

Original Article

Effect of Gastro-Hepatic Pack on Biochemical Changes in Type II - Diabetes Mellitus Patients - A Study Protocol for Randomized Controlled Trial

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ABSTRACT

Background: Diabetes, particularly Type 2 Diabetes Mellitus (T2DM), is a major global health concern that causes hyperglycaemia due to insulin dysfunction. According to recent studies, the prevalence of diabetes among adults ranges from 7.4% to 10.0%, varying by geography, urban/rural settings, and age groups. Gastro-hepatic Pack (GH pack) is a naturopathic treatment that involves simultaneously applying cold application on the abdomen and hot application under the lower back wrapped in a woollen cloth. Naturopathic physicians commonly use GH pack intervention to treat patients with liver disorders and diabetes. Hence, we designed this study to investigate the effect of GH pack on biochemical changes in type 2 diabetes mellitus patients. **Methods:** This study will be performed using a randomised control trial. All eligible subjects will be recruited from International Institute of Yoga and Naturopathy Medical Sciences (IYNMS), Chengalpattu and randomly assigned (1:1 ratio) to study group or control group using simple random methods with the use of computerised randomisation. The study group (n=40) will undergo GH pack for 20 mins daily, five days a week, for four months. The control group (n=40) will receive yoga and naturopathic interventions in addition to GH pack for every week for 5 days for the course of 4 months. Ethical clearance was obtained from IYNMS (IEC-IYNMS/Approval/004/2023) and registered in the clinical trial registry of India (CTRI/2024/02/063097) **Results:** The biochemical assessments involved in this study include glycated haemoglobin (HbA1C), liver enzymes such as Serum Glutamic Oxaloacetic Transaminase (SGOT) and Serum Glutamate Pyruvic Transaminase (SGPT). All subjects will undergo baseline and post-intervention assessments. Data analysis will be done using appropriate statistical test with R software. The data will be analysed using a paired Student's t-test for within-group parameters, and an independent t-test for between-group parameters. In this study, we will use a p (probability) value of 0.05 to determine statistical significance. The mean value of dependent variables will be used to illustrate the outcome in a bar diagram. **Conclusion:** If the results of this study are significant, GH pack could be used as an adjuvant treatment in the treatment of type 2 diabetes mellitus. The GH pack is a cost-effective, simple technique for managing Type II Diabetes mellitus.

Key words: Naturopathy, Gastro-Hepatic Pack, Type II Diabetes Mellitus, Glycated Haemoglobin A, Serum Glutamic Oxaloacetic Transaminase, Serum Glutamate Pyruvic Transaminase.

Diabetes Mellitus (DM) is one of the world's most serious health problems, ranking among the top ten causes of death alongside cardiovascular disease and cancer [1]. DM is characterized by hyperglycaemia due to insulin secretion abnormalities or diminished tissue sensitivity to insulin [2]. The International Diabetes Federation (IDF) estimates that approximately 8.8% of adults worldwide are affected [3], with rates significant higher in regions such as India, where diabetes and impaired fasting glucose prevalence are 9.3% and 24.5% respectively [4]. Diabetes encompasses several types, with Type 1 and Type 2 being the most prevalent [5].

Type 2 Diabetes Mellitus (T2DM) is particularly insidious and caused by an imbalance between insulin levels and insulin sensitivity, resulting in a functional deficit of insulin [6]. Insulin is a peptide hormone secreted by the β cells of the pancreatic islets of Langerhans. It regulates blood glucose levels by facilitating cellular glucose uptake, regulating carbohydrate, lipid, and protein metabolism, and promoting cell division and growth through its mitogenic effects [7]. Insulin resistance occurs when body cells, particularly those in the liver, muscle, and adipose tissue, become unresponsive to insulin. Due to this defect, several cells have reduced glucose uptake, resulting in significant hyperglycaemia [8].

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The liver is the vital solid organ that regulates carbohydrate metabolism by using glucose as fuel, storing it as glycogen, and synthesizing glucose from non-carbohydrate compounds [9]. Insulin resistance initiates a cascade of metabolic changes that lead to the accumulation of lipids, oxidative stress, and inflammation in the liver. All these events contribute to liver cell injury, which eventually causes the release of liver enzymes including SGOT and SGPT, into the bloodstream. Thus, liver enzymes are considered as one of the biomarkers of liver damage, indicating the effects of insulin resistance on the liver [10]. A previous study published the association of liver enzymes (SGOT, SGPT & GGT) with T2DM in Ethiopian population and found a significant association with elevated expression among T2DM patients [11].

Hydrotherapy is one of the therapeutic modalities in Naturopathy. It involves applying water to the body at cold, neutral, and high temperatures in the form of packs, baths, and affusions to produce thermic and circulatory effects [12]. The Gastro-Hepatic Pack, hydropathic treatment modality that combines hot and cold interventions, was used in this study to promote various health benefits, particularly in managing diabetes and liver disorders. GH pack treatment stands out for its non-invasive nature, as it uses natural temperature variations instead of medications to cause rapid blood sugar reductions through physiological responses induced by thermal changes. So, we hypothesized this study protocol will help to assess how GH packs affect individuals with type 2 diabetes mellitus in terms of HbA1c and liver enzymes after a 4 months follow up period.

METHODOLOGY

The study will be conducted using a randomized controlled trial methodology. This study will be conducted at the International Institute of Yoga & Naturopathy Medical Sciences (IIYNMS) outpatient department in Chengalpattu. The study was scheduled to begin in June 2024. A feasibility trial does not require formal sample size estimations. [11] Nevertheless, it is recommended that at least fifty individual participants be included in a feasibility trial. Thus, in this study, we would like to recruit eighty subjects while accounting for dropouts and loss of follow-up. The sample size of 80 individuals will be assigned to two groups (40 in the study group and 40 in the control group). Participants will be assigned in a 1:1 ratio to either the subject or control group using computerized randomization. A sequentially numbered, opaque, sealed envelope will be used for random concealment. The interventions and assessments for study participants and the control group will not be blinded.

In this study, we followed CONSORT 2010 flow diagram method as illustrated in Figure 1. The human-use study will follow all applicable national rules, institutional policies, and

Helsinki Declaration principles. This protocol was approved by the host institution's ethics committee via letter numbers Ref NO.446/ME-II/2023 with the number (No. IEC-IIYNMS/Approval/004/2023) and registered in the Clinical Trial Registry of India (CTRI/2024/02/063097). The study will recruit a total of 80 patients with Type II Diabetes Mellitus. Each participant will be asked to provide informed permission before being included in the research. The study will include Type 2 Diabetes Mellitus patients aged 35-55 years, of both genders, taking oral hypoglycaemic medicines with HbA1C levels ranging from 5.8% to 7.8%, can distinguish between heat and cold temperatures, and agree to participate in the trial. The study will exclude patients with Diabetes Mellitus who are currently on insulin therapy, those with systemic disorders such as diabetic retinopathy, neuropathy, or nephropathy, and those with recent abdominal surgery, spinal injury, or previous spinal surgery.

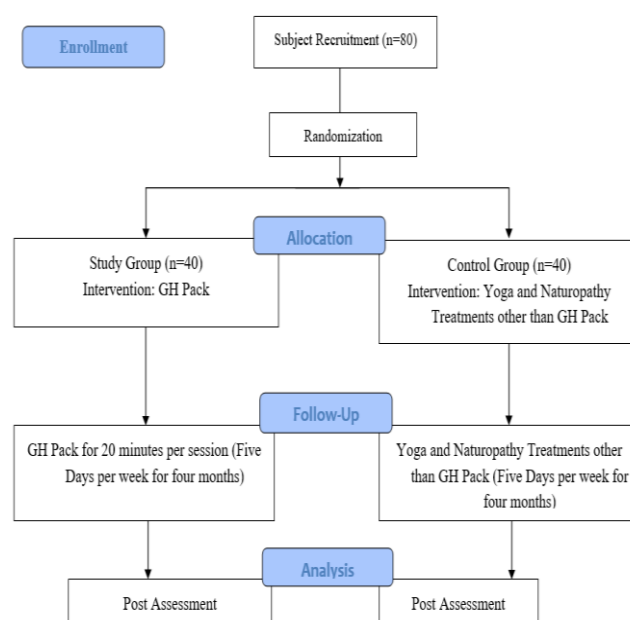


Figure 1: CONSORT Flow Diagram

Preparation and Procedure

Study Group: The study group will undergo Gastro-hepatic pack for weekly five days a week for 4 months. It will be administered in a supine lying knee-flexed position with hot fomentation (98 – 104° F) applied ventrally on the abdominal region, covering the epigastric, left and right hypochondriac region, right lumbar, left lumbar and umbilical region and then cold bag (55-65° F) at least eighteen inches long is applied to the dorsal and lumbar region [12]. Then covered with a dry cotton cloth and wrap with a Wool blanket. The overall therapeutic duration of GH pack will be 20 minutes in the morning before food. The intervention will be administered by a qualified therapeutic assistant, with the primary investigator present to monitor the treatment procedure throughout.



Figure 2: GH Pack Intervention

Control Group: The control group will undergo yoga and naturopathic interventions in addition to the GH pack five days per week for four months.

Outcome Parameters

The biochemical assessment parameters involved in this study are glycated haemoglobin (HbA1c) and liver enzymes such as SGOT & SGPT. A biochemical assessment will be performed before and the four-month course of interventions.

Glycated Haemoglobin A (HbA1c)

The HbA1c test is widely accepted and standardized, providing a reliable indicator for detecting diabetes with established cut-off values ($\geq 6.5\%$ for diabetes). The HbA1c test measures average blood glucose levels for two to three months [13].

Liver Enzymes (SGOT & SGPT)

Elevated SGOT and SGPT levels can serve as prognostic indications for diabetes progression and associated complications, implying that regular monitoring of these enzymes is essential in diabetic patients [14]. The normal ranges for SGOT and SGPT enzymes are 5-30 IU/L and 4-36 IU/L, respectively [15].

Statistical analysis

Data analysis will be performed using appropriate statistical tests in R software. The data will be analyzed using a paired Student's t-test for within-group parameters, and an independent t-test for between-group parameters.

DISCUSSION

The gastro-hepatic pack involves both hot and cold-water interventions. The hot intervention is applied with a fomentation bag, while the cold intervention is applied by using an ice bag. GH pack treatment targets specific abdominal areas, particularly liver and pancreas.

In generally, hot applications dilate cutaneous blood vessels, increasing the skin and underlying tissues activity and metabolism, potentially increasing glucose utilisation by the skin and underlying muscles. In contrast, cold application causes cutaneous blood vessels to contract, reducing skin

activity, and lowering the temperature of the affected areas [16] [17] [18]. This cold exposure can cause compensatory vasodilatation in the deeper vascular system, increasing blood flow to tissues beneath the exposed area. As a result, increased blood flow can boost metabolic rate and help maintain a constant deep tissue temperature [17] [19].

In patients with Non-Insulin Dependent Diabetes mellitus (NIDDM), GH pack intervention effectively managed fasting and post-prandial blood glucose levels. This effect could be attributed to increased blood flow to the abdominal organs (liver, pancreas, abdominal muscles, etc.) and thermoregulatory changes that facilitate glucose metabolism [20]. Twenty minutes of GH pack showed significant results on immediate reduction of blood glucose levels on continuous glucose monitoring in T2DM patients [21].

The hot application to the abdomen is hypothesized to increase blood flow to the liver, which is required for glucose metabolism and insulin sensitivity. Heat increases hepatic blood flow by dilating blood vessels, potentially boosting the liver's capacity to process glucose and reduce blood sugar levels. Simultaneously, cold application to the lower back promotes vasoconstriction, which redirects blood flow to other areas, particularly the abdominal organs. This mechanism maintain the elevated circulation and metabolic activity initiated by the heat, potentially lowering fasting blood glucose levels [22].

As a result, a possible mechanism of the GH pack could be a sudden increase in hepatic blood flow that enhances liver function, followed by a sustained reduction in flow that maintains blood flow at 5–6 times its initial rate. This process may also help to remove unwanted metabolites from the liver through the processes of phagocytosis. Furthermore, the vasoconstriction caused by the cold application to the lower back in the GH pack may aid in delivering blood to other bodily parts, such as the liver, where the demand for blood supply increases after heat is applied. This demonstrates that GH packs are an extremely effective treatment for Type II diabetes mellitus patients. The findings of this study protocol will contribute to the evidence base supporting or refuting the GH pack to eyes on glycated haemoglobin and liver enzymes. The scope of this study is limited by the small sample size, single-centre study, lack of long-term intervention, and open-label design of interventions, all of which may introduce biases. A randomized controlled trial with a larger sample size, multi-center trials, long-term follow-up and incorporating outcome measures (quality of life assessments, fasting insulin, lipid profiles, continuous glucose monitoring) is required to confirm the anti-hyperglycaemic effect of GHP and understand its underlying mechanism.

CONCLUSION

This protocol outlines a randomized controlled trial designed to investigate the effects of GH pack on glycated haemoglobin

A and liver enzymes such as SGOT & SGPT in Type II DM patients. The findings from this study will contribute to the growing body of knowledge in integrative health care in Type II DM patients and influence future research directions in this area.

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