European Journal of Integrative Medicine 8 (2016) 313–316

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim

Research paper

Reduction in measures of adiposity using a combination of radio frequency and ultrasound cavitation methods

Mahsa Mohammadzadeh[a,1], Samira Nasrfard[a,1], Pouya Nezafati[b], Mahla Arabpour Dahoue[a], Nahid Hasanpour[a], Mohammad Safarian[c], Majid Ghayour-Mobarhan[d,*], Abdolreza Norouzy[a,**]

[a] Department of Nutrition, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
[b] Department of Cardiac Surgery, Imam Reza Hospital, Mashhad University of Medical Sciences, Mashhad, Iran
[c] Biochemistry and Nutrition Research Center, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
[d] Cardiovascular Research Center, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

ARTICLE INFO

Article history:
Received 24 July 2015
Received in revised form 15 October 2015
Accepted 16 October 2015

Keywords:
Obesity indices
Radio frequency
Ultrasound cavitation
Reduction

ABSTRACT

Radio frequency (RF) and ultrasound cavitation are two new methods that have been reported to reduce measures of obesity. This pilot study describes the results of a clinical trial in which a group of women receiving a low-calorie diet also underwent RF and ultrasound cavitation of the anterior abdomen and flank areas.

Methods: This randomised clinical trial was conducted between January 2014 and June 2014 at Ghaem Hospital in Mashhad, Iran. In total, 50 healthy women were recruited to participate in the study. Participants were randomly assigned to two groups, both of which received a low-calorie diet containing a 500-kcal energy deficit per day. The case group comprised 25 subjects who were assigned to a combined alternate treatment with RF and ultrasound cavitation of the abdomen and flank areas. The controls comprised 25 subjects who received the low-calorie diet alone. Anthropometric parameters, including body mass index, abdominal circumference, waist circumference, fat mass and trunk fat, were measured before and after the intervention. The same trained nurse administered the treatment twice weekly for a total period of 40 min each.

Results: The mean abdominal circumference was reduced by 9% and 5% in the case and control groups, respectively. In both the case and control groups, waist circumference was reduced significantly by 3.76 ± 1.69 and 2.40 ± 1.04 cm, respectively ($P < 0.05$). In addition, abdominal circumference was reduced by 9.5 ± 2.66 and 3.12 ± 1.88 cm in these groups, respectively ($P < 0.001$). There were no adverse events reported in these study groups.

Conclusion: Measures of adiposity can be reduced significantly using RF and ultrasound cavitation in combination with a low-calorie diet.

1. Introduction

Obesity and overweight are major global public health issues [1]. It is reported that approximately 1.46 billion adults were overweight in 2008, and of this number, 502 million were obese [1]. According to a recent World Health Organization (WHO) report, in 2014, over 1.9 billion adults aged 18 years and older were overweight. Of these adults, more than 600 million were obese [2].

Overweight and obesity are associated with an increased prevalence of major cardiovascular risk factors, such as hypertension, hyperlipidaemia and diabetes [3], and they lead to major health problems, such as cardiovascular diseases and diabetes [4]. Several methods are currently used to manage obesity and overweight, including behaviour therapy, dietary changes, pharmacological treatments and surgical methods [5]. There is a growing trend among women to improve their body shape by removing localised fat deposits [6], and there is a desire to develop noninvasive techniques to reduce local deposits of fat tissues [6]. Noninvasive methods for body contouring include external laser

Abbreviations: RF, radio-frequency; WHO, World Health Organization; BW, body weight; BMI, Body Mass Index; BFM, body fat mass; WC, waist circumference.

* Corresponding author at: Cardiovascular Research Center, School of Medicine, Mashhad University of Medical Sciences, P.O. Box: 9137913316, Mashhad, Iran.
** Corresponding author at: Department of Nutrition, School of Medicine, Mashhad University of Medical Sciences, P.O. Box: 9137913316, Mashhad, Iran.
E-mail addresses: norouzy@gmail.com, ghayourm@mums.ac.ir (A. Norouzy).

[1] Both authors contributed equally to this work

http://dx.doi.org/10.1016/j.eujim.2015.10.007
1876-3820/

therapy, radio frequency (RF), cryolipolysis, injection lipolysis and external ultrasonic energy devices [6]. Each of these devices could be administered in an outpatient setting without the need for general anaesthesia. On average, these techniques result in fewer complications than liposuction [5].

RF and low-frequency non-thermal-focused ultrasound are two new techniques that have been described as useful methods for mobilising stored fat with the same efficacy as liposuction and with fewer invasive complications than liposuction [7]. Cavitation ultrasound leads to oscillating pressure, and the rapid change in pressure can produce micro-bubbles within tissues [8].

RF energy and ultrasound cavitation technology have been used in skin tightening procedures to reduce local fat deposits and cellulite by increasing the blood flow within the treated tissues while stimulating fibroblasts, disrupting subcutaneous fat cells without harming neighbouring tissues and improving the quality of the fibrotic septa within adipose tissue [9,10].

Overweight and obesity have significant impacts on human health. To the best of the authors' knowledge, there is a lack of randomised clinical trials focusing on the efficacy and safety of RF and ultrasound technology in reducing local fat deposits in the abdomen. This study was designed to evaluate the combined effect of RF and ultrasound technology plus a low-calorie diet compared to a low-calorie diet alone on measures of adiposity in 50 Iranian women.

2. Methods and materials

This randomised clinical trial was conducted between January 2014 and June 2014 at Ghaem Hospital in Mashhad, Iran. The Ethics Committee of Mashhad University of Medical Science approved the protocol of the study, and The Iranian Registry of Clinical Trials approved the study (IRCT 2014042817475N1).

All subjects gave informed written consent. A trained nurse collected the demographics, socioeconomic status and medical history of participants using a questionnaire. Anthropometric parameters, including body weight (BW), body mass index (BMI) and body fat mass (BFM), were measured using a Tanita BC-418 body composition analyser (Tanita, Tokyo, Japan) according to the standard protocol [11,12]. Height and weight were measured when subjects were wearing light indoor clothing without shoes. Waist circumference (WC) was measured at a level midway between the costal margin and the iliac crest at the end of a normal expiration. Inclusion criteria were women aged between 18 and 65 years with a BMI between 25 and 29.9 kg/m^2. Exclusion criteria were scarring, inflammation or infection of the area to be treated; pregnancy or lactation; diabetes; cardiovascular diseases; malignancy; implantation of a pacemaker device; use of non-steroidal anti-inflammatory drugs, vitamin A and Accutane; women with sensitivity to light; anaemia; malignancy and those who were on any weight-reducing diets in the previous three months. Participants were allowed to withdraw from the study whenever they wished.

2.1. Interventions

Volunteers were recruited through a public advertisement. Eligible participants were randomly assigned to two groups (25 cases and 25 controls). Randomisation was achieved using a computer-generated randomisation list.

Both groups received a low-calorie diet for five weeks that consisted of a 500-kcal energy deficit per day, which is below the individuals' daily energy requirements. Subjects were advised to follow the prescribed diet plan throughout the study, and each subject received a questionnaire to complete in follow-ups to confirm whether they adhered their diets to the one prescribed.

Table 1
Demographic characteristics of the study participants.

Variables	Case group $N=25$	Control group $N=25$	P value
Age (year)	36.52 ± 8.56	35.32 ± 8.70	0.625
Height (cm)	159.68 ± 4.95	161.32 ± 4.63	0.232
Weight (kg)	70.48 ± 6.24	70.44 ± 4.83	0.980
Education			
>12 years	1 (4)	2 (8)	0.664
12–16 years	12 (48)	14 (56)	
<16 years	12 (48)	9 (36)	

RF and focus ultrasound devices were utilised by a trained technician only in the case group. The devices were operated twice weekly by the same technician, with each device being used once per week. Each intervention session took 40 min. Any adverse effects, such as erythema, pain during treatment or blistering, were recorded.

Ultrasound cavitation was applied at a vibration frequency of 32–36 kHz to achieve a more profound impact of 6–8 cm using the Megason cavitation machine (EunSung Global Co Ltd., Seoul, Korea). The Magicpot bipolar RF (EunSung Global Co Ltd., Seoul, Korea) treatment mode used was 0.8 MHz, which is suitable for deep layer (2–4 mm) treatments.

Both cavitation and RF were applied in the abdominal area, and subjects were in a supine lying position and completely relaxed.

2.2. Statistical analysis

All statistical analyses were performed using SPSS software version 16 (Chicago, USA). The normality of the data was assessed using the Kolmogorov–Smirnov test. A paired sample t-test and an independent sample t-test were used for data with a normal distribution, and the Wilcoxon signed-rank test and Mann–Whitney U test were used for non-normally distributed data. All data were presented as mean ± SD in each group, and a P value <0.05 was considered statistically significant.

3. Results

There were no significant differences among age, weight, height and BMI between the case and control groups (Table 1). There was no significant difference in the demographic and socioeconomic characteristics between the groups. Table 2 demonstrates changes in the BMI and WCs in the two groups, revealing a significant decrease during the study period in both groups.

Table 2
Changes in BMI, WC and AC before and after.

Obesity indices	Week	Groups		P for changes
		Control Mean ± SD	Case Mean ± SD	
BMI (kg/m^2)	0	27.07 ± 1.55	27.61 ± 1.44	0.301
	3	26.52 ± 1.68	27.01 ± 1.40	
	5	26.31 ± 1.65	26.64 ± 1.49	
		$P<0.001$	$P<0.001$	
WC	0	80.96 ± 5.03	81.80 ± 4.21	0.896
	3	80.20 ± 5.46	80.40 ± 4.10	
	5	78.56 ± 4.82	78.04 ± 4.31	
		$P<0.001$	$P<0.001$	
AC	0	89.92 ± 6.99	92.90 ± 5.36	0.934
	3	87.92 ± 6.85	88.79 ± 5.12	
	5	86.80 ± 4.42	83.40 ± 4.94	
		$P<0.001$	$P<0.001$	

BMI = Body Mass Index, WC = waist circumference, AC = abdominal circumference.