

**VALIDATION OF A SCORE FOR SUPPLEMENTATION NEEDS OF VITAMINS,
MICRONUTRIENTS AND PROTEINS AFTER BARIATRIC SURGERY (BARSCORE PROJECT)**

PROTOCOL INFORMATION

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ABSTRACT

Obesity is currently a pandemic. The treatment of patients affected by obesity is very complex and requires the synergy of a multidisciplinary team that addresses the problem in its different spheres. Among the available treatment options, surgery remains the most effective in the long term. Among surgical techniques, there are different types based on different mechanisms. Among them, hypoabsorptive techniques, which are the most effective, can lead to malnutrition and vitamin deficiencies, so the creation of a standardized score -similar to Clavien-Dindo- could be a simple, reproducible tool with sufficient clinical relevance to allow comparison of nutritional outcomes between different surgical techniques.

Hypothesis: The BARSCORE score will allow estimation of supplementation needs for vitamins, micronutrients and proteins after bariatric surgery.

Objectives: To validate a score in bariatric surgery that grades supplementation needs by relating them to patient characteristics and the proposed surgical technique.

Methodology: Observational, longitudinal, multicenter study. The study sample will consist of patients who underwent bariatric surgery between January 2015 and December 2021 in participating centers. Patients will be divided into three groups based on the surgery performed and the score will be applied. Subsequently, surveys will be conducted to evaluate the score and cases for applying the score. For statistical analysis, Spearman's correlation test will be used to verify the consistency of the score and a two-way ANOVA analysis to measure its concordance.

INTRODUCTION

Morbid obesity is considered the great epidemic of this century. It is the leading cause of non-traumatic death in the Western population and is progressively affecting developing countries. In the latest epidemiological studies, it is estimated that in Spain more than 15% of the population is overweight, and approximately 5% suffer from morbid obesity.

The treatment of morbid obesity is multidisciplinary, ranging from changes in lifestyle habits and diet to surgery. Among all available therapeutic options, bariatric surgery is the only cost-effective long-term treatment for patients with morbid obesity. It offers better results than pharmacological treatments and lifestyle changes. Furthermore, it has been shown to reduce and improve comorbidities, improve quality of life, reduce the risk of cardiovascular diseases and mortality, and improve quality of life [1-3].

There are currently several standardized bariatric surgical techniques. These techniques can be restrictive such as vertical gastrectomy (VG), hypoabsorptive such as duodenal switch (DS) and single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S), or mixed such as gastric bypass (GBP). Their indication will depend on factors such as the patient's BMI, metabolic comorbidities, or the surgical team's experience, among others. All of them have proven to be safe in experienced teams, with mortality rates equal to or less than 0.5% and morbidity less than 10% [4-5].

Although postoperative risks are low, they must be considered along with the potential benefits of surgery on an individual basis and as accurately as possible in each case. This allows the decision to perform surgery to be made consensually with the patient based on objective data.

One of the main risks, especially of mixed and hypoabsorptive techniques, is the risk of malnutrition and vitamin deficiencies. This complication is recorded in the literature in a heterogeneous and non-comparable manner. Articles documenting levels of nutrients, vitamins, and trace elements in blood during follow-up after bariatric surgery are complex to assess since data collection is not performed in a standardized way and it is not specified whether blood levels are with or without supplementation or the supplementation dose received; making them non-uniform and difficult to compare with each other.

A classification based on the therapeutic effort needed to resolve nutritional deficits (similar to the concept of the Clavien-Dindo classification for short-term post-surgical complications) could have the advantage of simplicity, reproducibility, and sufficient clinical relevance to allow comparison between different surgical techniques. This score could be evaluated along with efficacy (amount of weight lost and resolution of comorbidities) and morbidity (short and long-term complications) to assess the pros and cons of each surgical technique for each patient profile [6-8].

The bariatric surgery, endocrinology, and nutrition teams from HUB, HCP, and VHG hospitals reached consensus on a score for predicting therapeutic effort in supplementation after bariatric surgery. The objective of the present study is to retrospectively validate its utility and reproducibility in patients operated on for vertical gastrectomy, gastric bypass, duodenal switch, and single-anastomosis duodenal switch with a minimum of two years of clinical and analytical follow-up.

HYPOTHESIS

The BARSCORE score will allow estimation of supplementation needs for vitamins, micronutrients, and proteins after bariatric surgery.

The BARSCORE score will be a coherent score, so that more complex surgeries will have higher scores in the score with a Spearman correlation test with $p < 0.05$.

The BARSCORE score will be a score with a high level of concordance since different investigators from each center will score the presented cases in the same way, obtaining a two-way analysis of variance with $p < 0.05$.

The BARSCORE score will be an easy-to-apply score since it will obtain a percentage of favorable results greater than 70% in the score evaluation survey.

OBJECTIVES

General Objective

To validate a score in bariatric surgery that grades supplementation needs by relating them to patient characteristics and the proposed surgical technique.

Specific Objectives

1. Demonstrate the coherence of the score after comparing different types of surgical techniques with different complexity and their obtained score.
2. Verify concordance through responses obtained by investigators from each center in the case survey to apply the score.
3. Verify ease of application through the percentage of favorable responses obtained in the score evaluation survey by participating investigators from each center.

METHODS

Study Design

Observational, multicenter, longitudinal study based on the medical records of a cohort of patients operated on for primary laparoscopic bariatric and metabolic surgery from January 2015 to October 2022, in participating centers.

Procedure

1. **Patient recruitment:** Inclusion of patients in the multicenter online database.
2. **Patient stratification:** Division of patients into three groups according to the surgery performed (vertical gastrectomy, gastric bypass, and single and double anastomosis duodenal switch) and categorization of patients using the supplementation needs score.
3. **Determine score coherence:** Comparison of score results between different groups of surgical techniques based on their complexity using Spearman's correlation coefficient.
4. **Verify score concordance (reproducibility):** At least two investigators from each center will answer the case survey to apply the score. Subsequently, a two-way ANOVA analysis will be performed on the case survey after applying a normal distribution transformation of the percentage of correct answers.
5. **Verify ease of score application:** Response from at least two investigators from each center to a survey about the complexity and utility of the score, performing a descriptive analysis of the results.

Study Population

Target Population: Patients undergoing primary minimally invasive bariatric surgery from the population area of all participating centers, between 18 and 65 years of age, in the period from January 2015 to July 2022.

Inclusion Criteria:

- Patients operated on for primary laparoscopic bariatric surgery using vertical gastrectomy, gastric bypass, duodenal switch, or single-anastomosis duodenal switch (SADI-S) techniques
- Surgery performed between 2015 and 2022 in participating centers
- Minimum 2-year follow-up
- Available analytical control and evaluation by endocrinologist and dietitian/nutritionist

Exclusion Criteria:

- Patients operated on for revisional surgery
- Patients with less frequent techniques such as single-anastomosis gastric bypass or intestinal bipartition
- Patients operated on via open approach or requiring conversion to open approach during surgery
- Patients with loss to follow-up

Experimental Treatment

Primary laparoscopic bariatric or metabolic surgery.

Primary Outcome Measures

1. **Score Coherence** (Time Frame: Minimum 2 years post-surgery follow-up)
 - Spearman correlation coefficient between surgical complexity and BARSCORE score
 - Success criterion: $p < 0.05$
2. **Score Concordance (Reproducibility)** (Time Frame: Single assessment after database completion)
 - Two-way ANOVA analysis of responses from different investigators on standardized cases
 - Success criterion: $p < 0.05$
3. **Ease of Application** (Time Frame: Single assessment after database completion)
 - Percentage of favorable responses in evaluation survey
 - Success criterion: $>70\%$ favorable responses

Secondary Outcome Measures

- Number of patients in each BARSCORE category after laparoscopic bariatric surgery
- Distribution of supplementation requirements by surgical technique
- Inter-center variability in score application

Sample Size Determination

This is an exploratory study in which the sample size cannot be numerically justified in usual terms. Reliable data on the expected magnitude of differences are currently unknown, given that homogeneous results regarding the risk of malnutrition and vitamin deficiencies are not available in the literature.

At least 1,200 patients will be included, corresponding to patients from the study period (January 2015 to October 2022) at the main investigational center (Bellvitge Hospital). This number seems reasonable in an exploratory context, supported by additional references with similar sample sizes in this field.

Statistical Analysis Plan

Descriptive Statistics:

- Categorical variables: number of cases and percentages
- Continuous variables: mean and standard deviation

Primary Analysis:

1. **Coherence:** Spearman correlation test (significance: $p < 0.05$)
2. **Concordance:** Two-way ANOVA assuming normality and homoscedasticity (significance: $p < 0.05$)
3. **Ease of application:** Descriptive analysis with percentages (target: >70% favorable responses)

Risk Factors: Initial risk factors include sociodemographic data (age, sex, BMI), comorbidities, type of bariatric surgery, and surgical complications.

TIMELINE AND WORK PLAN

- **Study initiation:** October 2024
- **Data collection:** October 2024 - December 2024
- **Database cleaning and statistical analysis:** January 2025 - March 2025
- **Survey administration:** March 2025 - April 2025
- **Final report completion:** October 2025

ETHICAL CONSIDERATIONS

Data Management

An electronic data collection questionnaire will be designed in REDCap. The data collection system will be online via web, with data stored on an IDIBELL server with high security measures. Each investigator will have password-protected access limited to their center's data.

Patient Privacy

Given that this study is based on anonymized medical record information and considering the difficulty of contacting patients and the number of patients lost to follow-up, written consent will not be requested.

Patients will be identified by an identification number assigned when entering the database, removing medical record numbers and dates of birth. Only an IDIBELL statistician and one reference person per center will have access to patient identification correlations, governed by GDPR Article 14 and Spanish Organic Law 3/2018.

Ethics Committee Approval

Clinical research ethics committee authorization is attached to the protocol.

RESOURCES AND INFRASTRUCTURE

Resources and infrastructure from each participating hospital will be used for patient recruitment according to usual surgical activity. Computer infrastructure will be provided by IDIBELL through the online database for data collection and analysis.

EXPECTED BENEFITS

This study will create and validate a score that allows measuring and quantifying supplementation needs after bariatric surgery in a standardized and comparable manner, enabling comparison between techniques, surgeons, and centers.

The BARSCORE will provide objective information to assess pros and cons of each surgical technique individually for each patient:

- **Pros:** Total weight loss percentage (%TWL) and comorbidity resolution
- **Cons:** Short-term surgical complications (Clavien-Dindo) and long-term complications (BARSCORE)

This will contribute to providing more comprehensive information for shared informed consent.

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PARTICIPATING CENTERS

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- Dr. David Merino de Villasante
- Dra. Nuria Vilarrassa (Endocrinology)
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APPENDIX A: CASE APPLICATION SURVEY

Instructions for Investigators

Please review each clinical case and assign the appropriate BARSCORE grade according to the classification system. This survey will be used to assess inter-rater concordance.

Case 1: 40-year-old man operated on for gastric bypass nine months ago, who during follow-up consults the emergency department for nausea and vomiting. He is admitted after diagnosis of B1 deficiency and treated with parenteral vitamin B1.

Correct Answer: GRADE IIIB

Case 2: Patient operated on for duodenal switch two years ago on oral supplementation with calcium, vitamin D and a multivitamin.

Correct Answer: GRADE I

Case 3: 32-year-old man operated on for gastric bypass three years ago who only takes a multivitamin complex as supplementation.

Correct Answer: GRADE I

Case 4: 35-year-old female patient operated on for single-anastomosis duodenal switch one year ago who receives intravenous iron supplements, oral vitamin B12 and regularly needs oral enteral nutrition due to hypoalbuminemia.

Correct Answer: GRADE IV

Case 5: 33-year-old man operated on for single-anastomosis duodenal switch two years ago requiring oral supplementation with iron, vitamin D, calcium and folic acid at higher doses than those established by the local protocol.

Correct Answer: GRADE IIB

Case 6: 62-year-old woman operated on for gastric bypass seven years ago currently without supplementation. During the second year she needed intravenous iron supplementation.

Correct Answer: GRADE IIIA

Case 7: 33-year-old man operated on for duodenal switch two years ago, after good initial control with oral supplementation, needs daily oral protein modules.

Correct Answer: GRADE IV

Case 8: A patient operated on for duodenal switch who during follow-up presents uncontrollable diarrhea 5-7 times a day associated with severe malnutrition, so surgical reversal is indicated.

Correct Answer: GRADE V

Case 9: 66-year-old female patient operated on for gastric bypass five years ago with vitamin B12 and D supplementation according to local protocol and iron oral supplementation at doses higher than usual.

Correct Answer: GRADE IIA

Case 10: 53-year-old man operated on for sleeve gastrectomy one year ago requiring calcium oral supplementation at 1200mg/day and high doses of vitamin B12 and D.

Correct Answer: GRADE IIA

Case 11: 45-year-old female patient operated on for duodenal switch four years ago, currently with oral supplementation according to protocol but during the first year needed high-dose vitamin A, calcium and vitamin D supplementation and parenteral vitamin K.

Correct Answer: GRADE IIIA

Case 12: 38-year-old woman operated on for gastric bypass three years ago. Currently supplemented with calcium, vitamin B12 and D orally at usual doses and oral vitamin E and zinc.

Correct Answer: GRADE IIB

Case 13: Patient operated on for duodenal switch one and a half years ago who presents up to three admissions for lower extremity edema and hypoalbuminemia requiring placement of nasojejunal tube for enteral nutrition.

Correct Answer: GRADE V

Case 14: 29-year-old man operated on for sleeve gastrectomy five years ago who takes as supplementation: multivitamin, vitamin B12, calcium and vitamin D according to his center's protocol.

Correct Answer: GRADE I

APPENDIX B: EASE OF APPLICATION SURVEY

Instructions for Investigators

Please answer the following questions about the BARSCORE classification system based on your experience reviewing the cases and the score definition.

1. How long did it take you to understand the score?

- 5–10 minutes
- 10–20 minutes
- >20 minutes
- I did not understand it

2. Do you think the score is simple?

- Yes
- No

3. Do you think the score is reproducible?

- Yes
- No

4. Do you think the score is logical?

- Yes
- No

5. Do you consider that the score could be useful for your patients?

- Yes
- No

6. Do you think the score will be beneficial from a hospital perspective?

- Yes
- No

7. Please note positive aspects of the score (optional):

8. Please note negative aspects of the score (optional):

APPENDIX C: BARSCORE CLASSIFICATION SYSTEM

BARSCORE <i>Bariatric Surgery Supplementation Classification</i>	
0	No Supplements No supplementation
I	Routine/Protocol Supplements Standard supplementation with multivitamins, calcium, folic acid, vitamin B12, vitamin D according to local protocol*
II	Oral Supplements (+Non-Protocol B12) IIA: Oral iron, folic acid, vitamin D, or vitamin B12 at higher than routine doses. Maximum 2 supplements.* IIB: Vitamin A, B1, K, E, Zinc, or Copper oral. OR >2 supplements, even if category IIA.
III	Parenteral Supplements (except B12) IIIA: Intravenous iron, parenteral vitamin K. IIIB: Parenteral vitamin B1 or A. Other parenteral supplementation.
IV	Mild Malnutrition Requires protein modules ± oral enteral nutrition regularly
V	Severe Protein-Energy Malnutrition Requires enteral nutrition via NG/NJ tube or parenteral nutrition, OR surgical reversal indication due to malnutrition/uncontrollable diarrhea
*Protocol definition: 2 tablets/day adult multivitamins plus minerals (iron, folic acid, thiamine) or 1 tablet/day bariatric-specific multivitamin plus: elemental calcium (≤2400 mg/d), vitamin D (≤3000 IU/d), iron (≤60 mg/d), vitamin B12 (≤500 mcg/d oral or ≤1000 mcg/month IM-SC).	

Score Application Considerations

- Patient categorization requires >2 years follow-up with analytical control and evaluation by endocrinologist + dietitian-nutritionist
- Patients are included in a category if they required supplementation at any time from the 3rd month post-surgery until present, even if currently not needed
- Supplements administered routinely by hospital protocol without demonstrated analytical deficit are excluded from categories >I