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Morbid Obesity: treatment with Bioenterics Intra-gastric Balloon (BIB), psychological and nursing care: our experience

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Abstract: Obesity is considered a chronic disease, difficult to treat, and is the first cause of death in the world that is predictable. The surgical approach is limited to patients with severe obesity but there is an intermediate group who are not candidates for immediate surgery. The BioEnterics Intra-gastric Balloon (BIB) is recommended for weight reduction as a bridge to bariatric surgery.

All patients in the study underwent a psychological evaluation prior to placement of the BIB.

Keywords: Obesity; Psychologist; Nurse, BioEnterics Intra-gastric Balloon (BIB)

1 Introduction

Obesity is a chronic disease caused by many factors and represents a major threat to the health of an individual

where the accumulation of body fat and excess weight, may lead to cardiovascular complications, or the musculoskeletal system [1]. There are also important associations between obesity and other diseases such as diabetes, hypertension and lipid disorders, diseases of the liver and gallbladder, and various forms of cancer. There are numerous studies that have investigated the relationship between excessive food intake, resulting in overweight and obesity, and increased mortality. According to the World Health Organization (WHO) the effect of overweight on mortality persists throughout the lifespan, although this effect is more marked among men and women under 50 years [2].

Compared to other European countries the problem of obesity in Italy is less but the upward trend in the number of obese and overweight individuals is still a concern, which justifies the authorities' health warning. The analysis of the spatial distribution of the phenomenon reveals profound differences: in the South where 11.4% of the population is obese, whereas the North-west 7.5% is over the obesity threshold [3].

In some cases, excess weight may cause serious problems in the levels of acceptance of their condition and affect the general level of self-esteem. The WHO has in fact noted the frequent incidence of psychological disorders among obese persons; in particular there seems to be a link between obesity and depression that shows a two-way relationship where one causes the other and vice versa.

Today, the WHO defines obesity as a disease where accumulated excess body fat has reached extent that can lead to a negative effect on health, leading to a reduction in life expectancy and a rise in health problems.

The definition of excess body weight involves identifying an ideal weight, varying from subject to subject, taking into account age, sex and height. The epidemiological criteria currently most used is the determination of the body mass BMI ($\text{kg} / \text{m}^2 = \text{weight} / \text{height}^2$).

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In this work, which opens with a description about the mechanism, causes and complications of obesity, provides an overview of the possibilities of treatment with BioEnterics Intra-gastric Balloon (BIB), and finally emphasizing the fundamental role of the psychologist and nurses in assessing and assisting the patient pre- and post-operatively [4-7].

2 Methods

The BIB (Bioenterics Intra-gastric Balloon) is a prosthetic device that, for several years, has been used successfully as an adjunct to weight loss in moderately obese patients. The BIB is made from a soft and expandable elastomeric material, which is inserted into the stomach with an endoscopic procedure and subsequently filled with saline. The filled intra-gastric balloon partially occupies the stomach, leaving less room for the amount of food or beverage that can be ingested [8]. This device, therefore, aims to reduce the feeling of hunger and helps you feel full for longer, even after consuming small meals. The intra-gastric balloon is designed for people who have failed to obtain a prolonged loss of weight by conventional means, such as diet that may be supplemented by physical activity and certain medications. The balloon is indicated for patients with a high body mass index or have other medical conditions related to obesity. The gastric balloon is not a permanent solution and is, usually, left in place for a maximum of six months, after which it is removed [9].

The weight loss that is obtained is variable initially, and may be quite rapid. The average weight loss obtained in the 6 months with the intra-gastric balloon in place is about 15-20 kg [10]. Ultimately, the amount of weight loss depends on patient compliance, ie the degree of adherence to a controlled diet and following a program that changes your lifestyle, starting with the practice of regular exercise [11].

Sometimes the intra-gastric balloon is used for severely obese patients in the short term to reduce their weight, down to a value which makes them amenable to a more complex and permanent surgical approach, such as a gastric banding or gastric bypass surgery [12].

From January 2010 to December 2012, 20 patients underwent implantation of the intra-gastric balloon in our Department of Digestive Endoscopy. Patients were selected according to NIH criteria [13]. Inclusion criteria were: BMI > 27-30, previous failure of dietary measures and the presence of at least one of the following co-mor-

bidities: hypertension, diabetes, respiratory disorders, osteoarthritis, dyslipidaemia.

BIB was placed in 20 patients (9 males, 11 females; age range: 19-57 years), BMI range: 37-46, weight range: 103-165 kg [13].

All patients underwent esophagogastroduodenoscopy (EGD) before the implant procedure. The complication of the procedure (deflation, rupture of stabilizer band, bowel migration, gastric ulcer, gastrectasia, intolerance, nausea and vomit) were discussed with the patients allowing for informed consent. All patient were hospitalized, and fasted for 12 hours before the procedure. The BIB was placed in the patient under general anaesthetic [14].

All patients received the same medical treatment. On the first postoperative day, intravenous saline (30-35 ml/kg/die) with omeprazole (40 mg/die), ondansetron (8 mg/die), and butyl-scopolamine bromide (20 mg x 3/die) were given to all patients.

On the second postoperative day, patients were discharged with drug therapy: omeprazole (40 mg/die) and a 1,000 Kcal diet.

In our study we evaluated the efficacy of the procedure by considering:

- weight loss parameters after 6 months (time of BIB removal);
- maintenance of weight after removal;
- short-term and medium-term complication;
- long-term complication for BIB;

These results were collected with a medical interview for retrospective study of the BIB.

Informed consent: Informed consent has been obtained from all individuals included in this study.

Ethical approval: The research related to human use has been complied with all the relevant national regulations, institutional policies and in accordance the tenets of the Helsinki Declaration.

3 Results

No complications occurred during the procedure.

In 2 of 20 patients treated with BIB, the balloon was removed for intolerance (1 patient) and for gastrectasia (1 patient). In the other 18 patients the balloon was removed after 6 months at the end of the therapy [15].

The average weight loss was 20 ± 3 kg.

The BMI at the end of therapy was 32 ± 2 kgm².

At long-term follow-up showed that no complications occurred for BIB.

4 Discussion

Endoscopic positioning of intragastric balloon is nowadays an effective procedure to obtain a significant weight loss. BIB is actually the most used devices before surgery [16].

According to data published by the International Obesity Task Force, more than 1 billion adults are overweight and 310 million are obese. In their estimates the numbers of children and adolescents are about 160 million and 40 million, respectively. In Europe, the prevalence of obesity has tripled in the last two decades and is expected to double in the next thirty years unless something is done effectively. In addition, obesity and overweight, were previously considered problems that occurs only in rich countries but are now also growing in developing countries. The pathological weight gain is the fifth risk factor for deaths globally, killing about 2.8 million adults annually. In Italy obesity reaps 52,000 victims a year and, according to the Italian Institute of Statistics (ISTAT) data reported in the twenty years from 1985 to 2005, the increase of overweight was 9.8 percentage points for males and 4.9 percentage points for females. Again according to ISTAT surveys the age group showing the highest values is that of 64-75 years.

Obesity develops when, the intake amount of calories exceeds calorie consumption over prolonged periods of time. The excess is converted and stored as fat. Certain endocrine and metabolic genetic factors may also contribute to the condition of obesity.

The main cause is still excessive food intake and an unhealthy diet or eating disorder of psychological basis.

From the point of view of aetiopathogenetics, obesity still remains a disease of unknown cause. However, it is possible to prepare a classification that distinguishes primary obesity to secondary obesity [17].

Essentially, primary obesity is a chronic multifactorial disease where the causes are not easily identified. Genetics, nutrition, the environment, psychology and lifestyle are all considered attributable factors.

Secondary obesity is where the pathogenic factor is known and constitute to about 3-5% of all forms of obesity. The most important complications related to being overweight are:

- metabolic complications;
- dyslipidemia;

- systemic arterial hypertension;
- respiratory disorders;
- syndrome of obstructive sleep apnea;
- the hepatic steatosis;
- calculus of gallbladder.

The most recent international guidelines recommend that the obese candidate for bariatric surgery should undergo a thorough preoperative multidisciplinary assessment that includes an evaluation of the mental state. However, the aims and scope of this evaluation are generally not well specified.

The motivation and objectives of mental status assessment in the obese patient can be summarized in two main points [18]:

a) There are prolonged psychopathological states with variable degrees of severity that represent a contraindication. In these cases, indication may be placed individually only for serious medical reasons and always with the formal consent of the referring psychiatrist.

b) There are specific psychological and behavioral attitudes of the patient that can play an important role in determining the outcome of the operation, even for those that are not considered clinically significant.

The evaluation of the mental state has objectives [19]:

1. recognition of major psychiatric disorders that can represent contraindications;

2. the recognition of personality traits, behaviors and fewer psychopathological disorders associated. The tools used for psychiatric-psychological assessment are the clinical interview and psychometric investigation that must be considered carefully for managing the post-operative period.

The clinical interview is used to investigate the mental state of the subject, the areas needed to assess the compliance intervention, the past history, and to identify psychopathological conditions which may hinder the intervention, and those who require specific treatment (pharmacological and / or psychotherapeutic) pre-operatively or post-operatively [20-21].

The psychometric survey, uses targeted tools corresponding to the areas to be investigated. It provides data on the personality, the presence of symptomatic conditions or stroke in response to changes of mood and anxiety, the relationship with food, on body image, intensity and quality of the impulsive component, quality of life, and the patient's own intervention.

The personality assessment tests and general psychopathology, are [20]:

- 1) Minnesota Multiphasic Personality Inventory - 2 (MMPI-2). Hathaway & McKinley, the MMPI Ristandardizzazione Committee of the University of Minnesota Press

(Butcher, Dalhstrom, Graham, Tellegen). Italian adaptation of P. Pancheri and Sirigatti S. (1995).

The MMPI-2 is the most widely used test in the literature related to bariatric surgery. The interpretation of this test allows us to identify some personality traits that may adversely affect the outcome of surgery.

The MMPI is a questionnaire consisting of 567 questions with true or false answer.

2) Symptom Checklist-90-R (SCL-90-R). Derogatis, L. (1983).

The SCL-90 test is a self-administered questionnaire consisting of 90 items, that includes disorders possibly tested in the last week; the subject provides an assessment from 0 (not at all) to 4 (very much) [Likert Scale].

3) Barratt Impulsiveness Scale (BIS-11). Titrated Barratt and M.S. Stanford (1995). Italian

adaptation by: Fossati, A., Di Ceglie, A., Acquarini, E., Barratt, titrated (2001).

The BIS-11 is one of the most used for the evaluation of impulsivity. It particularly suitable for the study of the relationship between impulsivity and psychiatric illness. It is also to assess changes in the clinical picture of impulsivity.

4) Beck Depression Inventory – BDI-II (Aaron T. Beck, Robert A. Steer and Gregory K. Brown)

(1996). Italian translation of Marta Ghisi, Giovanni Battista Flebus, Antonella Montano, Ezio Sanavio and Claudio Sica (2006).

The BDI-II is a self-administered instrument for the assessment of the severity of depression in already diagnosed patients and for the detection of the risk of depression in the normal population. It has also proven effective in discriminating patients with clinical depression from non-depressed psychiatric patients.

5) Beck Anxiety Inventory – BAI (Aaron T. Beck and Robert A. Steer) Italian Ed edited by: C.

Sica, D. Coradeschi, M. Ghisi and Sanavio E. (2006).

The BAI is a self-administered tool that allows you to assess the severity of anxiety symptoms. Anxiety disorders and depressive disorders are frequently associated and the tools to measure severity of anxious and depressive manifestations are highly correlated.

6) EDE-12.0D e EDE-Q.

The EDE-12.0D is a semi-structured interview, given at the end of the psychological interview, allows us to make a diagnosis of any eating disorder according to DSM-IV and provides important information on other important characteristics related to DCA. (19-20).

7) Eating Disorder Inventory-3 (EDI-3) David M. Garner. Italian adaptation by: Marco Giannini,

Linda Corn, Riccardo Dalle Grave, Filippo Muratori e Valentina Viglione (2008).

The EDI-3 is a test for the clinical evaluation of symptoms associated with eating disorders. E 'it divided into 12 major scales including 3 specific for eating disorders:

a) Drive for thinness (DT);

b) Bulimia (B);

c) Body dissatisfaction (BD).

8) Boston Interview for Bariatric Surgery (Revised) – S Sogg, L Mori, 2008.

The revised version of the Boston Interview is applicable to patients who undergo various bariatric surgery procedures. It is a structured interview built to be used by mental health professionals.

Unfortunately, it was noticed that some nurses may have negative attitudes towards obese patients, resulting in lack of valid support which can create a feeling of frustration and demotivation by the patient and therefore resulting in negative effects on psychological well-being and quality of life. In recent years, the increase in obesity in the general population has resulted in an increase in the number of hospitalized obese patients. This has consequently led to a considerable effort for both the medical personnel and nurses to improve the provision of varied types of assistance for the patients.

The general nurse understands the care needs of the patients better than the other healthcare professionals. The nurse collects data on the patient pre and post intervention and compiles it into a nurse record. This record allows them to identify patient care needs and ensure better continuity of care.

We can therefore say that the nurse is responsible for the patient in his physical needs as well the psychic ones. Often in obese patients it is not easy to establish a relationship of trust, as they often have low self-esteem and sense of helplessness. The nurses who are aware of these difficulties, must be able to interact with the patient, creating a comfortable environment and a relationship of trust, and making the patient feel no longer despised [21-22].

5 Conclusions

Obesity has a multifactorial pathogenesis related to the interaction of an unhealthy diet, reduced energy consumption, metabolic disorders, cardiovascular and joint disorders, mood disorders personality, and environmental factors.

The complexity of the disease must therefore be reflected in an equally complex approach, multidisciplinary.

nary and of integrated type, both in the evaluation phase and in treatment follow-up. All recent guidelines state that patient selection and pre- and post-operative care should be made by a multidisciplinary team consisting of:

- A surgeon;
- A specialist in internal medicine;
- A psychologist;
- A nutritionist or dietitian;
- A specialist nurse.

Only an approach of this kind may allow the long term maintenance of the results and reduction of complications.

To ensure that the results are maintained over time it is essential to obtain a change in the attitude of the patient towards food and physical activity. It is therefore essential to intervene on psychological problems and ensure that the patient is fully informed of the value and consequences of his behavior.

The BioEnterics IntraGastric Balloon (BIB) is effective in treating overweight patients with BMI > 27-30 kgm². In our study there were no significant differences in the complication rate reported compared to literature.

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Luigi Sivero: Participated substantially in the conception, design and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

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Pietro Forestieri: Participated substantially in the conception, design, and execution of the study and in the analysis and interpretation of data.

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