

ORIGINAL ARTICLE

Clinical and psychological evaluation of the probable influence of the SARS-2 pandemic on the results of moderate obesity therapy with Bioenterics Intra-gastric Balloon

Review of the literature and our experience

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ABSTRACT

BACKGROUND: Patients with moderate obesity are not candidates for immediate surgery, which is normally intended for patients with severe obesity. On the other hand, Bioenterics intra-gastric balloon (BIB) treatment is indicated, which can also be used for weight reduction as a bridging therapy for bariatric surgery.

METHODS: In the two-year period (2021-2022) we analyzed 53 patients with moderate obesity, 3 and 6 months after the implantation of a BIB, in compliance with the health provisions issued for the COVID-19 pandemic, through a telephone interview. The questions used focused on the possible presence of important clinical and psychological symptoms.

RESULTS: Analysis of responses to clinical symptoms revealed that gastrointestinal disorders were modest, in line with expectations based on various scientific society guidelines and literature reviews. The psychological evaluation showed that patients who underwent BIB placement during lockdown (N.=24) were significantly more likely to express a need for psychological support (Student's *t*-test, P=0.042), compared to patients who underwent BIB placement after restrictions were lifted (N.=29).

CONCLUSIONS: The literature review and the results obtained confirmed two of our hypotheses, firstly that COVID-19 significantly affected symptoms and clinical outcomes, exclusively and negatively during the lockdown period, resulting in poor weight loss, which was compensated for in the later phase, out of lockdown. Secondly, in the same phase the development of psychological disorders in some patients was detected. This picture has in fact become null and void in the second observation period. Another factor found was telemedicine, which was a valuable solution for collecting medical data and following up patients remotely.

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Fat accumulation and significant weight gain can cause numerous potentially serious and life-threatening complications.¹ Many articles in the literature confirm the relationship between

eating disorders with increased body weight, and therefore also obesity, and complications at the level of various organs and anatomical regions.

For this reason, the World Health Organiza-

tion (WHO) considers obesity to be the leading cause of predictable death, with a risk that persists throughout life. However, this risk is more important when obesity occurs in patients under the age of 50.^{2,3}

As a rule, obesity is not considered a mental disorder and as such is not considered psychiatric. There have been many studies on this topic, which have shown a correlation between the risk of obesity and the presence of psychiatric disorders. Obese people usually manifest insecurity, a sense of inadequacy and low self-esteem.

People's offensive and denigrating behaviors toward the obese can result in a reaction of isolation, and food is sought for compensation, gratification, and relief. In extreme cases, obesity-related depression can be so severe that it leads the patient to suicide.

One of the first studies on the use of a gastric balloon, with the aim of reducing the weight of obese patients, dates back to 1982. In the following years, various attempts were made with different types of balloons, but the presence of problems and adverse events advised against their use.

The materials and characteristics of current balloons (silicone, spherical, smooth and without traumatic edges) differ greatly from previous versions, which has led to a renewed interest in this method. Thanks to these successes, today there are many centers that use this technique.

The BIB (Bioenterics Intra-gastric Balloon) is a prosthetic device that is used prominently in patients with moderate obesity. It is made of soft, expandable and elastic material that once inserted into the lumen of the stomach fills with saline solution. The filled pectoral partially takes up space in the stomach, leaving less room for food and drink. This reduces the feeling of hunger, and the patient feels full for longer. The use of BIB is especially indicated in people who have failed to achieve a prolonged weight loss by conventional means, such as diets and physical activity. BIB is also indicated in patients with a high body mass index or in patients with other medical conditions related to obesity.

BIB is not a permanent solution and is usually left in place for up to six months, after which

it is removed.^{4,5} The results obtained in terms of weight loss are initially variable and are usually quite rapid. On average, weight loss over 6 months with the intragastric balloon in place is about 15-20 kg.⁶ The amount of weight loss depends on various factors such as the patient's compliance with the recommended accompanying diet, adaptation to a new lifestyle, and the practice of regular exercise.⁷ The BIB is used in patients with severe obesity with the aim of reducing their weight quickly and sufficiently to allow for a more complex and permanent surgical approach, such as gastroplasty or gastric bypass.⁸

To maintain contact with patients, we decided to use a telemedicine approach with a multidisciplinary team to understand and solve any problems.

Materials and methods

This study was conducted during a phase of COVID-19 infection. We were aware of the risk that these patients could be infected with the coronavirus; so, we chose to conduct interviews.

Sixty patients with obesity, classified as moderate obesity, with a body mass index between 29 and 39 (mean 35.47), were contacted by telephone. 53 patients, 20 males and 33 females, aged 23 to 53 years (mean 37.45), participated in the assessment. All patients had already undergone a BIB at our facilities. After the insertion of the BIB, precisely at the third and sixth months, the patients were administered, by telephone, two questionnaires, one for the evaluation of clinical symptoms (Table I) and the other for the psychological evaluation (Table II).

TABLE I.—*Clinical evaluation.*

Parameter	3 months		6 months	
	Yes	No	Yes	No
Weight loss (kg)	Yes	No	Yes	No
Reflux	Yes	No	Yes	No
Regurgitation	Yes	No	Yes	No
Nausea	Yes	No	Yes	No
Vomit	Yes	No	Yes	No
Epigastric pain	Yes	No	Yes	No
Constipation	Yes	No	Yes	No
Diarrhea	Yes	No	Yes	No
Infection COVID-19	Yes	No	Yes	No

TABLE II.—*Psychological evaluation.*

Item	3 months		6 months	
Eating habits				
1. To follow the diet	Yes	No	Yes	No
2. Pay attention to calories	Yes	No	Yes	No
Lifestyle				
1. Lead a healthier lifestyle	Yes	No	Yes	No
2. Physical activity	Yes	No	Yes	No
Influence of BIB				
1. The BIB has conditioned its relations	Yes	No	Yes	No
2. The BIB has conditioned the work/recreational activities	Yes	No	Yes	No
Satisfactions/expectations				
1. Satisfied with the results it is getting	Yes	No	Yes	No
2. If he went back, he would do the surgery again	Yes	No	Yes	No
Psychological support				
1. Following a psychological path	Yes	No	Yes	No
2. Feel you need psychological support	Yes	No	Yes	No
Body image				
1. She likes the image she sees in the mirror the most	Yes	No	Yes	No
2. Takes better care of its appearance	Yes	No	Yes	No
Mood				
1. Often feels irritable, frustrated	Yes	No	Yes	No
2. Feels sad	Yes	No	Yes	No
COVID-19 emergency				
1. Affects the ability to follow prescriptions	Yes	No	Yes	No
2. Condition the results you are getting	Yes	No	Yes	No

Results

In this study, the outcomes of BIB treatment for moderate obesity were evaluated via telephone interview, considering clinical and psychological factors and the possible influence of the COVID-19 pandemic on weight loss.⁹⁻¹²

The answers to the interviews were recorded anonymously, progressively numbering the patients from 1 to 53. The date of placement of the BIB was also recorded during the questionnaire. This was crucial, because the first 24 patients had been implanted with BIB during the first phase of the pandemic, characterized by a total lockdown, with the entire population placed in forced isolation.

Analysis of responses to the clinical questionnaire revealed that, in line with the results reported in literature reviews, gastrointestinal disorders were modest in both periods assessed. There was an incidence of 1.32% for reflux and constipation and less than 1% for other symptoms. As for weight loss at the end of the sixth month, a lower-than-expected reduction was reported by the first 24 patients treated during the lockdown, who already in the first 3-month check had values ranging from 0 to 10 kg. For the remaining patients,

weight loss, in both periods assessed, was in line with standards, ranging from 20 to 24 kg.

Only 6 patients contracted a COVID-19 infection, 4 during the lockdown phase and 2 after. None had severe symptoms or consequences on the respiratory system, and no patients required early removal of the BIB.

In evaluating the responses to the psychological questionnaire, an attempt was made to identify the possible psychological changes affecting the first 24 patients, to whom the BIB had been applied during the lockdown, compared to the others.

Patients who underwent BIB placement during lockdown (N.=24) were compared to patients who underwent BIB placement after blocking rules were lifted (N.=29). Patients treated during the lockdown experienced significant negative psychological changes and expressed the need for psychological support as early as 3 months after the placement of the BIB (Student's *t*-test, $P=0.042$).

The responses were not significant when we analyzed the second period, after 6 months (Student's *t*-test, $P>0.05$).

This suggests that with the passage of time

and the end of the lockdown, some psychological recovery occurred, and patients were less affected by this adverse condition.

Discussion

The review of the literature confirmed that the pandemic has led to changes in diet, especially during the lockdown 38.5% of people changed their eating habits. All obese patients treated with endoscopic or surgical therapy did not achieve the expected results from clinical trials. This situation has certainly been amplified in cases where patients have contracted a SARS-CoV-2 infection.

For our practice, we preferred a telemedicine approach to patient management. This method has been implemented in the network of health services and allows excellent integration of social and health assessments into existing management frameworks despite the necessary distancing of patients and operators.

Telemedicine has been shown to:

- improving the quality of healthcare;
- enable easier access to remote assistance, diagnostic services, and medical advice;
- helps regular monitoring of vital signs.

Therefore, it seemed pertinent to conduct this type of investigation on the possible effects of SARS-CoV-2 virus infection and/or isolation in patients with obesity after BIB placement.

The World Obesity Federation has published an in-depth analysis of the entire international literature, which confirmed that, following COVID-19 infection, obese patients with BMI > 30 kg/m² (grade I obesity) were at increased risk of serious complications, admission to intensive care units and death.

The World Obesity Federation has also estimated that in Italy, 58.5% of adult patients are overweight (>25 kg/m²) and 19.9% are obese (>35 kg/m²). A survey investigating the distribution of obesity in Italy has found a remarkable difference between Southern Italy, where 11.4% of patient is obese, and Northern Italy, where 7.5% is obese.¹³⁻²⁶

Conclusions

Our investigation aimed to demonstrate the possible effects of the pandemic on the outcomes of

Bioenterics intragastric balloon treatment, how the amplification of some symptoms, such as fear of contagion and isolation may have changed patients' behavior, leading to an increase in psychological disorders. Unfortunately, the number of patients included in our study can be considered small, not because of our choice or low demand, but rather because ministerial provisions during the pandemic have drastically reduced access to hospitals for patients suffering from diseases considered non-urgent, or of a non-oncological nature. The outcomes of BIB treatment for moderate obesity were assessed via telephone interviews, considering clinical and psychological factors and the possible influence of the COVID-19 pandemic. The answers to the interviews were recorded anonymously. The questionnaire was recorded with the date of registration. This was crucial, because the first 24 patients had been evaluated during a particular phase of the pandemic, characterized by total lockdown, with the entire population placed in forced isolation.

The reports obtained, in analogy with those present in the literature, have shown that the COVID-19 pandemic has aggravated psychological disorders. This was especially true for patients treated during lockdown, as can be seen in the 3-month follow-up after implantation. Patients with severe eating disorders were particularly affected and perceived a greater loss of control. The height of the lockdown, when it was impossible for patients to leave the house, aggravated their psychopathological state above all. Patients experienced increased anxiety, fear, stress, and boredom. These conditions favored food cravings. Despite the social isolation, the only comfort for these patients was the constant presence of their family, who helped them adhere to the prescribed diet.

Also, in the analysis of the responses to the clinical questionnaire there was an overlap with those present in the literature reviews, in particular gastrointestinal disorders were modest in both periods evaluated. We found an incidence of 1.32% for gastro-esophageal reflux and constipation and less than 1% for other symptoms. As for weight loss at the end of the sixth month, a smaller than expected reduction was reported by the first 24 patients. For the remaining patients, weight loss was in line with standards.

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Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions

Conceptualization: Stefania Sivero. Methodology: Giuseppe Galloro. Validation: Alessia Chini. Formal analysis: Mario Bottone. Investigation and resources: Rosa Maione. Data curation: Saverio Siciliano. Writing—original draft preparation: Luigi Sivero. Writing—review and editing: Nelson Mauro Maldonato. Visualization: Luigi Sivero. Supervision: Mario Musella. Project administration: Stefania Sivero. All authors read and approved the final version of the manuscript.

History

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