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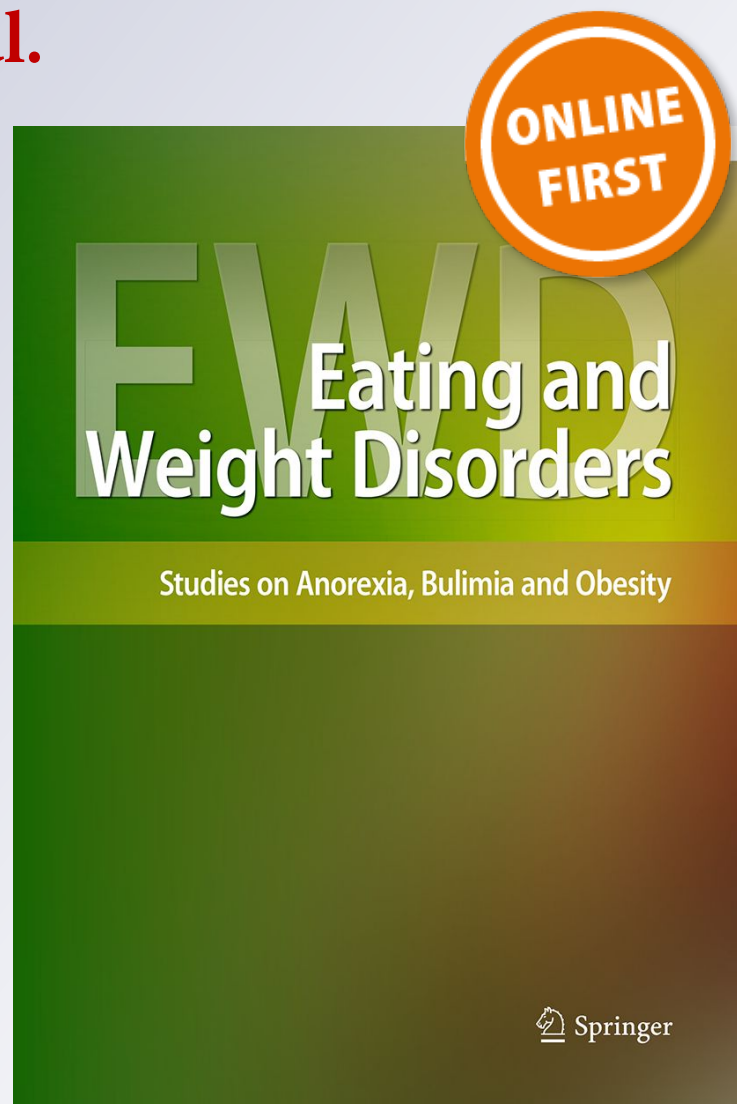
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Defining the appropriate setting for treating obese patients: do we have the right tools?

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Abstract

Purpose To allocate obese patients to the correct therapeutic setting, the Italian Obesity Society (SIO) has suggested a new algorithm based on the Edmonton obesity staging system (EOSS). The aim of our study was to apply in two retrospective cohorts of obese patients both the EOSS and the activities of daily life (ADL) scale to identify also their rehabilitation needs.

Methods 288 out-patients and 298 in-patients were recruited. All patients were evaluated with a multidisciplinary approach and the mental, mechanical, and metabolic comorbidities were scored.

Results The 2 groups differed for gender (28.8% men in out-patients, $p=0.001$), age (>60 years in in-patients, $p=0.03$), BMI (40.8 ± 6.3 kg/m² in in-patients, $p<0.001$), and ADL (44.0 ± 16.0 in in-patients, $p<0.001$). EOSS distribution was significant different: stages 0 and 1 were more present in out-patients and stages 3 and 4 in in-patients. In both groups, BMI increased significantly in EOSS category [95% CI +1.4 (+0.5; +2.2) for out-patients and +1.7 (+0.7; +2.6) for in-patients] and ADL were positively correlated with EOSS [95% CI +5.0 (+2.5; +7.4) for out-patients and +9.9 (+7.7; +12.2) for in-patients]. Mean ADL difference between the two groups, adjusted for age (over/under 60 years), BMI category, and EOSS was 24.8 ($p<0.0001$).

Conclusions SIO algorithm seems an effective tool for staging obesity in relation to the clinical impairment. To better define the correct rehabilitative allocation of obese patients, we suggest to integrate the SIO algorithm with the ADL score.

Level of evidence Level III, retrospective case-control analytic study.

Keywords Obesity · Edmonton Obesity Staging System (EOSS) · SIO algorithm · Activities of Daily Life (ADL) scale

Introduction

The appropriate approach in obesity consists of weight loss aiming at reducing health risks and promotion of weight maintenance in the long term [1]. There is no a unique effective standard protocol for obesity treatment, but different interventions that can achieve individualized weight loss, improvement of comorbidities, and prevention of weight regain. In the wake of such considerations, recently, the Italian Obesity Society (SIO) proposed a new algorithm based on the interaction of Body Mass Index (BMI), age, and Edmonton Obesity Staging System (EOSS) for allocating patients with overweight or obesity to the appropriate treatment setting [2].

The EOSS developed by Sharma and Kushner [3] is a classification using obesity-related comorbidities and functional limitations to assess the needs of obese patients and predict the outcomes of treatments [4]. According to

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EOSS and the SIO algorithm, patients in the first 2 EOSS stages (stages 0 and 1) require only lifestyle interventions to boost psychological motivation instead of a proper weight management rehabilitation program, which is, on the other side, mandatory EOSS stages 2 to 4, which include obese patients with several clinical, metabolic, psychological and psychiatric comorbidities [5].

However, the clinical use of EOSS presents with some limitations, as previously reported [6]. For instance, there is a subjective bias in the definition of some risk factors, because no clear criteria have been set for defining “mild/moderate/severe psychopathology, anxiety disorder, impact or functional performance”. For this reason, a “mnemonic for assessing obesity” was developed [7], allocating several complications or alterations into 4 categories: Mental, Mechanical, Metabolic, and Monetary (“four M’s Method”). However, EOSS and the “four M’s Method” do not provide clinically useful information concerning the severity of comorbidities.

The Italian Obesity Society has previously developed the Obesity-Related Disability test (TSD-OC) to measure self-reported aspects of disability in obese subjects [8]. This tool has been proved to be significantly correlated with functional and quality of life parameters.

In the present study, we aimed at evaluating the clinical usefulness of the SIO algorithm in assessing the appropriate treatment setting for obese patients. For this purpose, we studied the distribution of the EOSS stages and the categorization provided by the “four M’s Method” in two large samples of obese patients. Such data obtained from two retrospective cohorts of obese out- and in-patients were compared with the data related to the self-reported disability in activities of daily living (sub-score ADL of the TSD-OC). The assessment of ADL aims to acknowledge the individual rehabilitation needs and hence, define the individualized rehabilitation program, as out- or in-patients, for each category of the SIO algorithm.

Materials and methods

Patients

For this study, we have retrospectively analyzed two experimental heterogeneous groups of obese patients (body mass index $> 30 \text{ kg/m}^2$) with an age range of 15–75 years who had been referred either to the out-patients service of Clinica del Lavoro “Luigi Devoto” in Milan (Out-patient group) between March to December 2011 or to the Rehabilitation Medicine Unit of the Istituto Auxologico Italiano in Verbania from June to December 2011 (in-patient group).

Measurements

In all the patients, we measured: weight (kg), height (cm), systolic and diastolic blood-pressure (mmHg), fasting glycemia, total cholesterol, triglycerides, uricemia, insulinemia, and glycated hemoglobin (Modular Roche). BMI was calculated as the ratio of weight (kg) and height (m^2). A thorough medical assessment including medical history, clinical comorbidities, pharmacological treatment, and social conditions was performed. Patients were also interviewed by a psychologist to evaluate the presence of psychological or eating disorder conditions.

EOSS

EOSS [3] consists of 5 stages: Stage 0: no obesity-related risk factors (physical, psychopathological, and functional); Stage 1: mild physical, psychopathological, and metabolic symptoms; Stage 2: metabolic symptoms needing medical treatment and/or moderate psychological symptoms and/or moderate functional limitations; Stage 3: functional symptoms and organ damage affecting the living standard; Stage 4: severe disabilities from obesity, severe disabling psychopathology, and severe functional limitations. The EOSS stage was categorized on the basis of the highest stage risk factor present for each individual. For example, an individual with normal fasting glucose, normal lipids, no psychopathology, no functional limitations (stage 0), but with diagnosed hypertension (stage 2), would be categorized as EOSS stage 2. Similarly, an individual with borderline hypertension, impaired fasting glucose (stage 1), osteoarthritis, and anxiety disorder (stage 2), would also be categorized as EOSS stage 2.

Four M’s method

The several complications and/or alterations related to obesity are allocated into four categories, according to the following Mental/Mechanical/Metabolic and Monetary (MMM&M) criteria [7]: “Mental” (anxiety–depression syndrome, panic attack, emotional eating, binge eating disorder, psychosis, and work-related stress); “Mechanical” (osteoarthritis, esophageal reflux, obstructive sleep apnea, urinary incontinence, and thrombosis); “Metabolic” (type 2 diabetes, increased glycemia, hyperinsulinism, insulin resistance, hypertension, dyslipidemia, steatohepatitis, gout, and metabolic syndrome); and “Monetary” (education, employment, low income, life/health insurance, disability, bariatric supply, dietary products, and surgery).

TSD-OC

Disability was evaluated with a scale for measuring self-reported disability in obese subjects (TSD-OC) [8]. The TSD-OC is composed of 36 items divided into seven sections (pain: 5 items; stiffness: 2 items; ADL and indoor mobility: 7 items; housework: 7 items; outdoor activities: 5 items; occupational activities: 4 items; and social life: 6 items), which reflect the domains in which individuals experience the most common problems. In this study, we used only the ADL and indoor mobility section. Functional limitations in daily life activities and mobility, and not work inability or limitations in social life, represent together with comorbidities the criteria for admission to rehabilitation programs.

Patients were requested to provide a subjective assessment of their disability for each item on a 0–10 visual analogue scale (VAS), where 10 indicates the highest level of disability and 0 no difficulties in performing the task (total score range 0–70).

Statistical analysis

To compare quantitative and categorical variables between out-patients and in-patients, we used Wilcoxon–Mann–Whitney and Chi-square tests, respectively. We fitted linear regression models to analyze the relationship between EOSS category and age, BMI, and ADL, separately for out- and in-patients. Then, to compare slopes, we included a product-term in the regression models. Statistical analyses were performed with Stata 15 (StataCorp. 2017).

Results

In Table 1, we have reported the anthropometric parameters, ADL and the distribution in the EOSS categories in the two groups of patients. The gender distribution was different in the two groups, while mean age was similar, although there were more subjects over 60 years among the in-patient group. Body weight and BMI were higher in the in-patient group. The distribution of EOSS categories was markedly shifted towards higher values among the in-patients. The in-patients group showed higher levels of functional limitations (ADL crude difference: $44.0 - 10.1 = 33.9$).

The mean values of age, BMI, and ADL in each EOSS category are reported in Table 2. Age was positively associated with EOSS class in the out-patient group, while the relationship was negative among in-patients. BMI increased similarly in the two groups parallel to the increasing EOSS category. ADL score was positively associated with EOSS in both groups, with a steeper slope among in-patients. However, there were large variations of ADL score within

Table 1 Characteristics of patients

| | Out-patients | In-patients | P value |
|-------------------------------------|--------------|--------------|---------|
| N | 288 | 298 | |
| Men, N (%) | 83 (28.8) | 51 (17.1) | 0.001 |
| Women, N (%) | 205 (71.2) | 247 (82.9) | 0.001 |
| Age (years), mean (SD) | 48.7 (10.1) | 50.1 (10.9) | 0.65 |
| Range | 20.1–70.8 | 25.6–87 | |
| Age category, N (%) | | | 0.03 |
| Age < 60 years | 258 (89.3) | 246 (82.6) | |
| Age > 60 years | 30 (10.7) | 52 (17.4) | |
| Weight (kg), mean (SD) | 92.5 (14.8) | 103.0 (18.2) | < 0.001 |
| Range | 62–145 | 62–184 | |
| BMI (kg/m ²), mean (SD) | 34.4 (4.4) | 40.8 (6.3) | < 0.001 |
| Range | 30.0–54.7 | 30.3–62.5 | |
| Obesity category N (%) | | | < 0.001 |
| 1/BMI < 35 kg/m ² | 190 (65.7) | 53 (17.7) | |
| 2/BMI > 35 < 40 kg/m ² | 66 (22.8) | 105 (35.1) | |
| 3/BMI > 40 kg/m ² | 32 (11.4) | 140 (47.2) | |
| EOSS category N (%) | | | < 0.001 |
| 0 | 8 (2.8) | 0 (0.0) | |
| 1 | 95 (33.2) | 10 (3.3) | |
| 2 | 176 (60.1) | 124 (41.8) | |
| 3 | 9 (3.1) | 128 (42.8) | |
| 4 | 0 (0.0) | 36 (12.0) | |
| ADL, mean (SD) | 10.1 (12.1) | 44.0 (16.0) | < 0.001 |
| Range | 0–60 | 0–70 | |

EOSS categories (standard deviations ranging from 5.5 to 13.7 among out-patients and from 10.8 to 17.8 among in-patients) (Fig. 1). Finally, mean ADL difference between the two groups, adjusted for age (over/under 60 years), BMI category, and EOSS, was 24.8 (95% confidence interval: 21.9; 27.7; $p < 0.0001$).

In both groups, there was a high frequency of subjects with metabolic (46.8% hypertension and 26.6% diabetes) and mechanical (62.3% arthritis and 24.9% obstructive sleep apnoea syndrome) diseases; mental diseases were present in 22.5% of the patients. There were no important differences in the distribution of comorbidities across EOSS categories in the two groups (results not shown).

Discussion

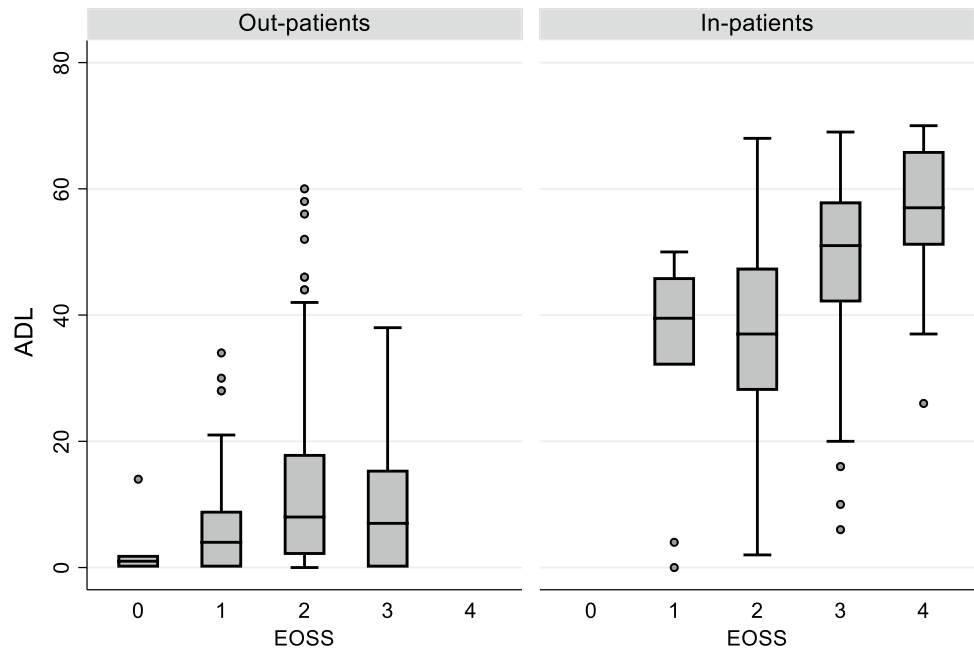
In our two experimental groups, the distribution of EOSS categories showed a higher prevalence of class 2 in the in-patient group characterized by significantly higher BMI and non-significantly higher age than in the out-patients. The most striking result was the higher degree of functional limitations in patients admitted to hospital rehabilitation with EOSS 3 and 4 classes.

Table 2 Mean values of age, BMI, and ADL for each EOSS class

| Age (years) | EOSS class | Out-patients mean (SD) | In-patients mean (SD) | P value ^a |
|---------------------------------------|------------|------------------------|-----------------------|----------------------|
| | 0 | 37.1 (8.4) | = | |
| | 1 | 45.4 (9.3) | 50.6 (13.0) | |
| | 2 | 50.7 (9.7) | 53.0 (12.5) | |
| | 3 | 55.6 (8.3) | 48.5 (8.8) | |
| | 4 | = | 45.9 (8.5) | |
| Slope (years per EOSS class) (95% CI) | | +5.6 (+3.8; +7.5) | -3.2 (-4.9; -1.57) | <0.001 |
| BMI (kg/m ²) | 0 | 31.4 (1.1) | = | |
| | 1 | 33.5 (4.4) | 34.6 (3.8) | |
| | 2 | 34.9 (4.4) | 39.6 (6.1) | |
| | 3 | 35.4 (4.1) | 42.4 (6.0) | |
| | 4 | = | 40.8 (6.7) | |
| Slope (BMI per EOSS class) (95% CI) | | +1.4 (+0.5; +2.2) | +1.7 (+0.7; +2.6) | 0.68 |
| ADL | 0 | 3.0 (5.5) | = | |
| | 1 | 6.2 (7.7) | 34.1 (17.8) | |
| | 2 | 12.6 (13.7) | 36.4 (15.4) | |
| | 3 | 10.4 (13.2) | 49.2 (13.3) | |
| | 4 | = | 56.2 (10.8) | |
| Slope (ADL per EOSS class) (95% CI) | | +5.0 (+2.5; +7.4) | +9.9 (+7.7; +12.2) | 0.004 |

^aOut-patient vs in-patient slope

Fig. 1 ADL score within EOSS category in the two groups



In this study, we considered the disability derived from comorbidities, as defined by the ADL section of the TSD-OC, in addition to the three elements (age, BMI, and comorbidities) considered in the SIO algorithm. This might indeed provide a better staging and definition of the patients' clinical and rehabilitative needs and related treatment strategies. In line with the suggestions of the SIO algorithm for EOSS stages 0 and 1, more prevention

strategies (i.e., lifestyle modifications) may be sufficient to produce effective results, while in patients with BMI > 40 kg/m², also pharmacological or surgical treatments should be suggested with the particular aim of reducing the progression of comorbid conditions. In fact, the prevalence of comorbidities (mental, mechanical, and metabolic) appears the same across all EOSS classes, with a lower rate of mental diseases. These data demonstrate

that the comorbidities, when appropriately evaluated with EOSS, are present even at lower BMI levels. Therefore, a strategy based on lifestyle interventions coupled with pharmacological or surgical approaches is to be recommended at this stage. We have previously demonstrated [9, 10] that the increase of BMI and age produces a significant impact in the obesity-related disability. Our data regarding disability integrate the EOSS and SIO algorithm data. The difference found between in- and out-patients and also the correlations found seem to justify the allocation into the proper clinical setting for obesity treatment. In particular, in EOSS stage 2, both out- and in-patients were present; in fact, some out-patients required lifestyle modification with or without pharmacological treatment or surgical approach, and some in-patients, because of high BMI values and disability indexes, needed a multidisciplinary rehabilitation program to reduce the risk of progressing to stages 3 and 4. For the same reasons, we can suggest that patients in EOSS classes 3 and 4 need a specific assessment and a multidisciplinary rehabilitation program with the goals of minimizing disability and the need of clinical assistance [5]. At this level, surgery has to be considered only in selected cases with a favorable risk/benefit profile, as suggested by SIO algorithm. In fact, the previous study reported that patients in EOSS classes 3 or more have a higher risk of postoperative complications [11].

In conclusion, we have presented in this study the first clinical application of the SIO therapeutic algorithm for the definition of the appropriate setting for obesity treatment. At present, the SIO algorithm is a tool not supported by evidence of recommendations; in addition, it is not easy to define subjective parameters, such as psychological impact or functional performance, whose assessment depends on the clinician's subjectivity. Implementing the algorithm with the assessment of "real life" daily tasks might provide clinicians and patients with elements useful for developing an effective rehabilitation program. For this reason, in this study, we evaluated if the prescription of in- or out-patient rehabilitation program, as indicated by SIO algorithm, was present also in the past. In particular, we found difficulties in EOSS stage 2 that might be overcome by the introduction of an ADL assessment to identify patients' disability. Our data suggest that this tool in association with the ADL assessment might help the clinician in allocating patients to the appropriate treatment setting. However, the clinical validation of the scoring system needs larger epidemiological studies designed to correlate the patient's final outcome, in terms of weight loss, recovery from metabolic impairment, degree of disability, or long-term survival to the independent variables represented both by the staging system data and the treatment setting.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Human rights statement This article does not contain any studies with human participants performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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