XLSTAT software (2020). Amongst 60 subjects, 65% were male and 93.3% were adults. 78% of subjects were following sedentary lifestyle and 40% had family history of diabetes. The results revealed that, obesity, family history of diabetes, uncontrolled glycemic status, sedentary lifestyles, and hypertension were prevalent among the Prameha subjects. The characterization of this risk profile and early detection of prameha by observing poorvarupa will contribute to designing more effective and specific strategies for screening and controlling Prameha in Maharashtra, India.

Keywords: Hospital-based. Observational study. Sthula Prameha. Diabetes mellitus.

INTRODUCTION

All medical sciences mainly deal with the health of individuals, but amongst them Ayurveda not only deals with health of the patients but also with the health of healthy individual. Awareness about health and approach of society towards Ayurveda is increasing day-by-day. Its holistic approach, natural and safe methods with minimal side-effects, potential to take care of global health needs is getting recognized globally. Diabetes is spreading throughout the globe rapidly. At present worldwide population of 387 million (8.3% of world population) is diabetic which is predicted to reach 592 million by 2035 (International Diabetes Federation, 2013). India (31.7 million) ranked first in the world with the highest number of people with diabetes mellitus followed by China (20.8 million). India alone, presently having 69 million diabetic people and is expected to double by 2040 (Kaveeshwar, Cornwall, 2014; Mohan *et al*., 2004). Diabetes is an important public health threat from many perspectives. It became silent killer to the mankind because of its high morbidity, mortality, economic impact, resource consumption, systemic complications and less curative options. The WHO predicted 50% increase in deaths from diabetes in next 10 years and it may be the 7th leading cause of death worldwide by 2030 (World Health Organization, 2013).

Diabetes mellitus is a 'Silent Killer' because disease is not responsible for death but its deadly

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complications such as diabetic nephropathy, retinopathy and neuropathy are bringing person near to the death. Various oral hypoglycemic agents, insulin formulation, life style modification consisting diet management and regular exercise are basic management. Inspite of this, world is seeking for a safer and effective remedy. Resistance to the drugs, increasing side-effects, lack of effectiveness in complications and high cost of newer drugs are basic problems in modern science. Because of these problems people are looking forward for a solution towards Ayurveda. Ayurveda has a treasure of antidiabetic medications like herbal as well as herbo-mineral formulations, and whose efficacy is already proved in previously done in animal as well as human interventional studies. (Bedarkar *et al.*, 2017; Gupta *et al.*, 2016) Along with medications, Dincharya (daily regimen) and Ritucharya (seasonal regimen) are also thoroughly explained in Ayurveda in the management of diabetes mellitus. (Guddoye, Vyas, 2013) Various studies are available, which shows efficacy of Ayurvedic medicine to control fasting and post-meal blood sugar level, reverses the level of glycated haemoglobin, managing diabetic complications. (Jaideep, Mehra, Anjana, 2017; Patel *et al.*, 2011

AYURVEDIC CONCEPT OF PRAMEHA

Prameha is characterised by the symptoms of increased frequency and turbidity (Avilata) of urine. All those factors (foods are regimens) which increase the quantity of Kapha in the body are said to be the causative factors of the disease. Prominent among these are the Sedentary habits, increased consumption of sweets and fats. The etiological factors vitiate Kapha Dosha which in turn vitiates Meda, Mansa, Kleda and enters in Basti. In consequence Prameha is manifested. The vitiated Pitta Dosha aggravates because of above said Dhatus and manifests Pittaj Prameha. In case of Vataja Prameha, there is quite different Samprapti. Here the Kapha and Pitta Dosha becomes Kshina and Vriddha Vata Dosha forcefully drags previously mentioned Dushyas in Bastipradesha and causes Vataj Prameha. In this way, Dosha enter in Basti and causes Dushan of Mutra and manifests into various types of Prameha with respect to

their Guna and symptoms. Prameha patients are classified on the basis of constitution of the body as Sthula and Krisha. These types should be taken in consideration while deciding line of treatment. (Kushavaha, 2018)

LINKING PRAMEHA WITH DIABETES MELLITUS

If we go through the etiopathogenesis of Sthula Prameha (Kushavaha, 2018) it is quite similar with that of Diabetes Mellitus. Remarkable associations found between stress, anger, and excess heat exposure with diabetes are a few causes which Ayurveda proposes as the possible cause of diabetes although not much explored in conventional understanding (Rastogi, Pandey, Sachdev, 2018).

OBJECTIVES

1. To evaluate the disease burden of Diabetes mellitus in society.
2. To assess the common risk factors for Diabetes mellitus.

MATERIAL AND METHODS

Study Setting

A hospital-based observational study was conducted during Oct 2015-Mar 2016 in Nagpur district of Maharashtra, India. Nagpur is the largest city of Vidarbha as well as central India, with an approximate population of twenty four lakhs. The city is famous for medical tourism because of its wide and efficient network of cost-effective tertiary-care hospitals serving to the need of population of not only from Maharashtra but also from neighboring states such as Madhyapradesh, Chhattisgirh etc.

Study Population

The study population comprised Sthula Prameha subjects. Newly diagnosed patients (diagnosed within the last 0-6 months) between age group of 20-60 years attending the OPD of Department of Kayachikitsa, Government Ayurved Hospital during the study period

for the first time and willing to participate in the study were included in study.

Sample-size

After reviewing previous data of the OPD of Kayachikitsa, it was observed that at least 50 subjects of Sthula Prameha (newly-diagnosed) were visiting every month. Hence, there would be a possibility of 600 subjects visit to the hospital during the study period. Out of 600 newly-diagnosed cases, at least 10% were selected for this study. So, a sample of 60 was decided for study.

Procedure for data collection

Total 70 subjects were enrolled after obtaining informed consent from all subjects. (Written consent from literate subjects and verbally informed consent from illiterate subjects). Out of 70, 10 patients were drop out due to their personal reasons like unavailability of time, lack of interest etc. After explaining the details of the proposed study which is going to be conducted, a complete case history was recorded in a specially formed case record form. Basic data related to age, sex, education, occupation, socio-economic status, habits, diet and physical activities were collected from all the subjects. All the subjects were also inquired regarding history of hypertension and other co-morbid conditions. A general physical examination was performed to rule out other disease conditions.

Chronicity as per mode of onset of Sthula Prameha was defined according to the duration of symptoms present in the subjects and categorized as acute (symptoms present from one month), sub-acute (symptoms present from one to three months), and insidious (symptoms present from three to six months). Physical activity was categorized in four categories as manual (standing, and driving for most of the day, cooking, light cleaning, light yard work, slow walking, and other major activities that involve sitting or a very active lifestyle, dancer, or very active sports played for several hours almost daily, or an extremely active lifestyle both at work and at play and sport or activity last for several hours, almost daily), sedentary (sitting for most of the day), labor (heavy laborious work), travelling (an occupation that includes travelling from one place to another, lots of walking, or other activities that keep you moving for several hours qualified as moderately active).

Anthropometric, clinical and biochemical measurements

Standardized procedures were followed to record all anthropometric measurements. The study subjects had undergone various clinical tests such as blood tests for complete haemogram, plasma glucose fasting and post-prandial, glycosylated haemoglobin (HbA1c), and lipid levels. Blood samples were collected after confirming 9-12 hours of fasting.

Blood pressure was recorded after advising rest for five minutes to the subjects. Hypertension was diagnosed based on history provided by the subject regarding same or if the blood pressure was >130/80 mmHg according to the Joint National Committee-8 (JNC-VIII) criteria (James *et al.*, 2014). The diagnosis of diabetes mellitus was made by using the criteria established by the American Diabetes Association (2015), i.e. either a fasting plasma glucose (FPG) level of >7.0 mmol/L or ≥126 mg/dL, and two-hour post glucose level (Oral glucose tolerance test) of >11.1 mmol/L or ≥200 mg/dL with or without symptoms of diabetes. If subjects were not having previous reports, then confirmation was done by performing fasting plasma glucose test and a two-hour oral glucose tolerance test (OGTT).

Body mass index (BMI) values were defined according to Indian Council of Medical Research for Indians. A study subject was considered to be overweight if BMI was ≥25 kg/m^2 (Misra *et al.*, 2009). The criterion for glycaemic status was <7% (good control), 7-8% (sub-optimal control), 8-9% (inadequate control), and >9% (uncontrolled) (Al-Kaabi *et al.*, 2008).

ANALYSIS OF DATA

Data were processed in Excel-sheet and analyzed using the XLSTAT software (version 2020). Quantitative variables were summarized using mean and standard deviation while categorical variables were tabulated using frequencies and percentages. Student's *t*-test was used for

testing the significance of differences between the mean values of two continuous variables. The probability (p) level of <0.05 was considered significant.

ETHICAL CLEARANCE

Institutional ethical committee of Government Ayurved College and Hospital, Nagpur has approved study protocol. IEC/GACN/P.G.D./279/2015

RESULTS

Total 70 subjects were enrolled for the study. Amongst 70, 10 were drop-out. So, total 60 patients finally completed the study.

Sociodemographic characteristics

Sociodemographic characteristics of 60 subjects are shown in following tables. The Sthula Prameha subjects were mostly between 50-60 years (55%). Out of total study samples (n=60), 39 (65%) were male, and 21 (35%) were female. 70% (n=42) subjects were following religion of Hinduism, and 89% study subjects were literate. Mostly subjects were belonging to middle class and upper middle class. (Table I)

TABLE I - Sociodemographic characteristics of Sthula Prameha subjects

Characteristics	No(n=60)	%
Age (years) Mean±SD	51±6.851	
Upto 40 years	04	07
40-50 years	23	38
50-60 years	33	55
Sex		
Male	39	65
Female	21	35
Marital Status		
Married	52	87
Unmarried	02	03

TABLE I - Sociodemographic characteristics of Sthula Prameha subjects

Characteristics	No(n=60)	%
Divorced	01	02
Widowed	03	05
Widower	02	03
Religion		
Hindu	42	70
Muslim	03	05
Christian	01	02
Buddha	14	23
Education		
No education	07	12
Primary school	03	05
Secondary school	16	26
Graduate	31	52
Postgraduate/ PhD	03	05
Economical Status		
Very Poor	00	00
Poor	02	03
Lower Middle class	14	23
Middle class	31	52
Upper Middle class	13	22
Rich	00	00

• All percentages are considered in whole numbers

Presenting complaints/symptoms/poorvarupa

Symptoms of Sthula Prameha are not explained in detail in Ayurveda literature. But all acharyas emphasized more on poorvarupa of Sthula Prameha. So data was collected regarding poorvarupa and surprisingly all subjects were having poorvarupa ranging between 25-95%. The subjects had classical poorvarupa of Sthula Prameha. Of the 60 subjects, 56 (93%) had Durbalata, 54 (90%) had Nidradhikya and Kara pad supti, 53 (88%) had

trishnadhikya and 52 (86%) had mutradhiyka and tandra. However, 15 (25%) subjects presented with maladhikya. (Table II)

S N	Clinical Feature/ Poorvarupa10	Total No. of Pts.	%
1	Mukhamadhurya (Sweetness in mouth)	44	73.33%
2	Kara-Pada-Supti (Numbness in hand & foot)	54	90.00%
3	Kara-Pada-Daha (Burning sensation in hand & foot)	49	81.67%
4	Trishnadhikya (Excessive Thirst)	53	88.33%
5	Aalasya (Laziness)	51	85.00%
6	Maladhikya (Excessive secretion of waste products from body)	15	25.03%
7	Nidradhikya (Sleepiness)	54	90.00%
8	Tandra (Drowsiness)	52	86.67%
9	Mutradhikya (Polyurea)	52	86.67%
10	Avilamutrata (Turbid urine)	46	76.67%
11	Kshudhadhikya (Polyphagia)	38	63.00%
12	Medadhikya (Obesity)	51	85.00%
13	Anutsaha (Lethargy)	51	85.00%
14	Durbalata (Weakness)	56	93.00%
15	DurgandhiSharira (Bad odour of body)	16	26.67%
16	Svedadhikya (Excessive Sweating)	40	66.67%

Behavioral Profile

Vyasana (Addiction): The findings of the study showed that 44 (73%) out of 60 subjects had some form of habits or addiction. For example, 11 (18%) were smokers, 20 (33%) were tobacco chewers, and 09 (15%) were consuming alcohol. **(Table III)**

Lifestyle: The findings of the study showed that mostly i. e. 46 (76%) subjects were following sedentary lifestyle. **(Table III)**

Risk profile

60% and 38% had positive family history of Sthula Prameha and Hypertension respectively. (Table III) Maximum subjects (45%) had good glycaemic control (HbA1c ≤7%). The findings showed a mean BMI of 25.47±4.113. According to BMI, 42% of the sample subjects had normal (BMI 23.0-24.9 kg/m^2) and remaining was overweight and obese (BMI ≥25 kg/m^2). Out of 60 T2DM subjects 38% had hypertension. All subjects had good lipid control **(Table III)**.

Characteristics	No(n=60)	%
Glycosylated hemoglobin	mean±SD	7.2±0.712
Good control (≤7%)	27	45
Sub-optimal control(7-8%)	26	43
Inadequate control(8-9%)	06	10
Uncontrolled (>9%)	01	02
Family history of diabetes		
Present	36	60
BMI Group		
Normal range(23.0-24.9 kg/m2)	25	42
Overweight (≥25.0kg/m2)	35	58
Hypertension		
Present	23	38
Physical activity		
Manual	05	08
Sedentary	46	77
Labour	07	12
Travelling	02	03
Vyasana (Addiction)		
Alcoholism	09	15
Smoking	11	18

TABLE III - Profile of clinical and other associated factors of Sthula Prameha subjects

Characteristics	No(n=60)	%
Tobacco	20	33
Charas- Ganja	00	00
Beetlenut	04	07

• All percentages are considered in whole numbers

TABLE IV - Characteristics of Sthula Prameha subjects

Characteristics	Mean±SD	p value
Age	51±6.85	<0.0001
Body mass index	25.47±4.113	<0.0001
Blood pressure		
Systolic (mmHg)	129.13±7.94	<0.0001
Diastolic (mmHg)	78.58±5.60	<0.0001
HbA1c	7.08±1.73	<0.0001
Lipid profile		
Cholesterol (mg/dL)	87.45±41.81	<0.0001
HDL (mg/dL)	44.47±1185	<0.0001
LDL (mg/dL)	121.27±29.97	<0.0001
Triglycerides (mg/dL)	136.23±51.70	<0.0001
VLDL (mg/dL)	30.96±12.75	<0.0001

HDL=High-density lipoprotein; LDL=Low-density lipoprotein; SD=Standard deviation; VLDL=Very low density lipoprotein

There was a significant difference (p<0.0001) in study population with respect to age (51±6.85), body mass index (25.47±4.113) and glycated haemoglobin (7.08±1.73). (Table IV)

DISCUSSION

Diabetes mellitus (Sthula Prameha) is a major public health problem worldwide. Its prevalence is rising day by day in developing countries like India and will become diabetes capital of the world in near future. Individuals with Sthula Prameha are considered on high priority as they have a potential of rapid evaluation to prevent and halt the progression of complications.

This study presented observational data from a few numbers of subjects with Sthula Prameha attending the Department of Kayachikitsa, Government Ayurved Hospital, Nagpur. Our main motivation for this analysis was to obtain the risk profile so that we can prevent or decrease the burden of Sthula Prameha in Maharashtra.

The main findings of the study were: only 45% of the study population had good glycaemic control (HbA1c ≤7%), 58% of the subjects with T2DM were obese which reveals its direct relation with Sthula Prameha. Our study population had a negligible proportion of illiterate Sthula Prameha subjects. This finding was expected because our sample was taken from an urban Ayurvedic hospital.

In this study 45% subjects had good glycemic control which may be due to newly diagnosed condition of diabetes mellitus and good care taken by patients. Achieving good glycemic control in diabetic subjects is a real challenge to healthcare providers. Studies have documented that self-care among T2DM subjects improved glycemic control and reduced complications (Ramachandran et al., 2006). Lipid levels of all subjects were within normal range, it may be due to newly diagnosed condition of diabetes mellitus. In the present study, the majority (58%) of the subjects with Sthula Prameha were obese. This is consistent with the findings of various studies (Bener et al., 2004) Obesity is also associated with family history of diabetes among the Indian population (Habib, Aslam, 2004)

Various observational studies have been done across the globe on Diabetes Mellitus through contemporary science, which showed similar results. (Diaz, Dilla, Reviriego, 2019; Babu et al., 2018) Some observational researches on Prameha are available in Ayurveda but mainly focused on ayurvedic concepts like Nidana, Prameha-Correlation with Obesity, Metabolic Syndrome, and Diabetes Mellitus etc. (Kumar et al., 2018) (Sharma, Chandola, 2011) I have not come across any clinical observational study corelating Ayurveda concepts with modern parameters of Diabetes Mellitus. Such studies are lacking in Ayurveda, so it was an attempt to co-relate contemporary and traditional science.

In Ayurveda, the first line of treatment of any disease condition/Prameha is Nidana-parivarjana i. e.

to avoid the known disease-causing factors in diet and lifestyle. (Kushavaha, 2018) This study revealed that obesity, sedentary lifestyle, various lifestyle disorders are accompanied with most of the subjects. So, by emphasizing on Nidana-parivarjana with or without pharmacological agents, one can treat DM successfully.

Modern science does not reveal about pre-diabetes in detail. On the other hand, there is detailed description of Sthula Prameha poorvarupa in Ayurveda literature. So, its need of hour to give more attention towards Sthula Prameha poorvarupa and try to stop the conversion of non-diabetic individuals to diabetic patients.

LIMITATIONS

Several potential limitations must be considered in interpreting the results of the present study. First, the study is restricted by cross-sectional design; so, temporality (cause-and-effect relationships) cannot be established. It can, however, provide a clear picture of the current situation and may help improve the management and design of future studies to explore further. Second, this is a hospital-based study in an urban set-up, which may not be representative and applicable to village population. However, this could provide a reasonably precise and reliable estimate of the risk profile of Sthula Prameha in Maharashtra. Third, we tried to include newly-diagnosed subjects but we are not sure that all subjects are newly diagnosed because we have relied on the subjects. Fourth, study was done on small sample size.

CONCLUSION

The present study directed at providing the profile of the Sthula Prameha subjects from Maharashtra, India, as an impetus for further exploration of the socio-cultural and subject-related factors affecting the outcomes of Sthula Prameha care that, in turn, will lead to redefine the diabetes control and preventive strategies. The findings of the study revealed that a high proportion of factors, such as obesity, family history of diabetes, uncontrolled glycaemic status, sedentary lifestyle and hypertension were prevalent in the Sthula Prameha subjects. The

findings also provide an early indication for development of Sthula Prameha-related complications.

Based on the findings of the study, we recommend the following steps for the appropriate management of Sthula Prameha subject:

3. Prevention of Sthula Prameha needs to have lifestyle modification interventions, i.e. body-weight control through diet and exercise should be emphasized.

4. Pre-diabetes is intermediate stage linking non-diabetes with diabetes mellitus. Sthula Prameha poorvarupa are nothing but the stage of pre-diabetes. So, humans can arrest the conversion of non diabetic to diabetic condition by concentrating on pre-diabetes and following diet and exercise indicated for the same.

Though this article reveals observational data of 4 years back observational study on Sthula Prameha, but we can link this to recent scenario of Sthula Prameha to understand increasing prevalence of Sthula Prameha or Diabetes Mellitus in community.

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