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Effect of Laghoo-Shankaprakshalana on Diabetes Mellitus Type 2 Pateints: A Single Arm Study

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Abstract

Background: Diabetes is a group of metabolic disorders that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces.

Objectives: The Effect of laghoo-shankaprakshalana on blood sugar levels in patients with type 2 diabetes mellitus.

Method: This was a single arm study. A total of 50 subjects were recruited and undergone Laghoo-shankaprakshalana for 45 minutes once in a week for 4 weeks (4 sessions).

Outcome measures: Primary outcome was the assessment of the Fasting blood glucose level and post prandial blood glucose level using glucometer and secondary outcomes has been obtained with systolic and diastolic blood pressure with pulse rate and body mass index has been monitored.

Results: There was significant reduction in blood sugar level ($p<0.0001$), Body Mass Index ($p<0.000$), Systolic blood pressure ($p<0.002$). However, there was no statistical significance difference in diastolic blood pressure, pulse rate.

Conclusion: The results confirm the positive effect of laghoo-shankaprakshalana on blood sugar levels in patients with type 2 diabetes mellitus.

INTRODUCTION

Metabolic diseases are collection of disease that comprise Diabetes which is caused due to deficient secretion of insulin level in the body or a state where body is not responding to the insulin secretion. Insulin is a hormone that plays a major role in regulating the blood glucose level. hyperglycemia is a state where the blood glucose level increased to a maximum level and also have the capacity to affect our entire body mechanism particularly the blood vessels and the neurons. Depending upon the defective mechanism it is divided in to two major classifications, that is

1. 1.Type 1 diabetes mellitus (Deficient insulin production)-IDDM
2. Type 2 diabetes mellitus (Inadequate utilization of insulin)-NIDDM

More than 95% of those population are affected by NIDDM caused by sedentary life style and obesity. Although they are frequently milder, the symptoms can resemble those of type 1 diabetes. (1)

Diabetes both common in juvenile and adult onset where it is estimated that 8.5% of persons who were 18 years of age or older had diabetes in 2014.In 2019 nearly 1.5 million deaths was directly related to diabetes, with 48% of these deaths happening before the age of 70. Diabetes more likely associates with kidney disease, cardiovascular disease elevated blood glucose and is responsible for 20% of fatalities. (1) The

International Diabetes Federation estimates that 415 million people globally suffered from diabetes in 2015. (2)

Based on Global Burden of Disease (GBD) data About 462 million people worldwide, or 6.28% of the total population, had type 2 diabetes in 2017. Diabetes is the tenth most common cause of death, accounting for over a million fatalities annually. In Worldwide population the prevalence of diabetes mellitus is increasing at a significantly quicker rate. The distribution of genders is equal, and by 2030, it is expected that there would be 7079 cases of type 2 diabetes worldwide per 100,000 people. (3)

By 2045, diabetes is expected to afflict 693 million adults worldwide, making it one of the diseases with the greatest rate of growth. The consequences that are mentioned above mainly affects the vascular system causing reduction in blood flow to the essential organs such as eyes and kidneys that may lead to cause increase in mortality rate and affects the quality of life among the affected people. (4)

Yoga helps to correspond the patterns of consciousness and according to sage Patanjali he stated that yoga helps to clear from all blockages in our mind and promoting a positive well-being of life. (5) In Gheranda Samhita the importance of shatkarma is explained in first step of concept, where self-purification is the way (6), followed by asana, mudras, pratyahara, pranayama, Dhyana, and samadhi. This purification technique comprises of six practices. Dhauthi, nauli, kapalbhati, basti, nethi, and trataka. Also, hatha yoga, clearly decodes the value of shatkarmas, which it heals the body of illness. The primary goal of shatkarma is to balance vata, pitta, and kapha in order to tone Ida and Pingala nadi and brings balance between physical and mental body. (7)

Six +Action = Shat karma, It brings hormony between the Ida and Pingala nadies,three doshas, which has been the primary goal of hatha yogis, where it purifies both body and mind.

The modern term for Varisara Dhauti is Shankhaprakshalana (8), wherein the patient is asked to drink sixteen glasses of warm, salted water and then pass it via their bowels. Shankhaprakhsālana is a yoga asana (kriya) that is suggested for bowel purification. This kriya is simplified into Laghoo-shankhaprakshālana (LSP), which takes less time to complete and requires less physical strain. (9)

Incretin hormones such as Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulin releasing polypeptide (GIP) are secreted in the distal intestine and upper small intestine.Both having insulinotropic activity on pancreas, and inhibition of glucagon secretion, emptying of stomach, reduction in acid secretion, enhancement of beta cell sensitivity, promotion of insulin production, and reduction of food intake. (10)

GIP acts as an additional pancreatic glucoregulatory and insulin-releasing hormone. (11) Laghoo-shankaprakshalana improves the bowel health there by stimulating the incretin hormones. By increasing the secretion of gut hormones, laghoo-shankaprashalana improves the health of the intestines. This will assist in lowering blood sugar levels. But no research on laghoo-shankaprakshalana in type 2 diabetes has been done. (12)

PREVALENCE OF DIABETES

A study was conducted on 219 countries and territories to estimate the age-specific prevalence of diabetes among adults aged 20 to 79. The results were applied to population estimates for the years 2013 and 2035. A total of 744 data sources were taken into reference; 174 of those were from 130 different nations and were approximated. By 2035, there could be 592 million diabetics worldwide, up from 382 million in 2013. (13)

In high-income countries, the prevalence of diabetes among 65–69-year-olds was three times greater than

in low-income ones. 221 data sources from 131 nations were estimated from a total of 613 data sources from 163 countries that were taken into consideration for another literature assessment. Confidence interval (CI) estimates for those aged 20–79 years in 2017 were 346–545 million cases, while estimates for those aged 18–99 years were 367–585 million cases. Those numbers are expected to rise by 2045, with CIs of 477–809 million for those aged 20–79 and 522–903 million for those aged 18–99. These findings suggest that the incidence of diabetes is rising as a result of demographic shifts like aging, and that the prevalence of risk factors like obesity and sedentary lifestyles is rising. Additionally, better health care is extending the life expectancy of individuals with diabetes. Also, they show that the prevalence for any given year has typically been underestimated in earlier simulated predictions. (14)

The World Health Organization (WHO) classifies diabetes mellitus into several categories based on ae tiology and pathogenesis. Here's a brief overview: (15)

1. Type 1 Diabetes: Resulting from autoimmune destruction of insulin-producing beta cells in the pancreas.
2. Type 2 Diabetes: Characterized by insulin resistance and relative insulin deficiency.
3. Gestational Diabetes: Diabetes diagnosed during pregnancy that was not clearly overt diabetes prior t o gestation.

Specific Types:

Including monogenic diabetes (e.g., MODY), diseases of the exocrine pancreas, endocrinopathies, drug- or chemical-induced diabetes, infections, and other genetic syndromes.

INCRETIN HORMONES

Glucose-dependent insulinotropic polypeptide was purified using a bio assay measuring the inhibition of gastric acid secretion, and hence the old name “gastric inhibitory polypeptide”

Incretin hormones are gut peptides that are secreted after nutrient intake and stimulate insulin secretion together with hyperglycemia. GIP (glucose-dependent insulinotropic polypeptide) und GLP-1 (glucagon-like peptide-1) are the known incretin hormones from the upper (GIP, K cells) and lower (GLP-1, L cells) gut. GIP and GLP-1 have low (basal) plasma concentrations in the low picomolar range (10−12 mol L−1) in fasting human subjects. GIP and GLP-1 plasma concentrations start to rise a few minutes after nutrient intake, reach a peak after approximately 1 h, and reach basal concentrations again after several hours. Nutrients that stimulate the secretion of GIP and GLP-1 are glucose and other carbohydrates including sucrose and starch, triglycerides, and some amino acids as well as proteins.

GLP-1 administered into the central nervous system, but also into the general circulation,reduces appetite and food intake and increases satiety. The relevant GLP-1 receptors seem to be in the hypothalamus.GLP-1 may enter the brain from the blood stream through circumventricular organs, which are characterized by a leaky blood–brain barrier. GLP-1 seems to be one of the meal-termination signals. These effects are the basis for weight loss with prolonged stimulation of GLP-1 receptors.1,2 Such an activity has not been known in the case of GIP, but recently hybrid peptides (also addressing, e.g., glucagon and peptide YY receptors) have been developed for the purpose of promoting more weight loss than GLP-1 receptor agonist alone can provide,46 by also activating GIP receptors.4 (33)

It has been proposed that secretion of α cell–generated glucagon-like peptide-1 (GLP-1) might contribute to some of the antidiabetic effects of attenuated glucagon (16)

The Hatha Yoga Pradipika, Gheranda Samhita, Shiva Samhita, and Hatharatnavali are the four discuss how to purify the body using six different cleansing techniques. The subtypes and advantages of the

Shatkriya are described in detail in the Gheranda Samhita. Shatkriya's primary goal is to balance the body's three humours (tridosha), which are wind (vata), bile (pitta), and mucus (kapha).

This basis of eliminative systems becomes lag in their functions due to many changes in the life style such as sedentary life, wrong way of eating habits, additions of alcohol, smoking and other such things this leads to the disharmony state and creates disease.

In psychology it states that disease starts from mind, where as in shatkarma a part of yoga it handles both the physical and mental pollutants and thus it helps to eradicate the obstacles and impurities and renders a positive health by regulating the three doshas such a Vata, Pitta, and Kapha. (17)

As it was already stated that through the shatkarmas, harmonization of three doshas are well established and it makes the free flow of prana energy thus balances the three states of well-being. As same concept was discussed in Ayurveda and hatha yoga, about the cause of disease, so it is essential to practice shatkarmas before doing pranayama or any other higher practices of yoga so that the body becomes free from disease and obstacles in the path will be eradicated to live a life free from disease.

Vari means water, sara means element, and dhauti means washing. Varisara dhauti is also known as shankhaprakshalana. Toxic elements are expelled from the body and the entire system revitalized, as this practice cleanses the entire alimentary canal from the mouth to the anus. (18)

The water drunk during this practice should be lukewarm, not hot or cold. Cold water causes constriction of the blood vessels that supply the digestive tract. Hot water is also contraindicated because it would burn the lining of the gut. There is also an important reason for adding salt. The body cannot absorb salt water easily. When plain water is drunk, it is absorbed through the intestines into the body and excess is eliminated in urine. If salty water is drunk, much of it is not absorbed and comes out via the anus.

It should be remembered that during shankhaprakshalana, water should not be drunk in excess so that one feels like vomiting. Laghu Shankha Prakshalan completely purifies the alimentary canal by removing all the accumulated fecal matter from the body through drinking of lukewarm water and those asanas performed in the series of practice strengthen the abdominal organs. (20)

AIM AND OBJECTIVES

Aim:

To evaluate the effect of laghoo-shankaprakshalana on Type 2 diabetes mellitus patients.

Objectives:

Primary Objective:

- To study the effect of laghoo-shankaprakshalana on fasting (FBS) and post-prandial (PPBS) blood sugar level in Type 2 diabetic patients.

Secondary Objectives:

- To study the effect of laghoo-shankaprakshalana on blood pressure in patients with type 2 diabetes mellitus
- To study the immediate effect of laghoo-shankaprakshalana on pulse rate in patients with type 2 diabetes mellitus
- To study the immediate effect of laghoo-shankaprakshalana on basal metabolic rate (BMI)in patients with type 2 diabetes mellitus

RESEARCH QUESTION AND HYPOTHESIS

Research Question:

- Does laghoo-shankaprakshalana produce any changes in blood glucose levels and cardiovascular functions in patients with type 2 diabetes mellitus?

Null hypothesis:

- Laghoo-shankaprakshalana may not have effect on Type 2 diabetes mellitus patients.

Alternate hypothesis:

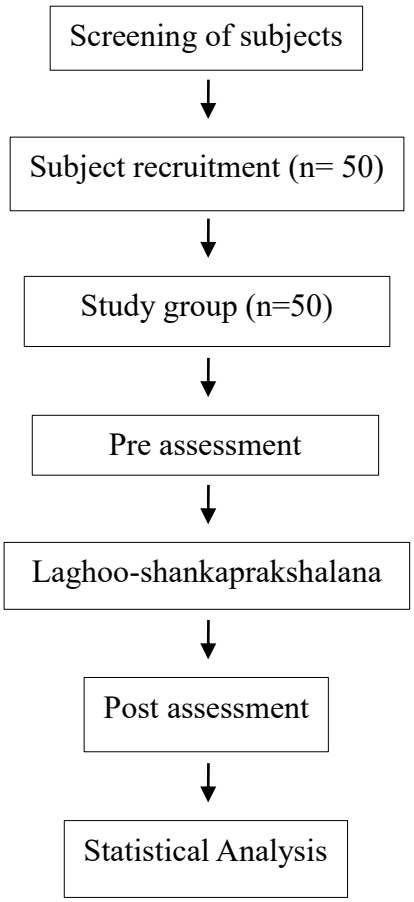
- Laghoo-shakaprakshalana may show significant changes in blood glucose levels and cardiovascular function in patients with type 2 diabetes mellitus.

MATERIALS AND METHODS

Study design:

A single group pre-post experimental study was adopted for this study. The study group were undergone Laghoo-shankaprakshalana for 45 minutes once in a week for 4 weeks.

Figure 1: Trail profile



Participants:

Sample size: n=50

Selection (Sampling techniques) and source of the subjects:

The subjects were recruited from Government yoga and naturopathy medical college and hospital, Chennai using convenient sampling method.

Inclusion criteria:

1. Age between: 25to 50 years
2. Both genders (Male & Female)
3. Subject diagnosed with type 2 diabetes mellitus
4. Willingness of the patient to accept intervention.

Exclusion criteria:

1. Patients with peptic ulcer, hernia, seizures and panic disorder.
2. BMIabove40 (kg) / $(m)^2$.
3. People who are pregnant, lactating and menstruating

Withdrawal criteria:

Participants were free to withdraw from the study at any point of time, for any reason, with or without prior intimation to investigators or with or without prior permission from investigators

Ethical Consideration:

- Institutional ethics committee (IEC) clearance was obtained from Government Yoga and Naturopathy Medical College and Hospital before recruitment of the first subject. Subjects who fulfilled inclusion criteria were explained about the purpose of the study and their rights as research subjects. An informed consent form was administered in English.
- As few subjects were unable to understand English, so, the signed informed consent form was translated into their native language i.e., Tamil was done. Adequate time was given to each patient to go through the information sheet and their queries were answered.
- Their right to withdraw anytime from the study and the need for willingness to participate voluntarily in the study was described. All the subjects expressed their willingness to participate in the study by giving a signed informed consent.

INTERVENTION

Study group:

Subjects were asked to practice Laghoo-shankaprakshalana once in a week for 4 times in a month. The session was lasted for 45 minutes and it was followed by rest period of 15 minutes in shavasana with normal breathing.

OUTCOME VARIABLES:

The primary and secondary outcome variable has been assessed before and after one day of intervention.

Primary outcome variables:

Fasting blood glucose level and post prandial blood glucose level has been assessed with the help of glucometer. Blood samples were collected in the strip; the strip has been loaded in to the glucometer

Secondary outcome variables:

- Blood pressure and pulse rate was monitored using digital blood pressure monitor, the hand cuff part has been tied above the cubical fossa in left hand the blood pressure has been obtained.
- Body mass index has been assessed with monitoring height (in centimeters) and weight (in kilograms) of the subjects using a stadiometer and electronic weighing scale. Body mass index (BMI) has been calculated using the formula=Weight (kg)/height (m) [2]

Data Analysis:

Data analysis has been done using appropriate statistical test in Statistical Package for the Social Sciences,

version, 16.

RESULT

Out of 70 patients screened, 50 patients were fit into the inclusion criteria and were selected for the study. Pré and post data on FBS, PPBS, BMI, Blood pressure and pulse rate were collected and data analysis was done.

Table: Demographic and anthropometric details

Demographic details		**Study Group (n=50)**
Age		44.28 ± 5.55
Gender	Male	19
	Female	31
Marital Status	Married	50
	Unmarried	0
Height		160.28 ± 5.61
Weight		67.40 ± 10.50
Body Mass Index		26.41 ± 3.04

Table: Assessment of Primary & Secondary dependent variables in the study group

Variables	**Pre**	**Post**	**p Value**
Fasting Blood Sugar	186.24 ± 52.57	165.66 ± 53.41	0.0001
Post Prandial Blood Sugar	234.30 ± 74.30	208.92 ± 69.90	0.0001
Body Mass Index	26.41 ± 3.04	25.98 ± 2.85	0.000
Systolic Blood Pressure	129.44 ± 13.30	125.48 ± 10.04	0.002
Diastolic Blood Pressure	83.56 ± 9.63	81.42 ± 7.19	0.028
Pulse Rate	81.90 ± 14.95	79.88 ± 13.15	0.129

Table 3 shows that significant difference between the groups in the Fasting blood glucose with the p- value < 0.0001 and Post Prandial blood glucose p- value < 0.0001. There is no significant difference between the diastolic blood pressure and pulse rate.

The practice of laghoo- shankaprashalana has statistically significant changes in the systolic blood pressure (p=0.002) in both the groups.

DISCUSSION

The result of present study showed significant changes in the FBS and PPBS level of the T2DM. Along with the Blood sugar levels changes in the systolic blood pressure and basal metabolic rate was also found to have changes within the patients.

Now a day's diabetes is the most common and prevailing disease in most of the country's leading to other complaints like stress, neurological problems, kidney failure, eye problems, dental disease, heart disease & Stroke, etc. and gradual rise in the death rate due to it. Therefore, to reduce the death rate due to high blood glucose level, this study was formulated. In spite of numerous studies already exist in the prevention of T2DM, there are very less studies on finding the impact of kriya techniques on the blood glucose level in T2DM.The effect of yogic practices on the management of diabetes has not been investigated well yoga

practice showed a significant improvement for those diabetic patients with pre-existing complications. (22)

A review of the literature was conducted by Singh VP et al. in 2005 in order to have a better understanding of the psycho-neuro-endocrine and immunological mechanisms of action of yoga in Type 2 Diabetes Mellitus. Using a focus on the psycho-neuro-endocrine or immunological linkages, a literature search was conducted to locate published research on the mechanisms of action of yoga in Type 2 diabetes mellitus. Yoga is believed to function by triggering the parasympathetic nervous system and serving as a stress-reduction method. Yoga improves general metabolic and psychological profiles like insulin sensitivity, glucose tolerance, and lipid metabolism by relaxing mental perception and activating the hypothalamic-pituitary-adrenal (HPA) axis.

Laghu Sankhaprakshalana (LSP) is a method that helps to keep the bowels healthy and promote intestinal movement. In addition to several cardiometabolic risk factors like obesity, dyslipidemia, and insulin resistance, bowel health is linked to the proper operation of other systems that have an impact on cardiovascular health. In addition, poor gut health influences the gut microbiota's metabolism, which is known to influence the risk of diabetes, cardiovascular disease, and other illnesses.

GIP stimulates glucagon secretion in healthy individuals and those with type 2 diabetes, especially at lower plasma glucose concentrations. GLP-1 suppresses glucagon secretion in healthy individuals and those with type 2 diabetes. Both glycemic control (often leading to normal HbA_{1c} levels) and body weight reduction are significantly better with tirzepatide than with the most efficacious selective GLP-1 receptor agonists. Incretin hormones (GIP and GLP-1) play an important role in the pathophysiology (reduced incretin effect) and progression (given the deterioration of postprandial glycemic control as a result of the reduced incretin effect) of type 2 diabetes. in human type 2 diabetes, GIP receptor agonism improves insulin sensitivity beyond the effects mediated by body weight reduction. (25)

GLP-1 is known as the most powerful incretin in humans and the lowers postprandial blood glucose via augmentation of glucose-dependent insulin release from pancreatic β-cells, inhibition of glucagon secretion from pancreatic α-cells, and delay of gastric emptying

GLP-1 and GIP act via G protein-coupled receptors. GLP-1R is expressed in many tissues, including pancreatic islets, the central nervous system, lung, kidney, heart, intestine, and also in immune cells, underlining the numerous roles for GLP 1-signaling beyond blood glucose control. (26)

Hence in the view of effect of Laghoo Sankhaprakshalana on blood glucose level of T2DM, there is a significant change in the FBS, PPBS of T2DM Patients.

LIMITATION:

The current study measures only the blood glucose level. The study was only withheld for a month of period.

RECOMMENDATION

The same study can be conducted for a longer duration along with other variables. In future laboratory test has to be with other bio chemical parameters.

CONCLUSION

The present study demonstrated the practice of Laghoo Sankhaprakshalana in reducing the fasting and post prandial blood sugar level in type 2 diabetic subjects. From the inferred that the practice of Laghoo

Sankhaprakshalana is more effective in reducing the blood sugar level which could have been the resultant effect of promoting the incretin hormones and raised parasympathetic effect has significant changes in the insulin sensitivity in patients with type 2 diabetes mellitus, as postulated in earlier studies.

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