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Effect of Weight Loss Induced by Intragastric Balloon Therapy on Cardiac Function in Morbidly Obese Individuals: A Pilot Study

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Key Words

Obesity · Intragastric balloon therapy · Echocardiography · Tissue Doppler

Abstract

Objective: The aim of the study was to investigate the effect of intragastric balloon therapy on left ventricular function and left ventricular mass in a cohort of morbidly obese patients. ***Subjects and Methods:*** A prospective trial was performed in a cohort of 17 class II and class III morbidly obese individuals. The intragastric balloon was retained in the stomach for an average of 6 months. Conventional and tissue Doppler echocardiography were performed in all patients before and after the procedure. ***Results:*** The mean age of the study participants was 36 ± 10 years (range: 18–55). The mean body mass index was significantly decreased following the intragastric balloon insertion procedure (44 ± 8 vs. 38 ± 5, p < 0.001). The left ventricular mass index and left atrial volume index were significantly decreased following the procedure (112 ± 21 vs. 93 ± 17, p = 0.001 and 20 ± 6 vs. 14 ± 5, p = 0.02, respectfully). In addition, the ratio of mitral peak early diastolic velocity to tissue Doppler-derived peak diastolic velocity and tissue Doppler echocardiography-derived left ventricular myocardial performance index were decreased significantly following the procedure (9.5 ± 1.9 vs. 7.7 ± 1.5, p = 0.002 and 0.57 ± 0.11 vs. 0.46 ± 0.06, p = 0.001, respectively). ***Conclusions:*** Intragastric balloon therapy resulted in significant weight reduction in morbidly obese patients. This weight reduction was associated with improved left ventricular function.

Introduction

Obesity is an increasingly prevalent problem worldwide and has been associated with increased cardiovascular disease risk and significant morbidity and mortality [1]. Obesity is associated with left ventricular (LV) hypertrophy, LV dysfunction and coronary artery disease [2]. Moreover, obesity results in increased LV mass (LVM), decreased LV performance and left atrial (LA) overload [3]. Although obesity may inhibit LV systolic function over time, diastolic functional deficits are the primary cardiovascular effect of obesity [2]. The myocardial performance index (MPI) is a new diagnostic technique for the simultaneous evaluation of LV systolic and diastolic

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functions. The MPI may be measured from the mitral valve annulus using tissue Doppler echocardiography (TDE) [2]. Previous studies have demonstrated that MPI is increased in obese patients independent of the presence of hypertension [2, 4].

Intragastric balloons may be implanted and explanted via endoscopy. Intragastric balloons aid in weight loss by providing a space-occupying mass in the stomach [5]. Improved LV function and decreased LVM have been reported following weight loss by dietary restriction or bariatric surgery in morbidly obese patients [6, 7]. To our knowledge no previous study has evaluated the effects of intragastric balloon therapy on LV function. Hence, the aim of this study was to investigate the effect of intragastric balloon therapy on LV function and LVM in a cohort of morbidly obese patients.

Subjects and Methods

Study Population

A prospective trial was performed in class II or class III obese individuals (body mass index, BMI, ≥35). The BMI was calculated by dividing patient weight (in kilograms) by height (in meters squared). Patients with hiatal hernia (>5 cm), peptic ulcer or related conditions, disorders of the alimentary tract, Crohn's disease, major psychiatric disease, pregnancy, or previous gastrointestinal surgery were not considered candidates for intragastric balloon therapy. Study exclusion criteria also included factors related to cardiac function such as prior diagnosis of coronary artery disease, congestive heart failure, renal failure, moderate or severe valvular heart disease, atrial fibrillation, ventricular pre-excitation, bundle branch blocks, intraventricular conduction delays, electrolyte imbalance, chronic obstructive pulmonary disease, and poor echocardiographic quality.

A total of 21 consecutive patients were considered as potential candidates for inclusion in the study. Ultimately, 4 patients were excluded from the study. Poor echogenicity was seen in 1 patient and another patient was diagnosed with atrial fibrillation. A further 2 patients were excluded from the study for refusing to undergo postoperative echocardiographic examination. Hence, 17 patients were included in the study. The study was reviewed and approved by the institutional Ethics Committee and written informed consent was obtained from all volunteers.

Echocardiographic Examination

Two-dimensional pulsed-wave Doppler and TDE were performed in all patients using a 2.5-MHz transducer (EnVisor C Ultrasound; Philips, Bothell, Wash., USA) with the patient in the left decubitus position during normal respiration according to the recommendations of the American Society of Echocardiography. The diameter of the LV and the thicknesses of the diastolic wall were measured from the parasternal window with M-mode echocardiography. Left atrial volume (LAV) was determined in the 2-dimensional single plane using Simpson's method and a 4-chamber view. The LAV index (LAVi) was calculated by dividing LAV by body surface area. The LV ejection fraction was calculated using the modified Simpson's method. The LVM was calculated using the equation from Devereux et al. [8]. The LVM index (LVMi) was calculated by dividing LVM by body surface area. Doppler recordings were obtained with the pulsed sample volume placed at the tip of the tricuspid leaflets from the apical 4-chamber view. Peak early (E) and late (A) velocities were measured. All measurements were obtained by calculating the mean of three consecutive measurements. All echocardiographic measurements were obtained by the same team of cardiologists (F.K. and K.O.).

The filter settings and gains were adjusted to the minimal optimal level to reduce noise and eliminate signals produced by flow during the pulsed-wave TDE measurements. A 3.5-mm sample volume was used. The TDE cursor was placed from the apical 4-chamber view to the lateral wall of the LV. A Doppler velocity range of –20 to 20 cm/s was selected and the velocities were measured online at a sweep of 100 mm/s. Peak systolic velocity (Sm) and peak early (Em) and late (Am) diastolic velocities were measured and the Em/Am ratio was calculated. The isovolumetric relaxation time was measured from the end of Sm to the beginning of Em. The isovolumetric contraction time was measured from the end of Am to the beginning of Sm. The duration of Sm was measured as the ejection time. The MPI was calculated using the equation (ICT + IRT)/ET, where ICT is the isovolumetric contraction time, IRT is the isovolumetric relaxation time and ET is the ejection time. All Doppler parameters were calculated as the mean of three consecutive cycles. All echocardiography measurements were made by the same team of cardiologists.

Intragastric Balloon Procedure

Following routine laboratory tests, patients underwent an upper gastrointestinal endoscopic examination to exclude the presence of active gastric or duodenal ulcer, hiatal hernia or esophagitis. A fluid-filled balloon (BioEnterics Intragastric Balloon; Allergan Inc., Irvine, Calif., USA) was used in the study. The balloon placement procedure was performed under deep sedation with heart monitoring and oximetry. The introduction of the deflated balloon through the mouth and the positioning in the stomach cavity were performed under endoscopic control. After the inflation of the balloon with an injection of 550–700 ml isotonic saline solution with 10 ml methylene blue through a small filling tube attached to the balloon under endoscopic control, the tube was removed by gently pulling on the external end, leaving the balloon inside the stomach. The procedure was completed after confirming the correct positioning of the balloon. The balloon remained in the stomach for an average of 6 months. To remove the balloon, an endoscopic procedure was conducted to puncture, deflate, grasp, and remove it.

Statistical Analysis

Categorical variables are presented as counts and proportions. The Kolmogorov-Smirnov test was used to evaluate the distribution of continuous variables relative to a normal distribution. Continuous variables are presented as means (with standard deviations). A paired Student t test was used to evaluate differences between the preoperative and postoperative periods. The associations between study parameters and weight loss were determined by the Pearson correlation test. SPSS software version 15.0 for Windows (Chicago, Ill., USA) was used for all statistical analyses. A two-sided p value <0.05 was considered statistically significant.

Table 1. Baseline characteristics of the study patients (n = 17)

Age, years	36±10
Female	15 (88)
Diabetes	1 (6)
Hypertension	4 (24)
Smoking	4 (24)
Hyperlipidemia	2 (12)

Values are n (%) or mean ± SD, as appropriate.

Table 2. Comparison of clinical and biochemical findings before balloon placement and 6 months later at balloon removal

	Before balloon placement	At balloon removal	p
BMI, kg/m^2	44±8	38±5	<0.001
Systolic blood pressure, mm Hg	133±9	123±11	0.001
Diastolic blood pressure, mm Hg	86±6	79±7	0.01
Body surface area, m^2	2.14±0.18	2.03±0.18	<0.001
Creatinine, mg/dl	0.63±0.11	0.60±0.13	0.44
Fasting blood glucose, mg/dl	108±44	101±28	0.16
Total cholesterol, mg/dl	192±37	186±33	0.34
Triglycerides, mg/dl	142±62	143±66	0.95
HDL, mg/dl	49±13	52±12	0.03
LDL, mg/dl	120±36	118±31	0.70

Values are means ± SD. BMI = Body mass index; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Table 3. Comparison of LV echocardiographic findings prior to balloon placement and 6 months later at the time of balloon removal

	Before balloon placement	At balloon removal	p
LV end-diastolic diameter, cm	4.86±0.19	4.54±0.27	<0.001
LA end-systolic diameter, cm	2.94±0.26	2.86±0.29	0.32
Interventricular septum thickness, cm	1.07±0.14	0.97±0.12	<0.001
Posterior wall thickness, cm	1.11±0.15	0.96±0.15	0.003
LV ejection fraction, %	65±4	63±3	0.42
LVMi	112±21	93±17	0.001
LAVi	20±6	14±5	0.02
Mitral E/A ratio	1.05±0.40	1.23±0.27	0.06
Mean E/Em ratio	9.5±1.9	7.7±1.5	0.002
Mean TDE-derived MPI	0.57±0.11	0.46±0.06	0.001

Values are means ± SD. LV = Left ventricle; LA = left atrium; LVMi = left ventricle mass index; LAVi = left atrial volume index; TDE = tissue Doppler echocardiography; MPI = myocardial performance index.

Results

The baseline characteristics of the 17 subjects are given in tables 1 and 2. The mean age of the patients was 36 ± 10 years. The mean BMI, as well as systolic and diastolic blood pressure, significantly decreased relative to preoperative status following the procedure (44 ± 8 vs. 38 ± 5, $p < 0.001$; 133 ± 9 vs. 123 ± 11 mm Hg, $p = 0.001$, and 86 ± 6 vs. 79 ± 7 mm Hg, $p = 0.01$, respectively). At the end of the study, 2 patients achieved a weight loss of <5%, 8 patients 5–10%, 5 patients 10–20%, and 2 patients >20%. The mean relative decrease in body weight was 14%. In addition, high-density lipoprotein levels significantly increased after the insertion of the intragastric balloon (49 ± 13 vs. 52 ± 12 mg/dl, $p = 0.03$).

The echocardiographic findings of the patients are shown in table 3. The LV end-diastolic diameter, LVMi and LAVi were significantly decreased after the procedure (4.86 ± 0.19 vs. 4.54 ± 0.27 cm, $p < 0.001$; 112 ± 21 vs. 93 ± 17, $p = 0.001$, and 20 ± 6 vs. 14 ± 5, $p = 0.02$, respectively). A statistically significant positive correlation between LAVi and weight loss was observed ($r = 0.647$, $p = 0.005$). In addition, the mitral E/Em ratio and the TDE-derived LV MPI significantly decreased after the procedure (9.5 ± 1.9 vs. 7.7 ± 1.5, $p = 0.002$ and 0.57 ± 0.11 vs. 0.46 ± 0.06, $p = 0.001$, respectively).

Discussion

In this study, BMI, along with systolic and diastolic blood pressure, significantly decreased following balloon-induced weight loss. As a result, TDE-derived LV MPI, LVMi and LAVi were significantly decreased in obese patients undergoing intragastric balloon therapy.

Obesity contributes to increased LVM and deterioration of LV systolic and diastolic function. Dietary restriction and medical or surgical therapy may decrease LVM and improve LV systolic and diastolic function [6, 7, 9]. In a previous study, maximum diet-induced weight loss was achieved at 6 months and correlated with improvements in cardiac function [9]. Following 6 months of dietary restriction, a 9% weight loss, improved LV systolic and diastolic functions and decreased LVM were reported [9]. Bariatric procedures may result in the loss of more than 50% of excess weight within a few years [10]. Moreover, decreased LV hypertrophy and improved LV function may occur following significant weight reduction [6]. The decrease in weight of the intragastric balloon therapy confirmed that of previous studies [11].

The TDE-derived MPI values were significantly decreased at 6 months after weight loss. This is an important finding because the TDE to derive MPI is a noninvasive method that enables the simultaneous evaluation of LV systolic and diastolic function, and MPI is superior in the evaluation of systolic and diastolic function in comparison to other methodologies [12]. Moreover, MPI can generate prognostic data relevant to a number of cardiac pathologies, including heart failure, hypertension and myocardial infarction [13]. Dayi et al. [12] reported that LV MPI was markedly decreased by weight reduction as a result of dietary modifications and medical therapy. TDE-derived MPI has enhanced sensitivity relative to conventional Doppler in the evaluation of ventricular function during the early asymptomatic stages of heart failure. Unlike conventional Doppler, MPI is not affected by heart rate, blood pressure or ventricular geometry [2, 7].

The significant decrease in the E/Em ratio and LAVi after follow-up showed positive effects on LV diastolic functions and LV filling pressures. The E/Em is a critical parameter of LV filling pressures. Em decreases and E/Em increases are correlated with a reduction in LV relaxation. The E/Em ratio is interrelated with LV diastolic function [14, 15]. Varli et al. [7] demonstrated that diastolic function was improved at 6 months after weight loss with dietary modifications and drug therapy. Also, LAVi predicts diastolic function independent of acute alterations in volume status. LAVi is closely related to diastolic function [14].

The limitations of this study include a relatively small number of primarily female patients, limited follow-up with no information being obtained regarding weight regain and associated cardiac function changes and, most importantly, no controls. Future studies are needed with a larger sample to confirm these observations.

Conclusion

In this pilot trial, BMI and arterial blood pressure were significantly decreased and LV functions improved in morbidly obese patients following weight reduction by intragastric balloon implantation.

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