

The Combined Effect of Integrated Naturopathy and Yoga Management with Cold Hip Bath for Ten Days on Glycemic Profile and Body Composition in Middle-aged Diabetic Patients.

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ABSTRACT

Background and Purpose: Chronic hyperglycaemia and central obesity play a major role in the pathophysiology of Type 2 Diabetes Mellitus (T2DM). We examined the effects of cold hip bath (CHB) with Integrated Naturopathy and Yoga treatment protocol (INY) on glycaemic profile and body composition in middle-age T2DM individuals. **Materials and Methods:** Participants were randomly assigned into study group (n = 50) and control group (n = 50), participants in both the group received INY treatment protocol for 10 days. Subjects in the study group received INY treatment protocol + CHB for 20 minutes for 10 days. Glycaemic profile and body composition parameters were evaluated before and following the interventions. **Results:** Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), and Waist Hip Ratio (W/H ratio) showed a significant reduction in both groups. However, the study group had a larger mean difference than the control group. **Conclusion:** A combination of INY treatment protocol and CHB improves the glycaemic status and body composition parameters by enhancing the glucose utilization through cold-induced thermogenesis compared to that of INY treatment protocol alone.

Keywords: *Integrated naturopathy and yoga; cold hip bath; Diabetes Mellitus; Cold-induced thermogenesis.*

Health For All is an expanded and broader goal of the “Global Health Agenda”, but in this comprehensively globalized world, where the health of the community is increasingly becoming a commodity has transcended a worldwide shift in health burden from communicable to non-communicable diseases (NCDs) [1-4]. Diabetes, a major cause of morbidity and mortality among NCDs, is a catastrophic illness that has gone from rarity to epidemic due to its multi-factorial cascade of etiology [5, 6]. Approximately 90-95% of cases are T2DM, the most predominant type of disease [7]. The major focus of therapy is about the hallmark metabolic abnormality associated with T2DM-hyperglycemia, which when left untreated progresses the development of other coincident features, such as obesity, hypertension, hypercoagulability, and insulin resistance [8]. Chronic hyperglycemia is associated with a wide range of diabetes-specific complications with acute and chronic effects such as ketoacidosis, neuropathy, retinopathy and nephropathy [9]. Obesity (BMI \geq 30kg/m²), a chronic inflammatory state

is the strongest risk factor for T2DM [10, 11], and is likely associated with increased concentration of circulating pro inflammatory cytokines that likely contribute to the development of insulin resistance and progression of DM [12, 13].

These complexities might be restrained or controlled with the assistance of conventional medicine in patients, whose lifestyle directed interventions fail to achieve acceptable glycemic control [14,15] The perfect way of combating this serious problem is by ensueing the Integrated approach of Naturopathy and Yoga (INY) regimen which are a part of Nature cure. It is primarily a preventive discipline of science with an education that recognizes the body’s innate power to heal itself through the stimulation of the inherent healing capacity of the individual. [16] Various forms of interventions incorporated in INY are yoga therapy, hydro, & mud therapy, manipulative and diet therapy [17], which are all a constituent of Complementary and alternative Medicine (CAM) [18].

In the recent past, numerous studies have concluded that following INY protocol for the treatment of T2DM has significant improvement in various parameters such as glycemic status (FBG, PPBG and HbA1C), lipid profile, oxidative stress (total anti-oxidative capacity, glutathione peroxidase), system scores (blood pressure (BP), weight, Body Mass Index (BMI), (W/H ratio)), hormonal status (adiponectin, insulin sensitivity, beta-cell function and insulin resistance) and symptom score (urination, visual symptoms, fatigue, drowsiness, hunger, thirst [19-21].

Hydrotherapy a treatment methodology that is performed in water can potentially improve a patient's health status. In general, hydrotherapy is believed to induce change in body temperature and blood flow through the effects of water temperature and hydrostatic pressure. These effects are believed to increase the cardiac output, which increases the blood flow, which accelerates the delivery of nutrients and oxygen required for the repair of damaged tissues and facilitates the removal of metabolites and waste product [22-24]. In recent years, a variety of physical and motor disabilities are treated using this complementary therapy [25]. Furthermore, hydrotherapy keeps patients psychologically fresh and improves their quality of life [26].

To date, a variety of research has investigated the effect of INY treatment protocol and CHB as a stand-alone treatment on patients with diabetes. To our knowledge, no comprehensive study has examined the potential beneficial effect of combined INY treatment protocol and CHB continuously for ten days in diabetic patients. Therefore, we planned this study to compare the effect of a combination of INY treatment protocol with CHB for ten days, to any changes in glycemic profile (FBG, PPBS) and system score (BMI, W/H ratio).

MATERIALS AND METHODS

Subjects: A subject flow diagram is presented in Fig.1. The subjects participating in the study were middle-aged diabetes patients recruited and screened from Shanthivana Yoga and Nature Cure hospital, Dharmasthala, Karnataka. Subjects were screened under inclusion criteria. Study participants were T2DM patients aged 30-60 years of both genders with concomitant overweight and obesity (BMI \geq 25 kg/m²) and those who satisfy the ICD 10 criteria for diabetes. Participants with any form of systemic micro and macrovascular complications, Type 1 Diabetes Mellitus (T1DM) and females during menstruation were excluded from the study. Before study entry, participants were provided with information about the research purpose and measurement procedures and screened by a Naturopathy doctor. The study protocol and design were approved by the

Institutional Ethical Committee. All participants provided written informed consent. The study was registered in the Clinical Trial Registry of India (Registration Number: CTRI/2019/11/022046).

Table 1 - Naturopathic treatment protocol

Day	Morning (9:30 AM - 11:00 AM)	Afternoon (2:30 PM - 4:00 PM)
1	Cold circular Jet	Cold hip bath
2	Full body massage	Cold abdominal pack
3	Neutral underwater massage	Gastro-hepatic pack
4	Sauna bath with cold chest pack	Hot Foot and Arm bath
5	Partial massage to back & legs	Cold spinal spray
6	Alternate immersion bath	Direct mud application to abdomen
7	Sauna bath with cold chest pack	Cold immersion bath
8	Full Mud bath	Cold chest pack
9	Cold Douche to Whole body	Alternate compress to abdomen
10	Stream bath with cold chest pack	Neutral circular Jet

Table 2 - Yogic management protocol for 90 minutes

Kriyas	Jalaneti
Loosening Exercise and Stretching	Neck Movements Arm, Shoulder and Wrist Movements Hip Rotation and Stretch Spinal Twist and Stretch Jogging Jumping
Standing Series	Ardhachakrasana, Padahasthasana, Trikonasana, Parivirtha Trikonasana
Supine Series	Uthitta Padasana, Sethubandhasana, Pavanamuktasana
Prone Series	Bujangasana, Shalabasana, Dhanurasana, Naukasana
Sitting Series	Vakrasana, Ardhamatsyandrasana, Pachimottasana
Pranayama	Basthrika (50 Strokes), Surya anuloma Villoma, Nadishodana, Sheetali, Sheetkari, Bhramari
Relaxation Technique	Deep Relaxation Technique

Study design: In the present randomized controlled trial, participants were recruited to participate voluntarily in the study. Subjects were then randomly assigned into two groups (computer-generated randomization), the study group (group 1) and the control group (group 2).

Intervention and assessment: The study group received INY treatment protocol along with CHB once a day during the morning treatment schedule, at 10-18°C for 20 minutes for ten days. The hip bathtub will be filled with cold water at 10-18°C, enough to cover the hips and reaching up to the navel region when the subject sits in it. The subject will gently rub the abdomen in the clockwise direction with a coarse wet cloth throughout bath (20 minutes) [27]. The control group received the INY treatment protocol interventions only for ten days. The common INY protocol, shown in Tables 1, 2 and 3 with calorie-restricted diet was implemented for all the subjects.

Assessments were done for FBG, PPBG, BMI and W/H ratio at pretest and after ten days of intervention at the same time of day (6am to 7am) in the morning. Participants were

asked to void completely and their body weight was measured with a calibrated digital scale (ESSAE, India) to the nearest 0.1 kg and height was measured using Bio-plus measurement scale (India) to the nearest 0.1 cm. Blood samples were collected from the forearm vein of all subjects and collected in vacutainers for analysis. Glycemic profile was measured by Automated Clinical Chemistry Analyser (Erba EM 360, Czech Republic).

Statistical analysis: The normality of data was tested via the Kolmogorov Smirnov test and Shapiro-Wilk test. Independent sample t-test and Paired t-test are used for data that follow a normal distribution and Mann Whitney U test and Wilcoxon signed ranked t-test were applied for data that were not followed by a normal distribution. All statistical analysis was conducted using SPSS software version 23.0.

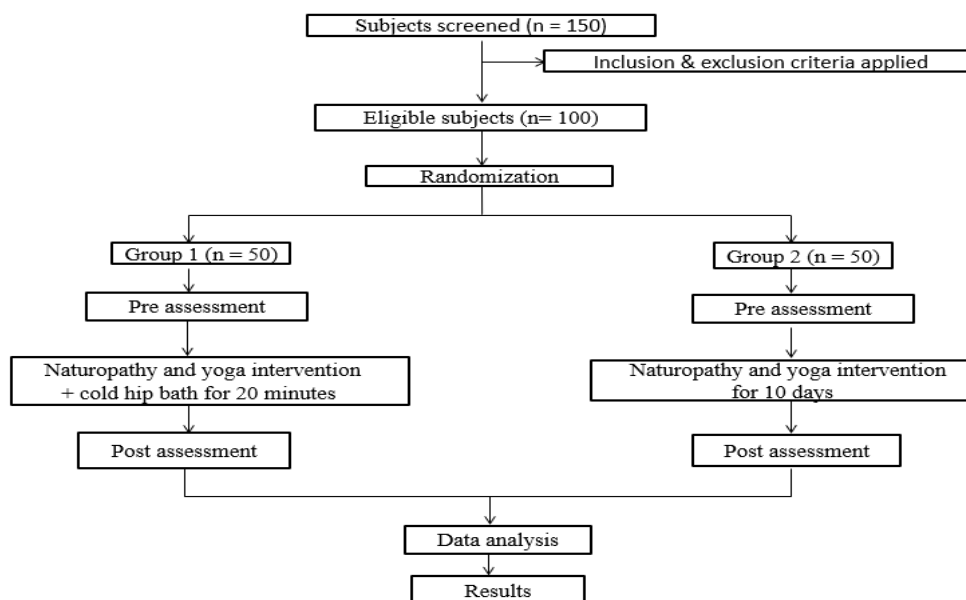


Fig 1: Subjects flow diagram

Table 3 - Diet protocol for 10 days

Days	7.30 AM	9.00 AM	11.00AM	2.00 PM	4.00 PM	6.30 PM	8.00 PM
Day 1	BGJ	RG	BD,PP,BM	KKJ	Cu, Spr	BD,PP,BM	Ap
Day 2	BGJ	RG	BD,PP,BM	KKJ	Cu, Spr	BD,PP,BM	Ap
Day 3	BGJ	RG	PP,BM	KKJ	Cu, Spr	PP,BM	Ap
Day 4	BGJ	RG	PP,BM	KKJ	Cu, Spr	PP,BM	Ap
Day 5	BGJ	RG	PP,BM	KKJ	Cu, Spr	PP,BM	Ap
Day 6	BGJ	RG	PP,BM	KKJ	Cu, Spr	PP,BM	Ap
Day 7	BGJ	RG	PP,BM	KKJ	Cu, Spr	PP,BM	Ap
Day 8	BGJ	RG	PP,BM	KKJ	Cu, Spr	PP,BM	Ap
Day 9	BGJ	RG	BD,PP,BM	KKJ	Cu, Spr	BD,PP,BM	Ap
Day 10	BGJ	RG	BD,PP,BM	KKJ	Cu, Spr	BD,PP,BM	Ap

BGJ- Bitter gourd juice, RG – Ragi Ganji, BD- Boiled diet, PP- Papaya, BM- Buttermilk, KKJ- knol-khol juice, Cu- cucumber, Spr – Sprouts, Ap- Apple

RESULTS

Total 150 middle-aged diabetic patients were screened, of these, only 100 qualified for the study. Pretest characteristics of the 100 participants are shown in Table 1. Table 5 and Fig 2 and 3 show levels of evaluating glycemic and body composition parameters. The result of this study shows that FBG (p=0.002), PPBG (p=0.03) and HWR (p=0.017) showed significant reduction after 10 days of intervention where BMI (p=0.94) was not significant between the groups.

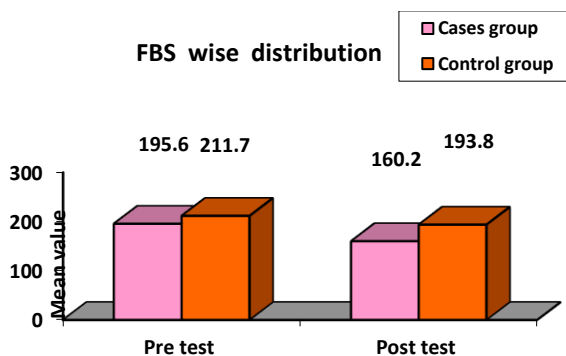


Fig 2: Graphical representation of a comparison of case and control groups concerning pre and post-test scores of FBG

The results of the pretest-post data comparisons for both the groups are, in the case group, there was a significant decrease in the FBG (p=0.001), PPBG (p=0.001), BMI (p=0.001) and HWR (p=0.001) with a mean difference of 35.38±14.01mg/dl, 61.84±29.92 mg/dl, 1.60±0.42 kg/m² and 0.01±0.014 respectively. Whereas in the control group, there was a significant

decrease in the FBG (p=0.001) and PPBG (p= 0.001), BMI (p= 0.001), HWR (p=0.003) with a mean difference of 17.68±9.05 mg/dl, 30.38±25.52 mg/dl, 1.31±0.72 kg/m² and 0.004±0.009, respectively.

Table 4 - Anthropometry and body composition characteristics of the participants

Characteristics	Study group	Control group	p-value
Male	22	23	0.841
Female	28	27	
Age (years)	44.08±6.95	42.96±7.36	0.955
Height (cm)	163.48±9.40	159.30±6.62	0.12
Weight (kg)	80.23±14.08	74.6±10.34	0.045*
BMI (kg/m ²)	29.9±4.28	29.4±3.98	0.560

*P<0.05 statistically significant. **p<0.01 and ***p<0.001 highly statistically significant

Table 5 - Comparison of pre-test and post-test outcome measures with and between the group

Variable	Gp	Pre-test	Post-test	p-value
FBG (mg/dl)	A	195.6±44.1	160.2±42.87	0.002**
	B	211.7±56.3	193.8±56.3	
PPBG (mg/dl)	A	270.9±62.2	209.1±65.3	0.03*
	B	270.3±67.6	239.9±69.3	
BMI (kg/m ²)	A	29.9±4.28	28.35±4.28	0.94
	B	29.4±3.98	28.1±3.74	
W/H Ratio	A	0.96±0.06	0.95±0.05	0.017*
	B	0.98±0.06	0.97±0.06	

Group A – Cases, Group B – Controls, *P<0.05 statistically significant. **p<0.01 and ***p<0.001 highly statistically significant

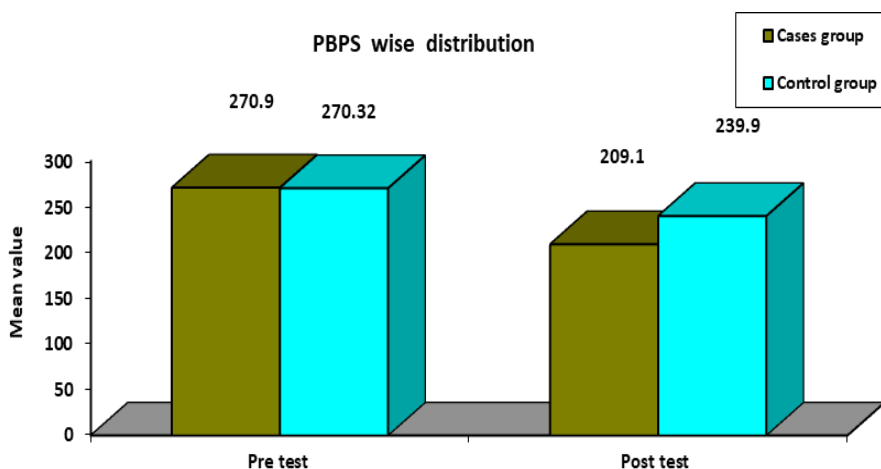


Fig 3: Graphical representation of a comparison of case and control groups concerning pre and post-test scores of PPBG

DISCUSSION

Evidence suggests that glycemic control, adiposity are strong indicators to measure diabetes performance to decide the future direction of therapy for individuals [28]. Hence, the present study investigated the combined effect of CHB and INY treatment protocol on anthropometric measures and glycemic profiles in middle-aged diabetic individuals. According to the findings, CHB in combination with INY treatment protocol improved the diabetic blood profile and reduced the WHR of middle-aged diabetic individuals. The results from our study are homogeneous with similar studies with INY protocol of strict dietary intervention and structured physical activity on both short and long-term basis, showing significant reduction in glycemic control, lipid profile, anthropometric measures, HbA1c levels and medication score [29-33].

Previous research has led researchers to conclude that water immersion alone (without any physical activity) shows improvement in the symptoms and overall health of diabetic individuals [25]. A previous study by Mizrahi et al has concluded that in comparison with healthy adults, immersion in dead seawater reduces glucose levels in T2DM patients [34]. In another study, were diabetic subjects immersed in warm water for 30 mins per day without any movement showed a significant decrease in glycosylated haemoglobin, weight and plasma glucose levels. In order to justify these physiological changes, researchers had reported that shunting of blood towards the skeletal muscle must be the underlying mechanism for the observed changes [35]. In agreement with our findings, Mooventhan and his colleagues reported that 20 minutes of a Cold abdomen pack (CAP) was effective in improving blood glucose levels and cardiovascular function in diabetic subjects [36]. Elevating energy expenditure is a potential strategy to reverse various metabolic conditions. In our study, CHB might have improved glucose utilization and energy expenditure by increasing the metabolic rate by enhancing Cold-induced thermogenesis (CIT) in brown adipose tissues [37].

Recent pieces of evidence conclude that cold exposure recreates a physiological condition where the energy expenditure is continuous rather than a transient stimulation [38] and prolonged cold exposure increases BATs thermogenic capacity by increasing BAT weight, cellularity and total cytochrome oxidase activity [39]. "Browning" is a process known to promote metabolic heat production by triggering the switching over of subcutaneous White Adipose Tissue (sWAT) to beige phenotype fat cells on exposure to low temperature [40-41]. Increasing evidence suggests that the association between mitochondrial

dysfunction, oxidative stress and defective mitochondrial biogenesis play a major role in the pathophysiology of T2DM and age-related insulin resistance [42,43].

Acute cold exposure enhances the browning of sWAT by increasing the upregulation of Uncoupling Protein1 (UP1) and by increasing the mitochondrial biogenesis [44]. Similarly, studies have correlated that cold exposure has a significant effect on circulating levels of adipocyte-derived hormones (adipokines) such as Fibroblast growth factor-21(FGF21) plays a vital role in energy homeostasis and insulin sensitivity [45]. FGF21 a brown fat adipokine-termed as batokine is a novel cold-induced endocrine metabolic regulator that has potential influence on the browning of sWAT, energy balance, glucose and lipid metabolism [46,47]. Hanssen et al have concluded that during acute cold exposure circulating levels of FGF21 are positively correlated with BAT activity [48]. β -adrenergic agonists, another promising treatment methodology to restore normoglycemia and improve glucose tolerance, that can significantly improve the thermogenic capacity of BAT [49,50]. A study by Fergly et al., has concluded that cold adaptation showed greater responsiveness to β -adrenergic agonist and BAT activity [51].

Cold exposure is also said to increase glucose utilization by pronounced translocation of GLUT4 at the cell membrane of sarcolemma [52]. A recent study has proposed that GLUT 4 translocation has been increased by cold-induced β -adrenergic stimulation by the phosphorylation of mammalian target of rapamycin complex 2 (mTORC2) [53], similar to those exposed to physical exercise, studies have observed that cold exposure enhances insulin sensitivity in peripheral tissues and improves glucose tolerance by markedly decreasing basal and glucose-stimulated levels of circulating insulin [54].

Studies have demonstrated that cold exposure in the form of, whole-body cryostimulation can be a supplementary method to reduce systemic inflammation in obese individuals by reducing the concentration of circulating pro-inflammatory cytokines [55]. According to Gimble and Yes, the blood flow may change through the subcutaneous tissues, attenuating a local hypoxic state, that may reflect a compensatory failure in the local vasculature in hypertrophic fat cells as a response to the cold exposure. Therefore, better blood flow may counteract inflammation, by enhancing the oxygen supply and limiting the production of reactive oxygen species [56]. This is in agreement with a study conducted by Miller, the study indicates that cryostimulation may reduce oxidative stress via attenuating a local hypoxic condition and by significantly improving the total antioxidant status [57].

The clockwise friction movement during the intervention has raised the possibility of increasing the blood circulation and fabricate a stress-reducing relaxation response, thereby counter regulating the stress hormones, which may be beneficial for allowing the body to use insulin more effectively [58,59]. Similarly, this friction movement could have enhanced the alteration in body composition parameters. In a further study, aquatic exercise reduced overall and local fat mass in the abdominal and pectoral regions [60].

The limitation of our study was the small number of subjects in each group. Additionally, we did not measure components such as HbA1c, inflammatory markers and serum insulin levels, which may have been useful in explaining the improvements in glycemic profile. Further studies involving larger populations and additional biochemical parameters are needed to provide stronger results.

CONCLUSION

Ten days of INY treatment regimen improved glycemic profile and body composition in middle-aged diabetic subjects, but its combination with cold hip bath further enhanced benefits in glycemic profile and system scores. These findings suggest that the implementation of cold hip bath routinely with INY treatment protocol by health professionals can improve the glycemic profile and body composition parameters of middle-aged diabetic patients and limit the progression of the disease.

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