Role of Sneha kalpana (Oil based formulation) in the management of Vataja Prameha (Vata predominance Prameha) w.r. to Khadira-kramuka kashaya siddha taila

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**ABSTRACT**

Diabetes mellitus is a fast-growing pandemic. In India, the urban population is more prone to disease rather than the rural Indian population. Dietary habits, faulty lifestyle, and urbanization leading to reduced physical exercise may be responsible to a large extent. Indian system of medicine, namely Ayurveda cited a disease entity named Prameha. It is a clinical syndrome that includes various clinical conditions like, obesity, pre-diabetes, diabetes, and metabolic syndrome. The symptomatology, types, and sub-types mentioned in the context shows relevance with modern times rationale of free fatty acid and its role in peripheral insulin resistance. The article put an emphasis on those cases of chronic diabetes (DM type 2) which becomes insulin dependent in later phase of life and its coherence with Vatolwana prameha of kaphaja and pittaja variety(Kaphaja and Pittajaprameha with predominant Vata). This review article focuses on the Ayurvedic management of chronic insulin dependent type 2 diabetics. Various research papers indexed in Pubmed, SCOPUS, and Web of Science was deeply studied and cited appropriately in the article. The closest possible correlation of modern and Ayurveda principles and their relevance in the present time is tried to be drawn. The treatment protocol given in Ayurveda texts is scientific enough to be taken into consideration for making it as the first-line treatment of not only diabetes mellitus but also in the cases of obesity and metabolic syndrome.

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INTRODUCTION

Prameha as mentioned in ancient Ayurveda texts depicting a disease of Mutravaha sansthana (Urinary system) but most importantly it is a disease of metabolism. Urinary tract related symptoms are frequently associated at every stage of the disease (Puranik and Patwardhan, 2012). The classical symptom representing of Prameha is passage of excess amount of Turbid urine (Prabhuta Avila mutrata) (Tewari \textit{et al.}, 2017). Prameha also derives its name from its character similar to Polyuria (Shrikantha, 2004). The ancient Ayurveda texts scripted Prameha roga (Disease) in a much elaborated manner. Detailed descrip-
tions on Prameha are available in the NCBI book database (Morandi et al., 2011; Sharma and Chandola, 2011a,b). This is the reason why Acharya Charaka mentioned it as one among the Asha maha gada (Eight major Ailments). Prameha is not a single disease rather it is a complex phenomenon covering a number of conditions ranging from obesity to pre-diabetes, diabetes mellitus, thyroid dysfunctions and metabolic syndrome (Sharma and Chandola, 2011a,b). With growing economy and disturbed lifestyle, the problem has become so grave that India is supposed to be the diabetes capital of the world (Pandey and Sharma, 2018). In Diabetes Atlas 2015 it was said, in India presently 69.2 million patients is expected to rise to 123.5 million by 2040 unless prompt prophylactic measures are taken. Onset of Diabetes in India is 2 decades ahead contrast to rest of the world. This further validates the possibility of a more combative diabetes phenotype prevailing to this very part of the world (King et al., 1998; Mohan et al., 2007; Dutta and Mukhopadhyay, 2018).

**Dosha** (Three fundamental bodily humours - Vata, Pitta, and Kapha) and Dushyas (Body tissues and other elements) in Prameha roga

Overeating of Kapha Vardhaka Ahara (Kapha dominant diet) together with sedentary life-style, day time sleeping, lack of exercise, faulty dietary habits, etc. are the varied etiological factors for Sthaulya (Obesity). Overindulgence in these etiological factors finishes up in increase in Guru (Heavy), Snigdha (Slimy), Manda (Dull), Sthira (Steady) Gunas (Properties) within the body which ends up into Kaphaja vikaras (Kapha dominant diseases). Excessive formation of Meda dhatu (Adipose tissue) is a persistent feature of Sthaulya (Obesity). Medo vriddhi (Adipose deposition) in a Sthula (Obese) person is of two types: (i) Baddha Meda Vriddhi (Bounded lipids), (ii) Abaddha Meda Vriddhi (Cirulating lipids). The aetiology of Prameha is analogous to Sthaulya (Obesity) and goes hand in hand (Singh et al., 2014).

Prameha is a Tridoshaja Vyadhi (Three fundamental bodily humours - Vata, Pitta, and Kapha but it is basically a disease with dominance of Kapha dosha (Sharma and Chandola, 2011a,b). Prameha has Ten Dushyas (Body tissues and other elements) viz. Rasa (Plasma), Rakta (Blood), Mamsa (Muscles), Meda Adipose, Majja (Marrow), Shukra (Semen), Oja (Immunity), Ambu (Water), Vasa (Fat), Lasika (Lymph). The dosha (Principal systems functions - Vata, Pitta, and Kapha) and the dhatu (Tissue) involved in the pathogenesis of Prameha roga (Disease) bears liquid tendency i.e. the liquefied nature of Kapha dosha (Principal systems functions - Vata, Pitta, and Kapha) involved in the pathogenesis of Prameha roga (Disease).

At the same time, the primary dushya (Body tissues and other elements) involved in the pathogenesis of Prameha are Meda (Adipose), Mamsa (Muscle) and Shariraj Kleda (Bodily wetness) (Pandey, 2009). The Meda dhatu (Adipose tissue) is actually the Abadha Meda (Cirulating lipids) representing the fat which is mobile in nature and circulates freely in the plasma in the form of plasma lipids. Free fatty acids (FFA) are one important link between obesity, insulin resistance, and Type 2 diabetes mellitus (Valaiyapathi et al., 2020).

**Types of Prameha**

In Ayurveda text, Prameha rogi (Patient) are classified into two categories i.e. Sthula (Obese)/Balwan (Strong) and Krishna (Lean) / Durbala (Weak) and Sahaja (Hereditary) and Apathyanimitaja (Acquired). Sahaja prameha (Hereditary) is due to Beeja dosha (Genetic anomaly) while Apathyanimitaja prameha (Acquired) is due to faulty dietary habit and lifestyle leading to Sthaulya (Obesity) (Tewari et al., 2017).

Depending upon the Dosha and Dushya involved, Prameha is classified into three categories.

1. Ten Kaphaja Prameha (Prameha with Kapha predominance) are considered Sadhya (Curable) due to similar nature of Dosha and Dushya (Principal systems functions - Vata, Pitta, and Kapha and body tissues and other elements) leading to which the treatment is quite easy.
2. Six Pittaja Prameha (Prameha with Pitta predominance) are considered as Apathya (manageable but not curable) i.e. recurrence occurs once treatment is put on hold due to opposite nature of both the Dosha and the Dushyas.
3. Four Vataja Prameha (Prameha with Vata predominance) are Asadhya (Incurable) (Pandey, 2009; Baruah and Gupta, 2002; Nanda et al., 2001).

**Pathogenesis of Vataja Prameha (Prameha with Vata predominance)**

Vataja Prameha has three possible pathogenesis:

1. Kapha-Pitta Kshinata (Loss of Kapha – Pitta dosha) leading to Vata prakopa (vitiation of Vata)
2. Dhatu Kshaya (Tissue emaciation) as a result of chronicity of disease leading to Vataprapakopa (vitiation of Vata)
3. Pure Vata Prakopa (Vitiation of Vata) due to etiological factors aggravating Vata Dosha causing Dhatukshaya (Loss of Body tissues), leading to Vataja Prameha (Prameha with Vata predominance).

Out of the three possibilities, first and second signifies the chronic nature of the disease. The chronicity leads to Dhatukshaya (Tissue emaciation) and the gateway to this is the Dhatwagni Nasha (Loss of metabolic energy at the tissue level), leading to loss of all the Sapta dhatus (Seven tissues), ultimately leading to Ojakshaya (Immuno-compromised status). Ayurveda and Contemporary science both supports the fact that newer the disease easier is its management. Dhatu Kshaya leads to Vata Prakopa which again leads to Vishamagni (disturbed metabolic fire) and a vicious cycle occurs. Thus this gives an insight towards the poor prognosis of Vataja Prameha of either category (Sharma and Chaudhary, 2014).

Selection of Khadira (Acacia catechu) and Kramuka (Areca nut) for the study

Acharya Chakrapani on his commentary over charaka siddhi sthana mentioned the properties and actions of any compound formulation or Karma follows the principles of Prakritivishamasamavaya and Vikritivishamasamavaya. According to these principles Samyoga (combination) of many drugs in a compound formulation gives rise to some new properties and actions (Vikritivishamasamavaya) along with existence of the inherent one (Prakritivasamavaya). Therefore, while considering the Gunas, Karma of Khadira Kramuka Kashaya Siddha Taila, we should consider the Guna, Karma of their ingredients.

Acharya Sushruta wisely mentioned the use of Khadira (Acacia catechu) and Kramuka (Areca catechu) decoction in the management of Madhumeha (Chronic Diabetes mellitus). The decoction has Kashaya (Astringent) - Tikta (Bitter) Rasa (Tastes) and Katu Vipaka (Pungent post digestive effect). Kashaya Rasa (Astringent taste) has Stambhana (Suppression) properties. Thus by virtue of this property the decoction is capable of curbing excess micturition and through this the eventual loss of Oja (Immunity) is also restricted. It also absorbs the Kleda (Wetness), Abaddha Meda (Circulating lipids), Vasa (Fat) and Kapha Dosha, this reduces the peripheral insulin resistance which improves the disease status (Archana et al., 2015). Kasaya rasa not only reduces the peripheral insulin resistance as well as clinical manifestation of the disease. ‘Tikta’ rasa in addition to Kashayarasa, has predominance of Akasha and Vayumahabhoota. So it has ability of permeate to sushmastrotasas. Due to this drug can reach at cellular level and help to reduce meda and Kleda. Thus, helps in breakdown of Pramehasampranti and reduces related symptoms. In pathogenesis of Madhumeha, Vata Dosha is predominant factor. For controlling of Vata Dosha, the contents of Khadira Kramuka Kashaya Siddha Taila have properties of Snigdha, Rasayana and Yogavahi effects.

Acacia catechu belongs to family Leguminosae and is found in various parts of Asia. The flavonoids from the hard wood of A. catechu have been used in many traditional medicine pharmaceutical products, especially in Asia, for a variety of purposes including anti-inflammatory, anti-virus, antibacterial, anti-cancer, and cardiovascular application. Acacia catechu commonly known as Kattha or Khadir is a member of leguminosae family found in various parts of Asia. The anti-inflammatory activity of wood extracts flavanoid from Acacia have been reported, may be due to its antioxidant properties (Stohs and Bagchi, 2015; Oliveira et al., 2020). Khadir (Acacia catechu) has anti-diabetic and anti-dyslipidemic properties (Ikarashi et al., 2011). An experimental study carried out on animal model of Type-2 Diabetes mellitus (T2DM) showed significant anti hyperglycemic activity. The Oral glucose tolerance test (OGTT) was carried out post sucrose load in normal rats and streptozocin induced diabetic rats (Eyth et al., 2019). The study showed that the aqueous as well as ethanolic extracts of Khadira (Acacia catechu) hard wood have marked ability to improve oral glucose tolerance comparable to standard anti-diabetic drug. In the same study, this was also established that Khadira (Acacia catechu) have the potential to prevent the secondary complications associated with T2DM (Srivastava et al., 2011). Thus Antioxidant, anti-inflammatory and anti-diabetic properties of Khadira (Acacia catechu) is well established. Its aqueous and ethanolic extract was studied and it was found to have potent anti oxidant activity. This antioxidant nature of Khadira (Acacia catechu) was believed to be responsible for the anti-inflammatory activity in both in-vitro and in-vivo (Stohs and Bagchi, 2015).

Khadira (Areca catechu) belongs to family Arecaceae and is a species of palm found in various parts of Asia. Khadira (Areca catechu) is used in traditional medicine and as well known folk remedy for the treatment of Diabetes in southern parts of India. In Ayurvedic literature it has been mentioned that Kramuka (Areca nut) is widely used as Pramehagnha (Antidiabetes). Acharya Sushruta mentioned it in Salsaradi gana whereas Acharya Vagbhatta mentioned it in Asanadi gana, both are dedicated to Prameha and have Kapha-Medohara karma
(Decreases Kapha and Anti-obesity property), as Kapha and Meda (Adipose tissue) are the root causes in initiating pathogenesis. Anti diabetic effect of Khadira (Areca catechu) flower extract was assessed in alloxan induced diabetic rats. Study revealed significant anti-diabetic activity of ethanolic and aqueous extract of Khadira (Areca catechu) flowers in animal model. The study was confirmed by significant restoring of biochemical parameters. The phytochemical study showed presence of phenolic content in both the extracts (Salehi et al., 2019).

Khadira Kramuka Kashaya Siddha Taila (Black catechu and Areca nut decoction based Oil)

Khadira kramuka kasaya siddha taila is a new formulation based on the ancient idea of the two great saints of Ayurveda, Acharya Charak and Acharya Susrutta. Susruta Samhita has mentioned the Khadira kramuka kasaya in the management of Madhumeha and Acharya Charaka has given the instruction to use Medicated oils and ghee prepared by processing with the decoctions and that should be administered to patients suffering from Vatika Prameha. The decoctions correct the vitiated Medas and Kapha and the aggravated Vata in these patients gets alleviated by the unctuous ingredients. So by merging the idea of these great saints we prepare a formulation named Khadira kramuka kasaya siddha taila (KKST) by classical method of sneha kalpana mentioned in Ayurveda and the quality analysis of prepared formulation is done in a CPCSEA certified lab as per the norms of API -II(Ayurvedic Pharmacopia of India).

As stated above, Khadira (Areca catechu) and Kramuka (Areca nut) exhibit anti-diabetic as well as anti-dyslipidaemic properties. When the decoction of both has to be used in the cases of Madhumeha (chronic diabetes mellitus) per se lean and thin chronic uncontrolled hyperglycaemic with comorbidities, we use a base of oil. As mentioned earlier in the text, the chronic PHs is the cases which are coherent with Vata predominant cases of Prameha. The drugs in the decoction balance the incoherence of Doshas and Dushyas while the Oil base mitigates the elevated Vata dosha. The Sesame oil is the best suited oil for medicinal use. The Anti-hyperglycaemic effect of Sesame indicum oil is well established (Sankar et al., 2005).

Various studies have evaluated the anti hyperglycaemic effects of Sesamum indicum. An experimental study on Wistar albino rats done in controlled condition demonstrated that ethanolic extract of Sesamum indicum seeds has a potential effect on Hyperglycemia. The study was backed up with biochemical investigation like blood glucose, glycosylated haemoglobin, serum insulin and liver glycogen levels, which showed that glucose level in streptozocin induced diabetic rats were reduced to near normal after treatment (Bhuvaneswari and Krishnakumari, 2012).

Dietary saturated fatty acids (SFA) increase the risk for obesity and cardiovascular disease, whereas monounsaturated fatty acids (MUFA) and polyunsaturated fatty acids (PUFA) decrease those risks by modification of lipids (Hu et al., 2001). Studies have shown that Sesame oil is a rich source of mono unsaturated and poly unsaturated fatty acids (Goodman et al., 1988).

Advantages of Taila Kalpana

Formulations prepared from the Taila enhance shelf life, having high bio-availability, enhances drug absorption ensures absorption of active principles of ingredients. It enhances the therapeutic effect via the nutritive and Rasayana effect of Til taila. The water soluble as well as fat-soluble active principles can be transformed into oil media and this addition of properties of material made the Taila potent and effective.

Method of Preparation

Ingredients of Khadiraa KramukaKashayaSiddha Taila has been given in Table 1 (Srivastava, 2003).

1. 1 part of kalka dravya (paste of herbs- KhadiraAa Kramuka)
2. 4 parts of oil (Til taila)
3. 16 parts of drava (kwatha of KhadiraAa Kramuka)

These are to be mixed together & heat on Mandagani to prepare the medicated Taila. Then it is filtered and stored.

DISCUSSION

Vataja prameha is said to be untreatable, but here a question arises, which Vataja prameha is treatable then. Acharya Charak in Charak samhita clarified that only those Vataja prameha in which exacerbation of Vata is secondary to reduced Kapha and Pitta is the one which is manageable rest other Vataja Prameha due to the vitiation of pure Vata, is not treatable (Pandey, 2009).

Out of above mentioned three possible pathogenesis of Vataja prameha (Prameha with Vata predominance), first and second pathogenic pathway is compared with the long standing Type 2 Diabetes Mellitus (T2DM) while the third is comparable to T1DM.
Table 1: Ingredients of Khadiraa Kramuka Kashaya Siddha Taila

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Name of Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Khadiraa(Acacia catechu)</td>
</tr>
<tr>
<td>2.</td>
<td>Kramuka(Areca catechu)</td>
</tr>
<tr>
<td>3.</td>
<td>Tila(Sesamum indicum)</td>
</tr>
</tbody>
</table>

Table 2: Resemblance between types of Prameha and Diabetes Mellitus

<table>
<thead>
<tr>
<th>Prameha</th>
<th>Diabetes Mellitus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sthula/ Balwan (Obese/ Strong)</td>
<td>T2DM</td>
</tr>
<tr>
<td>Krish/ Durbala (Lean/ Weak)</td>
<td>T2DM with chronicity / Later phase of MODY</td>
</tr>
<tr>
<td>Sahaj prameha (Hereditary)</td>
<td>T1DM</td>
</tr>
<tr>
<td>Apathyanimitajja (Acquired)</td>
<td>T2DM</td>
</tr>
</tbody>
</table>

The aforesaid first and second pathogenesis is somewhat two stages of one clinical condition. The first one is the early stage type 2 DM while the second one is the later stage where dosing of OHA increases and still fair control is not reached and ultimately these patients are put on Insulin therapy, this makes a large number of "OHA non-responding" group of patients which brings a new category of diabetics called as Insulin dependent type 2 diabetes mellitus (IDT2DM).

The chronic, uncontrolled or poorly controlled hyperglycaemia leads to multiple systemic illness e.g. CKD, diabetic retinopathy etc. and has associated higher risk of mortality (Sperry et al., 2009). Conventional system of medicine had progress a lot in the field of medicine still a promising management of diabetes mellitus is not available. Present medical solutions available; ensure maintaining optimum insulin level in the body by means of OHA or by means of Insulin therapy. But a complete reversal of the pathogenesis is not taking into account. Here is where Ayurveda holistic management scheme comes into play. Starting from Nidana parivarjana (Elimination of basic cause) and treatment as per Kriya Kala (Stages of disease progress) is of huge importance.

Staging of Prameha and its modern parlance

The Sthula pramehi (Obese diabetics) in the early stage, say (S₁) simulates with the Pre-diabetic phase which can be reversed through diet and exercise only. Once the patient slips into Persistent hyperglycemia (PH) which is manageable through OHA’s (Oral hypoglycaemic agents) in conventional system of medicine say stage 1 (S₁), certain medications are necessary to reverse the pathogenesis. Since these patients need to be treated with evacuative (Shodhana) and Pacificatory (Shamana) measures. Repeated Shodhana and Shamana along with diet and exercise practices pacify the enhanced Kapha dosha and also stabilises the Dushyas (Body tissues and other elements).

The Prameha rogi (Patient) with Hinabala (Weak body strength) or the Krishapramehi (lean and thin Patient) are the patients of T2DM with chronicity leading to Dhatukshaya (Loss of Body tissues). These Prameha rogi are hard to manage as in these patients, exercise and diet restrictions have a limited role. These patients are analogous to chronic uncontrolled hyperglycemic with comorbidities, for say stage 2 of T2DM (S₂).

Our ancient sages mentioned 20 types of Mutra atipravritti janyaroga (Disease associated with excessive urine output) as Prameharoga (Disease). In Ayurveda, Prameha is the disease with a prodrome of polyuria and the name given to these types depends upon their physical properties. Madhumeha is end stage of Vataja Prameha that can occur as the terminal stage of type 2 diabetes, or as type 1 diabetes. The latter is defined as Jatah Pramehi Madhumehin (Hereditary DM) (Sharma and Chandola, 2011a, b). At the same time nomenclature was so wisely done that it also depicted the gravity of the clinical state. E.g. Ojomeha refers to Immuno-compromised state (Pandey, 2009). Oja (Immune) is the essence of all the Dhatu (Body tissue) and is referred as Bala (Strength) by Acharya Sushruta. It provides the innate immunity that produces resistance against many diseases (Ranade and Acharya, 2015). Therefore we understand the seriousness of PH with co-morbidities which were very well known to our ancient sages. The concept of immunosuppression through various metabolic pathways due to persistent hyperglycemia is a well known phenomenon (Graves and Kayal, 2008). This Madhumeha or Ojo meha or Kshaudra meha due
to progressive illness is the $S_2$ of T2DM. These patients need promotive (Brihmana) treatment. The management of $S_2$ patients focuses on the utilisation of the decoctions mentioned in the context of Prameha roga (Diabetes), to be cooked with Oils and Ghritas (Clarified butter). By doing so, the drugs in the decoctions diminish the Dushta medas (Impure lipids) and Kapha, whereas the Oil and Ghee (Clarified butter) pacifies Vata (Pandey, 2009). Resemblance between types of Prameha and Diabetes Mellitus has been given in Table 2.

Mode of Action of Khadiraa Kramuka Kashaya Siddha Taila

Khadiraa Kramuka Kashaya Siddha Taila has a maximum of Kashaya Rasa followed by Tikta Rasa and Laghu vipaka, Kashaya Rasa, Tikta rasa helps in Shireekarana of Dhatus and also does KledaUpapashoshana. Kashaya Rasa is helpful in Shareea Kleda Harana, Laghu, Rooksha Guna produces Rookshana and Shoshana effect and they are having opposite qualities to that of Kapha and Medas which is the main entity of the Pathogenesis of Madhumeha. Kasaya Rasa acts as a controller of excessive urination; Dhatu kasaya and OjaKsaya through urine by their Stambhana properties. It absorbs Kleda, Meda, Vasa and Kapha Dosha.

CONCLUSION

Prameha roga is not a single clinical condition nor could it be compared to any one disease set. Knowledge of Kriya kala (Stage of a diseases progress) and its application in learning the disease process is of very importance in Prameha. Broad classification given by our ancient sages is needed to be elaborated and scrutinized in present era. Stage wise medical and non medical management will not be able to just prevent but also cure the diabetes which the conventional medical system is not able till today. The line of treatment mentioned in Ayurveda texts and the drugs indicated in the clinical conditions are effective even in today’s context. Only the need is, to evaluate it according to the advance clinical and biochemical parameters.

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Conflict of Interest

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