

Assessing the appropriateness of the level of care for morbidly obese subjects: validation of the CASCO-R scale

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Parole chiave: Obesità, riabilitazione, appropriatezza

Abstract

Aim of this study was to validate the Comprehensive Appropriateness Scale for the Care of Obesity in Rehabilitation (CASCO-R) and to determine the cut-off score for indicating the most appropriate health care setting for patients with obesity.

Methods: The CASCO-R scale was developed according to the available scientific literature and expertise of an expert panel working for a Consensus document endorsed by the Italian Society of Obesity (SIO) and the Italian Society for the Study of Eating Disorders (SISDCA). 16 Italian centres, specialized in the treatment of obesity, characterised by different settings of care (specialist outpatient service, day-hospital service, intensive inpatient rehabilitation), participated in the study.

Results: 449 obese subjects were enrolled in the study (30.5% males and 69.5% females): 38.3% from outpatient services, 20.7% from day-hospital services and 40.9% from intensive inpatient rehabilitation units. After 2-month of treatment, a workload summary sheet, including medical and nursing interventions, number of expert advices and diagnostic procedures, and adverse clinical events (ACEs) was fulfilled for each patient. Statistically significant correlation was found between the CASCO-R scale score, overall workload and ACEs. The CASCO-R scale demonstrated also an excellent performance in terms of internal validity and test-retest analysis. Three total score cut-off have been proposed: >25 for inpatient intensive rehabilitation; 20-25 for day-hospital service; <20 for outpatient treatment.

Conclusions: In conclusion, the CASCO-R scale was demonstrated to be a valid tool for assessing the appropriateness of the choice of the level of care. Hence, it can be used to verify the proper allocation of patients, as it was well correlated with measures of workload and the incidence of ACEs.

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Introduction

Obesity is a chronic disease associated with increased risk of morbidity and mortality (1), and a variable degree of disability impairing the quality of life (2-4). Moreover, obese patients often address health care services when their clinical and functional conditions are so severe that the short- and long-term management of the disease becomes a serious challenge.

On the contrary, in view of the stabilization of the clinical picture and the secondary prevention of relapses, as for all chronic diseases, obesity should require a continuous health care professional contact based on a multiprofessional and integrated team approach, as recommended by the available national and international guidelines. This comprehensive therapeutic and rehabilitative program should encompass nutritional intervention, functional rehabilitation and physical reconditioning program, psycho-educational and psychotherapeutic interventions, and rehabilitation nursing, combined in an interdisciplinary multidimensional approach. These multiple procedures need the integrated work of different health care professionals (e.g., physicians [nutritionists, physiatrists, psychiatrists], psychologists, dietitians, physiotherapists, educators and nurses) as well as different *settings* integrated in a network of care, ranging from general practitioner to acute care, mainly based on a specialist outpatient service, and in selected cases intensive inpatient rehabilitation unit (5-15).

In Italy the National Health Plan 2003-2005 (16) estimated the direct health costs of obesity to be 23 billion euros per year, with more than 60% determined by hospital admissions. It is likely that these costs might be reduced if the disease is faced early in a rehabilitative approach. On the other hand, health care costs for the management of obesity are anyway high, when costs to treat obesity itself and its comorbidity and disability are taken into account.

These data suggest the need to define how to make the best use of the available resources in the community to address obese patients' clinical problems. Moreover, it is important to clarify how to choose the most appropriate health care setting for the single patient according to the principle of appropriateness of care required by all the National Health Systems (NHSs).

In a recent consensus document endorsed by the Italian Society of Obesity (SIO) and the Italian Society for the Study of Eating Disorders (SISDCA) guidelines were drawn up for the good clinical assessment and treatment of obese patients (17). As part of the work done for the SIO-SISDCA Consensus, a scale of appropriateness called 'Comprehensive Appropriateness Scale for the Care of Obesity in Rehabilitation' (CASCO-R) was developed for the access to different settings of care, in accordance to the extant scientific literature and to the clinical expertise of an expert panel working in public and private academic facilities.

The aim of this study was to validate the CASCO-R and to determine the cut-off values giving indication for the optimal allocation of obese patients in different settings of care.

Materials and methods

A multicentric study, coordinated by the SIO and the SISDCA, was performed from January to June 2009. Each Centre enrolled obese patients undergoing multidisciplinary rehabilitation for obesity in different care settings: out-patient service, day-hospital service, in-patient rehabilitation unit. The study protocol was approved by the Ethical Committee of the "Sapienza" University of Rome and written informed consent was obtained from all the participants.

Sample selection

The following Italian facilities, devoted to the treatment of obesity, were involved

in the study: AO Niguarda “Cà Granda”, Milano; AO Spedali Civili di Brescia; IRCCS “Auxologico” – Piancavallo (VB); CdC “Solatrix” – Rovereto (TN); Università di Verona; CdC “Villa Margherita” – Vicenza; CdC “Villa Garda” – Garda (VR); CDAA – Pietra Ligure (SV); Università di Pisa; CdC “Villa dei Pini” – Firenze; Università di Roma “Sapienza”; Università di Roma “Tor Vergata”; IRCCS “INRCA” – Roma; ICR “Villa delle Querce” – Nemi (RM); CdC “Villa dei Pini d’Abruzzo” – Chieti; Università di Napoli “Federico II”; Sapienza University of Rome; Villa Garda Hospital, Garda-Verona; Villa dei Pini Hospital, Chieti; Niguarda “Ca’ Granda” Hospital, Milan; Villa dei Pini Hospital, Firenze; S Giuseppe Hospital, Istituto Auxologico Italiano IRCCS, Piancavallo-Verbania; Ospedale Valdese, Torino; University of Pisa, Italy.

Following a randomized procedure, a total of 30 consecutive obese patients for each facility were recruited among those treated in three settings of care (specialist outpatient service, day hospital rehabilitation service, intensive inpatient rehabilitation unit).

Demographic and clinical data

The demographic and clinical data (age, gender, body weight, height, educational level, marital status, occupation, age of onset of obesity and weight history, previous treatments for obesity, actual clinical status and pharmacological treatments) were collected by physicians at the time of enrolment through direct interviews of the patients. Body weight (to the nearest 0,1kg) was measured using medical scales and height (to the nearest 0,1 cm) by stadiometers in patients in underwear and without shoes.

The disability degree was evaluated through the short-form questionnaire for Obesity-related Disabilities developed by the SIO, TSD-OC (18).

The CASCO-R was fulfilled by physicians

at the time of the enrollment. The scale consists of four sections (Figure 1):

- Body mass index, Body mass index, BMI (kg/m²) and waist circumference.

- Comorbidity associated with obesity (type 2 diabetes, dyslipidemia, cardiovascular diseases, respiratory, gastrointestinal, skeletal and genital-urinary tract diseases, pro-inflammatory and pro-coagulative status, malnutrition)

- Risk factors potentially increasing morbidity associated with obesity (family history, age, lifestyle habits such as smoking and physical inactivity, major disturbances in eating behaviour, other clinically significant psychopathological disorders)

- Previous hospitalizations for metabolic-nutritional rehabilitation (this section assigns negative scores after one or more hospitalizations in metabolic and nutritional rehabilitation units).

The expert panel proposed the score to be attributed to each item. Potential explanatory variables were collected using an utilization review procedure (19, 20). Utilization review information was derived from the patients’ medical record, their treating clinical team, or a combination of these sources. Both concurrent and retrospective data were recorded and both clinical data (i.e., severity of illness and stability) and day care criteria (i.e., services provided) were collected. In particular, emphasis was placed on the following elements:

Adverse Clinical Events (ACEs) occurred during the two months following the enrollment. Only class C or D ACEs, according to the classification by Bernardini et al. (20) were considered. Class Adverse Clinical Events (ACEs) occurred during the two months following the enrollment. Only class C or D ACEs, according to the classification of Bernardini et al (21) were considered. Class C refers to events requiring therapeutic intervention, with 8-21 days of medical monitoring and nursing with no residual functional impairment. Class

Patient name		Date	
		Attributable score	Obtained score
Obesity degree And related risk for cardiovascular and metabolic disorders	BMI ≥ 40 Kg/m ²	8	
	BMI 35-39.9 Kg/m ²	6	
	BMI 30-34.9 Kg/m ²	4	
	Waist circumference > 102 cm ♂; 88 cm ♀	2	
Comorbidity	Dyslipidemia	LDL-cholesterol ≥ 130 mg/dl or antidiabetic medications	4
		HDL-cholesterol ≤ 40 mg/dl ♂; 50 mg/dl ♀	2
		Triglyceride > 150 mg/dl or antidiabetic medications	1
	Impaired glucose metabolism	IFG (fasting blood glucose 110-125 mg/dl) or hyperinsulinemia (insulin > 25 mcU/ml or >80 mcU/ml on the 75-g OGTT between 60' and 120' or with a peak > 90') or HOMA (Glic * Ins/405) > 2.77	2
		IGT (2 h glucose levels of 140 to 199 mg/dl on the 75-g OGTT)	4
		T2DM (fasting plasma glucose ≥ 126 mg/dl) or 2h glucose levels ≥ 200 mg/dl on the 75-g OGTT) or antidiabetic medications	6
	Cardiovascular system	Hypertension (SBP > 130 mmHg or DBP > 85 mmHg or antihypertensive medications)	3
		Atherosclerosis (ischemic cardiomyopathy, stroke, ...)	4
		NYHA: class III (marked limitation in activity due to symptoms, even during less-than-ordinary activity) or IV (severe limitations; symptoms even while at rest)	4
		Asymptomatic left ventricular hypertrophy	3
	Respiratory system	OSAS, restrictive respiratory failure	4
		Dyspnea, Epworth scale > 10	2
	Skeletal system	Osteoarthritis (hip, knees, spine)	3
	Genitourinary system	Gynecological problems (dysmenorrhea, PCOS)	2
		Impaired sexual function	2
		Urinary incontinence	2
Gastrointestinal tract	NAFLD, biliary calculi	1	
Proinflammatory status	C-reactive protein > 10 mg/l	3	
Procoagulant status	Fibrinogen > 450 mg/dl	3	
Risk factors that contribute to increase the obesity-related comorbidity	Family diseases	Early cardiovascular diseases (myocardial infarction, stroke, sudden death before age 65 in ♀ relatives or before age 55 in ♂ relatives)	4
	Age	≥ 45 years ♂; 55 years ♀ (or premature menopause without hormonal replacement treatment)	2
	Life habits	Sedentary lifestyle (<10 METs/week)	1
		Smoking > 10 cigarettes/day	1
	Behaviour	Psychic alterations (depression, anxiety)	2
		Eating disorders: prandial hyperphagia, grazing, emotional eating, night eating	3
		Eating disorders: bulimia nervosa, BED	4
Anamnesis	Failure of > 3 out-patient treatments for weight loss	2	
Malnutrition (undernutrition)	Hb < 12 g/dl ♀, 13 g/dl ♂; albuminemia < 35 g/l; total cholesterol < 150 mg/dl (without antidiabetic medications); arm circumference < 22 cm; calf circumference < 31 cm	4	
Previous in-patient rehabilitation treatments	First return (weight gain > 50% of that lost during the previous admission)	-5	
	Following returns (weight gain > 50% of that lost during the previous admission)	-10	
a. >25: in-patient rehabilitation b. 20-25: intensive out-patient rehabilitation c. < 20: out-patient treatment		TOT	

Figure 1 - CASCO-R.Comprehensive Appropriateness Scale for the Care of Obesity in Rehabilitation

D refers to events with residual functional impairment.

Workload: after two months of treatment a workload summary sheet was filled including medical and nursing interventions, number of expert advices, and diagnostic procedures. Routine programmed interventions were not considered in the validation procedure.

Validation procedure

The validation procedure (22-24) was performed analysing the correlation (Pearson’s r) between the CASCO-R score, workload (total number medical/nursing interventions, diagnostic procedures) and number of ACEs occurred. workload (total number of medical/nursing interventions, diagnostic procedures) and number of ACEs occurred correlation (Pearson’s r) between the CASCO-R score, workload (total number of medical/nursing interventions, diagnostic procedures) and number of ACEs occurred. correlation (Pearson’s r) between the CASCO-R score, workload (total number of medical/nursing interventions, diagnostic procedures) and number of ACEs occurred.

Correlation (Pearson’s r) between the CASCO-R score, workload (total number of medical/nursing interventions, diagnostic procedures) and number of ACEs occurred. The CASCO-R score was supposed to increase together with workload and ACEs, confirming by this way the thresholds total score established *a priori* for the access into the three different settings (i.e., >25

for inpatient intensive rehabilitation; 20-25 for day-hospital service; <20 for outpatient treatment).

The validity of the CASCO-R was also evaluated through:

- The analysis of internal consistency to determine the degree of correlation between elements of the questionnaire, through Cronbach’s Alpha standardised model based on average correlations between elements (25).

- Test-retest reliability determined by calculating the Cohen’s Kappa (26).

- Statistical significance was fixed at p<0.05. Data were analyzed using the SPSS for Windows 10.0 (SPSS Inc., 1989-1999) statistical software package.

Results

Clinical characteristics (Table 1)

449 obese patients (mean BMI: 42.5 kg/m², 30.5% males and 69.5% females) were enrolled in the study. Their distribution in the three settings of care was as follows: 34.5% in outpatient services, 18.2% in day-hospital services, and 49.3% in intensive inpatient rehabilitation wards. The mean age of obese patients was 51.1±14 years, the age of obesity onset was 26.7±16 years and the duration of obesity was 21.7±13 years. More than half of the patients (60.5%) were married. The education level was characterized by a high prevalence of patients with secondary school degree (34%)

Table 1 - Clinical characteristics of the sample

Sex	female	N (%)	348 (69.5)
	male		153 (30.5)
Age (year)		Mean (SD)	48.8 (12.2)
		Range	30–75.3
BMI (kg/m ²)		Mean (SD)	42.4 (7.9)
Setting	outpatient	N (%)	163 (32.5)
	rehabilitation day hospital		91 (18.2)
	intensive inpatient rehabilitation		247 (49.3)

or higher degrees (43%). The distribution of the sample by employment showed a high prevalence of retirees (40%), a moderate prevalence of employees (23%) and a low prevalence of workers or farmers (15%).

Efficacy of the CASCO-R (Table 2)

Regardless of the setting of care, a statistically significant correlation was found between the CASCO-R score and workload [medical and nursing interventions ($r = 0.47$ and 0.46 respectively; $p < 0.05$), laboratory and diagnostic procedures ($r = 0.36$ and 0.3 respectively; $p < 0.05$), medical consultancies ($r = 0.23$; $p < 0.05$)] and adverse clinical events ($r = 0.35$; $p < 0.05$). The correlation between the CASCO-R score and overall workload (considering together medical and nurses interventions, laboratory and diagnostic procedures, consultancies) raised to 0.48 ($p < 0.05$). The CASCO-R score was also significantly correlated with disability ($r = 0.46$) and age ($r = 0.3$) ($p < 0.05$).

The CASCO-R score ($M \pm SD$) also increased in the transition from a setting of low-intensity treatment (specialist outpatient service = 21.5 ± 9) to an intermediate intensive

care setting (day hospital service = 25.6 ± 10) up to a maximum setting of intensive care (intensive rehabilitation ward = 30.3 ± 8) ($p < 0.05$). These correlations increased when the network of care was complete and effective even within the same facility (Villa Garda Hospital, Villa delle Querce Clinical Rehabilitation Institute and Niguarda “Ca’ Granda” Hospital) where all the therapeutic-rehabilitation settings (specialist outpatient service, day hospital service and intensive rehabilitation ward) were present. Here the differences of the CASCO-R score were more pronounced (21.2 ± 7 , 23.2 ± 7 and 32.7 ± 6 respectively; $p < 0.05$), and therefore appropriateness of access seemed to be greater. These differences confirmed the cut-off CASCO-R total score established *a priori* for the access in the three different settings. The analysis of the correlations between the subscales or single items of the CASCO-R and the potential explanatory variables (workload and ACEs) did not give any further contribution (data not shown).

Reliability Reliability of the CASCO-R

Construct validity of the CASCO-R, obtained by correlating the total score with the scores of each section (standardised Chronbach’s alpha), were, respectively: 0.74 for the obesity level, 0.91 for comorbidity related to obesity, 0.64 for risk factors potentially increasing the morbidity related to obesity.

Inter-rater reliability found an observed proportion of agreement concordance of results of 93.3% with a Cohen’s $K = 0.882$ (CI 95% : $0.73-1.035$).

Discussion

In this study the validation of the CASCO-R showed that its overall score was significantly correlated with the parameters chosen as a measure of appropriateness (workload and ACEs). Moreover, the

Table 2 - Correlation between CASCO-R workload and adverse clinical events

		Pearson’s r
Workload	Medical interventions	0.47^*
	Nurse interventions	0.46^*
Procedures	Laboratory	0.36^*
	Diagnostic	0.3^*
	Consultancy	0.23^*
Overall workload (workload + procedures)		0.48^*
Adverse Clinical events		0.35^*

* $p < 0.05$

CASCO-R showed an excellent performance in terms of internal validity and inter-rater reliability, and confirmed the cut-off CASCO-R total score established *a priori* for the access in the three different settings of care (outpatient services, day-hospital services, and intensive inpatient rehabilitation units).

The choice of the most appropriate setting of care for patients with obesity is of primary importance with reference to cost-effective treatment (5-15). As a consequence, it is a priority to have validated tools aimed to measure the appropriate level of care that the patient's clinical status requires. In particular, appropriateness is defined "*specific*" when in a specific setting of care expected benefits outweigh the potential risks, and "*generic*" when the organization level of the setting is adequate in terms of safety and economic use of the resources. National Health Care Services are interested in particular to generic appropriateness (27-29).

To date, despite the urgent public health attention to obesity epidemic given by several national and international institutions (primarily World Health Organization), the characteristics of the different settings of care that should address the management of obesity have not been established yet. Moreover, there is a scarcity of studies trying to develop and validate scales for the appropriate allocation of patients in the different settings for the management of obesity. To our knowledge, only one study, performed in the Netherlands and published in 2007, described in detail the criteria for inclusion patients undergoing bariatric surgery in a multifaceted project in pre-surgical treatment and post-surgery follow-up (25).

To overcome this problem, an experts panel of the SIO-SISDCA Consensus developed the CASCO-R to assess the appropriate level of care of patients with obesity. The explanatory variables of the CASCO-R were chosen on the basis of

considerations made by the panel of experts who designed the study, according to their clinical expertise and to the literature. Two classes of variables were selected. The first group of variables took account of clinical criteria designed to identify inappropriate access or days of hospitalization (severity of disease and clinical stability). The second group of variables was established on the basis of criteria related to daily care (procedures and interventions provided). The variables considered in the CASCO-R (obesity level, comorbidity related to obesity, risk factors potentially increasing the morbidity related to obesity) responded to these criteria and contributed to the validity of the test.

In the validation study of the CASCO-R data collection followed the "utilization review" procedure (19, 20), a method that assesses the appropriateness of the care provided to a patient, including the setting appropriateness and the duration of care. Inappropriate hospital utilization includes both over- and under-utilization. Overutilization is relative to the admission to hospital of patients who could have been managed, from a clinical perspective, in a less intensive care setting, or patients who remain in a more acute setting for longer than required. Under-utilization occurs when patients do not receive the intensity of care required (30, 31). The appropriateness of a given level of acute care is mainly based on the assessment of the patient's clinical status and the services provided. The criteria include objective clinical findings, corresponding medical and other professional interventions typically provided at the proposed level of care, and clinical indicators reflecting readiness for safe discharge (either without further services or with the expectation for continued care at another level). Additionally, the criteria provide a mechanism to determine the need for an alternate level of care (such as rehabilitation or other subacute levels of

care) and, likewise, the appropriateness of admission, continued stay, and discharge readiness from such levels (19, 20).

The main strength of study was the inclusion of a relatively large and, although the percentage of women was significantly higher than men, the distribution of the sample (considering age, education level, marital status, etc.) was quite representative of the Italian obese population. Moreover these parameters did not significantly influence the CASCO-R score (data not shown).

A limitation of the study may be represented by the fact that clinical facilities participating in the study were located in various Italian regions, differing both in terms of networks care and in terms of regional regulations for access to the pathways of rehabilitation. This can somehow justify some differences that, although not reaching statistical significance, were observed between centres. In particular it was observed that, when no alternatives were available to day hospital or intensive rehabilitation treatment, the tendency was to use these facilities even for patients with less or greater clinical severity. When, instead, the network was complete and effective even within the same structure differences, in terms of score at the CASCO-R scale were more pronounced and appropriateness of access was greater.

Another study limitation was the difficulty in obtaining precise information about the management of patients treated in outpatient settings. In particular, it was not completely possible to accurately quantify the workload required for this level of assistance. It is therefore possible that the commitment of resources among outpatients (seen by a general practitioner, home care, etc.) was underestimated.

The last limitation of the study is represented by the a priori choice of a score of appropriateness. However, this decision was made by a panel of physicians

with extensive experience in rehabilitation treatment of obesity and eating disorders. Whatever the results of the study essentially confirmed the validity of the threshold values selected.

Conclusions

In conclusion, the CASCO-R appears to be a valid tool for assessing the appropriateness of the choice of the level of care (outpatient service – day hospital service - intensive rehabilitation unit) and can be used to verify the proper allocation of patients in the different settings dealing with the metabolic-nutritional-psychological rehabilitation of obesity. Although the cut-off values to refer patients to the different levels of care have to be defined considering the resources available in the National Health Service, the expert panel proposes, on the basis of this study results, three possible thresholds: total score >25 for inpatient intensive rehabilitation; 20-25 for day-hospital service; <20 for outpatient treatment. Future studies are needed to verify cost-effectiveness of this preliminary proposal.

Riassunto

Definizione dell'appropriatezza ad un percorso di cura per i soggetti con obesità complicata: validazione della scala CASCO-R

Scopo di questo studio è stato quello di validare la Comprehensive Appropriateness Scale for the Care of Obesity in Rehabilitation (CASCO-R) determinando il punteggio di cut-off più adatto ad indirizzare i pazienti al setting assistenziale più adeguato.

Metodi: La scala CASCO-R è stata sviluppata sulla base della letteratura scientifica disponibile e attraverso il lavoro di un gruppo di esperti impegnati nella stesura di un documento di consenso approvato dalla Società Italiana dell'Obesità (SIO) e dalla Società Italiana per lo Studio dei Disturbi del Comportamento Alimentare (SISDCA). 16 centri italiani, specializzati nel trattamento dell'obesità, caratterizzati da diverse modalità assistenziali (ambulatorio specialistico, servizio di day-hospital,

riabilitazione ospedaliera intensiva), hanno partecipato allo studio.

Risultati: 449 soggetti obesi sono stati arruolati nello studio (30,5 % maschi e 69,5 % femmine): 38,3 % dai servizi ambulatoriali, 20,7 % dalle strutture di day hospital e 40,9 % dalle unità di riabilitazione ospedaliera intensiva. Dopo 2 mesi di trattamento, una scheda di sintesi del carico di lavoro, che considerava gli interventi medici ed infermieristici, il numero di consulenze specialistiche e procedure diagnostiche e gli eventi clinici avversi (ACE) è stata compilata per ogni paziente. Una correlazione statisticamente significativa è stata riscontrata tra il punteggio della scala CASCO-R, il carico di lavoro complessivo e gli ACE. La scala CASCO-R ha dimostrato anche un'eccellente performance in termini di validità interna e test-retest analysis. Tre diversi cut-off sono stati proposti: > 25 per l'accesso alla riabilitazione intensiva ospedaliera; 20-25 per il ricovero in day-hospital; <20 per il trattamento ambulatoriale.

Conclusioni: la scala CASCO-R si è dimostrata essere uno strumento valido per valutare l'adeguatezza della scelta del livello di cura. Può essere utilizzata per verificare la corretta collocazione dei pazienti nei diversi setting assistenziali, risultando ben correlata con le misure del carico di lavoro e l'incidenza di ACE.

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