

Effect Of High Intensity Electromagnetic Technology On Metabolic Profile In Men With Central Obesity

Ebtehal Atef Ramadan Afya¹, Prof. Dr. Awny Fouad Rahmy², Prof Dr. Heba Kamal Sedrak², Prof. Dr Ali Mohamed Ali Ismail³

¹Professor of physical Therapy for Cardiovascular/ Respiratory Disorder and Geriatrics
Faculty of Physical Therapy Cairo University, dean of faculty of physical Therapy Sinai University

²Professor of Internal Medicine, Diabetes Endocrinology Faculty of Medicine Kasr Al-Aini Cairo University

³Assistant Professor of Physical Therapy for Cardiovascular/ Respiratory Disorder and Geriatrics Faculty of Physical Therapy Cairo University.

ABSTRACT

Objective: To investigate the effect of high intensity electromagnetic technology on metabolic profile in men with central obesity. **Design:** A single-blinded randomized clinical study.

Setting: Outpatient-setting.

Subjects: Sixty male participants with central obesity were allocated randomly into two groups. Group (A) received high-intensity electromagnetic technology, plus routine physical therapy protocol; Group (B) received traditional physical therapy protocol.

Intervention: Forty minutes per session, three sessions a week for three months, plus routine physical therapy protocol for group A; and while group B received dietary caloric restriction and 10.000 continuous steps daily using a pedometer application. **Outcome measures:** weight waist circumference and triglyceride were measured pretreatment and posttreatment.

Results: No significant differences between pretreatment between both groups ($p > 0.05$). There was a significant decrease in weight, waist circumference in both groups at posttreatment compared with that pretreatment ($p < 0.001$). There was a significant decrease in triglyceride in both groups at posttreatment compared with that pretreatment ($p < 0.001$).

Conclusion: Adding of high intensity electromagnetic technology (40 minutes per session, three sessions/week for 3 months) has a significant improvement on metabolic profile in male with central obesity.

Keywords: Central Obesity, Triglyceride, High-intensity electromagnetic field technology

INTRODUCTION

Obesity is a complex disease involving an excessive amount of body fat with body mass index (BMI) $> 30\text{kg}/\text{m}^2$. Obesity is not just a cosmetic concern. It is a medical problem that increases the risk of other diseases and health problems, such as heart disease, diabetes, high blood pressure and certain cancers (Samuels et al., 2019). It is estimated that 75% of Egyptian males, over the age of 30 years old are overweight or obese (Kasemy et al., 2019).

Abdominal obesity that is known as central obesity and is a condition when excessive abdominal fat around the stomach and abdomen has built up to the extent that it is likely to have a negative impact on health. Abdominal obesity has been strongly linked to cardiovascular disease, Alzheimer's disease and other metabolic and vascular diseases (Oellingrath et al., 2020).

Calorie restriction (CR) diets appear to be effective in decreasing body weight, fat mass, and potentially, visceral fat mass. There is growing body of evidence showing that CR may be implemented as another viable option for weight loss in overweight and obese populations (Hoddy et al., 2020).

Main approach for treatment of obesity is weight loss and exercise interventions that included both reduced energy intake (e.g., $\geq 500\text{ kcal}/\text{d}$) and increased physical activity (e.g., ≥ 150 minutes a week of walking), with traditional behavioral therapy, generally produced larger weight loss (Williams et al., 2020).

Liposuction has been used for a long time and has been regarded as the most effective method for fat treatment, but it does have some disadvantages. It is a surgical procedure that requires anesthesia, which can place strain on the patient, and it has a long recovery time and is accompanied by surgical risks,

including hematoma, infection, and deep vein thrombosis. In recent years, patients have tended to prefer noninvasive body contouring, which has the advantages of a quicker recovery, fewer side effects, and less discomfort (Duncan and Busso, 2023).

There are many types of noninvasive body contouring, including high-intensity focused ultrasound, radiofrequency treatment, low-level laser therapy and cryolipolysis. Each procedure has its advantages and disadvantages and the overall situation is ripe for improvement (Boutari and Mantzoros, 2022).

The advantage of the high intensity focused electromagnetic technology (HIFEM) over such other body contouring devices its mechanism of a rapidly changing electromagnetic field which initializes thousands of supra maximal contractions during one therapy, something that cannot be achieved by any conventional training program (Julene et al., 2019).

Recent studies suggest that HIFEM field based on focused magnetic stimulation can simultaneously induce muscle strength and reduce subcutaneous fat when applied to the abdomen. Although the effects of magnetic stimulation on muscle are well established and have been described in several studies, its effects on fat tissue have not yet been thoroughly investigated (Busso and Denkova, 2019).

Based on ultrasonographic observations, the application of HIFEM field is a unique, safe, and effective alternative for the noninvasive reduction of subcutaneous fat thickness. but further research is needed to assess the full clinical potentials of this technology (Katz et al., 2019).

The aim of this study was to investigate the effect of high intensity electromagnetic technology on metabolic profile in men with central obesity.

MATERIAL AND METHODS:

Study design:

All participants read and signed informed consent form before initiation of the study The study was approved by the research ethical committee of Faculty of Physical therapy, Cairo university.

Participants:

Sixty male participants allocated randomly into two groups (thirty patient per group) suffering from central obesity were selected randomly to participate in this study from private clinic for physiotherapy and weight loss in 6th of October city, Giza. They were assigned into two equal groups; They were selected according to the following criteria: Inclusion criteria: Central obesity participants` age ranged from 40 to 50 years (Katz et al., 2019). All participants` BMI range was 30-34.9 kg/m² (Carolyn et al., 2021). All participants` waist circumference was > 102 cm (Carolyn et al., 2021).. Exclusion criteria: Patients with diabetes mellitus, heart and/ or vascular, renal, hepatic, pulmonary, neurological, psychological, and or mental disorders are excluded (Carolyn et al., 2021) Patients who had autoimmune diseases were excluded. Patients with hypertension, metal or electronic implants were excluded (Jacob et al., 2018). Patients, who have intra-abdominal mesh and/ or unrepaired abdominal hernia were excluded (Carolyn et al., 2021). Patients who have cancer were excluded (Jacob et al., 2021). Patients who have scars, open lesions and wounds at treatment area were excluded (Jacob et al., 2021). Patients who have any intervention to lose weight or body contouring within the last 6 months (diet, exercise or body contouring devices) were excluded (Jacob et al., 2021). Unmarried men, or men with erectile dysfunction were excluded (Jacob et al., 2021). Patients who received pharmacological drugs for controlling obesity were excluded (Jacob et al., 2021).

Randomization

All participants agreed to an informed consent form before the beginning of the study, anonymity and privacy were guaranteed, and all the methods were done consistently with relevant laws and institutional rules. Participants were equally divided into two groups (control and study groups) equally by a computed randomization program.

Interventions

The subjects divided randomly into two groups equal in number, (group A) and (group B):

Group (A) received high-intensity electromagnetic technique, 3 sessions per week for three months and dietary caloric restriction for three months and 30 male participants were been instructed to walk 10,000 continuous steps every day using the pedometer application.

Group (B) received dietary caloric restriction for three months and 30 male participants were been instructed to walk 10,000 continuous steps every day using the pedometer application.

For treatment:

High-intensity electromagnetic Apparatus:

Slim pro physiotherapy instrument for high-intensity electromagnetic therapy, 0.9 (+/- 20%) tesla himet electromagnetic non-invasive slim machine, mobile unit that is Design and construction are based on a high level of ergonomics to be user-friendly, Air-cooling applicators that allows long time operation without any overheat issue, 1000 VA, 10.2 inch LCD touch screen and it permits manual and auto working modes, 1-30 minutes working time and 1-100% working intensity, F1 (1-80Hz), F2 (1-120Hz) and F3 (1-50Hz) with 100-240 V ranges, plus FL5*20 T15AL250 V (220V), RT 28-32 (RO15) 20A 500V (110V) fuse, as well could provide users with clinical indications and parameters.

Diet:

First, the researcher has measured the participant's basal metabolic rate (BMR) using the following equation

$$\text{BMR} = 10 \times \text{weight (kg)} + 6.25 \times \text{height (cm)} - 5 \times \text{age (years)} + 5 \text{ (Nichols et al., 2021).}$$

The researcher has determined the total calorie needed for each participant through multiple BMR by specific activity factor for each participant as the following

Sedentary activity level (little or no exercise);

Calorie calculation =

BMR x 1.2 Lightly active (light exercise/sports

1-3 days/week)

Calorie-Calculation = BMR x 1.375

Moderately activity level (moderate exercise/sports 3-5 days/week);

Calorie-Calculation = BMR x 1.55

Very active level (hard exercise/sports 6-7 days a week);

Calorie-Calculation = BMR x 1.725

Extra active level (very hard exercise/sports or physical occupation);

Calorie-Calculation = BMR x 1.9

Subtracted reasonable calories (e.g., 500Kcal/ day) permits weight lose gradually in a steady maneuver (Kent and Kinney, 2021).

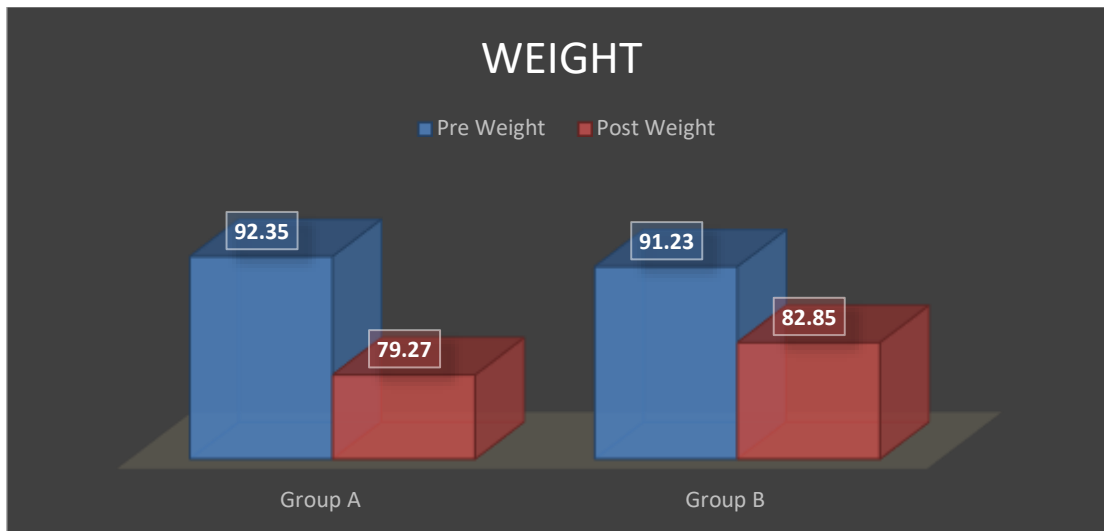
Outcome measures:

Lipid profile analysis:

lipid profile including triglyceride levels were assayed. Participant prepared by explanation test purpose, and procedures in simple terms, then participant was asked to relax in comfortable position with loosen any tight clothes, phlebotomist has secured a snug rubber band around participant's upper arm whom was asked to pump his fist several times. Phlebotomist has palpated participant's vein, then cleansed with an alcohol prep pad, after that a needle was introduced into the vein and a vial of blood was been drawn. After removal of the band, and needle, a pressure to venipuncture was sated up to one minute, then a bandage was applied over the site. Noting that normal values for measured outcome measures were as follow, normal triglycerides is 10-150 mg/dL were mg means milligram and dL means deciliter.

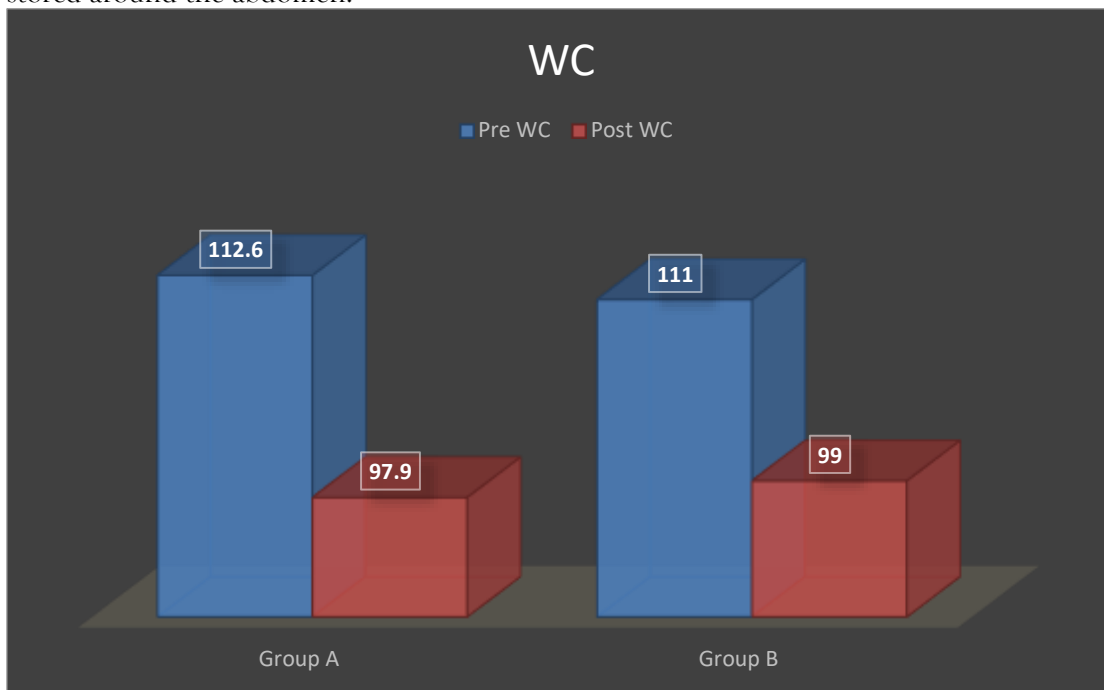
Weight measurement:

The researcher has used digital weight measurement scale by using kilograms units. Each participant was be weighted in light clothes at the morning time after emptying their bladder and bowel. Each participant was asked to stand up on the center of the weigh measurement instrument steady, then the researcher recorded the weight shown on the instrument.



Waist circumference:

Waist circumference is a measurement of the distance around the waist, typically used as an indicator of overall health and fitness. It's a practical measure of central adiposity, which is the amount of fat stored around the abdomen.



Statistical procedures:

Descriptive statistics and t-test were done for comparison of the mean of weight and height of both genders to consider the homogeneity of groups (Chan, 2003a).

T-test was conducted between pre and post measurements of mean values of sweat out put mass between groups.

T test was conducted within pre and post measurements of mean values of sweat out put mass between groups.

The level of significance for all statistical tests was set at $p < 0.05$.

Effect of treatment on weight and WC:

Pretreatment:

The mean difference in weight and WC values between groups pretreatment were 1.12 Kg and 1.6 cm respectively. There was no significant difference in weight and WC between groups pretreatment (p

>0.05).

Post treatment:

The mean difference in weight and WC values between groups post treatment were -3.58 Kg, -1.1cm respectively. There were high significant differences in weight and WC of group A compared with that of group B post treatment ($p = 0.001$).

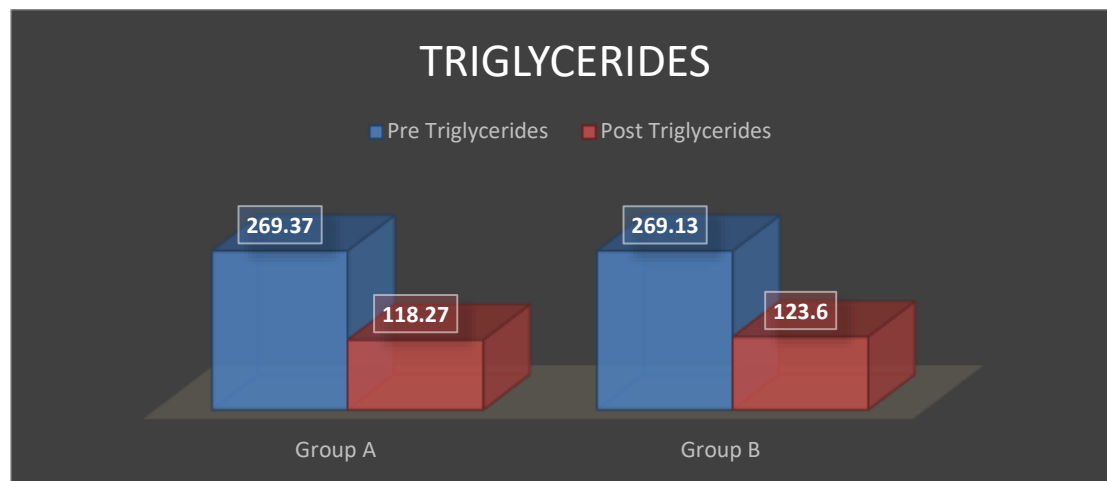
Effect of treatment on triglycerides:

Pretreatment:

The mean difference in triglycerides values between groups pretreatment was -0.2 mg/dL. There was no significant difference in evaluated values between group A and B pretreatment ($p > 0.05$).

Post treatment:

The mean difference in triglycerides between groups post treatment was -5.3 mg/dL. There were high significant differences in total triglycerides values of group A compared with that of group B post treatment ($p = 0.001$).



DISCUSSION:

Recently, a strong desire for slimmer, and looking healthier has become a crucial issue that greatly influences obese individuals. Fortunately, adipose fat structure is addressed for multiple cardiovascular and metabolic comorbidities as confirmed by (Neeland et al., 2019). Numerous complications were associated with chronic elevated proinflammatory cytokines within overweight and obese populations (Ellulu et al., 2017). Comprehensive evaluation of obese individuals has ensured that their actual needs for a specialized particular management protocol that focusing on real barriers, and physical limitations among sufferers rather than restricted in modulating their metabolic profile negatively influenced with suspected comorbidities (Burguera et al., 2018).

Upon that, there is an actual need to determine the most appropriate clinical and effective, as well as safe therapeutic approach for modulating metabolic profile, which will be more efficient in suppressing chronic raised proinflammatory biomarkers, and related various outcomes i.e., waist circumference, abdominal subcutaneous, and visceral fat thickness, thus enhance and maximize adequacy of required therapeutic response as a permanent lifestyle behavior (Pasarica and Topping, 2017).

Current advances of aesthetic medicine have estimated a new trend through non-invasive body contouring via HIFEM that is suspected to provide favorable therapeutic gains (Goldberg et al., 2021).

Therefore, current study was performed to investigate the effect of high intensity electromagnetic technology on metabolic profile in men with central obesity.

For that, sixty males' participants with central obesity from private clinic for physiotherapy and weight loss in 6th of October city, Giza, their ages were in the range of 40-50 years old, also their BMI 30- 34.9 kg/cm² with their waist circumference >102 centimeters. Those participants were randomly divided to

equal groups thirty per group. Group A had received high-intensity electromagnetic technique, 3 sessions per week for three months and dietary caloric restriction for three months and 30 male participants were been instructed to walk 10,000 continuous steps daily using the pedometer application, where second group was B whom received dietary caloric restriction for three months and 30 male participants were been instructed to walk 10,000 continuous steps every day using the pedometer application, as well current trial has been performed between June 2022 to December 2023. Participants with any diabetes mellitus, hypertension, cardiac or vascular, renal, hepatic or pulmonary, neurological, psychological and/ or mental disorders, also any individuals with autoimmune diseases, as well whom have electronic implants, intra-abdominal mesh and/ or unrepaired abdominal hernia, and/ or malignancies, scars, erectile dysfunction, open wounds individuals, plus whom participating in weight loss or body contouring interventions within previous six months were excluded from this study . All the forty participants had received full protocol explanation, also undergone full assessment procedures, also were informed about consent form, which was assigned from all subjects before share actively in current study.

Analysis of the subjects` demographic data in the present study show that, of both groups revealed null differ between groups in demographics features (P value > 0.05), where at baseline demographic characteristics of group A were mean \pm SD of demographic features were 44.3 ± 2.85 years. While, the baseline demographic characteristics of group B was Mean \pm SD demographic characteristics was 44.53 ± 2.69 years.

The previous enumerated epidemiological point of view in the literature review correlated with what results` of the present study analysis show regarding worldwide growing and aged percentage of global population with higher prevalence of central obesity, as supported by the report of (Wang et al., 2020) that had stated that central obesity incidence growth is suspected rise among worldwide population with unclear explanations i.e., overweight. Also, current clinical trial demographic results were in agreement human being extended life span incidences of central obesity according to Harris et al. (2018).

The findings showed that there was a significant decrease in weight, BMI, WC in both groups` posttreatment in compare with pretreatment ($p < 0.001$), while there was no significant difference between pretreatment between both groups ($p > 0.05$).

There was a significant decrease in weight, BMI, WC of group A compared with that of group B at posttreatment ($p < 0.001$).

Central obesity is a global disease that negatively influence sufferers` physical appearance, where body contouring through thermal fat reduction for managing superficially accumulated subcutaneous adipose tissue (Merlotti et al., 2017). Central/ abdominal obesity often creates obvious subcutaneous fat that leads to unpleasant aesthetic appearance addressed as 'Pot or beer belly; mainly among males, with negative influences on their physical, emotional and/ or social discomfort those restrict their quality of life (Joy et al., 2018).

As well findings in the present study were supported by Katz et al. (2019) who had quantified HIFEM treatment effects on abdominal subcutaneous fat among thirty-three. They had reported significant reduction of abdominal subcutaneous fat thickness aby 19% by one month that improved to 23.3 after three months follow up.

Findings in the presented study were supported by a recent multi-center clinical trial conducted by Kent et al. 2023 who had studied forty-one participants (17 men, and 24 women), unless they have huge demographic features '22-62 years old, and $21.2-34.3\text{kg}/\text{cm}^2$ '. They have used a combined HIFEM, plus radiofrequency modality for only, three weeks. Kent et al. have used magnetic resonance imaging to clarify therapeutic efficacy on visceral fat structures than subcutaneous fat thickness, unless they have extended follow up for six months and lifestyle questionnaire that revealed no physical training routine was added. They had ensured no visceral structural changes or abnormalities, which enhance HIFEM modality safety. As well, they revealed a significant reduction of targeted adipose structures with analogous, homogenous, and uniform percentages, plus around 57.1% '12 out of 21 participants' had shown significant gains on their health risks stemming from pretreatment raised adipose tissues.

Furthermore, Ket et al. (2023) had ensured that HIFEM promotes easier targeted musculoskeletal

hypertrophy and hyperplasia that depends on musculoskeletal contained adipose tissues. Therefore, due to lipolysis the triglycerides are broken down to a form of free fatty acids and glycerol and released into the blood-stream to supply the energy demand. Where, abdominal visceral fat became the main focus for lipolysis (Kent and Kinney, 2021).

In agreement with our findings, Jacob and Paskova, (2018) had investigated twenty-two participants, their age mean was 32 ± 7.1 years old, but with lower BMI that current clinical trial ' $23.8 \pm 3.3 \text{ kg/m}^2$ '. They had applied only four therapeutic high-intensity focused electromagnetic field sessions twice weekly. They reported an average reduction by $3.29 \pm 1.9\text{cm}$ in term of waist circumference that continues for further three months to reach $4.37 \pm 2.63 \text{ cm}$ compared to their baseline only among 84% '16 of 19 participants continue their clinical trial.

High-intensity electromagnetic technology was Approved US Food and Drug Administration as an effective, safe therapeutic modality, that by last decade was recommended for musculoskeletal strengthening, and toning abdomen and buttocks (Swanson, 2023). HIFEM is recommended for whom have poor diet choices, lack of exercise with an increased sedentary lifestyle and the natural aging process (Evert and Franz, 2017).

In the same line, muscular structures do not have time to relax between double of consecutive stimuli and is exposed to an extreme state that triggers a stress response. Energy for supplying muscular contractions is taken from the fat cells presumably through lipolysis. Therefore, muscular tissues begin to use lipolysis as an energy supply, has already been seen during intense acute resistance exercise (Chatzinikolaou et al., 2008).

A conflicting opinion to our findings was across a recent case series clinical trial conducted by Valdivia, (2022) had stated investigated a protocol of ten sessions of high-intensity Tesla magnetic stimulation using the Star Former® device along three and a half weeks with 2-100% total intensity. Valdivia has stated that Average weight change from baseline at 10-week follow-up was -0.31kg , which was not statistically significant (0.53), but waist circumference revealed a significant improvement up to 3 cm on average.

Another conflicting opinion was concluded by Kent et al. (2021) who enumerated that validity of HIFEM in regards to visceral fat reduction is not clear yet. However, considering that visceral fat is more susceptible to lipolysis, it is most likely that visceral fat and subcutaneous fat structures' respond similarly when skeletal musculature is exposed to supramaximal contractions. Also, the visceral fat has a greater capacity to generate free fatty acids which may explain its significant reduction when energy expenditure is elevated during and postexercise, and the muscle mass increase elevates the metabolic rate (Halaas and Bernardy, 2020).

The findings showed that there was a significant improvement in laboratory metabolic profile ↓Triglycerides in both groups' posttreatment in compare with pretreatment ($p < 0.001$), while there was no significant difference between pretreatment between both groups ($p > 0.05$).

The high-intensity electromagnetic field technology induces therapeutic modulation of both connective and subcutaneous tissues that could be explained based on improvement of viscoelasticity of abdominal skin to gain abdominal subcutaneous fat contouring and underlying muscular toning (Jacob et al., 2018).

Previously published data suggest that high-intensity focused electromagnetic field (HIFEM) is an inexpensive safe suitable approach enhance efficient induce body contouring that influenced by three issues including amount of abdominal subcutaneous fat that detected via its thickness, skin laxity, also underlying musculoskeletal mass. Therefore, HIFEM permits reduction of subcutaneous fat and toning of underlying musculatures, also improving skin laxity. Thus, it aids in controlling severity of metabolic suspected comorbidity those almost reported by 3rd and later on life span (Kent et al., 2019).

According to Duncan, (2021), who had documented effect of consecutive use of HIFEM technology using (BTL Industries Inc.), for both abdomen and buttocks treatment on fifteen participants (44.3 ± 14.2 years, $22.3 \pm 2.3 \text{ kg/m}^2$ with range 18.3–25.5 kg/m^2), as a conservative noninvasive approach to lipolytic fat reduction depends upon Faraday's law of electromagnetic induction to increase the penetration. Duncan has ensured the noticeable therapeutic benefit (86.6%

improvements, with 13.3% of participants were undecided), regarding their improvements in terms of metabolically influences adjacent fat tissue, which explains the recognizable improved abdomen shaping that agreed with current study findings.

According to Giesse, (2021) had evaluated fourteen individuals with central obesity with range 22-64 years old, 17.6-32.8Kg/m². Their undergone aesthetic appearance protocol using HIFEM procedure as a noninvasive body contouring four individual sessions completed within two weeks with 3 to 4 days apart, with additional period of double months for follow up. They had supported our findings regarding efficacy and tolerability of HIFEM procedure those were ensured to achieve high doctor and patient satisfaction.

Findings in the present study were supported by conclusion stated by Duncan and Busso. (2023) who had evaluated efficacy of a novel device simultaneously delivering HIFEM for abdominal subcutaneous, and visceral fat reduction on thirty-two participants (21-64 years, 17.4-33.5 kg/m²) as a convenient alternative to whom requiring no physical exertion (Goossens, 2017).

According to a recent Chinese clinical case series trial of Wong, (2022) whom defined HIFEM devices on muscular training and in abdominal subcutaneous fat thickness of thirteen Chinese participants whom received six treatment sessions for six weeks, where iontophoresis group received three sessions per week. Their recorded remarkable reduction in subcutaneous fat thickness by the end of the treatment, couple follow up sets by percent of improvement 19.9%, 25.6%, and 34%, respectively (p value 0.001) without any reported adverse effects for iontophoresis.

On the other hand, majority of therapeutic approaches aim at reducing the subcutaneous fat layer. Unless, extended therapeutic gained that targeting musculoskeletal tissue is forced to adapt to such stress, resulting in muscle thickening. That based on knowledge of muscular structures continue to improve in longer term, both in terms of their overall mass and lateral separation (Seynnes et al., 2007). Furthermore, a conflicting issue of releasing free fatty acids intoxicate the adipocytes and trigger their death (Gunduz et al., 2012; Zhang et al., 2012).

Findings in the present study were reported as the prime clinical trial that involved metabolic profile for evaluating the therapeutic HIFEM efficacy while, according to Robert et al., (2022) whom examined effects of novel synchronized radiofrequency and HIFEM on subcutaneous adipose tissue in a porcine animal model, and ensured remarkable sustained subcutaneous fat reduction with no adverse effect.

CONCLUSION:

Adding of high intensity electromagnetic technology (forty minutes per session, three sessions per week for three months) has a significant improvement in weight, WC and Metabolic profile outcome measures in central obese men. The results of the current study would introduce a scientific applicable protocol to help physical therapists dealing with central obesity and organize a plan of care to overcome this problem and prevent the development of associated morbidities and improve the quality of life of such patients

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