TO STUDY THE SAFETY AND IMMEDIATE EFFECT OF YOGIC GUT CLEANSING TECHNIQUE IN DIABETES PATIENTS

(A SELF AS CONTROL STUDY)

Submitted by

Seema Patil

Towards the partial fulfillment of

MASTER OF SCIENCE IN YOGA

UNDER THE GUIDANCE OF

Dr Vijay Kumar

SWAMI VIVEKANANDA YOGA ANUSANDHANA SAMSTHANA

(Declared as Deemed University under Section 3 of the UGC Act, 1956)

BENGALURU - 560 019

I N D I A

CERTIFICATE

The doctoral committee confirms that this is an authentic approved copy of the thesis.

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Title of the Thesis	**:**	**TO STUDY THE SAFETY AND EFFECT OF YOGIC GUT CLEANSING TECHNIQUE IN DIABETES PATIENTS**
Viva Examination Detail	**:**	
Venue	**:**	***PrashantiKutiram, Jigani, Bengaluru***
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CERTIFICATE BY THE GUIDE

This is to certify that Ms. **Seema Patil**who has been given M.Sc. registration with effect from 08 Jan, 2013 by Swami Vivekananda Yoga AnusandhanaSamsthana (S-VYASA), Deemed University, has successfully completed the required "training" in acquiring the relevant background knowledge in Yoga and has completed the M.Sc. course of two years to submit this dissertation entitled "To study the safety and immediate effect

of Yogic gut cleansing technique in Diabetes patients (A self as control study) as per the regulation of the University.

We also declare that the subject matter of the dissertation entitled**,**""To study the safety and immediate effect of Yogic gut cleansing technique in Diabetes patients (A self as control study) has not previously formed the basis of the award of any degree, diploma, associate-ship, fellowship or similar titles.

Guide ,

Dr.Vijay Kumar

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M.Sc. Psychology

Place: Bengaluru

Date: 01 DEC, 2014

D E C L A R A T I O N

I, hereby declare that this study was conducted by me under the guidance of Dr. Vijay Kumar, S-VYASA University Bengaluru.

I also declare that the subject matter of my dissertationentitled**,"To study the safety and immediate effect of yogic gut cleansing technique indiabetes patients (Aself as control study)"**has not previously formed the basis of the award of any degree, diploma, associate-ship, fellowship or similar titles.

Date: 30thDec2014 Place: Bengaluru	**Name: Seema Patil** (Candidate)

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STANDARD INTERNATIONAL CODE

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ABSTRACT

Background:

Hatha Yoga emphasizes the role of cleaning the body through various kriyas (cleansing techniques) as a preparation for maintaining a healthy body. Health is of the utmost importance for spiritual progress.Cleaning the gut is one of the first steps in the practice of Hatha Yoga.

Studies have shown that Varisar Dhauti (LSP = Laghu Shankha Prakshalan) reduces Blood preassure, pain in the lumbar region, disability, anxiety and depression and increases spinal flexibility and quality-of-life in chronic low back pain (CLBP) patients.

Observations during the pilot studies on the yogic gut-cleansing technique called Varisar Dhauti, popularly known as laghu shankha prakshalana, appeared to be one of the most feasible, adoptable, detoxifying and safe methods in immediate reduction of (FBS) Fasting Blood Sugar levels in Diabetes patients.

Objective: To study the safety and effect of Varisar Dhauti, the yogic gut-cleansing technique in Diabetes patients.

Materials and Methods: This self as control study recruited 30 mild to moderate Diabetic patients.The study involved drinking lukewarm water (with or without a herbal combination of Triphala) followed by a set of specific yoga postures that would apparently move the water through the digestive tract and hold it, as per the capacity.

The practice was administered on the $4^{th}$and 6^{th} day. In this self as control study, 30participants who satisfied the selection criteria were given LSP with normal water and Tripahal water. All 30subjects were assessed on two occasions (4th and 6th day) before and after the practice of LSP either with normal water orwith Triphala water.

Results of these two days have been analysed.

Results: Data were analysed for fasting blood sugar levels in diabetes group after Varisar Dhauti (Laghu Shanka Prakshalana = LSP), the data were normally distributed in Triphala water LSP, paired sample T-test was conducted and the P- value is □0.001. and the data of Normal water LSP were not normally distributed, wilcoxan signed rank test was conducted and the P-value is 0.001, so reduction in fasting blood sugar level is more significant in Triphal water LSP compared to Normal water LSP. There were no adverse effects reported during or after the Varisar Dhauti. The number of visits to clear the bowel after the procedure was significantly higher after Varisar Dhauti with Triphala water than with normal water. There was an increase in comfort level and quality of sleep after both the sessions.

Note: Sampling was not randomized control, it was convenient sampling. Our aim was not to generalize the results of the study to the population.

CONCLUSION: This study provides the first evidence of immediate blood sugar levels afterYogic gut-cleansing kriyas. The study makes it clear thatboth Normal water and Triphala water can be used safely in patients suffering from DiabetesMellitus. Addition of Triphala to the water of Varisar Dhauti provides better cleansing and significant reduction in FBS. Thus Triphala seems to be more beneficial in reduction FBS as an immediate effect.

Three days of practice of exercises of the same specific set prior to the experiment was more useful in improving the subjective and probably even the objective measures of health in patients although this design has had a very high number of dropouts.

Key words: Yogic gut cleansing, hypertension, diabetes, Laghu shankha prakshalana, kriya, Triphala, yoga.

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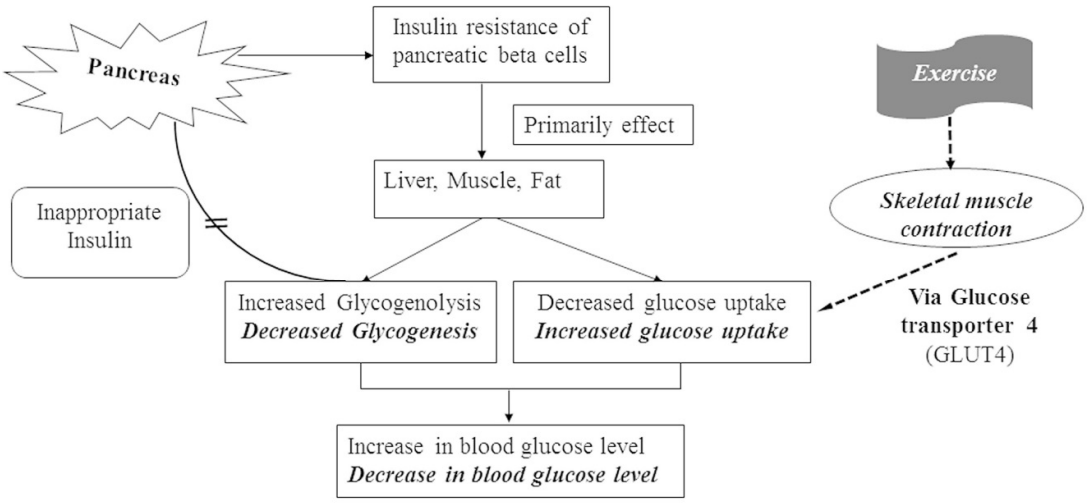
CHAPTER 1

INTRODUCTION

Modern style of living might have given man all comforts that he craved for, but in the meantime it has its darker side too. There is increasing prevalence of many metabolic disorders, lifestyle diseases, Obesity, Diabetes, Hypertension, etc.

The term Diabetes Mellitus describes a metabolic disorder of multiple etiologies, characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of Diabetes Mellitus include long-term damage, dysfunction and failure of various organs. Diabetes Mellitus may present with characteristic symptoms such as thirst, polyuria, blurring of vision, and weight loss. In its most severe forms, ketoacidosis or a non-ketotic hyperosmolar state may develop and lead to stupor, coma and, in absence of effective treatment, death. Often symptoms are not severe, or may be absent, and consequently hyperglycaemia sufficient to cause pathological and functional changes may be present for a long time before the diagnosis is made. The long-term effects of Diabetes Mellitus include progressive development of the specific complications of retinopathy with potential blindness, nephropathy that may lead to renal failure, and/or neuropathy with risk of foot ulcers, amputation, Charcot joints, and features of autonomic dysfunction, including sexual dysfunction. People with Diabetes are at increased risk of cardiovascular, peripheral vascular and cerebrovascular disease[1].

Type 2 Diabetes Mellitus



Several pathogenic processes are involved in the development of Diabetes. These include processes which destroy the beta cells of the pancreas with consequent insulin deficiency, and others that result in resistance to insulin action. The abnormalities of carbohydrate, fat and protein metabolism are due to deficient action of insulin on target tissues resulting from insensitivity or lack of insulin.

The new classification contains stages which reflect the various degrees of hyperglycemia in individual subjects with any of the disease processes which may lead to Diabetes Mellitus.

All subjects with Diabetes Mellitus can be categorized according to clinical stage, and this is achievable in all circumstances. The stage of glycaemia may change over time depending on the extent of the underlying disease processes. The disease process may be present but may not have progressed far enough to cause hyperglycemia. The etiological classification reflects the fact that the defect or process which may lead to Diabetes may be

identifiable at any stage in the development of Diabetes - even at the stage of normoglycaemia. Thus the presence of islet cell antibodies in a normoglycaemic individual makes it likely that that person has the Type 1 autoimmune process. Unfortunately there are few sensitive or highly specific indicators of the Type 2 process at present, although these are likely to be revealed as etiology is more clearly defined. The same disease processes can cause impaired fasting glycaemia and/or impaired glucose tolerance without fulfilling the criteria for the diagnosis of Diabetes Mellitus. In some individuals with Diabetes, adequate glycaemic control can be achieved with weight reduction, exercise and/or oral agents. These individuals, therefore, do not require insulin and may even revert to IGT or normoglycaemia. Other individuals require insulin for adequate glycaemic control but can survive without it. These individuals, by definition, have some residual insulin secretion. Individuals with extensive beta-cell destruction, and therefore no residual insulin secretion, require insulin for survival. The severity of the metabolic abnormality can either regress (e.g. with weight reduction), progress (e.g. with weight gain), or stay the same.

Costs include insulin maintenance, hospitalization, GP and out-patient consultations, renal replacement therapy, and payments to informal cares. Expenditure is concentrated on younger age groups and higher costs are directly attributed to IDDM, with the remainder associated with a range of complications of the disease.

Risk of Hypoglycemia and exercises:

Hypoglycemia is defined as blood sugar below 70 milligrams per deciliter (mg/dL) or 4 millimoles per liter (mmol/L).

Diabetic hypoglycemia is a low blood glucose level occurring in a person with diabetes mellitus. It is one of the most common types of hypoglycemia seen in emergency departments and hospitals.

Low blood sugar (hypoglycemia) can affect people who have diabetes. It occurs when there's too much insulin and not enough sugar (glucose) in your blood.

Several factors can cause hypoglycemia in people with diabetes, including taking too much insulin or other diabetes medications, skipping a meal, or exercising harder than usual.

Left untreated, diabetic hypoglycemia can lead to seizures and loss of consciousness. This is considered a medical emergency.

Early warning signs and symptoms

Early signs and symptoms of diabetic hypoglycemia include:

- Shakiness
- Dizziness
- Sweating
- Hunger
- Irritability or moodiness
- Anxiety or nervousness
- Headache

Nighttime symptoms

Diabetic hypoglycemia can also occur during leep.

Signs and symptoms include:

- Damp sheets or bed clothes due to perspiration
- Nightmares

- Tiredness,

irritability or confusion upon waking

Severe symptoms

If early symptoms of diabetic hypoglycemia go untreated, signs and symptoms of severe hypoglycemia can occur. These include:

- Clumsiness or jerky movements
- Muscle weakness
- Difficulty speaking or slurred speech
- Blurry or double vision
- Drowsiness
- Confusion
- Convulsions or seizures
- Unconsciousness

Diabetic hypoglycemia can increase the risk of serious even deadly accidents. Identifying and correcting the factors contributing to hypoglycemia, such as medications, exercises, irregular meal times, can prevent serious complications.

1.1 PREVALENCE OF NON COMMUNICABLE DISEASES (NCDs):

In countries like the United States, Germany, the United Kingdom and Japan, the prevalence of communicable diseases is much lower compared to chronic non-communicable diseases (NCD). In India, as in other low and middle income countries, Diabetes and other NCDs are relatively overshadowed by the continued burden of communicable and

nutrition-related diseases. While these health threats are still present (albeit, slowly decreasing), the rise of NCDs has been rather rapid. According to the World Health Report 2005, NCDs already contribute to 52 per cent of the total mortality in India and these figures are expected to increase to 69 per cent by the year 2030. Therefore, countries like India are currently facing an epidemiologic transition with a 'double burden' of disease as shown in Fig.

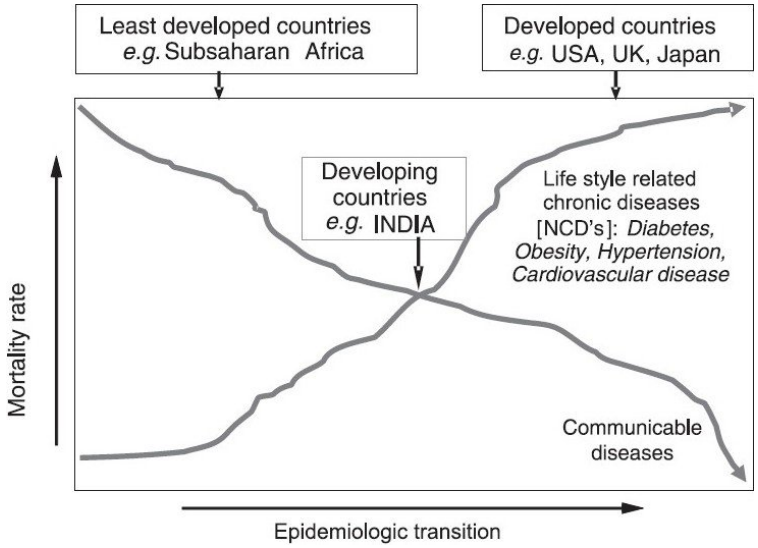


Fig: Epidemiologic transition of communicable vs non-communicable diseases.

Globally, many of the risk factors for NCDs are lifestyle related and can be prevented. Ebrahim & Smeeth et al conclude that NCDs in low and middle income countries are a priority and that it would be a serious mistake to ignore their prevention and control. Another study which looked at the burden of NCDs in South Asia reports that 'research and surveillance is urgently needed with new studies following more rigorous and standardized methods to assess the true extent and impact of NCDs in South Asia.[2]

The World Health Organization is urging health decision makers to develop effective prevention strategies to halt the rising trend of NCDs through the control of risk factors. Although most of the developed world has reacted by instituting pragmatic measures for risk factor control, the global burden of NCDs continues to grow. This is largely because developing countries like India provide the bulk of numbers of individuals with Diabetes and

other NCDs and in most developing countries the focus is still on infectious diseases and NCDs continue to be neglected. Thus, there is an urgent need for strategies to detect and control Diabetes and other NCDs in developing countries.[2]

1.1.1 DIABETES:

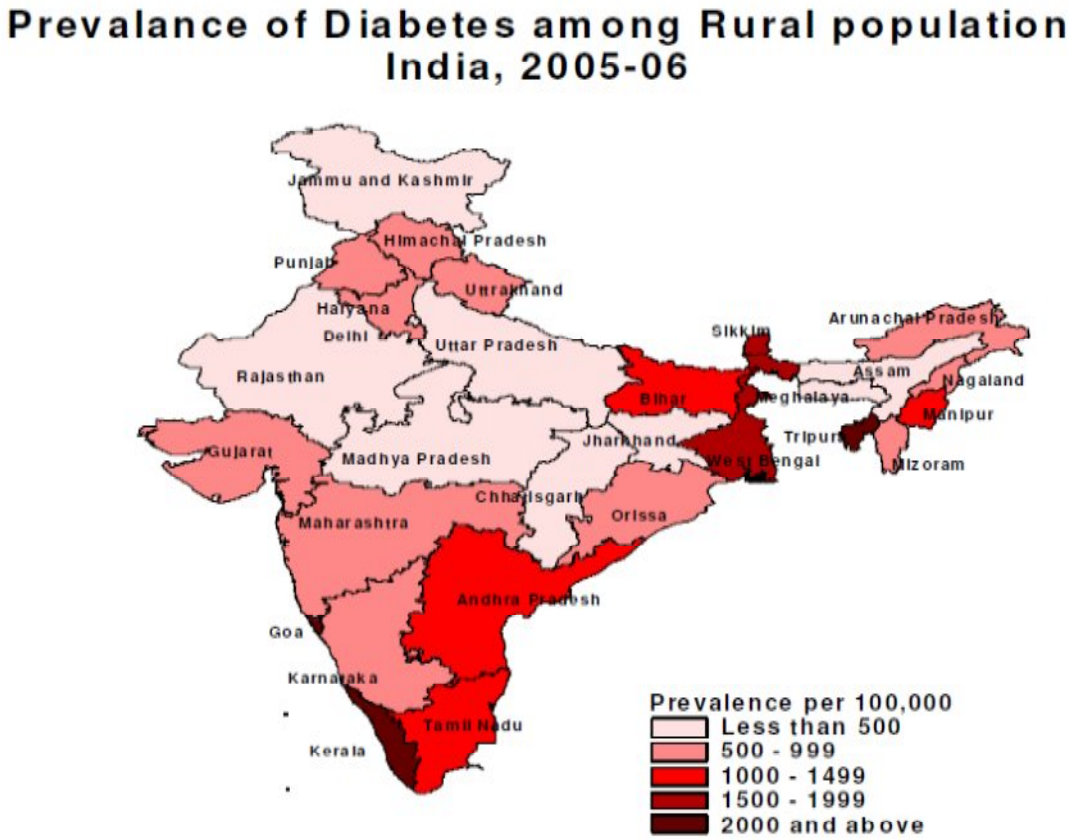
1.1.1.1 PREVALANCE OF DIABETES

Global Prevalence: The number of cases of Diabetes worldwide in the year 2000 among adults (≥20years) was estimated to be 171 million and will rise to 366 million by 2030 (Wild et al. 2013). In terms ofrank of countries for DIABETES prevalence, Ukraine (3.2 million) is at the bottom of the list, Pakistan (5.2million) comes at number six, China is second with 20.8 million people and India has the highest number(31.7 million) of people with rate of 3% for DIABETES (see Table-1).. The Pima Indians of Arizona in theUnited States (US) and have the highest prevalence rates (21%) of DIABETES (King et al. 1998; Knowler etal. 1978). A study by Ravussin et al. (1994) compared the prevalence of DIABETES in Pima Indians living inArizona to members of a population of Pima ancestry living in northwestern Mexico. In association withmarked lifestyle differences, the two genetically related populations had very different prevalence ofDiabetes. The Pima Indians living in Mexico were found to have a prevalence of 6% and 11%, for menand women, respectively, as compared to the frequency of 54% and 37% reported in the Pima Indiansliving in Arizona.[3]

Rank	Country	Year 2000 People with DIABETES (million)	Rank	No.Country	Year 2030 People with DIABETES(million)
1.	India	31.7	**1.**	India	79.4
2.	China	20.8	**2.**	China	42.3

3.	USA	17.7	**3.**	USA	30.3
4.	Indonesia	8.4	**4.**	Indonesia	21.3
5.	Japan	6.8	**5.**	Pakistan	13.9
6.	Pakistan	5.2	**6.**	Brazil	11.3
7	Russia**.** Fed	4.6	**7.**	Bangladesh	11.1
8.	Brazil	4.6	**8.**	Japan	8.9
9..	Italy	4.3	**9.**	Philippines	7.8
10.	Ukraine	3.2	**10.**	Egypt	6.7

Table-1: Top ten countries for number of persons with Diabetes(Wild et al. 2013)



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1.1.1.2 Economic Burden of Diabetes in India

Despite Diabetes being a life-long disorder and is expensive to manage and treat for the large proportion of subjects in developing societies, there is lack of data on its economic burden in India. In the Indiancontext the financial burden is often shared by relatives of the patients (Ramachandran 2007). The healthcare budget of the government in India is a meager 2% (Shobhana and Ramachandaran 2007) comparedto 14% to defense (Indian Budget 2010: http://indiabudget.nic.in/). The total amount needed for India totreat DIABETES is estimated to around 2.2 billion USD. (Ramachandran 2007). In India the direct medicalcost to identify one subject with insulin glucose tolerance is INR 5,278 (Ramachandaran et al.2007a). The cost of insulin amounts to 350.00 USD (16,000 Indian Rupees) per year, while medicationfor non-insulin-requiring patients costs about 70.00 USD per year (Shobhana and Ramachandaran 2007).In the Indian context these costs are prohibitive: 75.5% of the Indian population is earning less than $2per day and 41.6% less than $1.25 per day (Prabhakaran and Ajay 2009)[3].

Kumar et al. 2008 analyzed the community based data available from the middle and high income groupsin Delhi (DEDICOM survey) to determine the direct cost of ambulatory Diabetes care, to evaluate thesocio-demographic associates of spending, and to ascertain the relationship of spending with the deliveredquality of Diabetes care. They concluded that a majority of Diabetes patients spend a significant proportionof their family income on Diabetes related expenditure (~Rs. 6000 i.e. ~US$ 150) per year. The cost ishigher for subjects with longer duration since diagnosis, than those with higher education or income, thosewith co-morbidities and those requiring oral hypoglycemic agents or insulin.[3]

1.1.1.3 CLASSIFICATION OF DIABETES:

1. **Type 1** Insulin dependentDiabetes Mellitus(IDDM) characterized by destructive lesions of pancreatic beta cells either by an autoimmune mechanism or of unknown cause.[4]

2. **Type 2** or Non-insulin dependent Diabetes Mellitus (NIDDM) due to a combination ofdecreased insulin secretion and insulin sensitivity (insulin resistance).[4]

3. Diabetes due to specific mechanisms and diseases which includes two subgroups: [4]

a. Diabetes in which specific mutations have been identified as a cause of geneticsusceptibility and

b. Diabetes associated with other pathologic conditions or diseases.

4. Gestational Diabetes Mellitus characterized by onset during pregnancy.[4]

1.2 CLINICAL FEATURES:

In clinical practice, symptoms, examination and investigations are important to diagnose the disease. History and examinations are the fundamental things and they give evidence of the condition.[5]

1.2.1 Symptoms

Polyuria (increased frequency of urination), polydipsia (thirst), and polyphagia (Increased appetite) are the cardinal features of type 1 Diabetes. Patients can have other features like lassitude, nausea and blurred vision as well. These symptoms are due to the hyperglycemic state. Usually the onset is sudden. Disease maybe diagnosed following an infection. Usually patients are lean and present with features of ketoacidosis. History may reveal following features;[5]

1. Polyuria: this is due to osmotic diuresis secondary to hyperglycemia.
2. Thirst is due to the hyperosmolar state and dehydration.

3. Polyphagia with weight loss: The weight loss with a normal or increased appetite is due to depletion of water and a catabolic state with reduced glycogen, proteins, and triglycerides.
4. Fatigue and weakness: This may be due to muscle wasting from the catabolic state of insulin deficiency, hypovolemia, and hypokalemia.
5. Muscle cramps: This is due to electrolyte imbalance.
6. Nocturnal enuresis: Severe enuresis secondary to polyuria can be an indication of onset of Diabetes in young children.
7. Blurred vision: This also is due to the effect of the hyperosmolar state on the lens and vitreous humor. Glucose and its metabolites cause dilation of the lens, altering its normal focal length.
8. Gastrointestinal symptoms: Nausea, abdominal discomfort or pain, and change in bowel movements may accompany acute DKA. Acute fatty liver may lead to distention of the hepatic capsule, causing right upper quadrant pain. Persistent abdominal pain may indicate another serious abdominal cause of DKA, eg, pancreatitis. Chronic gastrointestinal symptoms in the later stage of Diabetes are due to visceral autonomic neuropathy.
9. Patients may maintain their normal weight or exhibit wasting, depending on the interval between the onset of the disease and initiation of treatment.
10. Peripheral neuropathy: It presents as numbness and tingling in both hands and feet, in a glove and stocking pattern. It is bilateral, symmetric, and ascending neuropathy, which results from many factors, including the accumulation of sorbitol in peripheral sensory nerves due to sustained hyperglycemia.

11. Symptoms at the time of the first clinical presentation usually can be traced back several days to several weeks; however, beta cell destruction may have started months, or even years, before the onset of clinical symptoms.

1.2.2 Examination findings

Usually physical examination is normal. If the patient present with Diabetes ketoacidosis, signs of Kussmaul respiration, dehydration, hypotension will be there.In established cases, patients should be examined every 3 months for macrovascular and microvascular complications. They should have funduscopic examination for retinopathy and monofilament testing for peripheral neuropathy[5].

1.3 COMPLICATIONS OF DIABETES

People with Diabetes have an increased risk of developing a number of serious health problems. Consistently high blood glucose levels can lead to serious diseases affecting the heart and blood vessels, eyes, kidneys, nerves and teeth. In addition, people with Diabetes also have a higher risk of developing infections. In almost all high-income countries, Diabetes is a leading cause of cardiovascular disease, blindness, kidney failure, and lower limb amputation.

1.3.1 Pregnancy complications: Women with any type of Diabetes during pregnancy risk a number of complications if they do not carefully monitor and manage their condition. To prevent possible organ damage to the fetus, women with type 1 Diabetes or type 2 Diabetes should achieve target glucose levels before conception. All women with Diabetes during pregnancy, type 1, type 2 or gestational should strive for target blood glucose levels throughout to minimize complications. High blood glucose during pregnancy can lead to the foetus putting on excess weight. This can lead to problems in delivery, trauma to the child and mother, and a sudden drop in blood glucose for the child after birth. Children who are exposed for a long time to high blood glucose in the womb are at higher risk of developing Diabetes in the future.

1.4 DIFFERENTIAL DIAGNOSIS:

The confirmation of chronic hyperglycemia is a prerequisite for the diagnosis of Diabetes Mellitus. The staging (Albertietal,1998)of glycemia falls under three categories: diabetic type; borderline type; and normal type.

1..Diabetic type

Fasting plasma glucose (FPG) of 126 mg/dl or higher, and or Plasma glucose 2hours after 75 g glucose load of 200 mg/dl or higher and/or a casual plasma glucose (PG)≥ 200 mg/dl also indicates diabetic type.

2..Normal type

FPG is below 110 mg/dl and 2hr PG below 140 mg/dl. These cut off values are for venous PG measurement

3.**Borderline type or Pre-Diabetes**

This includes those who are neither diabetic nor normal types. Pre-Diabetes isa stagebetweennormalandDiabetesstage.Othertermsforthese areBorderline Diabetes, Chemical Diabetes, and Touch of Diabetes. About 11 percent of people with pre-Diabetes in the Diabetes Prevention Program standard or control group developed type 2 Diabetes eachyear during the average 3years of follow-up. Decreasing the cutoff for impaired fasting glucose from 110 mg/dl to 100 mg/dl could increase diagnoses of pre Diabetes by approximately 20%.

4.Gestational Diabetes Mellitus characterized by onset during pregnancy.

Currently, Diabetes and preDiabetes screening is recommended by the ADA for patients with risk factors for the disease including obesity, age 45 years or

older,familyhistory,orgestationalDiabetes.Ifthetestisnormal,retestingis recommended every three years. IfpreDiabetes or impaired glucose tolerance is diagnosed, there is a higher risk of developing Diabetes within 10 years and lifestyle modification is recommended (Diabetes Care, 1997).

1.5 APPROACHES TO MANAGEMENT OF DIABETES IN MODERN MEDICINE:

Diabetes is a chronic condition that requires continuing medical care and self-management in order to minimize the risk of complications and mortality. The goals of treatment are (Norris et al. 2008),

1. To achieve optimal glycemic control;

2. To reduce other cardiovascular risk factors, including hypertension, hyperlipidemia, and overweight and obesity; and

3. To diminish complications such as heart disease, peripheral vascular disease, renaldisease, and neuropathy. DIABETES may be treated by diet and exercise, often combined with 1 or more oral hypoglycemic agents. Optimal treatment, however, may require the use of insulin with or without oral agents. Among adults with diagnosed Diabetes, the current distribution of types of treatment is as follows: 12% use both insulin and oral drugs, 16% use insulin only, 57% use oral agents only, and 15% do not use pharmacotherapy (Norris et al. 2008)

Periodic monitoring of conditions and complications[6]

Condition/complication	Test(s)	Frequency
Hypertension	BP taken with appropriate size cuff using optimal technique	Every visit
Blood glucose control	HbA1c	Every 3 months until the target level is reached; thereafter, patients should be monitored at least every 12 months

Foot ulcers	Physical exam focused on ankle reflexes, dorsalis pedis pulse, vibratory sensation, and 5.07 monofilament touch sensation performed by a provider qualified to determine the level of risk for foot ulcers	Patients at **very high risk**2 should be seen every 3 months by a wound care nurse Patients at **increased risk**2 and **average risk**2 should be screened annually
Microalbuminuria	Micro albumin/creatinine ratio1	Annually
Hyperlipidemia	Fasting LDL	Annually
Retinopathy	Dilated eye exam by a trained eye services professional **or** Nondilated digital photography followed by a comprehensive exam for those who test positive	Patients **with** evidence of retinopathy should be screened annually Patients **without** evidence of retinopathy should be screened every 2 years3
Electrolyte and chemistry abnormalities	Serum creatinine **and** Serum potassium	At least annually

1 The micro albumin/creatinine ratio test can identify patients with microalbuminuria by giving a quantitative estimate of protein loss that correlates with 24-hour urinary protein measurements. Test results are expressed in micrograms of urinary albumin per milligram of urinary creatinine (or A:C ratio). A positive test is more than 30 mcg/mg. Two positive tests are diagnostic for micro albuminuria, ideally 3–6 months apart.

3 Annual screening is not recommended because the benefits of more frequent screening are marginal: For every 1,000 persons screened annually (instead of every second year), one additional case of proliferative diabetic retinopathy and one additional case of clinically significant macular edema will be detected.

Medication monitoring[6]

Monitoring for medication side effects

Eligible population	**Test**	**Frequency**
Patients who are being treated with metformin1	Serum creatinine	Annually if serum creatinine is 1.5 or lower **or** Twice a year if serum creatinine is higher than 1.5

1 For patients on metformin, serum creatinine should be monitored because the medication is primarily excreted by the kidney. Metformin can be prescribed if the serum creatinine is lower than 2.5 and if the eGFR is higher than 30, provided this value is not 25% worse than the previous reading. Use of concomitant medications that may affect renal function (i.e., affect tubular secretion) may also affect metformin excretion. **Metformin should be withheld in patients with dehydration and/or prerenal azotemia**; also hold prior to radiologic procedures (i.e., studies requiring administration of IV contrast) and prior to surgery.

1.6 LIFE STYLE CHANGE:

1.6.1 Diet and physical activity

There is some evidence that intensive programs of lifestyle interventions targeting patients with impaired fasting glucose reduce the incidence of type 2 Diabetes. Lifestyle interventions include dietary and physical activity counseling[6].

All patients should strive to:

- Make smart choices from every food group to meet their caloric needs.
- Get the most and best nutrition from the calories consumed.
- Find a balance between food intake and physical activity.
- Get at least 30 minutes of moderate-intensity physical activity on most days.

For patients who have been inactive, recommend slowly working up to at least 30 minutes of moderate physical activity per day. If they are unable to be active for 30 minutes at one time, suggest accumulatingactivity in 10- to 15-minute sessions throughout the day.

1.6.2 Weight management, including bariatric surgery

There is fair evidence from one RCT that surgically induced weight loss results in better blood glucosecontrol and less need for diabetic medications than conventional Diabetes therapy focused on weight lossthrough lifestyle changes[6]. There is insufficient evidence on long-term effectiveness and safety (Dixon2008). Evidence from a large cohort study suggests

that failure to sustain blood glucose control is anadverse predictor of Diabetes relapse after surgery (Arterburn 2013).

1.7 NEED FOR THE PRESENT STUDY

According to Ayurveda and yoga, health is a state of balance and disease is imbalance. Treatment of a disease involves restoration of balance by considering many factors that are involved in producing the imbalances in the body. The imbalances are said to be caused by life style which results in production of endotoxins (*āma*), the result of improper digestion. The therapy aims at clearing these toxins from the tissues by increasing the elimination of the three *malas* (excreta), the feces, urine and sweat. Hence, according to yoga and *āyurveda*, clearing the bowel through either physical techniques called *kriyās*/ *panchakarmas* or use of herbal preparations as medication, is mandatory in the management of all chronic diseases.

During the pilot studies

1) *kriyā called Shankha Prakshalan*was taught and FBS was measured as an immediate effect. As this technique was very strenuous it was not feasible to the attending patients. Some developed body pain and had to give up the practice. Normal healthy adults who completed the Shankha Prakshalan also got slight lower blood sugar level for a few hours. Hence we had to look for simplified versions of the same.
2) In one of the experiments, hypoglycaemia patients participated. Their blood sugar level increased after LSP to normal.
3) Other experiment included use of saline water LSP but many Diabetics are Hypertensive and it was not possible to continue the study due to risk of increase in Blood pressure.

Hence *Laghu śankha prakśālana* with Normal water was tried and found to be safe with add on benefits. *Āyurveda* recommends the use of*Triphalā*, an herbal preparation as a mild laxative for

clearing the bowel. There are no published studies on the safety or effect of Varisar Dhauti (LSP) in patients with Diabetes. Hence the present study was planned to look at the feasibility, safety and also the add-on effects of Varisar Dhauti (LSP) and LSP with *triphalā* water, in a non-residential set up for patients with Diabetes.

CHAPTER 2

REVIEW OF LITERATURE (Ancient research)

2.1 YOGA:

Yoga is the original mind-body medicine that has enabled individuals to attain and maintain *sukha sthanam,* a dynamic sense of physical, mental and spiritual wellbeing. Bhagavad-Gita defines Yoga as *samatvam* meaning thereby that Yoga is equanimity at all levels, a state wherein physical homeostasis and mental equanimity occur in a balanced and healthy harmony.

2.1.1 DEFINITION OF YOGA

Patanjalidefines in hissecond patanjali's aphorism as 'yogais process of gaining mastery over modifications of the mind '.

योगःचि वृ निरोधः॥पयोसू१।२

yoga□ citta v□ttinirodha□ ||Pa Yo Sū1|2

Then goes on to describe the mastery in the next sutra: 'The seer estblishes himself in his causal true state'.

तदा ः व पेऽव ॥पायोसू१।३

tadā dra□□u□ svarūpe'vasthānam|| Pa Yo Sū1|3

In Yoga Vaśis□ha the essence of yoga is beautifully portrayedas: 'Yoga is a skillful trick to calm down the mind'. It is an upāya, a skillful subtle process and not a brutal, mechanical gross effort to stop thought in the mind.

मनः शमनोपायःयोगइ याभिधियते।योगवासि ः

mana□ praśamanopāya□ yoga ityābhidhiyate|Yogavāsi□□ha□

Yoga Vasistha defines Yoga as balance or equinity.

सम वंयोगउ यते।भगी२।५८

samatva□ yoga ucyate| Bha. Gī .2|48

Krishna goes on to say that Yogaisa capacity to function in a relaxed state: 'yoga is dexterity in action'. Dexterity refers to maintaining relaxation and awareness during work. Relaxed action is the process. Efficiency in action is an outcome. Action in relaxation is the skill49.

योगःकम सुकौशलम्भगी२।५०

yoga□ karmasu kauśalam|Bha. Gī .2|50

Ka□hopaniśaddefines Yoga as the state in which all our sense organs (indriyās) are beheld steadily; i.e.this is a stateof mastery over all senses including the mind.

तांयोगमितिम य ते ्थिराम यधारण्मम्

tā□ yogamiti manyante sthirām indriya dhara□ām| ka□hopani□at 2|54

Thus, the subtler state of mind featured by 'steadiness' is referred to as Yoga. Yoga is a state of great steadiness at emotional level; balance of concentration and detachment at mental level and homeostasis at body level. It integrates the personality by bringing body-mind coordination in a well-balanced way.

2.2 SHATKARMAS: (Cleansing as the first step to purification.)

The Shatkarma or the six purification techniques in Hatha Yoga are designed to make the body strong and healthy. 'Shat' means six and 'Karma' here means a method or technique. Shatkarmas are considered preparatory steps towards higher practices of Pranayama and Meditation. The ancient Rishis recognized the importance of a healthy body for all activities, whether worldly or spiritual. Hatha Yoga, as explained in the texts'Gherand Sanhita,Hatha Ratnavali &Hatha Yoga Pradeepika', is aimed at making the body and mind fit for higher practices of Raja Yoga.

The Shatkarmas apart from spiritual & psychological benefits, make the body clean and strong, free of diseases, remove toxins and improve concentration. These techniques can also improve the flow of prana into the organs and the pranic meridians or nadis. The six techniques are – Dhauti, Bhasti, Neti, Trataka, Nauli and Kapalabhati. All these techniques should be learned from an experienced teacher. Here is a list of all the kriyas Hatha Yoga texts.

DHAUTI	**Antar dhauti**vatsara (plain) (internal) varisara (shanks-prakshalana) vahnisara (agnisara kriya) bahiskrita (rectal cleaning)
	Danta dhauati jihva (tongue) (teeth)karna (fear) kapalrandhra (frontal sinuses) chakshu (eyes)
	Hrid dhauti vastra (cloth) (cardiac) danda (stick)

	vaman (kunjal & vyaghra kriya)
	Moola shodhana (anal)
BASTI	**Jala** (water) **Sthala** (dry)
NETI	**Sutra** (thread) **Jala** (water) **Dugdha** (milk) **Ghrita** (ghee)
TRATAK	**Antaranga** (internal) **Bahiranga** (external)
NAULI	**Dakshina** (right) **Vama** (left) **Madhyama** (middle)
KAPALBHATI	**Vatakrama** (breathing) **Vyutkrama** (reversed) **Sheetkrama** (cooling)

Intervention chosen for Diabetes is Varisar Dhauti.There have been many benifits of cleansing the digestive system.

2.3 घेर ड सं हता

ghera□□a sa□hitā

आक ठंपूरये ा रव `णच पबे नेः।

चालयेदुदरेणेवचोदरा `चयेदधः॥घे सं १।१७

āka□□ha□ pūrayedvāri vaktre□a ca pibecchne□ |

cālayedudare□eva codarādrecayedadha□ ||ghe sa□ 1|17

Laghuśankhaprakśālana can be correlated with Vārisāra Dhauti which according to Ġheran□aSa□hitā, one of the types of antara dhauti. In Vārisāra Dhautithe mouth is filled with water and drank slowly, then forced down through the stomach, and expelled downwards through the rectum. VārisāraDhauti is said to be the highestDhauti and one who practices it with ease, purifies his filthy bodyand turns it into a shining one.

One of the main commentators of Ha□ha YogaPradipika, Swami Muktabodhananda, correlated the Varisāra Dhauti to śankhaprakśālana. In this practice the practitioner should drink stomach full of water and evacuate it through the bowel by performing a series of practices like waist rotation, spinal twist, utkatāsana, ardhakatichakrasana, heal & toe walk, crow walk etc. And after every two glasses of water the asana should be performed until the water starts flowing out through the anus. Once clear water starts coming through anus then practice is stopped & then rest is advised.

There is a shorter technique called Laghuśankhaprakśālana. Laghu means ‘short’. In this practice drink stomach full of water once then perform a series of practices & evacuate it through the bowel.

वा रसारंपरंगो यंदेहन्नेम लकार्क्कम

साधये य `नदेवदेहं प ते॥घे सं १।१८

vārisāra□ para□ gopya□ dehanermalakārakam |

sādhayettatprayatneena devadeha□ prapadyate ||ghe sa□ 1|18

2.4 हठ दपीका

ha□hapradipīkā

Hatha Yoga Pradipika also states importance of cleaning the digestive track through kriyas.

कास ास ली कु ंकफरोगा वंशतिः।

धौतिकम भावेण यां येवनसंशयः॥ह २।२५

kāsaśvāsaplīhaku□a□ha□ kapharogāśca vi□śati□ |

dhautikarmaprabhāve□a prayā□tyeva na sa□śaya□ ||ha pra 2|25

There is no doubt that coughs, asthma, diseases of the spines leprosy and twenty kinds of- diseases caused by excess mucus are destroyed through the effects of Dhauti karma.

The combination of all the practices of Dhauti cleans the entire digestive tract and respiratory tract. It removes excess and old bile, mucus and toxins and restores the natural balance of the body's chemical composition, thus alleviating ailments caused by such

imbalances. The various practices help remove infectious bacteria from the mouth, nose, eyes ears, throat, stomach, intestines and anus. The results are reduction of excess fatty tissue and relief from flatulence constipation, poor digestion and loss of appetite.

यदा तु नाड शु दः या था चि ानि बा तः ।

काय य कृशता का त तदा जायेत नि ं ॥ ह म २।१९

yadā tu nā□īśudhdi□ syāttathā cihrāni bāhyata |

kāyasya kruśatā kāntistadā jāyeeta niścitama ||ha pra 2|19

When the nadis are purified there are external symptoms. Success is definite when the body becomes thin and glows.

मे ` माधिकःपूव ष कमा ण्समाचरेत

अ य तुनाचरेतानिदोषाणांसमभावतः॥ह २।२१

medaśle□mādhika□ pūrva □a□akarmā□i samācareta |

anyastu nācaretāni do□ā□ā□ samabhāvata□ ||ha pra 2|21

When fat or mucus is excessive, shatkarma: the six cleansing techniques, should be practised before (paranayama). Others, in whom the doshas, i.e. phlegm, wind and bile, are balanced, should not do them.

There are three humors in the body classified as Kapha ‘mucus’, Pitta ‘bile’ and Vata ‘wind’.

In Yoga and Ayurveda they are called as Tridosha. A balanced proportion of these three facilities body functions, but if there is an excess of one and a shortage of another, aliments develop due to overheating or lack of heat in the body.

धौतिब त तथानेति ाटकंनौलिकंतथा।

कपालभाति ैतानिष कमा ण च ते॥ह २।२२

dhautirbastistathā netistrā□aka□ naulika□ tathā |

kapālabhātiścetāni □a□a karmā□i pracak□ate ||ha pra 2|22

Dhauti, basti, neti, trataka, nauli and kapalbhati; these are known as shatkarma or the six cleansing processes.

कम ष कमिदं गो यं घ शोधनकारकम ।

वचि गुणसंधायि पु यते योगिपुंगव॥ ह २।२३

karma□a□akamida□ gopya□ gha□aśodhanakārakama |

vicitragu□asa□dhāyi pujyate yogipu□gava□ ||ha pra 2|23

These shatkarma which effect purification of the body are secret. They have manifold, wondrous results and are held in high esteem by eminent yogis.

The shatkarma are very powerful practices that cannot be learned from books or taught by inexperienced people.

There is another technique called Basti which also cleans the digestive track.

नाभिद जलेपायौ य तनालो कटासनः।

आधाराकुंचनंकुया ा नंब त्कर्म ततर२।२६

nābhidaghrajale pāyau nyastanālotkatasan□ |

ādhārāku□cana□ kuryātk□ālna□ bastikarma tat||ha pra 2|26

Sitting in utka□āsana□, navel deep in water, insert a tube into the anus and suck the water into the intestine. This cleansing with water is called Basti.

2.4.1 IMPORTANCE OF VARISAR DHAUTI (LAGHU SHANKHA PRAKSHAN)

गु म लीहोदरंचा पवात प कफो वाः।

ब तकम भावेण ीय तेसकलामयाः॥ह २।२७

gulmaplīhodara□ cāpi vātapittakafodabhavā□ |

bastikarmaprabhāve□a k□īyante sakalāmayā□ ||ha pra 2|27

Enlargement of the glands and spleen, and all diseases among from excess wind, bile and mucus are eliminated from the body through the practice of basti.

Varisar dhauti cleans the digestive system and thus can be interpreted to have similar benefits like Basti.

धा वं या तःकरण सादंदघा चकांतिंदह्न्ा द ि म

अशेषदोषोपचयंनिह याद य यमानंजलबं तकम ॥ह २।२८

dhātvi□driyānta□kara□prasād□ daghācca kā□ti□ dahanapradīptim |

aśe□ado□opacaya□ nihanyādabhyasyamāna□ jalabastikarma||ha pra 2|28

By practising jala basti the appetite increases, the body glows, excess doshas are destroyed and the dhatus, senses and mind are purified.

Basti completely washes the bowel and removed excess bacteria, old stool, threadworms and heat from the lower intestines.

Varisar Dhauti(Laghu Shankha Prakshan) can also be adopted and individualized to have similar effect as both methods focus on cleaning the digestive system.

2.5 हठर ावली

ha□haratnāvalī

अथवापी वाकंठंसतिगुडजलनालिकेरोदकंवा

ीरांभोवायुमाग पव जलयुतःकुंभये ाथश या

नि शेषंशोधयि वाप रभवपवनोव तवायु ्काशात

कुंभा भःकंठनालेगु गजनिकरणी ो यतेयंहठा॥५०॥

Athavāpītvāka□□ha□sati gu□ajala nālikerodaka□ vā

k□īrā□bho vāyumārge pavanjalayuta□ ku□bhayedvāthaśatkyā

niśśe□a□ śodhayitvā paribhavapavano vastivāyuprakāśāt

ku□bhāmbha□ ka□□hanāle gurugajanikara□ī procyateya□ ha□hajnai 1||50||

OR By Drinking sweet Jaggery water, coconut water or milk with water upto the neck and retaining water and air both according to the strength one should wash out from top to

bottom.After purifying thoroughly, to control ‘Pavana”, one should pass the air through Vasti marga.

Hatha Ratnavali also explains the technique of cleaning the digestive system as follows.

2.6 ĀMA:

Āma is often loosely translated as undigested food resulting from a process that is entirely gastrointestinal. A careful study of the texts, however, indicates that the production of Āma is a systemic process that extends to metabolic and other physiological processes in the body.[1]

2.6.1 CONCEPT OF ĀMA ACCORDING TO AYURVEDA:-

आहर यरसःशोषोयोनप वोऽ नलाघ्ववात

समूलंसव रोगाणाम्आमइ यभिधीयते॥मानि२५।१३

āharasya rasa□ śo□o yo na pakvo'gnilāghavāt|

sa mūla□ sarva rogā□ā□ āma ityabhidhīyate|| Mā Ni | 25|13

The final product of the āhāra rasa which does not get properly transformed due to feeble digestive fire is called āmaand is considered as the root cause of all diseases.[1]

Hence āmacan be considered as an undigested or partially digested/metabolised substance which requires further process (pari□āma)and if retained as such it may produce impairement in the micro and macro channels of the body (srotovaigu□ya). This ultimately leads to accumulation of the provoked dośa’s converting it in the form of any disease. Thus,āyurvedahas given much importance to the concept of āma thanāmaya (disease) which is only the end product of accumulation of āma; āmain allacute, sub-acute or chronic conditions relates to the gastro-intestinal as well as metabolic disturbances engendered due to impairment of antarāgni.[1]

In particular, and hence said to be a toxic by product (generated due to improper digestion) that results in diseases. These can be correlated to different types of cellular toxins, reactive oxygen species and excessive inflammatory markers[1].

2.6.1.1 Definition of āma according to Āyurveda.

ऊ मणोऽ पबल वेनधातुमा ामपाचितम

दु मामाशयगतंरसमाममं च ते॥

अ येदोषे यःएवातिदे योऽ यो यमूछ नात

को वे यो वष येववद याम य अ भसूभ ।२४

ū□ma□o'alpa balatvena dhātu mādyāmapācitam|

du□□amāmāśaya gata□ rasamāma□ pracak□ate||

anye do□ebhya□ evāti du□□ebhyo'nyonyamūrchanāt|

kodravebhyo vi□asyeva vadantyāmasya sambhavam|| A H□Sū 13|24

Due to hypo-function of ū□mā (agni), the food which is not completely digested, yields immature rasa in āmāśayaand due to its retention, undergoes fermentation. The resulating substance called āma. Other description of āmarefers to āmathat is produced in āmāśaya, the word āma also has a generalized meaning which can be applied to any sort of working agni in body.[1]

आमाशय थःकाया नेदौब याद वपाचितः।

आ आहारधातुय ःसआमइति कति तः॥मानि२५।१

āmāśayastha kāyāgne daurbalyādavipācita|

ādyam āhāradhāturya sa āma iti kirtita| Mā Ni 25|1

Due to the feebleness of kāyagni, the āhāra rasais not properly formed in the āmāśayaand in this state it is known as āma. In other sense it is also told that the first dhātu i.e. rasa dhātu, if not formed properly, then this uncovered rasa dhātu is termed asāma[1].

Properties of āma (āmagu a's):

अ वप वमस युग द धुंबह्म छलं।

सदनंसव गा ण्ह्मामइ यभिधियते॥ (अ णद अ सू१३

Avipakva masamyukta durgandha bahuapicchila|

sadana sarvagātra ā āma ityabhidhiyate|(Aru adatta A H Sū 13)

Avipakkvam (incompletely transformed) – This property of āma is quite clear from the definition and etymology of āma. The production āmaoccurs due to malfunction of agni; the undigested or improperly digested substance lies in incomplete metabolic state; this is termed as āma; this is described by the word avipakkvam[1].

Asamyukta (non-homogeneous) – Though āma has properties likepicchila(slimy) andsnigdhata (unctuous) due to which it sticks quickly to the other body tissues,asamyukta property refers to the stage ofāma when it is just formed and is non-assailable to tissues due to incomplete metabolism. at this stageāmalies in its free state, and after some time if not digested or excreted from the body, adheres to tissue. Thus , the intermediate state, when it lies freely in the tissue is indicated by asamyukta [1].

Durgandha□ (Foul smelling) – Every dravya in the body has its specific odor. Thoughāma is also made up of samedravya's there is a change in normal structure due to incomplete metabolism. As a result of these changes in structure it has different smell than normal body structure and usually this smell is foul in nature. Also due to fermentation and putrification occurring in the formation of āma it has bad odor. This property ofāma is descibed by durgandha□[1].

Picchilam(slimy) According tohemadri, definition of picchila gu□a is yasya lepaneśakti□ sa piccila□ i.e. that substance which is capable of coating is called is called as picchila. Due to this property āma sticks to healthy body tissue. Due to this property it adheres to the srotas, to different dośa dusyaand malas (vagbha□a).

Sadana□ sarvagātrā□ā□: āmahas drava gu□a (caraka) and due to this property āmaspreads in every part of body.

2.6.1.2 Symptoms of āma accumulation in the body (āmalak□a□ās):

ोतोरोधबल ंशगौरवानिलमूटता

आल याप नि वमलस गा चि लमाः॥अ सू१२।२३

srotorodhabalabhra□śagaura vānilamū□atā|

āla syāpattini□□hivamalasa□gāruciklamā□|A h□Sū 12|23

Srotorodha(Obstrution in the channels of circulation) – Normal functioning of srotas is very important in maintaining health. Due to the properties likepicchilam, snigdhata etc.āmaadheres to walls of srotasand as aresult the lumen of srotasbecome narrowed. Once this narrowing of lumen occurs, the normal functioning of srotas gets disturbed and this leads

to disease. This mechanism is common to both micro and macro channels, and accordingly disease of that particular srotas is produced[1].

Balabhra□śa(loss of strength) - It is due to the systemic effect of āma that circulates in the body. Balabhra□śa also occurs because of lack of proper nutrition; thus the working power of dośa, dhātuandmala'sthroughout the body is reduced that results in balabhra□śa[1].

Gaurava (Heaviness): āmacauses heaviness in the whole body and/or different parts of the body. When āma accumulates at different sites this heaviness is felt.[1]

Anilamū□atā□(restricted movement ofvāyu - āma causessrotorodha in srotasand hence there is an obstruction to the normal flow through the lumen. Due tosrotorodha, free flow of vāyu becomes obstructed and that condition is termed as anilamū□atā□[1].

Ālasyā (Stupor) - This due to psychological effect produced by the presence ofāma along with its effect of guruta etc. Patient suffering from āma gets disturbed psychologically and becomes unable to perform this normal body activity, which is known as ālasyā.[1]

Apatti (Incomplete digestion) - The production of āmasets off a vicious circle. Due to this agnimāndya āma is produced. Now this āma again causes further agnimāndyaand hence this symptom of appetite is seen. It appears to refer to metabolic impairment taking place due to effect ofāmaat micro level.[1]

Nis□hiva(Spitting/expectoration) - When food is not digested properly a reflex is set which increases salivary secretions and results in frequent spitting.[1]

Malasanga (obstruction to the movement of waste products)- This is again due to srotorodha at mahasrotas level. Also due to properties of picchilam, snigdhataand guruta, themala(waste product) produced after completion of ja□harāgni, sticks to the walls of

intestines and is difficult to expel out. At micro levels also the same processes occur. Due tosrotorodha and sticking nature of sāma mala,malasangatakes place.[1]

Aruci - This shows the effect of sāma (associated with dośa/dhātu/ malawithāma) over psyche. Due to improper digestion etc.Patient have loss of desire for taking food[1].

klamā□(Debility)- In this state patient feels exhausted without doing work. Again this is due to damage caused in the entire body by the circulating āma[1].

There are the main symptoms produced due to presence of āmain the body at various levels. The association of these symptoms along with signs and symptoms of disease help in diagnosing a disease as sāma or nirāma. The treatment of a disease is based on this diagnosis[1].

2.6.2 TYPES OF ĀMA:

Sāmavāta:

वायःसामो वब ध नसाद त ा कुजनौः।

वदनाशोथानिर तोदौः मशोऽङ्गानि पढ्ाेत

वचरेतयुगप चा पगृ ातिकु पत्ो ुशम

नेहा ॅ ु मा नोतिसुय मेघोदयेनिशि॥माधवनिदानमधुकोश१।४

vāya□ sāmo vibandhagnisādastandrāntrakujanau□|

vadanāśothānirastodau□ kramaśo'□agāni pi□hayet||

vicareta yugapat cāpi g□hvāti kupito bhruśam|

snehādyaivruddhimāpnoti suryameghodayeniśi|| mādhava nidānamadhukośa 1|4

Sāmavāta produces obstructions in the passages and various movements of organs and channels. This produces symptoms such has loss of appetite, drowsiness, borboregmi, pain, edema, pin prick sensation, peeling type of pain in the body and /or pain in different parts of the body. These symptoms are aggravated by oleation in the morning, at night, and during cloudy time.[1]

Nirāmavāta:

निरामो वषदो ोनि व ब धोऽ पवेदनः।

वप रतगुणौशा त न धौया ति वषतः॥माधवनिदानमधुकोश१।४

nirāmo vi□ado ruk□o nirvibandho'lpavedana□|

viparitagu□au śāntim snigdhauryāti vi□ata□|| mādhava nidāna madhukośa 1|4

Nirāma vātais a state of vitiatedvātain which obstruction due to āma is removed. Therefore it shows only the symptoms of aggravation of vātaand not those of abnormal movements or actions. Hence aggravation of the normal qualities of vātais observed e. g. Dryness, mild pain and ache etc. which can be removed by oleation treatment.[1]

As āma is the root cause of all the diseases so in order to treat the diseases one should get rid of the accumulated āma first and then should avoid the all possible causes of āma formation.[1]

2.6.3Treatment of āma (āma cikitsā):

आमंजये ल घनंको णपेयल व न ौदनति युषौःनि हेनैः वेदनपाचनै ंशोधनैत व म तः॥योगर ाकरः॥

āma□ jaye lla□ghana□ ko□□a peya laghvanna ruk□audana tikta yu□au□ niruhenai□ svedana pācanaiśca sa□śodhanairūrdhvam adha□stata□|| yogaratnā kara□

Ayurveda explains several remedies forāma treatment which involves three main procedures. First is the use of la□ghana(fasting) which helps in load shedding on agniand arrests the formation ofāma. Second is the use of dipana dravya(fire enhancer) which helps in improving the status of agni and enhancing its action. Next is pācana, done withpācana dravya.pācana dravya(appetizer) helps in digestion of already producedāma. The last step is samśodhana(purificatory procedures)which involves the use of purificatory procedure in order to remove out the āma which is accumulated. Inpancakarma virecana (therapeutic purgation)is one of purificatory process to expel toxins through the rectum. The Varisar Dhauti kriya has similar actions.[1]

2.7 TRIPHALA

Suśruta mentioned Triphala as a specific ga□a (specific group of medicinal herbs having similar properties). Description of Triphala and its application is found in all āyurvedaic texts. It is often said by traditional vaidyas that Triphala alone can treat 50% of cases in clinical practice[1];

Triphala is a group of three medicinal fruits as below:

(1) Haritaki (Terminalia chebula)

(2) Āmalaki (Emblica officinalis)

(3) Vibhataki (Terminalia bellirica)

These are also known as ‘phala traya or ‘varga’.

It is essential to note that the ratio in which the 3 phalās are to be mixed is not quite clear.

According to suśruta	: Haritaki: āmalaki: vibhataki	= 1:1:1
According to Bhavamishra	: Haritaki: āmalaki: vibhataki	= 1:1:1
According to cakradatta	: Haritaki: āmalaki: vibhataki	= 1:2:4
According to Yogaratnākar	: Haritaki: āmalaki: vibhataki	= 1:2:4

The traditional approach is to accept an equal volume or the weight of the fruit pulp (dried) i.e., 1:1:1.

In this study, we have used the traditional formulas of 1:1:1

2.7.1 Properties of Triphalā : kapha pittahara, cakcuśya, rasāyana

Indications: prameha, kusta, agnimāndya, netraroga, viśāma jvara, śotha, kapha pittahara, cakcuśya, rasāyana, prameha, kusta, agnimāndya, netraroga, viśāma jvara, śotha, malaband.[1]

According to research evidence, Triphalā has a wide spectrum of medicinal value with be diuretic effect in nature, mild laxative effect studies have shown that it prevents functional constipation in healthy individuals , prevents bleeding in bleeding piles , has antidiabetic , anticataract , anticarcinogenic , antibacterial , antidental plaque , ant gout properties; wound healing and enhances the liver and spleen functions , prevents radiation induced acute intestinal mucosal damage , inhibits vascular endothelial growth and may prevent the occurrences of stroke ; reduces bronchial hyperactivity and immune modulation[1] .

Vibhitaki

āmalaki

Fig.1.Three fruits *of triphalā*

CHAPTER 3

SCINTIFIC LITRATURE

3.1 MODERN SCIENTIFIC RESEARCH

Randomized Control Trials (RCTs) in Diabetes: Montori's et al. 2006 systematic assessment of RCTsin diabetes found that RCTs trend to be published in pertinent top journals, both general and specializedand, have important deficiencies in reporting of key methodological features (not closely adhering toCONSORT guidelines i.e. Consolidated Standards of Reporting Trails). These deficiencies are mostcommon in laboratory investigations and RCTs that measured patient important outcomes showed betterreporting. Many RCTs measured patient important outcomes, but very few of these assessednonpharmacological interventions (Montori et al. 2006). Despite the worldwide explosion of diabetes as amajor public health problem, most trials came from researchers working in the northern hemisphere.Thus, to enhance the practice of evidence-based diabetes care, trialists need to pay closer attention to therigorous implementation and reporting of important methodological safeguards against bias (Montori etal. 2006). Further, Gandhi et al. 2008 found that in their study sample of registered ongoing RCTs(worldwide) in diabetes, only 18% included patient-important outcomes (death and quality of life likemorbidity, pain, function) as primary outcomes.[3]

In India there are currently a number of research programs in prognosis of Diabetes and the most reputedresearch organization is "Madras Diabetes Research Foundation" (MDRF)(http://mdrf.in/department/research_department.html), and their most ambitious projects include[3]:

World Health organization (WHO) Collaborating center for Non-communicable diseases-

Prevention & Control – designated by WHOM, Geneva: MDRF carries out research on diabetes and other non-communicable chronic diseases like hypertension, obesity, dyslipidemia and cardiovascular diseases. The objectives of the WHO Collaborating Centre are to provide continuous surveillance, prevention and control of these diseases[3].

Establishment of a Centre for Prevention and Control of Diabetes and Cardio-metabolic Diseases in South Asia: Supported by The National Heart, Lung and Blood Institute (NHLBI) of the NationalInstitutes of Health (NIH) and Ovations Chronic Disease Initiative of the United Health Group. Theirmain objective is to establish a multi-disciplinary, Centre of Excellence to address Cardio-metabolicdiseases (CMD) in South Asia. This Centre will build world-class investigator and research capacity,produce and disseminate innovative, science-driven, and low-cost solutions. The Centre will study theburden and risk factors for cardiovascular disease and diabetes in India and Pakistan and investigate waysto prevent the diseases. In addition will also help train young scientists in these countries to conductimportant diabetes and heart disease research.[3] More Specifically their research agenda includes the following studies:

1. Chennai Rural Epidemiology Study (CURES)

CURES started in 2001 with objectives to estimate the prevalence of diabetes and itscomplications in urban Indian population and to identify the risk factors for NCDs. CURES is alarge ongoing epidemiological cohort study involving a representative population of Chennai(screening 26,001 individuals from 46 corporation wards), in southern India[3].

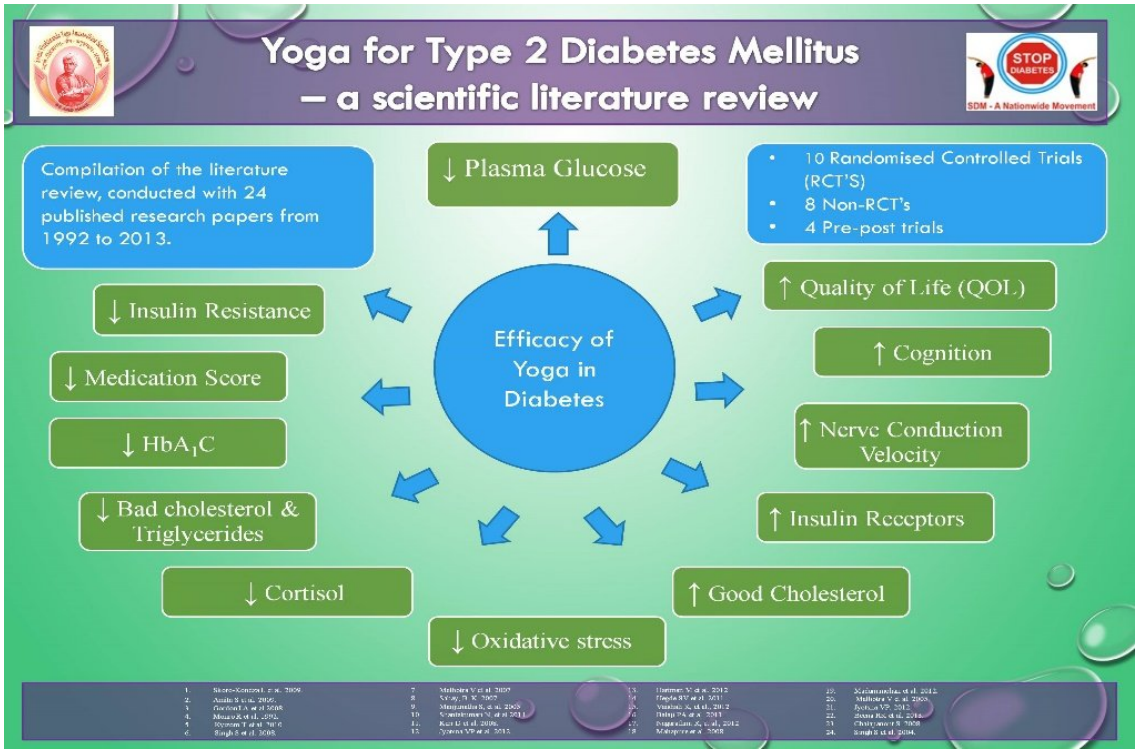
2. ICMR Advanced Centre for Genomics of Type 2 Diabetes

In the context of genomics of diabetes (and diabetic eye complications), this advanced centreaims to improve the quality and multidisciplinary nature of diabetes research by providing sharedaccess to specialized technical expertise and resources. This center will build capacity anddevelop basic infrastructure for carrying out genomic research related to diabetes. The overallgoal is to bring together clinical and basic science investigators, from relevant disciplines, in amanner that will enhance and extend the effectiveness of research related to the genomics ofdiabetes and its complications.[3]

3. Market survey of foods from various retail outlets in the South Indian metro city of Chennai and its relevance to chronic disease epidemiology: This study aims at providing thelacuna of information related to the profiling of foods in the urban market and their relevance tochronic diseases epidemiology with focus on T2DM. Unfortunately, no reported data on resultshas been provided yet.[3]

4. ORANGE Study (Obesity Reduction and Awareness of Non-communicable diseases through Group Education) 2008-2010: Orange, is aimed at screening children in schools andcolonies to determine the prevalence of obesity, diabetes, pre-diabetes, hypertension,dyslipidemias, metabolic syndrome and MODY. Unfortunately, no reported data on results hasbeen provided yet.[3]

5. D-CLIP (Diabetes Community Lifestyle Improvement Program) is a trial of a culturallyspecific lifestyle intervention program for diabetes prevention in India. It is three year project andwas started in 2009.[3]



3.2 COMPARISON WITH EARLIER STUDIES

The science of yoga is an ancient one. It is a rich heritage of our culture. Several older books make a mention of the usefulness of yoga in the treatment of certain diseases and preservation of health in normal individuals. The effect of yogic practices on the management of diabetes has not been investigated well.[7]

We carried out well designed studies in normal individuals and those with diabetes to assess the role of yogic practices on glycaemic control, insulin kinetics, body composition exercise tolerance and various co-morbidities like hypertension and dyslipidaemia. These studies were both short term and long term[7].

These studies have confirmed the useful role of yoga in the control of diabetes mellitus. Fasting and postprandial blood glucose levels came down significantly. Good glycemic status can be

maintained for long periods of time. There was a lowering of drug requirement and the incidence of acute complications like infection and ketosis was significantly reduced. There were significant changes in the insulin kinetics and those of counter-regulatory hormones like cortisol. There was a decrease in free fatty acids. There was an increase in lean body mass and decrease in body fat percentage. The number of insulin receptors was also increased. There was an improvement in insulin sensitivity and decline in insulin resistance. All these suggest that yogic practices have a role even in the prevention of diabetes. There is a beneficial effect on the co-morbid conditions like hypertension and dyslipidemia[7].

3.3 Effect of Yogic Practices on Elderly Type 2 Diabetics

Study in elderly diabetics 20 subjects aged more than 60 years with a mean age of 66 years were followed up for a period of 7 years. They achieved good glycemic control which was maintained over the period of 7 years[7].

3.3.1 Studies on Lean Diabetics

A subset of lean diabetics with a BMI of less than 18 was studied. There was improvement in their glycemic control with reduction in body fat content and improvement in lean body mass. There was reduction in their cholesterol triglyceride, LDL and free fatty acid levels and an increase in the HDL levels[7].

3.3.2 Long Term Follow up

Long term follow-up studies: 32 type 2 and 3 type 1 diabetic patients who attended the institute regularly were studies for a period ranging from 2 to 7 years[7]**.**

3.3.3 Effect of Yogic Practices on Exercise Tolerance

Comparative studies of the effect of Yoga and physical exercise on the exercise tolerance in normal healthy volunteers as well as athletes showed improved exercise tolerance and

postponement of the anaerobic threshold with both, but with yogic practices this occurred with a significant reduction in the minute ventilation and oxygen consumption.[7]

Diabetic patients also showed an improvement in their exercise tolerance after 2 months of yogic practices as noted by their ability to carry out exercise for longer period of time[7].

3.3.4 Effect of Yogic Practices on CMI in Type 2 Diabetes

Cell mediated immunity is defective in patients with type 2 diabetes, particularly with poor glycemic control. The defective cell mediated immunity predisposes the diabetics to various infections. Our studies have shown that yogic practices have a favorable effect on the lymphocyte migration test, suggesting an improvement in the cell mediated immunity[7].

3.4 Effect of Yogic Practices in Prevention of Type 2 Diabetes

Yogic practices in all these studies have produced an increase in the lean body mass and decrease in the body fat percent. This leads to an improvement in insulin sensitivity and reduction in insulin resistance. Insulin resistance is the major abnormality in type 2 diabetes and precedes the development of overt diabetes by several years. The reduction in free fatty acid levels also reduces the lipotoxicity, which has now been shown to have a significant effect on beta cell function. Therefore it is reasonable to postulate that the beneficial effect of yogic asanas on the insulin kinetics and the lipid metabolism, prevents the beta cell exhaustion and the development of a beta-cell secretory defect, thereby preventing the development of type 2 diabetes.[7]

Past research findings related to types of exercise and intensity were tabulated [22-46] (Table 1). The table also depicts the study design adapted by various researchers all over the world and the salient findings.

Varisar Dhauti (LSP) is also recommended twice a week and thus could be more feasible if the risk factors and complications are properly studied[7].

Table 1

Sr. No.	Year	Country	Patients	Intervention	Pattern of exercise	Results	Study Design	Reference
1	2012	New Zealand	18 patients	Aerobic and resistance training	3 times/week, 16 weeks, 40-60 minute	Exercise has positive impacts on glycosylated haemoglobin (HbA1c), related diabetes markers	Cohort study	[22]
2	**2012**	**Italy**	**25 patients**	**Aerobic and resistance training**	**2 times/week, 60 minutes, 3 4 months**	**Aerobic exercise reduces blood glucose concentrations to a greater extent than resistance exercise, and both have higher risk of exercise-induced hypoglycemia**	**Randomized controlled trial**	**[23]**
3	2012	Italy	606 patients	Aerobic (treadmill, step, elliptical, arm or cycle-ergometer) and resistance training	2 times/week, 12 months,55% - 70% of predicted maximal oxygen consumption	Low intensity exercise is as effective as high intensity exercise in reducing risk factors for cardiovascular disease in T2DM (VO2max) for aerobic exercise,60% of	Multicenter randomized controlled trial	[24]

						predicted 1-Repetition Maximum (1-RM) for resistance exercise		
4	2012	Netherlands	40 patients	Resistance exercise and endurance type exercise	24hr period, 45 min. session, resistance type exercise (75% one repetition maximum) and endurance-type exercise (50% one maximum workload capacity)	Both resistance- and endurance-type exercise can be integrated in exercise intervention programmes designed to improve glycaemic control.	Randomized crossover study	[25]
5	2011	Netherlands	20 patients	Aerobic or resistance training	12 weeks	Exercise improves blood glucose regulation (HbA1c), muscle strength (isometric peak torque)	Pre-post design study	[26]
6	2011	Australia	34 patients	Cardiorespiratory and resistance exercise	4 weeks, 2 session/week, (1 hr supervised and 30 minutes unsupervised)	Decrease in blood glucose, resting heart rate, systolic blood pressure and increase in cardiorespiratory fitness with short-term	Quasi experimental design	[27]

						exercise training		
7	2011	Brazil	10 patients	Resistance and aerobic exercise	24 hr period, 60 minutes interval	Single bout of resistance exercise decreases blood pressure in T2D patients over a 24h period, more effective than aerobic exercise	Randomized controlled trial	28
8	2011	Ghana	18 patients	Prescribed aerobic exercise	3 times/week, 30 minutes, 50-75% maximum heart rate	Aerobic exercise improves physiological parameters such as fasting blood glucose level and lipid profile level in T2DM patients	Randomized controlled trial	29
9	2010	Netherlands	9 patients	Isoenergetic bout of endurance - type exercise	Low-intensity, 60-30 minutes, 24 hrs	Single bout of low- intensity exercise reduces post prandial hyperglycaemia	Randomized cross over study	30
10	2010	Iran	65 patients	Aerobic exercise	16 weeks (3 days/week, 90 min, 50-80%VO2 max)	Aerobic exercise show potential reduction of glycosylated haemoglobin values in T2DM patients	Randomized controlled trial	31

11	2010	United States of America, Los Angeles	262 patients	Aerobic and resistance training	150 minutes/ week, 9 months, 50% to 80% of maximum oxygen consumption.	Combination of aerobic and resistance training improved HbA(1c) levels	Randomized controlled trial	[32]
12	2010	Japan	24 patients	Joba riding	7 times/ week, 30 minutes, 3 months	Daily Joba exercise is potentially useful in improving insulin sensitivity and restoring metabolism in T2DM patients	Randomized controlled trial	[33]
13	2010	Singapore	68 patients	Progressive resistance exercise and aerobic exercise	2 times/day, 50 minutes, for 8 weeks	Progressive resistance exercise has similar effects to aerobic exercise towards T2DM patients	Randomized controlled trial	[34]
14	2009	Brazil	40 patients	Physical (treadmill) exercise	3-5 times/ week, 30 minutes walks, for 20 weeks at 70% maximum heart rate	High frequency of regular exercise showed significant effect on glycaemic control in T2DM	Cohort study	[35]

15	2009	London	59 subjects	Yoga classes	2 times/week, 90 minutes, 12 weeks	Yoga (exercises) reduced HBA1C level in T2DM patients (statistically not significant)	Exploratory randomized controlled trial	[36]
16	2006	United States of America	30 patients	Resistance training	16 weeks	Resistance training results in muscle hypertrophy and improves glycaemic control in patients with type 2 diabetes.	Randomized controlled trial	[37]
17	2006	United States of America	62 patients	Strength training exercise	16 weeks	Strength training exercise improved muscle quality insulin sensitivity and metabolic control	Randomized controlled trial	[38]
18	2004	Japan	40 patients	Aerobic exercise (bicycle ergometer)	40 minutes/day, 5 days, at 3 weeks intervention	Aerobic exercise restore the insulin sensitivity with regardless of changes in adiponectin	Randomized cross over study	[39]

19	2004	Australia	13 subjects	Short-term exercise training	3 days/week, 120 minutes, 8 weeks	Short-term exercise enhances insulin sensitivity and reduces triglyceride level in T2DM patients compared to control subjects	Case control study	[40]
20	2003	Finland	50 patients	Resistance training exercise	30 minutes/day, for 12 months, 10-12 times repetitions	Resistance training exercise program is preventive measures for sudden cardiac death in T2DM patients	Randomized control led trial	[41]
21	2003	United States of America, Boston	75 patients	Walking exercise	3 times/ week, 60 minutes walking, for 12 weeks	Simple exercise improves glycaemia and cardiovascular risk factors in T2DM subjects	Randomized control led pilot study	[42]
22	2002	United States of America	62 patients	Resistance training exercise	3 times/week, 45 minutes, 16 weeks	Exercise showed positive effect towards glycaemic control and metabolic outcomes in T2DM	Randomized control led trial	[43]

23	2001	Australia	16 patients	Exercise (Bicycle ergometer, treadmill walking, resistance training)	1 hr/day, 70%-80% of Heart rate for bicycle and walking, 55%-65% for resistance training	Combined aerobic and resistance exercise restore endothelial dysfunction in patients with vascular disease occurred in T2DM	Randomized cross over study	[44]
24	2001	Sweden	15 subjects	Exercise (cycle ergometer)	45 minutes/day, 70% of workload, acute exercise	Normal exercise improves AMPK activity which is an attractive target for the treatment of T2DM	Case-control study	[45]
25	2001	Japan	50 patients	Walking and cycling exercise	5 times/week, 1 hr, 50% maximum oxygen uptake	Exercise training in T2DM subjects reduces serum leptin levels	Randomized controlled trial	[46]

CHAPTER 4

METHODOLOGY

4.1 AIMS

To study the safety and effect of yogic gut cleansing technique in diabetes patients

4.2 OBJECTIVES

The book‘HathayogaShuddhikriya’by a well-knownMarathi author called Vishwas Mandlik explains that there was a successful research conducted on 60 Diabetes patients. The blood sugar level was tested before and after ShankaPrakshalan. The blood sugar level of patients was lowered, but unfortunately some of them had to be given sugar to eat because they went into Hypoglycemia.

योग विद्या धाम या संस्थेच्या वतीने अहमदनगर, नांदेड, कोल्हापूर येथे मधुमेही रुग्णांची उपचार शिबिरे आयोजित केली होती. या शिबिरात एकूण ६० रुग्ण सामील झाले होते. यांच्या बाबतीत शंखप्रक्षालन करण्यापूर्वी व नंतर रक्तशर्करा तपासण्यात आली. जवळ जवळ सर्वच रुग्णांचे बाबतीत रक्तशर्करा कमी झाल्याचे आढळून आले. काही रुग्णांचे बाबतीत ती रक्तशर्करा खूपच कमी झाल्याने त्यांना साखर खाण्यास द्यावी लागली.

This particular note played an important role in deciding the following factors.

1) RISK OF HYPOGLYCEMIA: The need to check if LaghuShankhaPrakshalan would also lead to Hypoglycaemia.
2) USING WATER, SALINE WATER, TRIPHALA WATER or LEMON-SALINE WATER: The interview with the professional instructors made it clear that the previous patients were given lemon, salt and water. I conducted a similar study on 10 patients with lemon, salt and water, and salt water. Unfortunately, the doctors of the patients did not

allow them to continue the course with a suspicion of havingincreased their blood pressure. Thus, water and Triphala had to be checked for safety and feasibility.

3) DURATION OF THE COURSE:

It was important to explain the method and to teach the exercises of LaghuShankhaPrakshalan. Thus prior to the experiment, 3 days of training was given to teach exercises and orientation, writing theconsent forms and for the follow up and standardization of the study details.

4) USING THE SAME PLAN FOR ALL THE DIABETES PATIENTS or INDIVIDUALIZING IT:

FBS (fasting blood sugar) will depend on many factors. It increases depending on the time it is measured, whether the patient takes two tablets or one or what was eaten on the previous night and at what time.

The changes in blood sugar level would also depend on whether the patient has had a sedentary lifestyle or exercises regularly. Thus, it is very important to check if one needs to further individualize the VarisarDhauti and which factors would matter the most.

RESEARCH QUESTIONS

A. Is Varisar Dhauti (LSP) safe for patients with Diabetes?
B. Does *laghu śankha prakśalana* (*yoga* based bowel cleansing technique) affect the blood sugar immediately after the practice in patients with essential diabetes?
C. Does adding of *triphalā,* an A*yurveda* herbal preparation*,* to the water used for *laghu śankha prakśalana* improve the bowel clearing effect and FBS too?
D. Does clearing the bowel through LSP improve the results of blood sugar level better?
E. Does Varisar Dhauti give other complications like body pain, uncontrollable urination,and burden on bladder, disturbance in sleep or Hypoglycemia?

HYPOTHESIS

A. Varisar Dhauti (LSP) can be given safely to patients with mild to moderate Diabetes.
B. Varisar Dhauti (LSP) done with the right understanding does not increase the blood sugar.
C. Varisar Dhauti) LSP with *triphalā* water will give better reduction in FBS than LSP with Normal water.
D. Clearing the bowel through LSP gives a good feeling of comfort and compliments the effect of blood sugar level for patients with diabetes.
E. Varisar Dhauti does not create any complications like fatigue, disturbance in sleep, excessive urination or Hypoglycaemia.

NULL HYPOTHESIS

A. LSP will increase the blood sugar in patients with diabetes
B. LSP is not a safe practice for patients with diabetes
C. LSP with *triphalā* water is not better than LSP with Normal water in patients with diabetes.
D. Varisar Dhauti will create complications like fatigue, disturbance in sleep, excessive urination or Hypoglycaemia.

4.3 Sample

I. SAMPLE SIZE30

In earlier studies, effect size of 30 was calculated. The effect size was calculated by computing (G power software) the values for alpha (0.05), effect size (0.6) and power (0.8). The effect size was taken as reference for this study.[1]

ii. SOURCE

Public talks at different institution like Rotary clubs,school helped to gather volunteers. Advertisement was given in the local newspaper.

iii. INCLUSION CRITERIA

A. Patients with essential Diabetes Mellitus age from 30-90years.
B. Both Genders
C. Those with mild and or moderate(T2DM) Diabetes Mellitus.
D. Diagnosed as primary/essential Diabetes Mellitus.
E. Mild to moderate Diabetes Mellitus under control with medication.
F. Those with no prior experience of *yoga*, and Mild to moderate Diabetes Mellitus with Hypertension under control with medication

iv. EXCLUSIVE CRITERIA

A. Those with severe range of Hypertension.
B. Patients with renal complications.
C. Those with severe Diabetic complications.

v) INFORMED CONSENT

Informed consent was signed by all subjects of the study. For those who satisfied the selection criteria after admission, special class was organized, Purpose and design of the study before obtaining the signature on the consent form was explained.

4.4 DESIGN OF THE STUDY

Self as control

This was self as control design with four assessments i.e. pre-post assessments after two different sessions of practice in the same participant on the fourth and sixth day.

DIABETES MELLITUSN= 30

Day 4⁻NWLSP

6-15 to 8-15 am

Day 6⁻TWLSP

6-15 to 8-15 am

Assessment1 Assessment 2 Assessment 3 Assessment 4

NWLSP-Normal water *laghu śankha prak□ālana,*TWLSP- *Triphalālaghu śankha prak□ālana*

A) Design for Primary Objective

DIABETES MELLITUS Patients-N= 30

CHAPTER 5

INTERVENTION

A) Schedule of Varisar Dhauti

Day	Time	Session
Day 1	7:00 am to 7:45 am	**Patients were asked to read the board and a lecture was given on the method. Demonstration and practice of the 6 different types of exercises.**
Day 2	7:00 am to 7:45 am	**Exercises were practiced. Consent form was signed.**
Day 3	7:00 am to 7:45 am	**Exercises were practiced. Simple diet and other instructions were given.**
Day 4	6-15 to 8-15 am	**Blood test, Varisar Dhauti (LSP) Blood test.**
Day 5	7:00 am to 7:45 am	**Exercises practice and FBS results were shown.**
Day 6	6-15 to 8-15 am	**Blood test, Varisar Dhauti (LSP) Blood test**

There were a huge number of dropouts.Participants could not attend regularly and with punctuality due to the morning hours of practice schedule.

B) Schedule Of LSP Practice

S. No.	SCHEDULE	TIME
1	General preparations	6-30 to 7-00 am
2	Assessment	6-30 to 7-00 am
3	Varisar Dhauti (LSP) Drinking Luke warm water	7-00 to 7-45 am

	(6 glasses)	
4	Practices:*tā□āsana* (palm tree pose), *tiryakatā□āsana* (swaying palm tree pose), *ka□i cakrāsana* (waist rotating pose),*tiryaka bhujangāsana* (twisting cobra pose), *modified version of*(abdominal stretch pose) and abdominal pose. Both the modified poses are in standing posture.	7-00 to 7-45 am
5	Evacuation of bowel	As per individual need
6	Deep Relaxation Technique	7-40 to 8-00 am
7	Assessments	8-00 to 8-15 am

Vārisāra dhauti is more commonly known today as *laghu śankha prak□ālana*. During this practice One should drink 6 glasses (200 ml/glass) of warm water or (*triphalā* water), exercise so that the water moves through the body, hold the water as per capacity and evacuate it through the bowels when there is an urge. To begin, first two glasses of water are drunk and above mentioned series of *āsanās* are performed.

After every two glasses of water the *āsanās* should be performed .One feels an urge to empty the bowels. After 45 minutes and after a deep relaxation, a saltless liquid mixture of cooked rice, mung dal and ghee has to be eaten until the stomach is completely full.

Varisar Dhauti was administered with Normal water and the other with Triphala water. Pre Data wascollected before the LSP and post data after LSP. This was a self-as-control design with assessments after two sessions of practice in the same participant on the fourthand sixth day. The patients were introduced to the program by their friends (word of mouth), local newspaper or attended a lecture.

The patients who satisfied the inclusion criteria for the present study were selected, informed consent was obtained, and all assessments were documented on the first day. Nature of the study and the procedure of LSPwas explained. All the recruited patients practiced LSP with normal water (NWLSP) on 4th day under close supervision. LSP with triphala water (TWLSP) was administered on the 6th day. Primary outcome measures were recorded by the researcher before and after both Deep relaxation session was conducted after the active phase of LSP practice.

Ethical consideration:

Informed consent form was signed by each and every participant. Doctor's permission was obtained wherever necessary and sought to be necessary. Institutional ethical consideration was obtained from IEC committee Svyasa University -Bengaluru

viii) ASSESSMENTS

Socio-demographic questionnaire:

A socio-demographic checklist was prepared for this study to document the following: Name, address, gender, age, presence of major diseases and medications taken if any.

A) PRIMARY OUTCOME MEASURES

FBS:

A glucose meter (or glucometer) is a medical device for determining the approximate concentration of glucose in the blood. It is a key element of home blood glucose monitoring (HBGM) by people with diabetes mellitus or hypoglycemia. A small drop of blood, obtained by pricking the skin with a lancet, is placed on a disposable test strip that the meter reads and uses to calculate the blood glucose level. The meter then displays the level in units of mg/dl or mmol/l.Since approximately 1980, a primary goal of the management of type 1 diabetes and type 2 diabetes mellitus has been achieving closer-to-normal levels of glucose in the blood for as much of the time as possible, guided by HBGM several times a day. The benefits include a reduction in the occurrence rate and severity of long-term complications from hyperglycaemia as well as a reduction in the short-term, potentially life-threatening complications of hypoglycemia.

Accucheck Company

SECONDARY MEASURES

Blood pressure: Blood pressure was recorded by using electronic portable cardiac monitor equipment (OMRON Company).

Digital cardiac monitor device:

The phrase cardiac monitoring generally refers to continuous monitoring of the heart activity, generally by electrocardiography, with an assessment of the patient's condition relative to their cardiac rhythm. It is different from hemodynamic monitoring, which monitors the pressure and flow of blood within the circulatory system. The two may be performed simultaneously on critical heart patients. A small monitor worn by an ambulatory patient is known as a monitor. Transmitting data from a monitor to a distant monitoring station is known as a telemetry or a biotelemetry.

Pulse rate: Pulse rate recorded by electronic cardiac monitor

Respiratory rate: Manually recorded by counting the number of breaths/minute by the researcher while the attention of the patient was diverted.

No. of stools (Bowel): Total number of visits to empty the bowel after NWLSP or TWLSP reported by the participant was documented.

VARIABLES:

i) **Fasting blood sugar** (FBS)**:**

It is a blood glucose test which measures the amount of a type of sugar, called glucose, in your blood. Glucose comes from carbohydrate foods. It is the main source

of energy used by the body. Insulin is a hormone that helps your body's cells use the glucose. Insulin is produced in the pancreas and released into the blood when the amount of glucose in the blood rises.There are several different types of blood glucose tests.Fasting blood sugar (FBS) measures blood glucose after you have not eaten for at least 8 hours. It is often the first test done to check for prediabetes and diabetes.

ii) **Blood Pressure;**

Blood pressure was measured just to make sure that during the course of LSP, patients are safe and no further complications are being developed.

	Diastolic	**Systolic**
Definitions	It is the pressure that is exerted on the walls of the various arteries around the body in between heart beats when the heart is relaxed**.**	It measures the amount of pressure that blood exerts on arteries and vessels while the heart is beating**.**
Blood Vessels	Relaxed	Contracted
Normal Range	60 – 80 mmHg (adults); 65 mmHg (infants); 65 mmHg (6 to 9 years)	90 – 120 mmHg (adults); 95 mmHg (infants); 100 mmHg (6 to 9 years)
Blood Pressure	Diastolic represents the minimum pressure in the arteries	Systolic represents the maximum pressure exerted on the arteries.
Blood Pressure reading	The lower number is diastolic pressure.	The higher number is systolic pressure.

CHAPTER 6

OPERATIONAL DEFINITIONS

The following are the definitions that would be used in the present study:

1. Type 2 Diabetes Mellitus (T2DM) - Individuals suffering from elevated blood (How elevated, write figures) glucose level due to inefficient use of insulin.

2. Triphala- An herbal preparation made of three different fruits namely Haritaki, Bibhitaki and Amalaki which works as a mild laxative for detoxifying the digestive track.

3. Feasibility- As assessed with the help of pre and post interviews with the patients regarding the doability of the yoga programme along with observations during the training period to assess overall performance from patients and the difficulties from the therapist's point of view.

4. Pilot testing- Testing the safety and efficacy ofVarisar Dhauti (LSP) by checking the FBS, B.P, Comfort levels of patients, pre and post the various LSP.

5. FBS- The result showing the blood glucose level by assessment of bloodsample drawn in morning after minimum 8 hours of fast.

6. PPBS- The result showing the blood glucose level by assessment of blood sample drawn after 2 hours of giving 75 grams of glucose.

7. Height- The height of the patient measured in comes while standing erect.

8. Weight- The weight of patient measured in kilograms in standing.

9. B.Y. – Before Yoga

10. A.Y. - After Yoga

11. LSP – Laghu Shankar Prakshalan

CHAPTER 7

RESULTS

Demographic Data

Demographic Data			
	Mean	Sd	
Age	55.3	±9.70	
Gender	Male =14	Female =16	
Marital state	unmarried=01	married=29	
Education	UG=28	PG=02	
Occupation	employed=16	Students=0	House wife=14

Triphala water LSP:

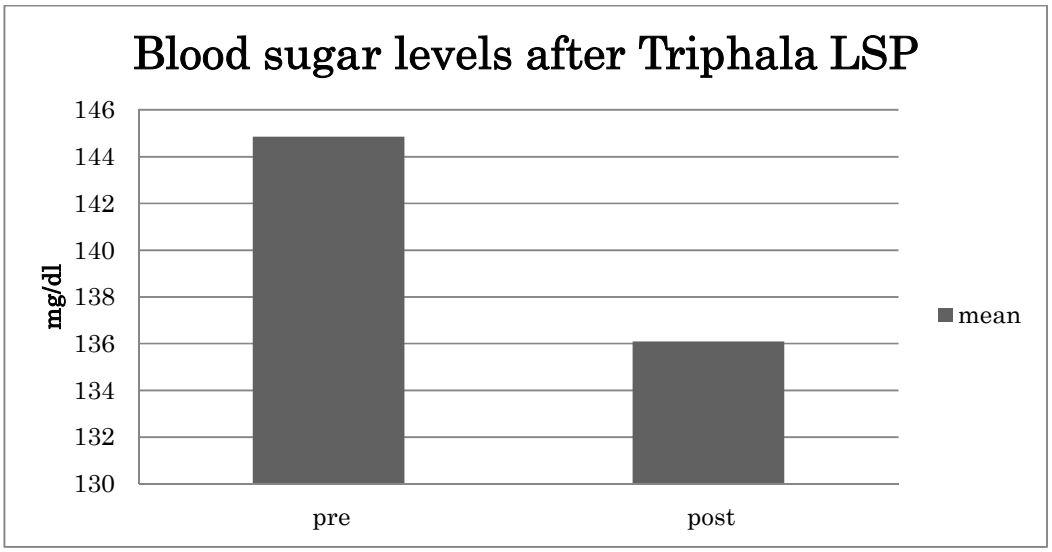
The baseline data were normally distributed. Paired T-test showed significant reduction in fasting blood sugar levels ($p<0.0001$) after plain water LSP. Table and fig. show the details

Table. Changes in Blood sugar levels after Triphala water LSP

Triphala water LSP group	Mean	Std Dev.	% change	P sig.
Pre	144.86	±37.74	5.69	<0.001
Post	136.09	±36.10		

Legend: there is significant reduction in fasting blood sugar levels.

Fig. Changes in Blood sugar levels after Triphala water LSP



Legend: there is significant reduction in fasting blood sugar levels.

NORMAL water LSP

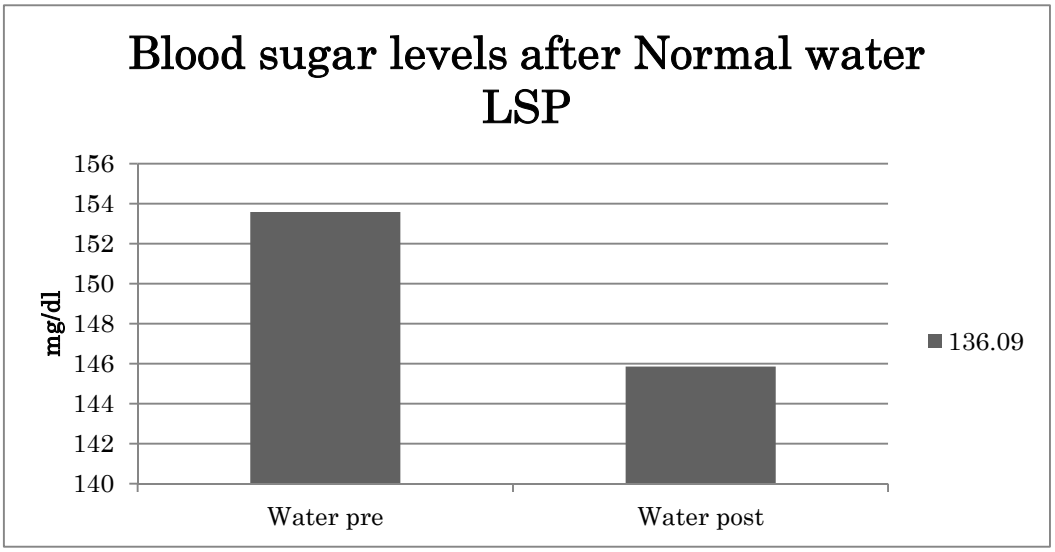
The baseline data were not normally distributed. Wilcoxon's signed rank test showed significant reduction in fasting blood sugar levels ($p<0.001$) after Normal water LSP. Table and fig. show the details

Table. Changes in Blood sugar levels after Normal water LSP

Normal water LSP group	mean	Std Dev.	% change	P sig.
Pre	153.60	±38.50	4.12	<0.001
Post	145.86	±35.78		

Legend: there is significant reduction in fasting blood sugar levels.

Fig. Changes in Blood sugar levels after Normal water LSP



Legend: there is significant reduction in fasting blood sugar levels.

Difference between plain water LSP and Triphala water LSP

Between group comparison					
Variable	Mean of difference	Std	Shapiro-wilk p-val	p-value	% change
Triphala Pre-post	-8.77	±13.08	0.056	0.000	5.69
Plain water pre-post	-7.73	±16.65	0.001	0.006	4.12

Legend: there is significant reduction in fasting blood sugar levels after Triphala water LSP than plain water LSP

Data was analyzed for fasting blood sugar levels in diabetes group after Laghushankaprakshalana (LSP), the data were normally distributed in Triphala water LSP, paired sample T-test was conducted and the P- value is □0.001. and the data of Plain water LSP were not normally distributed, wilcoxan signed rank test was conducted and the P-value is

0.001, so reduction in fasting blood sugar level is more significant in triphala water LSP compare to plain water LSP.

Note: Sampling was not randomized control, it was convenient sampling.Our aim was not to generalize the results of the study to the population.

CHAPTER 8

DISCUSSION

Many researchers have shown that exercise plays a crucial role in improving T2DM. Exercise not only improves the glycaemic control, but it can also improve the insulin sensitivity and restore the diabetic associated complication such as cardiovascular damage, which is considered as one of the major complications. Based on the past findings, the present study was carried out to measure the carryover effect of yogic gut cleansing technique in Diabetic Mellitus patients.

This self as control pre-post study of

30 participants with essential Diabetes Mellitus was conducted at the non-residential setting in Kolhapur and Goa. It assessed the immediate effect of NWLSP and TWLSP on blood sugar level in participants of mild to moderate primary Diabetes Mellitus. There was significant reduction in FBS(B.Y. and A.Y.), immediately after both sessions. TWLSP offered better bowel clearance than NWLSP as seen by the total number of stools passed immediately after the practice.

There was overall improvement in comfort level and quality of sleep

CHAPTER 9

CONCLUSION

1. **RISK OF HYPOGLYCEMIA:** The results show very clearly that LaghuShankhaPrakshalan is a very safe and feasible method for Diabetes patients. There is not a single case that developed Hypoglycemia. On the contrary, in one of the Pilot studies, there were 5 young ladies who were suffering from Hypoglycemia and their blood sugar level was found to be normal after LaghuShankhaPrakshalan.
2. **WATER, SALINE WATER, TRIPHALA WATER** or **LEMON SALINE WATER:**Both normal warm water and Triphala water were found to be safer.
3. **DURATION OF THE COURSE**: It was interesting to note that the concept of Ama from Ayurveda applies here.It takes a couple of days for the body to start the toxin removal. This process of detoxification will depend on the age, lifestyle and especially the exercise routine.
4. **WHETHER TO USE THE SAME PLAN FOR ALL THE DIABETIC PATIENTS or INDIVIDUALIZE IT**:This study has brought attention to the fact that it is important to individualize the VarisarDhautidepending on age, profession, flexibility and other health-related factors for a result oriented plan.
5. This study has demonstrated that it is feasible and beneficial to integrate LSP in management of Diabetes Mellitus with no side effects.
6. The BP, Pulse &FBS reduce immediately after LSP and hence is safe.
7. LSP with Triphalā water is acceptable and helps in clearing the bowel with lesser effort compared to Purna Shankha Prakshalan.
8. The practice was found to be overall feasible in terms of acceptability, doability and effectivenessand could be implemented effectively in various community settings for type 2 diabetic populations.

CHAPTER 10

APPRAISAL

10.1) Strength of the study

1. This is the first study that has looked at the effect of Varisar Dhauti (LSP) and a module especially to assess the safety and effect of Varisar Dhauti (LSP*)*
2. Provided the first evidence for the safety of this practice in Diabetes Mellitus and many patients were with mild to moderate Hypertension.
3. The first study evidence about bowel cleansing and it'sdirect and relation in the management of Diabetes Mellitus.
4. Practice was taught under complete supervision by ONLY ONE yoga therapist so uniformity was maintained throughout.
5. It was a single blind study as the laboratory blood test professional did not have any idea on what was the intervention or other details.
6. This study provides the scientific evidence for promoting and recommending Varisar dhautifor Diabetes Mellitus as a cost effective module for enhancing the physical &psychological state Diabetes Mellitus, which does not require any gadgets or need to create a gym or a park.
7. Through review ofLiteraturesfrom ancient texts it was clear that the Varisar Dhauti is the right name of LSP and modifications in the asanas practiced or other details need to be cross checked.The original references from the text book have been used in various places for those interested in taking this study forward.
8. The study has been carried out under an expert guide from the field of Yoga and Ayurveda.

9. The study did not use only one type of LSP to decide the Methodology but tried many methods during Pilot study
10. The positive results in the main outcome variables in spite of short duration of Intervention emphasizes the effectiveness of Varisar Dhauti.

    Unfortunately, there is a lot unknown about Varisar Dhauti as well as Metabolic disorders like Diabetes. Varisar Dhauti can be a boon to humanity if right parameters can be matched to validate its effects.

10.2) Limitation of the study

1) This was a single arm study with pre-post design.
2) It was a short term design but had too many dropouts due to the practice hours. (too early or inconvenient timing)
3) Though the current study was primarily conducted to assess the feasibility of the programme, inclusion of a control group could have strengthened the design of the study (use of Randomised Control Trial) and the acceptability of the results.
4) There were multiple factors that affected the FBS. Lack of standardization in food (daily food regime, suppertime and menu) could have been avoided by having a residential camp setting.

10.3) Application of the study

The present study suggests that even thesole treatment of LSP is effective in lowering blood sugar levels and provide good standards of health with respect to physical and mental well-being. Varisar Dhauti can be tested in larger communities so as to test its efficacy. This study has been successful in delivering its objective viz. exercises without the risk of Hypoglycemia or other complications.

1) **For participants and institutions**:

The present study could be utilized to motivate diabetics as well as patients suffering from other co-morbidities to undergo this Varisar Dhauti as its efficacy has been proven in this study, in spite of short duration of intervention. As it covers all dimensions of health, the beneficial effects of these 'lifestyle modification practices' could prove to be aboon for them in long run. Participants, who have undergone this module and experienced beneficial effects, could motivate others to undergo this yoga module or train others in their community in this module to help them manage their diabetes. Yoga institutions could also use this module for patients with diabetes in their camps.

2) **For Researchers:**

Systematic and scientifically proven methods of research, through Pilot studies could help future researchers and professionals in the field, to design further studies.Further the module could be tested in a longitudinal study

by many trials with controlled designs to prove its efficacy in large samples in the community.

10.4) Suggestion for future

Based on the current study, suggestions for future studies are

1) This study can further check the PPBS after Normal water and Triphala water Varisar Dhauti (LSP).
2) Study the efficacy of Varisar Dhautiand a combination of other kivas on Diabetes patients.
3) Standardize a simplified version of Varisar Dhauti with normal water, Triphala water or other liquids as a daily exercise routine.
4) Study and compare the results of Varisar Dhauti administered with other herbs and spices to Normal water Varisar Dhauti.

5) Study and compare the results of Varisar Dhauti experimented at differenttime (eveninghours) to suit the modern lifestyle.
6) Follow-up for compliance of life style and checking for relapsing of sugar level will throw light on the feasibility of Varisar Dhauti for long term promotion.
7) Studies may be designed to compare the effect of yoga life style change with conventional life style in Diabetics especially with the Manas Bhava concept.
8) Studies using more objective and molecular measurements in a large sample to see the relationship between bowel clearing and rejuvenation of Diabetes patients.
9) Based on this study, a new module with LSP should be developed to use nationwide in the Stop Diabetes Movement (SDM) propagated by SVYASA.
10) Efforts should be made to improve this Varisar Dhauti module in its implementation in future researches, clinical services, to achieve maximum benefits as observed in this study.

APPENDIX:

INFORMED CONSENT FORM

Title of the project : Safety and Effect of of Yogic gut cleansing technique called as Varisar Dauti or LSP (Laghu Shankha Prakshalan) on Diabetic patients.

Investigator : Patil Seema (Vishnupant)

Name of the guides **:** Dr. Vijay (SVYASA)

Name of the Participant : _____

Date and Time : _____and _____

About the Project:

This work deals with the safety and EFFECT of Varisar Dhauti popularly known as Laghu Shankha Prakshalan on Fasting Blood sugar levels and other variables on Diabetes patients. The study aims to specify and verify results of the above the mentioned process on health. This Kriya (practice) includes drinking 6 glasses of Normal luke warm water, warm saline water (Normal warm water with 1% rock salt), or Normal luke warm water with Triphala powder and a set of stimulating exercises. Participants are required to drink 2 glasses the above said water after each set of exercises and repeat the procedure 3 times. All information obtained during the study will be kept confidential and report of the test will be given.

1. You can withdraw from the study at any point of the time unconditionally.
2. In case the study does cause any adverse effects, the institution or the Instructor is not liable.
3.

I hereby have understood the above and consent voluntarily to participate in the study.

Place_____

Date_____ **Signature of the participant**

CHAPTER 11

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7. The Type 2 Diabetes Screening and Treatment Guideline development team included representatives from the following specialties: family medicine, nursing, and pharmacy.

Clinician lead: David K. McCulloch, MD, Medical Director, Clinical Improvement, mcculloch.d@ghc.org

Guideline coordinator: Avra Cohen, MN, Clinical Improvement & Prevention, cohen.al@ghc.org

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THANK YOU