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Original Article

Complementary/Alternative Medicine Section

A Study on Immediate Effect of Cold Abdominal Pack on Blood Glucose Level and Cardiovascular Functions in Patients with Type 2 Diabetes Mellitus

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ABSTRACT

Introduction: Diabetes mellitus is one of the metabolic disorders which is characterised by chronic hyperglycaemia due to insulin resistance or deficiency or both. Though a hydrotherapy text reported the use of Cold Abdominal Pack (CAP) for various metabolic disorders, there is a lack of scientific evidence for the use of CAP in a metabolic disorder like Type 2 Diabetes Mellitus (T2DM).

Aim: To evaluate the immediate effect of CAP on blood glucose level and cardiovascular functions in patients with T2DM.

Materials and Methods: In this prospective single group pre-test and post-test study, a total of 20 male T2DM subjects with the mean age of 51.75±7.71 years were recruited from June 2016 to December 2016. Study was conducted in SVYASA University, Bengaluru, Karnataka, India. All the subjects underwent CAP for 20 minutes. Assessments were taken before and immediately after the intervention using standard methods. Statistical analysis was performed using Student's paired samples t-test with the use of Statistical Package for the Social Sciences (SPSS), version 16.0.

Results: Results of this study showed a significant reduction in random blood glucose level (p=0.011), pulse rate/heart rate (p=0.028), systolic blood pressure (p=0.023), mean arterial pressure (p=0.010), rate pressure product (p=0.006), and double product (p=0.003) compared to its respective pre-test and no such significant changes were observed in diastolic blood pressure (p=0.095) and pulse pressure (p=0.306).

Conclusion: Results of this study suggest that 20 minutes of CAP might be effective in improving blood glucose level and cardiovascular functions of patients with T2DM.

Keywords: Blood pressure, Cold pack, Hydrotherapy, Naturopathy

INTRODUCTION

Cold abdominal pack is one of the hydrotherapeutic procedures employed in many naturopathic hospitals for various metabolic disorders. It consists of a cotton cloth dipped in cold water and wrung out and then wrapped around the abdomen. A dry cloth and the flannel are also wrapped over the wet cloth to reduce evaporation. The mechanism of therapeutic effect of CAP is mainly through improving metabolism by thermoregulation [1]. Diabetes mellitus is one of the metabolic disorders which is characterised by chronic hyperglycaemia due to insulin resistance or deficiency or both T2DM is a global health problem since it is projected to increase by 51%, reaching 552 million by 2030 from the prevalence of 366 million in 2011. In India, it is projected to increase by 63%, reaching 98 million by 2030 from the prevalence of 31 million in 2000, and 60 million in 2011 [2]. Reduced parasympathetic activity, increased sympathetic activity, and enhanced cardiovascular reactivity have reported to be associated in the pathogenesis of insulin resistance syndrome, atherosclerosis and cardiovascular diseases [3]. Long-term drug usage has its own drawbacks, like drug resistance, drug dependency, and adverse effects. Hence, a search for non medical measures is increasing in recent years, not only to control T2DM, but also to prevent its complications [2,4].

Naturopathy is a science of health and healthy living [5]. Naturopathy approach is basically holistic rather than compartmental [6]. It's main objective is to change the unhealthy living habits of people and to teach them the healthy lifestyle in accordance with the laws of nature [5]. It consists of various therapies including hydrotherapy, diet therapy, fasting therapy, mud therapy, heliotherapy, and air therapy [7]. Water is the main component of naturopathy [5]. Hydrotherapy employs the external/internal use of water in any of its forms (ice, water and steam) at various temperatures, pressures, durations and locations on the body for the promotion of health or the treatment of various diseases [7].

Though cold exposure has reported to be useful for the management of T2DM as a third lifestyle factor (along with diet and exercise) to optimise health and a hydrotherapy text reported the use of CAP for various metabolic disorders, there is a lack of scientific evidence for the use CAP in a metabolic disorder like T2DM [1,8]. To the best of our knowledge this is the first ever study conducted to evaluate the immediate effect of CAP on blood glucose level and cardiovascular functions in patients with T2DM.

MATERIALS AND METHODS

Subjects

A total of 20 male T2DM subjects with the mean age of 51.75±7.71 years based on convenient sampling were recruited form a residential holistic health center, South India. Sample size was not calculated based on any previous study, which is one of the limitations of the study. Male subject with the history of T2DM with more than one year and on regular medication and the ones who were willing to participate in the study were included in the study. Subject with the history of Type 1 diabetes mellitus or uncontrolled T2DM with complications including cardiovascular complications, sensitive to cold application, and subject who underwent CAP for the past one week were excluded from the study. Study was approved by the Institutional Ethics Committee and a written/informed consent was taken from each subject included in the study.

Study Design

A single group pre-test and post-test design was adopted. All the subjects underwent a single session of CAP for the duration of 20 minutes. Assessments were taken before and after the intervention.

Assessments

Random Blood Glucose (RBG) level: It was assessed before and after the intervention using a glucometer (hemocue 201+, Angelholm, Swedan).

Blood Pressure (BP) and Pulse Rate (PR): Assessment of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and PR were measured before and after the intervention using a non-invasive arm type automatic BP monitor (Omron HEM-7120, Kyoyto, Japan). Minimum of two measurements with the rest period of one minute between the measurements were taken and averaged to get a final value. In case of difference between the two measurements by >10 mmHg, a three measurement was taken after one minute of rest period followed by the second measurement and the average of the two measurements which did not differ >10 mmHg was averaged to get a final value. By using the following formula, assessments like pulse pressure (PP), Mean Arterial Pressure (MAP), Rate Pressure Product (RPP), and Double Product (Do-P) were calculated. PP was calculated as (SBP-DBP); MAP as (DBP+1/3 PP); RPP as (PR×SBP/100); and Do-P as (HR×MAP/100) [9].

Intervention

All the subjects underwent CAP that consists of a cotton cloth dipped in water (15-16°C) and wrung out and then wrapped around the abdomen from lower part of the ribs to the groin. A dry cloth and the flannel were wrapped over the wet cloth in order to reduce evaporation. The duration of the intervention was kept 20 minutes since a previous study reported that the physiological effects of cold therapy appear when it continues for 20 minutes [7,10].

STATISTICAL ANALYSIS

Data were checked for the normality using Kolmogorov-Smirnov test. Statistical analysis of was performed using Student's paired samples t-test with the use of SPSS for Windows, version 16.0. (Chicago, SPSS Inc.). A p-value <0.05 was considered as significant.

RESULTS

Recruited 20 subject's demographic details are given in [Table/Fig-1]. Results of this study showed a significant reduction in RBG levels, PR, SBP, MAP, RPP and Do-P compared to its respective pre-test and no such significant changes were observed in DBP and PP [Table/Fig-2].

Variables	Study Group (n=20)
Age (years) (mean±SD)	51.75±7.71
Gender (Males)	(n=20)
Height (meter) (mean±SD)	1.66±0.06
Weight (kg) (mean±SD)	72.2±7.76
Body mass index (kg/m^2) (mean±SD)	26.12±3.13

[Table/Fig-1]: Demographic variables of the study group (n=20).

DISCUSSION

Increased blood glucose level (hyperglycaemia) is the most important characteristics of T2DM [1]. Since, the aetiology, pathophysiology, severity, age of the onset, and the management of the Type 1 and T2DM is quite different, the response to the treatment may also be different. Moreover, prevalence of the Type 2 diabetes is quite more than that of Type 1 diabetes [8]. Hence, we thought of having the Type 2 diabetes patients as present subjects. Moreover, to get the homogeneity in the study group we have excluded the subjects with Type 1 diabetes. Result of this study showed a significant reduction in RBG level. It suggests that the application of 20 minutes of CAP might be effective in reducing the blood glucose level in patient with T2DM. The possible mechanisms for the reduction of blood glucose level are as follows: 1) Utilisation of glucose by increased metabolism; 2) Increased insulin release through activation of (closure) of Adenosine Triphosphate (ATP) sensitive potassium (KATP) channels and Calcium ion (Ca^{2+}) permeability; 3) Increased insulin sensitivity; and 4) Activation of Transient Receptor Potential Melastatin-like 8 (TRPM 8) ion channel and brown adipose tissue.

Variables	Pre-test (mean±SD)	Post-test (mean±SD)	t-value	p-value
RBG (mg/dL)	154.35±4.09	149.55±33.25	2.799	0.011*
SBP (mmHg)	122.95±11.74	120.60±10.73	2.475	0.023*
DBP (mmHg)	79.55±7.74	78.40±7.59	1.758	0.095
PR (beats/minute)	74.85±7.15	73.25±6.43	2.373	0.028*
PP (mmHg)	43.40±11.63	42.20±10.76	1.051	0.306
MAP (mmHg)	94.02±7.47	92.47±7.15	2.850	0.010*
RPP (units)	92.25±14.22	88.48±12.20	3.062	0.006*
Do-P (units)	70.49±9.84	67.77±8.39	3.333	0.003*

[Table/Fig-2]: Baseline and post-test assessments of study group (n=20). (Paired samples t-test)
*All values are in Mean±Standard Deviation. **=p-value <0.05. RBG=Random blood glucose; SBP=Systolic blood pressure; DBP=Diastolic blood pressure; PR=Pulse rate; PP=Pulse pressure; MAP=Mean arterial pressure; RPP=Rate pressure product; Do-P=Double product

1) Utilisation of Glucose by Increased Metabolism

Cold induced thermogenesis is the ability to generate heat by increasing metabolism in response to cold, to maintain a stable core body temperature which is the basic property of endothermic thermoregulation [11]. When we expose a small surface area to cold as like CAP application, cold fibers evoke transient afferent discharges, inducing cold sensation and heat-gain responses while the temperature of skin decreases cold exposure is associated with hypothalamic signals to constrict the peripheral blood vessels [8,12,13]. This in turn produces a compensatory vasodilatation in deeper vascular system resulting increased blood flow to the tissues underlying the site of exposure and that increase the metabolic rate in order to maintain constant deep tissue temperature. For example, according to a previous study, immersion in cold water of 20°C almost doubles metabolic rate, while at 14°C it is more than quadrupled [12]. Hence, application of CAP might have produced an increased metabolic rate by the utilisation of blood glucose.

2) Increased Insulin Release through Activation of (closure) of ATP-sensitive Potassium (KATP) channels and Ca^{2+} permeability

The KATP channels play a key physiological roles in many tissues. In pancreatic β cells, these channels become the target for sulfonylurea drugs that is used to treat T2DM and regulate glucose dependent insulin secretion. By regulating membrane K^+ fluxes, KATP channels couple cell metabolism to electrical activity of the plasma membrane. Opening K^+ channels followed by K^+ efflux, membrane hyperpolarisation, and suppression of electrical activity occurs when metabolism reduces. Conversely, closure of KATP channels followed membrane depolarisation and stimulation of electrical activity occurs when metabolism increases [14]. A previous study reported that a brief cold exposure produces increased blood flow by compensatory vasodilatation in deeper vascular system to the underlying site of exposure and that increase the metabolic rate [12]. Similarly, the application of CAP might have produced an

increase in plasma glucose through increased blood flow to internal organs including pancreas which stimulates glucose uptake and metabolism by the β cell, producing changes in cytosolic nucleotide concentrations that result in closure of KATP channels. This leads to insulin secretion by producing a membrane depolarisation that opens voltage gated Ca^{2+} channels, initiating β cell electrical activity, Ca^{2+} influx, a rise in intracellular calcium concentration [14]. In a study, cooling of a particular part was reported to induce an inward cold current which is a non selective cation current with high Ca^{2+} permeability [13]. This implies that receptor potential increases from resting potential toward 0 mV, when whole cell conductance is activated fully by cooling. Hence, application of CAP might produce high Ca^{2+} permeability in pancreatic beta cells that leads to the secretion of insulin [13].

3) Increased Insulin Sensitivity

Hyperinsulinemia is known to be present in patients with T2DM due to reduced insulin sensitivity while, cold exposure has been suggested to improve glycaemic control for T2DM through improving insulin sensitivity [8]. In a study, 10 days of cold acclimation (14-15°C) has shown to induce a 43% increase in insulin sensitivity which was explained by a 60% increase in GLUT-4 translocation (i.e., the membrane channel that allows glucose to enter a muscle cell or adipocyte) in patients with T2DM. Hence, application of CAP might have produced increase in insulin sensitivity and thereby reduced the blood glucose level [8,15].

4) Activation of Transient Receptor Potential Melastatin-like 8 ion channel and Brown Adipose Tissue

Transient Receptor Potential (TRP) ion channels like TRPM 8, TRP Ankyrin rich 1 (TRPA1) and TRP Canonical 5 (TRPC5) have been found to be cold sensitive ion channels. Among all TRPM8 plays a crucial role in detecting cool to cold temperature in vivo [16]. In humans, TRPM8 activation has been associated with 'browning' of white adipose tissue there by possibly promoting energy utilisation [16]. Cold exposure was reported to be a potential therapy for diabetes by increasing brown adipose tissue mass and activity [15]. Cold exposure is associated with increase in metabolic heat production (i.e., shivering and non shivering thermogenesis) to prevent dangerous drops in core temperature. Although, shivering is the major contributor to increases in heat production, during mild cold exposure, non shivering thermogenesis play a vital role to produce physiological response. Non shivering thermogenesis is primarily mediated by metabolically active brown adipose tissue. Hence, application of CAP is also believed to reduce the blood glucose level by producing energy utilisation and non shivering thermogenesis through activation of TRPM8 ion channel and brown adipose tissue activity respectively [8].

Results of this study also showed a significant reduction in PR, SBP and MAP compared to its respective pre-test. However, no such significant changes were observed in DBP and PP. It suggests that 20 minutes of CAP were effective in improving various cardiovascular variables except DBP and PP. Significant reductions in SBP followed by 20 minutes of CAP might attribute to the effects on either baroreceptor reflex or significant reduction of HR/PR. Because SBP=cardiac output (CO)×peripheral resistance, wherein CO=HR × stroke volume and thus HR forms one of the determinants of SBP [9]. Significant reduction in MAP might attribute to the reduction in SBP (a component of PP, i.e., PP=SBP-DBP).

Autonomic dysfunction is one of the major complications of T2DM. The cardiac autonomic neuropathy is one of the leading causes of morbidity and mortality in diabetics [17]. Results of this study also showed a significant reduction in RPP and Do-P. This reduction might attribute to the reduction in PR and BP. RPP and Do-P are the important indirect indicators of myocardial oxygen consumption and load on the heart. Reduction of these variables in this study suggests a strain lowering effects on the heart. When HR Variability (HRV) analysis is not available, the RPP can be used as a simple measure of overall HRV [9]. Hence, a significant reduction in both RPP and Do-P after 20 minutes of CAP indicates its strain lowering effect and better autonomic regulation of the heart. Significant reduction in both RBG level and other cardiovascular functions, suggests that the 20 minutes of CAP was effective not only in improving blood glucose level but also effective in improving cardiovascular functions in patients with T2DM. Hence, CAP might be considered as one of the therapeutic tools for the prevention and the management of T2DM and its cardiovascular complications.

It is a well known fact that the patients with T2DM have a lowered immunity than the people with non diabetes and that is one of the complications of diabetes [2]. Whereas, acute cold exposure has reported to have a immune stimulating effects. Because, the major effectors of adaptive and innate tumour immunity such as Natural Killer (NK) cells and peripheral cytotoxic T-lymphocytes respectively were reported to increase both in numbers and its activity after brief cold stress. Hence, we believe that, a brief cold stress like CAP might help in improving the immunity in patients with T2DM [12].

None of the subjects reported any side effects during the intervention. Use of drugs has its own drawbacks, such as drug dependency, drug resistance and adverse effects, if used for a long time [2,4]. However, CAP is a safe, simple, feasible and cost effective treatment modality that can be used without any technical assistant for the management of T2DM. And, based on the present study findings studies on large sample size and covering all the limitations should be conducted.

LIMITATION

The study was conducted in male patients with T2DM that limits the scope of this study in its application to the female patients with T2DM. Small sample size and it was not calculated based on the previous study. Assessments such as fasting blood glucose level and/or post prandial blood glucose levels, insulin sensitivity, continuous BP monitoring, peripheral resistance and baroreceptor sensitivity would have given better understanding. Current study assessed only the immediate effects of CAP on blood glucose level and cardiovascular functions but did not assess its long-term effects and its underlying mechanisms. Hence, further studies are required with large sample size, longer duration and advanced techniques for the better understanding of its effects and its underlying mechanisms.

CONCLUSION

Results of this study suggest that 20 minutes of CAP might be effective in improving blood glucose level and cardiovascular functions of patients with T2DM. Based on the present study findings the use of CAP in T2DM patients and patients with cardiovascular diseases is recommended.

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