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Efficacy of Cold Abdominal Compress and Cold Abdominal Mud Pack on Young Adults with Increased Body Weight – A Parallel Randomized Comparative Trial

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Abstract:
Background*: Obesity among young adults is associated with negative metabolic, social and economical consequences in later adulthood. According to Naturopathy, obesity is less about diet and more about correcting underlying imbalance through lifestyle. Abdominal Compress is a simple application of water at any temperature by means of a cloth or a sponge. Abdominal Mud pack is a mixture of water with organic or inorganic material produced from biological and/or geological processes and used for treatment purpose in the form of a pack. This study was conducted to evaluate and compare the effect of cold abdominal compress and cold abdominal mud pack in young obese individuals.*
Materials and Methods*: 66 young adults, aged 18-30 years, who fulfilled the inclusion criteria, were recruited for the study. Excluding six dropouts, remaining subjects were randomized into two groups by using computer generated randomization method: Group 1 – Cold abdomen compress (n = 30) and Group 2 – Cold abdominal mud pack (n = 30). Both the groups received intervention twice daily, for the duration of 20mins, for 10days. Heart rate variability and anthropometric measurements were assessed; baseline and post-intervention assessment data were collected on 1st and 10th day of the intervention. The data analysis was carried out using SPSS version 25.*
Results*: When comparing both the groups, application of cold abdominal mud pack, showed significant parasympathetic dominance after 10days of the treatment. This was further evidenced by the findings observed in anthropometric measurements and other components of HRV (p =0.0001).*
Conclusion: *Cold abdominal mud pack showed significant changes in anthropometric measurements and variables when compared to cold abdominal compress, representing ANS implicating the parasympathetic arousal. Hence, it can be concluded that cold abdominal mud pack has a role in maintaining the cardiac tone and preventing various cardiovascular ailments in young obese individuals.*
Key Word*: Naturopathy; Mud-pack; Cold compress; Obesity; Hydrotherapy.*

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I. Introduction

Overweight and obesity are defined as a multivariate syndrome, which affects the whole-body functioning[1]. Evidence suggests that young adulthood is a vulnerable period for weight gain[2]. Based on previous studies, it is evident that over-weight and obese children and youths are at high risk of developing diseases such as diabetes mellitus, cardiovascular diseases and musculoskeletal disorders in later adulthood[3]. Most recent study indicates that excess weight gain, especially when associated with increased visceral adiposity, is linked with increased sympathetic nervous system (SNS) activation and this contributes to the development of hypertension and other cardio vascular risk factors in obese humans [4]. Also, it has been emphasized that obesity provokes reduction in vagal tone coupled with an increase in cardiac sympathetic activity[5].

Because of the complex nature of obesity, a holistic approach is always identified as the best practice[6]. The impact of six days of naturopathic treatment protocol among abdominal obese persons resulted in significant reduction of body weight for about 2.52kg and 1.95kg for male and female respectively with significant decrease in waist circumference of 5.05cm in male and 4.25cm in female participants. The protocol included steam bath, hot immersion bath, mud pack to abdomen, cold abdominal pack, cold hip bath, neutral enema and massage to abdomen and hips[7]. A case report done by Shetty et al. concluded that there was

significant weight reduction over a period of 6 years, through integrative approach with yoga and naturopathy. The transition in the grade of obesity (WHO) was from class - II to class - I and then to overweight. Yoga intervention included asana, pranayama, kriyas (cleansing techniques) and Naturopathic treatment included hydrotherapy, diet and fasting therapies, mud therapy, and massage therapy [8]. Yet one more similar study resulted in significant reduction in weight (97.9 kg to 74.6 kg) and Body Mass Index (35.1 kg/m2 to 27.86 kg/m2) after 6 weeks of integrated approach of naturopathy and yoga therapy[9].

In one of the studies, it is said that Sulphur mud baths act on the parasympathetic nervous system leading to intense vasodilatation, and decrease in the blood pressure[10]. Local mud application along with bicarbonate- sulphate mineral water is shown to modify plasma levels of the adipocytokines including leptin and adiponectin which are the important mediators of cartilage metabolism[11]. Another study suggests that, mud application increases the synthesis of beta endorphins[12]. According to one of the reference [13], it is concluded that prolonged cold application causes an immediate stimulation of the autonomic nervous system with a predominance of the parasympathetic tone, as inferred from heart rate and heart rate variability indices. Cold application initially causes skin vasoconstriction and if a cold compress covers a large area of the body, a significant amount of blood will be driven into the internal organs[14]. In one of the study, it is concluded that cold exposure metabolically increases the active brown adipose tissue and suggests a role in body temperature and adiposity[15].

So, the current study is designed to evaluate the individual effect of cold abdominal compress and abdominal mud pack and compare between the two interventions on heart rate variability and anthropometric variables in individuals with obesity. And also, this study is undertaken to formulate a take home remedy or a prescription for clinical practice, which suggests a better treatment modality among the two interventions to adapt on a daily basis.

II. Material And Methods

This parallel randomized comparative trial was carried out on students of Sri Dharmasthala Manjunatheshwara College of Naturopathy and Yogic Science, Ujire, Dakshina Kannada, Karnataka from December 2018 to January 2019. Total 66 young adult subjects (both male and females) of aged 18-30 years were for in this study.

Study Design: Parallel Randomized Comparative trial

Study Location: This was a study on college going students, done in Sri Dharmasthala Manjunatheshwara College of Naturopathy and Yogic Science, Ujire, Dakshina Kannada, Karnataka

Study Duration: December 2018 to January 2019.

Sample size: 66 subjects.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. The target population from which we randomly selected our sample was considered 120. The sample size actually obtained for this study was 66 subjects in total. With 6 subjects dropout, the remaining subjects were randomly divided into 2 groups, by using computerized randomization method, Group 1 (n=30) - cold abdominal compress group (CAC) whereas Group 2 (n=30) - cold abdominal mud pack group (CMP).

Subjects & selection method: The study population was recruited from the students who presented with increased body weight. The diagnosis was made according to the redefined version of World Health Organization (WHO) classification criteria of Body Mass Index BMI[9] (table no. I). they were screened through medical check- up and those satisfying diagnostic criteria for obesity were randomized into two groups (each group had 30 subjects).

Table no 1: Classification of Obesity based on BMI

Category	BMI (kg/m^2)
Underweight	≤ 18.5
Normal range	18.5 – 22.9
Overweight	≥ 23.0
At risk	23.0 – 24.9
Obese class – I	25.0 – 29.9
Obese class –II	≥ 30.0

Inclusion criteria:

1. Body Mass Index (BMI) ≥ 25 kg/m^2)[9]
2. Either sex
3. Aged 18-30 years.

Exclusion criteria:

1. Subjects with open wounds
2. Subjects who underwent recent surgeries
3. Subjects with previous history of co-morbid conditions like hypothyroidism, chronic obstructive pulmonary lung disease, organomegaly or other life threatening diseases[16].
4. Females undergoing menstruation[17].
5. Subjects who are physically inactive.
6. Subjects with a history of drug or alcohol abuse[18].

Procedure methodology

Institutional Ethics Committee approved the study and written informed consent was obtained from all the participants. Subjects, identified through the screening process as potentially eligible, underwent a baseline medical assessment and were randomly divided into 2 groups. Group 1 (n=30) received cold abdominal compress (CAC) and group 2 (n=30) received cold abdominal mud pack (CMP).

All the subjects received intervention for the duration of 20mins, twice daily for 10 days. Assessments of HRV, body weight, anthropometric measurements like waist circumference and waist-hip ratio, was done on 1st and 10th day of the intervention [fig 1].

The intervention given for the subjects of each group was as follows:

Group 1 – Cold abdominal compress (CAC)

Procedure of the hydrotherapeutic modality - Prior to the intervention the subjects were asked to drink sufficient amount of water. After a while, subject of group 1 (CAC), was asked to lie on the couch in supine position and expose his/her abdomen. Medium sized towel was dipped in cold water (12°C) and wringed out. The towel was folded 4 times to a size of 12 - 14" (length) X 10" (width) and placed on the abdomen and covered with a dry towel for 20 minutes. After the intervention, the subject was advised to dry himself with a dry towel and dress up. Intervention was given twice daily, that is at 6am and 6pm[19].

Group 2 - Cold abdominal mud pack (CMP)

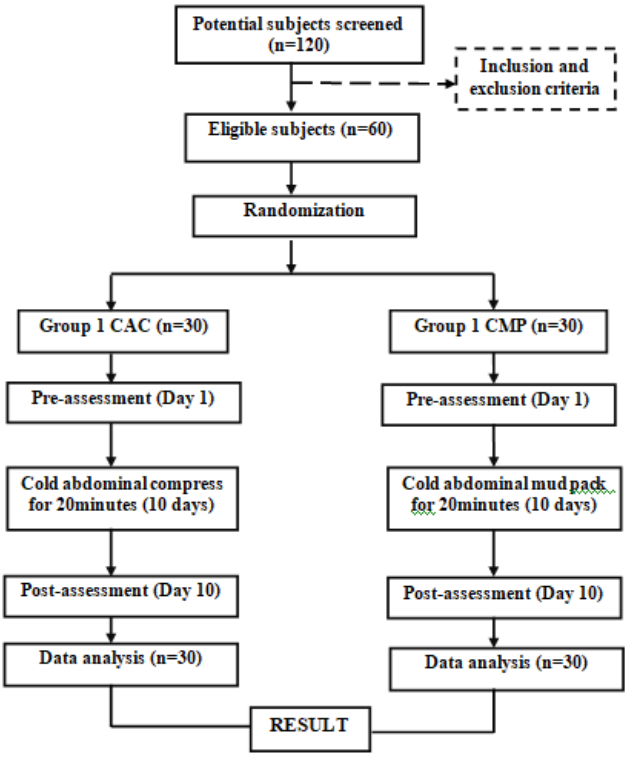
Procedure of the hydrotherapeutic modality - Black color soil with water absorbing quality was collected from hills, 10 feet below the ground level. Precautions were taken to make sure that mud was free from impurities, composts, pebbles. Collected mud was finely sieved and kept under sunlight for 24hrs. Sufficient quantity of cold water (12°C) was added to the mud to make it like a paste. Soaked mud was kept in a thin, wet muslin cloth (22.86cm x 15.24cm x 1.27cm)[19] and made into a thin flat brick depending on the size of the patient's abdomen, and was applied over the abdomen for 20 minutes[20,21]. Care was taken not to slide off the mud from body surface and no movements were given after application.

Statistical analysis

The raw data obtained from each subject, in each recording session were tabulated separately. Baseline and post intervention assessment of each intervention was taken. The normality assumption was verified and statistical tests were chosen accordingly.

Statistical analysis was done to compare baseline and post – intervention assessments of between the group (independent sample t-test) and within the group (dependent sample t-test). There were no significant differences between the two groups at baseline. The data obtained were analyzed for normality by using Shapiro-Wilk test. The paired t-test was used to analyze whether pre and post averages of these variable are same or not. Wilcoxon Signed Rank test was adopted whenever the variables do not follow normal distribution. The comparison of post assessment results of two groups was carried out using Shapiro Wilk test for normality. The two-sample t-test was used to analyze the post averages of these variables. Mann Whitney U test was adopted whenever the variables did not follow normal distribution. Statistical analysis was done using SPSS statistics version 25. The level $P \leq 0.05$ was considered as the cutoff value or significance for the analysis and interpretation.

Fig 1: Illustration of the Study Plan



III. Result

After 10days of the intervention,

In Group 1, there was a reduction in weight ($p<0.0001$), BMI ($p<0.0001$) and waist-hip ratio ($p<0.0001$), along with significant reduction in mean HR ($p = 0.0002$), whereas increase in mean RR ($p<0.0001$), RMSSD ($p = 0.0073$), NN50 ($p = 0.007$), pNN50 ($p < 0.0001$). In frequency domain of HRV, there was significant reduction in LF ($p = 0.0001$), LF/HF ($p < 0.0001$), but insignificant changes in HF and VLF.

In Group 2, there was significant decrease in weight ($p <0.0001$), BMI ($p<0.0001$) and waist-hip ratio ($p<0.0001$). Significant reduction was seen in mean HR ($p = 0.003$), whereas increase in mean RR ($p<0.0001$), pNN50 ($p = 0.0001$), but insignificant changes in RMSSD and NN50. In frequency domain of HRV, there was significant reduction in LF ($p < 0.0001$), HF ($p <0.0001$), LF/HF ($p < 0.0001$), except VLF.

On comparing, the median of BMI, mean HR, RMSSD, VLF, LF / HF differ among the two groups. That is, the median of BMI ($p = 0.004$), mean HR ($p = 0.01$), RMSSD ($p = 0.005$), VLF ($p < 0.0001$) of group 1 were less when compared with the respective measurements of group 2. However, the median of LF/HF ($p = 0.001$) of group 1 was more when compared with group 2. The medians of Weight, Waist: Hip ratio, mean RR, NN50, pNN50, LF, HF did not vary significantly.

Table no 2 Shows mean age of the subjects in two groups. 20.1±1.72 in Group 1 and 19.96±1.47 in Group 2 respectively.

Table no 2: Mean Age in Group 1 and Group 2

Groups	n	Mean age ± SD
Groups 1 (CAC)	30	20.1±1.72
Group 2 (CMP)	30	19.96±1.47

Table no 3 Shows the gender distribution in two groups. 11 men and 19 women in group 1, where as 10 men and 20 women in group 2.

Table no 3: Gender Distribution in Group 1 and Group 2

Gender	Group 1 (CAC)	%	Group 2 (CMP)	%	Total
Male	11	37.00	10	33.00	21
Female	19	63.00	20	67.00	39
Total	30	100.00	30	100.00	60

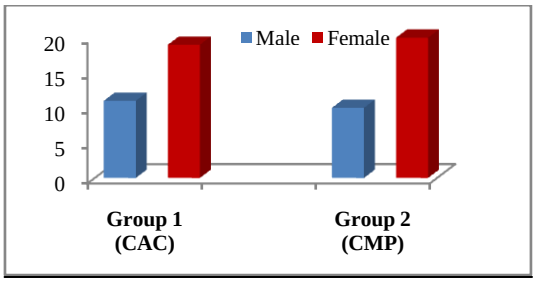


Table no 4 Shows pre and post data of anthropometric variables and heart rate variability parameters of group 1 and group 2 and comparison of the post data of the two groups. In CAC, weight 71.77 ± 8.05, BMI 28.29 ± 2.96, waist: hip ratio 0.83 ± 0.04, mean RR 921.16 ± 88.38, mean HR 77.17 ± 7.42, RMSSD 79.28 ± 34.12, NN50 136.70 ± 63.38, pNN50 49.13 ± 19.73, VLF 43.01 ± 16.79, LF 56.08 ± 18.04, HF 58.83 ± 19.60, LF/HF 1.72 ± 0.63. In CMP, weight 78.02 ± 12.03, BMI 30.78 ± 4.58, waist: hip ratio 0.82 ± 0.03, mean RR 879.58 ± 91.89, mean HR 80.39 ± 8.18, RMSSD 61.15 ± 28.56, NN50 110.18 ± 49.34, pNN50 36.83 ± 19.21, VLF 78.75 ± 16.66, LF 56.90 ± 15.54, HF 58.63 ± 18.12, and LF/HF 1.13 ± 0.71.
Level of significance: $p \leq 0.05$

P value within the group

* Paired t test
** Wilcoxon test
Alternative Hypothesis for Wilcoxon Signed Rank test
Alt: less-The median of autonomic variable before therapy is less than that after therapy.
Alt: greater- The median of autonomic variable before therapy is greater than that after therapy
Alternative Hypothesis for Paired sample t test
Alt: less-The mean of autonomic variable before therapy is less than that after therapy
Alt: greater- The mean of autonomic variable before therapy is greater than that after therapy

P value between the groups

* Two sample t test
** Mann Whitney U test
Alternative Hypothesis for Mann Whitney U test
Alt: less-The median of autonomic variable after therapy in CAC is less than that in CMP.
Alt: greater- The median of autonomic variable after therapy in CAC is greater than that in CMP
Alternative Hypothesis for Paired sample t test
Alt: less-The mean of autonomic variable after therapy in CAC is less than that in CMP
Alt: greater- The mean of autonomic variable after therapy in CAC is greater than that in CMP

Table no 4: Pre and Post Data of Anthropometric Variables and Heart Rate Variability Parameters of Group 1 and Group 2 and Comparison of the Post Data of the Two Groups

Variables	Group	Pre Mean ± SD	Post Mean ± SD	p value within the group		p value between the group	
				two tailed	one tailed	two tailed	one tailed
Weight	CAC	73.51±8.19	71.77±8.05	0.0000*	0.0000 Alt : greater	0.969*	-
	CMP	79.74±11.99	78.02±12.03	0.0000*	0.0000 Alt : greater		
BMI	CAC	28.98±3.005	28.29±2.96	0.0000**	0.0000 Alt : greater	0.0081**	0.004084 Alt :less
	CMP	31.46±4.62	30.78±4.58	0.0000*	0.0000 Alt : greater		
Waist: Hip ratio	CAC	0.85±0.04	0.83±0.04	0.0000*	0.0000 Alt : greater	0.3622**	-
	CMP	0.86±0.05	0.82±0.03	0.0000*	0.0000 Alt : greater		
Mean RR	CAC	835.93±92.18	921.16±88.38	0.0000*	0.0000 Alt : less	0.05881*	-
	CMP	802.38±143.3	879.58±91.89	0.0000**	0.0000 Alt : less		

Mean HR	CAC	83.18±7.88	77.17±7.42	0.0002572**	0.0001286 Alt : greater	0.0344**	0.0172 Alt :less
	CMP	83.88±8.73	80.39±8.18	0.00350*	0.001753 Alt : greater		
RMSSD	CAC	66.91±31.18	79.28±34.12	0.007332**	0.003666 Alt : less	0.01175**	0.005873 Alt :less
	CMP	57±23.74	61.15±28.56	0.1494**	-		
NN50	CAC	115.37±67.13	136.70±63.38	0.007808**	0.003904 Alt : less	0.06198*	-
	CMP	95.63±54.76	110.18±49.34	0.00565*	-		
pNN50	CAC	37.42±20.07	49.13±19.73	0.0000*	0.0000 Alt : less	0.8519*	-
	CMP	28.76±16.76	36.83±19.21	0.0001391*	0.0000 Alt : less		
VLF	CAC	45.84±23.16	43.01±16.79	0.99999**	-	0.0000**	0.000 Alt :less
	CMP	73.82±15.41	78.75±16.66	0.3359*	-		
LF	CAC	67.05±18.36	56.08±18.04	0.0001998*	0.0000 Alt : greater	0.6187*	-
	CMP	66.35±17.77	56.90±15.54	0.0000*	0.0000 Alt : greater		
HF	CAC	56.27±21.91	58.83±19.60	0.2941*	-	0.7499*	-
	CMP	48.65±19.01	58.63±18.12	0.0000*	0.0000 Alt : greater		
LF/HF	CAC	2.78±1.18	1.72±0.63	0.0000**	0.0000 Alt : greater	0.0022**	0.001149 Alt :greater
	CMP	4.75±1.42	1.13±0.71	0.0000*	0.0000 Alt : greater		

IV. Discussion

In the current study, following the cold abdominal compress group, after treatment resulted in significant reduction of median BMI, average weight, average Waist-Hip ratio, along with mean HR and LF, but increase in the average of mean RR., median RMSSD, median NN50, average pNN50 of the time domain (table IV). Whereas, in cold abdominal mud pack, there was a significant reduction in mean BMI, average weight, average Waist Hip ratio, mean HR, besides decrease in average LF, average HF, average LF/HF of frequency domain and increase in median of RR and average of pNN50 of the time domain (table no.4). The comparative analysis based on post-test measurements revealed much interesting inferences (table no.4). The median of post measurement of BMI, mean HR, RMSSD, VLF, LF/HF were more in group 2(CMP) when compared with the related measures of group 1(CAC). However, the medians of weight, Waist-Hip ratio, mean RR, NN50, pNN50, LF, HF do not vary significantly.

Intentional weight loss in obese individuals is said to minimize the risk factors and improves the symptoms of obesity related conditions including cardiovascular disease, type-2 diabetes mellitus and osteoarthritis[22]. Three - week program was conducted to assess the efficacy of diet combined with spa therapy in obese individuals with and without type 2 diabetes. Patients were on 1000kcal diet and spa therapy included mineral bath, mud pack applications. It was concluded that 3week program induced significant decrease of body weight, body mass index, triglycerides, total cholesterol, low-density lipoprotein (LDL) cholesterol, glycemia, and serum levels of leptin and high-sensitivity C-reactive protein. So, a cycle of mud-bath therapy associated with a controlled diet was considered as a promising treatment for obesity and type 2 diabetes decreasing body weight and many risk factors for atherosclerosis and metabolic syndrome[23].

Considering the fact, HRV is one of the most sensitive and easily accessible tools to assess the parasympathetic and sympathetic activity and autonomic regulation[23]. In previous study, it was evident that, chronic stimulation of the sympathetic nervous system has the potential to augment risk for the metabolic syndrome through the development of obesity, hyperglycemia, insulin resistance, and hypertension. Latest findings from pharmaceutical and device-based clinical trials encourage targeting central sympathetic activity to improve metabolic control in patients with the obesity, who is at risk for diabetes and cardiovascular disease[24].

In this study, the significant results found in both groups, could be due to reduction in sympathetic activity and dominance of parasympathetic activity. When comparing both the groups, that are cold abdominal

compress and cold abdominal mud pack, cold mud application on abdomen showed significant parasympathetic dominance after 10 days of treatment[25,26]. This was further evidenced by the findings observed in anthropometric measurements and other components of HRV in each group, such as a significant reduction of weight, BMI, and waist-hip ratio, including the decrease in time domain that is mean HR, and frequency domains like LF component, LF/ HF ratio and a significant increase in time domains like RMSSD, Mean RR, pNN50 and NN50 which are suggestive of a shift in sympathovagal balance towards parasympathetic dominance.

Similar results were reported in earlier study done by Kumar G et al., where full mud bath for 45 minutes in healthy volunteers had shown a strong parasympathetic dominance immediately following the full mud bath. The same effects persisted even one hour after the intervention indicating prolonged beneficial effect of full mud bath[27]. The probable mechanism of action indicating a parasympathetic dominance in both the modalities might be due to peripheral vasodilatation following an exposure to cold temperature. Hence in this 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 reducing sympathetic nerve activity while shifting autonomic heart rate control towards a parasympathetic dominance[28]. When a small surface area is exposed to cold as in Cold abdominal pack and cold abdominal mud pack 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[25]. This in turn produces a compensatory vasodilatation in deeper vascular system thereby follows increased blood flow to the tissues underlying the site of exposure and that increase the metabolic rate so as to maintain constant deep tissue temperature. For example, according to another previous study, immersion in cold water of 20°C almost doubles metabolic rate, while at 14°C it is more than quadrupled[3].

When considering the mechanism involved in mud pack alone, the chemical effect of the mud can be justified by the absorption of the minerals from the mud through the skin[8]. Specific properties of minerals present in the mud such as the nanometer size and thin platy or fibrous shapes, the negative electric charge, and high adsorption and absorption capacities explain its therapeutic uses as they can act as catalysts for potentially benign chemical processes[29]. Ions in mud selectively penetrate the skin and the soluble elements transfer from the liquid components of mud, through epithelial cells which is activated by an "enzymatic barrier" represented by cytochrome, alkaline phosphatase and adenosine triphosphatase[30]. Transdermal permeation of hydrophilic solutes is mainly through intercellular route, besides absorption through pores and cutaneous follicles (trans-appendicular route) and absorption into the interior of corneocytes also called as transcellular route[27]. Mud therapy is also known to produce a sense of relaxation[23]. Even the subjects in the present study have reported of obtaining a sense of deep relaxation along with the improvement in gastrointestinal related disorders, following full mud bath. It has been proven that acute physiological changes associated with relaxation response includes reduction in heart rate, blood pressure and respiratory rate which have been explained to be the result of increased parasympathetic tone as well as the reduction in sympathetic tone[31].

Hence it can be suggested that both the treatments, hydrotherapy in the form of cold abdominal compress and mud therapy in the form of cold abdominal mud pack induces relaxation and a cardio protective state by increasing the parasympathetic activity with a simultaneous sympathetic withdrawal. The cold abdominal mud pack possibly enhanced the cardiac health more efficiently than cold abdominal compress. These can be attributed to various effects of cold mud such as reflex baroreceptor activation favoring a better autonomic control, release of local vasodilators, hormonal regulation, and chemical effect through mineral absorption. These might be the mechanisms underlying the beneficial effect of mud pack in young obese individuals.

Strengths of the study

It was a randomized controlled trail with the clinical application. There were no adverse effects or serious complications, recorded. This is the first study done to assess efficient treatment modality among abdominal compress and abdominal mud pack.

Limitations - All the variables in body composition were not studied. Smaller sample size might have influenced the result observed.

Recommendations for future research

Study can include larger sample size and assessments during the intervention as well as with a longer follow up period.

V. Conclusion

Application of cold abdominal mud pack showed a strong parasympathetic dominance and has a role in maintaining the cardiac tone and preventing various cardiovascular ailments. Considering, the significant reduction in anthropometric variables, along with the other components of HRV, during the application of cold abdominal mud pack, is suggestive of a shift in sympathovagal balance towards parasympathetic dominance. It can be concluded that, cold abdominal mud pack can be used as an efficient complementary approach for the treatment of obesity in young individuals

Further its application can be extended in prevention and management of cardio vascular and other stress related disorders as elevated parasympathetic activity at rest is classically associated with health and well-being.

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