

EFFECT OF ABDOMINAL MUD PACK ON BLOOD GLUCOSE LEVEL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A RANDOMIZED PLACEBO-CONTROLLED TRIAL

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ABSTRACT:

Background and Objectives:

The application of mud pack to the abdomen is one of the treatment modalities commonly used in alternative medicines, mainly by Naturopathic physicians. Present study evaluated the effect of mud pack over the abdomen on FBS, PPBS and HbA1C in patients with Type 2 diabetes mellitus. Hence, this study aims to evaluate the magnitude of placebo response and treatment response patterns in clinical trials.

Materials and Methods:

A study has been conducted in Outpatient unit of SDM Yoga and Nature cure hospital, Ujire, Karnataka. 120 subjects were screened and 60 subjects were recruited for the study and were randomly allocated into two groups; Group-A intervention group(n=30) and Group-B placebo group(n=30) using lottery method. In the intervention group, the mud pack was applied over the abdomen for 20 minutes along with life style modification and in placebo group, the wheat flour pack applied over the abdomen for 20 minutes along with life style modification. Subjects were assessed for FBS, PPBS and HbA1C levels on the first day. On the 10th day FBS and PPBS are again collected and patients are asked to send the HbA1C reports after 3 months of follow up.

Result:

Results of this study showed a significant reduction in FBS, PPBS and HbA1C in patients who had taken abdominal mud pack. And no such significant changes were observed in placebo group.

Conclusion:

Addition of abdominal mud pack with life style modifications augments the therapeutic effects of Yoga & Naturopathy interventions in the management of Type2 Diabetes Mellitus.

Keywords: Diabetes type 2; Fasting Blood Sugar; Post Prandial Blood Sugar, Mud pack.

INTRODUCTION:

Diabetes mellitus is a nutritional disorder, characterised by an abnormally raised level of blood glucose and by the discharge of the excess glucose in urine, it results from a total or relative absence of insulin which leads to abnormalities in carbohydrate metabolism as well as in the metabolism of protein and fat(1). The disease burden related to diabetes is high and rising in every country, fuelled by the worldwide ascent in the prevalence of obesity and unhealthy ways of life. The most recent estimates show a worldwide prevalence of 382 million individuals with diabetes in 2013, expected to rise to 592 million by 2035. The aetiological classification of diabetes has now been broadly acknowledged(2).

Type 1 and type 2 diabetes are the two primary sorts, with type 2 diabetes representing for the majority (>85%) of total diabetes prevalence. The two types of diabetes can lead to multisystem complications of microvascular endpoints, including retinopathy, nephropathy and neuropathy, and macrovascular endpoints including ischaemic heart disease, stroke and peripheral vascular disease. The premature morbidity, mortality, decreased life expectancy and financial and other costs of diabetes make it a significant general wellbeing condition(2).

Naturopathy is a system of drugless, non-invasive, rational and evidence based system of medicine imparting treatments with natural elements dependent on theories of vitality, toxemia and self-recuperating capacity of body as well as principles of healthy living(3). Naturopathy system consists of non- invasive treatment modalities like diet therapy, fasting therapy, mud therapy, massage therapy, hydrotherapy, air therapy, chromo therapy and magneto therapy. It lays more significance on the preventive aspect of health care rather than curative one.(4)

In naturopathy, mud is one of the core components and also happens to be an element of earth. One of the exceptional properties of mud is that it can retain the warmth and eliminate these toxins in various ways(5). Mud therapy is being utilized to treat the cardiovascular, musculoskeletal, gynecological, dermatological conditions etc.(6)

The mud utilized for treatment purposes should be collected from a depth of 122cm to 153 cm from the surface of the ground. The mud utilized for the treatment purposes ought to be extremely clean and pure and free from all contaminations. Before utilizing the mud, it should be sieved, powdered and afterward dried under the sun. This technique prepares mud for treatment purposed. This mud can likewise be stored for long durations by taking necessary precautionary measures to maintain cleanliness. If it is contaminated, then it should be sterilized by utilizing different heating modalities or drying it under the sun(5). Mud begins its action on the body right from the moment of its application, and the patients get quick outcomes. Mud is utilized in different ways like packs, compresses and full body applications to treat different ailments. A mud pack is prepared by spreading a thin layer of mud on a cotton cloth with the help of a wooden stick. The size of the mud pack is 22.86 cm in length, 15.25 cm in width, and 1.27 cm in thickness. The size of the pack is redone as indicated by the surface zone of the body part(7).

METHODOLOGY:

Subjects: A study has been conducted in Outpatient unit of SDM Yoga and Nature cure hospital, Ujire, Karnataka. 120 subjects were screened and 60 subjects were recruited for the study and were randomly allocated into two groups; Group-A intervention group(n=30) and Group-B placebo group(n=30) for a period of 10 days. The selected patient should satisfy the inclusion criteria i.e., age must be 35-65 years, both males and females were included and patients who were diagnosed as subjects of type 2 diabetes mellitus who are under medication. Exclusion criteria includes patients with uncontrolled diabetes on insulin and patients with other systematic complications. The subjects were instructed about the study and all subjects who are willing to take part in the study were considered. A signed informed consent was obtained from each individual. Institutional Ethical Committee approved the study.

Study design:

The study adopts a randomized Placebo-controlled trial design. The subjects were randomly divided into 2 groups, the intervention group(30), and placebo group(30) subjects. The subjects were assessed on day 1 for FBS, PPBS and HbA1c, and on day 10 for FBS, PPBS and after 3 months for HbA1C along with both group received life style modification.

INTERVENTION:

Abdominal Mud Pack: Black color soil with water absorbing quality is collected from hills. Mud will be collected from 10 feet beneath the ground level. Mud should be free from impurities, composites, pebbles... Etc. Collected mud will be finely sieved and kept under sunlight for 24hrs. Sufficient quantity of water

should be added to the mud so as to make it paste like substance. The pasty mud is placed in a muslin cloth and the pack is placed over the abdominal region. Care should be taken not to slide off the mud from body surface. No movements should be given after application. The Duration of treatment is 20 min for 10 days. Temp:12^o C-18^oC (5)

Wheat flour Pack: The placebo product was formulated using wheat flour. It should be free from impurities, composites, pebbles... Etc. Sufficient quantity of water should be added to it so as to make it paste like substance. The pasty wheat flour is placed in a muslin cloth and the pack is placed over the abdominal region. Care should be taken not to slide off the wheat flour from body surface. No movements should be given after application. The Duration of treatment is 20 min for 10 days. Temp:12^oC-18^oC

DATA ANALYSIS:

The pre and post data collected were analysed using SPSS version 26. Normality of the data was assumed and Kolmogorov Smornov test was employed. HbA1C variable was normally distributed, hence parametric tests were applied. For FBS and PPBS which were not normally distributed, Mann-Whitney U test and Wilcoxon matched pairs test were employed. For all the analysis, we present 95% confidence intervals and considered $p < 0.05$ as significant.

RESULTS:

Results of the present study indicates significant ($*p < 0.05$) improvement in FBS, PPBS and HbA1c in subjects of intervention following treatment ($p = 0.0001$). There were no significant results observed in the Placebo group. Results suggested significant role of abdominal mud pack in controlling type 2 diabetes.

Table 1: Comparison of placebo group and intervention group with pretest and posttest FBS scores

| | PRE TEST | | | | POST TEST | | | | DIFFERENCE | | | |
|--------------------|----------|-------|---------|---------|-----------|-------|---------|---------|------------|-------|---------|---------|
| | Mean | SD | Z Value | P Value | Mean | SD | Z Value | P Value | Mean | SD | Z Value | P Value |
| Placebo Group | 163.00 | 44.89 | -0.5766 | 0.5642 | 169.30 | 46.11 | -0.6357 | 0.5250 | -6.30 | 13.55 | -4.7828 | 0.0001* |
| Intervention Group | 170.07 | 43.55 | | | 161.23 | 42.49 | | | 8.83 | 8.89 | | |

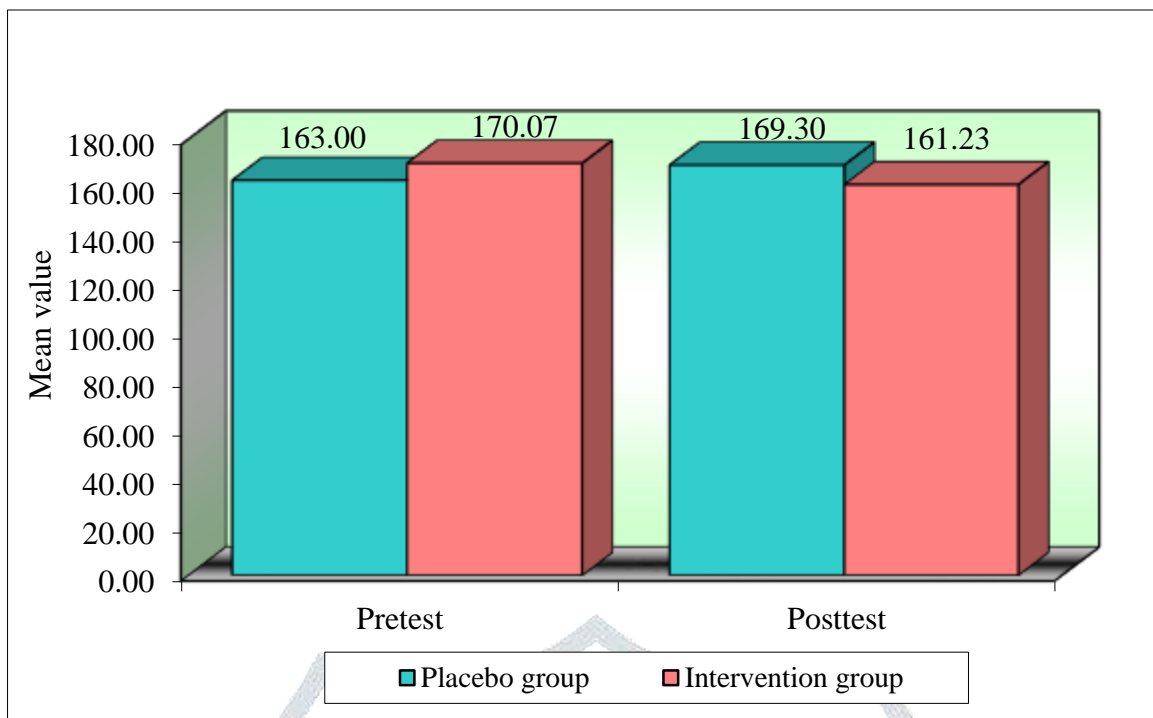


Figure 1: Comparison of placebo group and intervention group with pretest and posttest FBS scores

Table 2: Comparison of placebo group and intervention group with pretest and posttest PPBS scores

| | PRE TEST | | | | POST TEST | | | | DIFFERENCE | | | |
|--------------------|----------|-------|---------|---------|-----------|-------|---------|---------|------------|-------|---------|---------|
| | Mean | SD | Z Value | P Value | Mean | SD | Z Value | P Value | Mean | SD | Z Value | P Value |
| Placebo Group | 199.70 | 49.65 | -0.6801 | 0.4965 | 204.20 | 48.20 | -1.2049 | 0.2282 | -4.50 | 17.44 | -4.1175 | 0.0001* |
| Intervention Group | 206.80 | 56.90 | | | 187.13 | 57.37 | | | 19.67 | 26.43 | | |

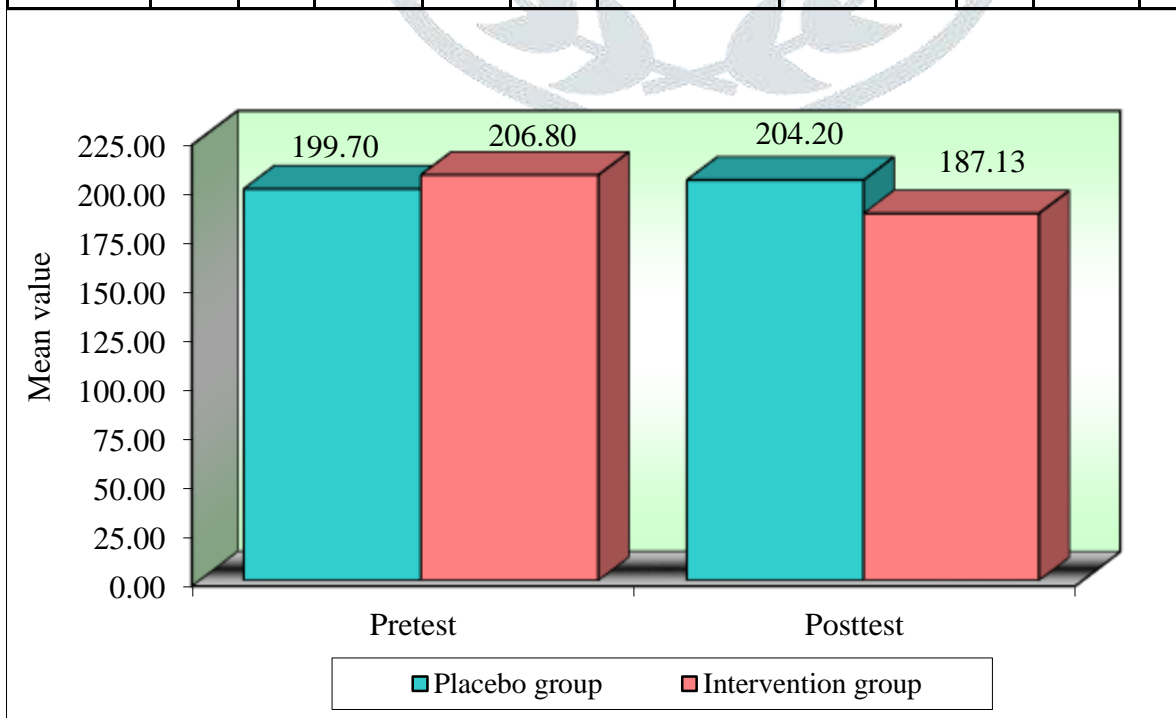


Figure 2: Comparison of placebo group and intervention group with pretest and posttest PPBS scores

Table 3: Comparison of placebo group and intervention group with pretest and posttest HbA1C scores

| | PRE TEST | | | | POST TEST | | | | DIFFERENCE | | | |
|--------------------|----------|------|---------|---------|-----------|------|---------|---------|------------|------|---------|---------|
| | Mean | SD | Z Value | P Value | Mean | SD | Z Value | P Value | Mean | SD | Z Value | P Value |
| Placebo Group | 8.36 | 0.73 | -1.5913 | 0.1170 | 8.30 | 0.89 | 2.0576 | 0.0441* | 0.06 | 0.96 | -4.5379 | 0.0001* |
| Intervention Group | 8.83 | 1.44 | | | 7.78 | 1.07 | | | 1.05 | 0.72 | | |

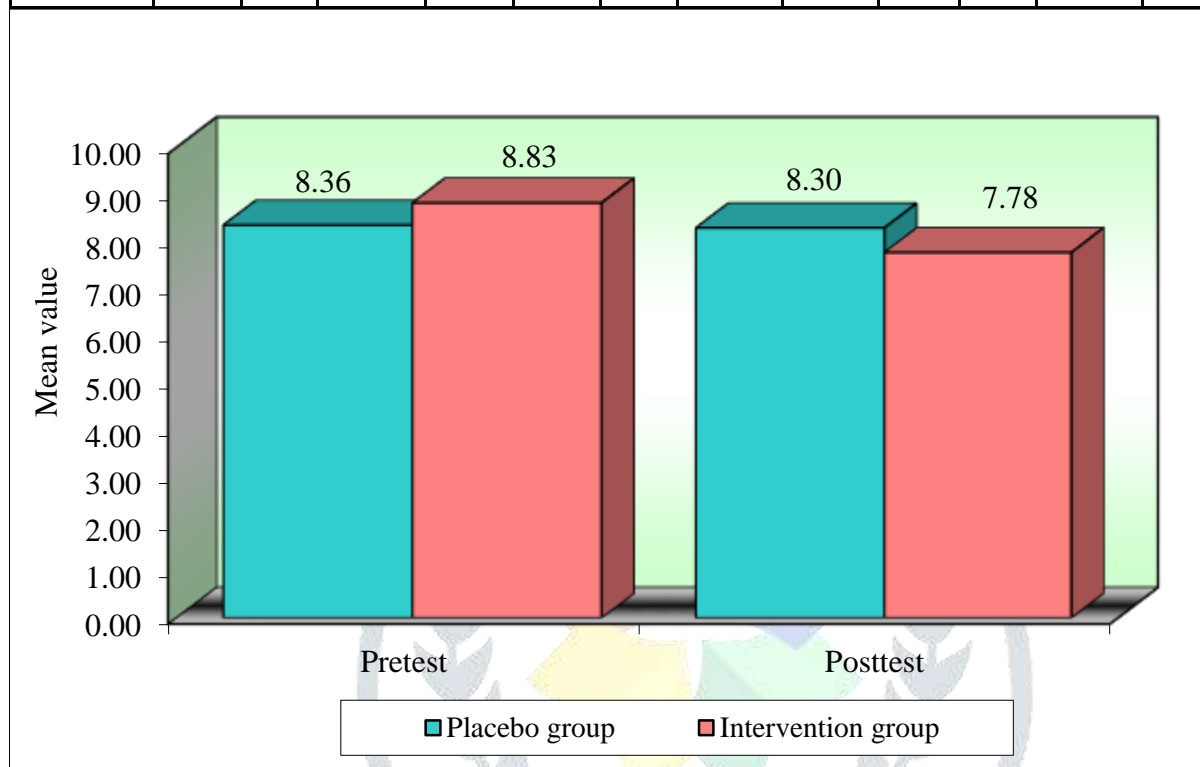


Figure 3: Comparison of placebo group and intervention group with pretest and posttest HbA1C scores

DISCUSSION:

The main aim of this study evaluate the magnitude of placebo response and treatment response patterns in clinical trials. The study results shows that FPG has significantly reduced subsequent to the test intervention whereas no such significant change is noticed in the placebo group; PPBS and HbA1c showed significantly reduction subsequent to the intervention and there was no significant change noticed in the placebo group. This result shows that the addition of abdominal mud pack in Yoga & Naturopathic intervention facilitates better clinical outcomes in the management of type 2 diabetes mellitus.

In Naturopathy mud being one of the core component and one of the unique properties of mud is that, it can absorb the heat and can dissolve the toxins and can wipe out too(5).

In this study the significant results found could be because of decrease in sympathetic activity and dominance of parasympathetic activity. When comparing both the group mud pack on abdomen showed significant parasympathetic dominance following 20 minutes of treatment(8,9).

The probable mechanism of action indicating a parasympathetic dominance may be because of peripheral vasodilatation following an exposure to cold temperature. Effects of mud bath could also be thermic and chemical in origin(10). Hence in our study superficial cold receptors could have played a role is increasing parasympathetic activity. The resulting increase in central pressure in turn activates the baroreflex,

responsible for diminishing sympathetic nerve activity while shifting autonomic heart rate control towards a parasympathetic dominance(11).

Cold temperature plays a huge role in the increased peripheral vasoconstriction with enhanced central blood volume(12). A Significant decrease in local blood volume was found for cold gel pack in healthy ankles. This decrease was attributed to pack's temperature(13). Cold application initially causes skin vasoconstriction, and if a cold compress covers a enormous area of the body, a significant amount of blood will be driven into the internal organs. Prolonged cold causes a secondary reaction, inducing vasodilatation of the surface skin blood vessels(14).

Application of a mud pack to the abdomen enhances peripheral circulation, increases metabolic rate, and thus lessens blood glucose levels(15). Of course, exercise and physical activity also help to improve insulin sensitivity, thereby bringing down blood glucose(16).

Most of the research in regards with the effects of cold exposure in type 2 diabetes is associated with its therapeutic potential. One of the physiological defenses for preventing a lessening in core temperature during cold exposure is a greater rate of metabolic heat production induced by shivering and non-shivering thermogenesis(17).

Earlier evidence showing that hyperinsulinemia, which is known to be present in individuals with type 2 diabetes because of decreased insulin sensitivity, can be associated with moderate skin vasodilation in resting conditions(18). However, individuals with type 2 diabetes seem to have lower skin blood flow comparative to their age-matched controls(19).

Although this might be seen as useful with regards to minimizing heat dissipation during cold exposure, type 2 diabetes is also associated with marked impairments in vascular responsiveness to cold. This was best evidenced by Stanberry and colleagues(20) who indicated decreases in the contribution of local, reflex, and centrally-mediated mechanisms which can determine skin blood flow. Furthermore, this blunted responsiveness is at least in part attributed to the reduction in the control of blood vessel diameter by the sympathetic nervous system(21,22).

Collectively, there is some evidence to indicate that individuals with type 2 diabetes might be less able to prevent decreases in core temperature associated with cold exposure. Even found the significant result in control group too, could be because of the treatment and pattern of diet given. Naturopathic care for diabetes at this representative academic facility remains mostly adjunctive, although physicians possess the training and skills necessary to participate as primary care providers. The naturopathic treatment approach frequently includes important dietary and life style recommendations included in current medical treatment guidelines for diabetes, despite the fact that enhancements can be made on the precision of recommendations(22).

Previous studies have indicated decrease in the levels of FBS, PPBS and HbA1c by the intervention of Yoga, Diet and Naturopathic intervention. A clinical report has indicated that the Naturopathic care to individuals with T2DM significantly improved glycemic control, increased self-monitoring of blood glucose, improved diet, increased physical activity, greater self-efficacy, improved mood and reduced problem areas in diabetes(23). Another study demonstrates the modifications in risk-factors that occur with long-term naturopathic care for T2DM with notable percentages of patients achieving improvements in glucose levels as measured by HbA1C and blood pressure measures(24).

The present study on abdominal mud pack is named because it acts on stomach and pancreas. The present results also suggest that the abdominal mud pack given to T2DM patient's decreases FBS, PPBS and HbA1c. While the underlying mechanism of the clinical benefits of abdominal mud pack remains to be studied, this particular finding associated with metformin is a worthwhile lead in future explorations. Strengths of the study are it is a randomized placebo controlled trial, no dropouts, cost effective, no life threatening serious complications. Limitations of the study are this study is of short duration, smaller sample size, guidance was given during follow-up period of the study through phone calls, but personal observation was not given.

CONCLUSION:

The above study concludes that abdominal mud pack is having positive results on controlling FBS, PPBS and HbA1C along with life style modifications in type 2 diabetes mellitus patients. However long term and prolonged observation is required for beneficial application of mud pack on an abdomen in type 2 diabetes mellitus patients.

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