

Clinical Management of Overweight and Obesity

Recommendations
of the Italian Society
of Obesity (SIO)

Paolo Sbraccia
Enzo Nisoli
Roberto Vettor
Editors



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Editors

Paolo Sbraccia
Department of Systems Medicine
Medical School
University of Rome "Tor Vergata"
Rome
Italy

Roberto Vettor
Center for the Study and the Integrated
Treatment of Obesity
University of Padua
Padua
Italy

Enzo Nisoli
Department of Medical Biotechnology
and Translational Medicine
University of Milan
Milan
Italy

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Preface

It is with great pleasure that we present *Clinical Management of Overweight and Obesity: Recommendations of the Italian Society of Obesity (SIO)*.

This book of guidelines is the result of efforts by a group of Italian experts in the treatment of obesity. Responsibility for individual sections has rested with, Luca Busetto, Barbara Cresci, Massimo Cuzzolaro, Lorenzo M. Donini, Pierpaolo De Feo, Annunziata Lapolla, Lucio Lucchin, Claudio Maffei, Fabrizio Pasanisi, Carlo Rotella, Ferruccio Santini, and Mauro Zamboni. To everybody, who has been involved in the project, but especially to those just mentioned, we express our heartfelt thanks.

The book addresses the obesity problem in diverse circumstances from pregnancy to old age, ending with a treatment algorithm that hopefully will lead over the years to new and more effective therapeutic tools. There is no doubting the need!

The book is intended as a guide, based on scientific evidence. It should be useful not only to those who are at the forefront in caring for people with obesity but also to the many other specialists whose encounters with obese patients and their problems are becoming ever more frequent.

Nevertheless, launching these guidelines, in which we take much pride, we would also like to draw attention to some particular considerations and possible caveats.

In recent years, there has been a significant increase in the publication of guidelines for clinical practice, even if there is a growing awareness that the mere publication of a guide does not guarantee that what is being suggested as best practice translates effectively into the clinical choices made on a daily basis. The continuing need for major revisions to clinical practice reflects the gap that can exist between advice in guidelines and what actually happens in daily routine. On the other hand, there is a danger that is potentially creeping into the relationship between the publication of guidelines and clinical practice a danger resulting from the accelerating turnover of knowledge in specific sectors.

Guidelines are part of the decision-making process, offering the support of a shared body of knowledge and operational choices tested in respect of efficacy and safety. They proceed from shared theoretical assumptions and solid experimental conclusions (clinical trials, validated meta-analysis) and propose solutions, decisions, and behaviors widely accepted and adopted by the scientific community. It is in this context that mistakes can arise. Those who use established knowledge and apply codified rules to clarify, for example, a diagnostic problem or to decide on a particular course of therapy may fall short of their objective for a whole range of

reasons. For example, they may not have used the concepts best suited to the case in hand. Alternatively, they may not have employed the concepts and/or techniques available, or they may have resorted to an inappropriate rule or regulation, and so on. The guidelines have been laid down precisely to bring order to a massive body of knowledge, often not consistent, centering around specific topics so as to classify and standardize choices in clinical practice and so reduce operational errors. At least as regards the limited period of time in which they were proposed, they are the result of a theoretical construct deemed true in that it is based on the probability that the observed data match the body of theoretical assumptions considered highly likely by the scientific community.

At a historical moment when there is a potential discrepancy between the tremendous acceleration in knowledge turnover and guideline publication, guidelines may already be obsolete by the time they come to be defined and applied.

In effect, “evidence-based medicine” and clinical guidelines rarely provide the definitive answer to clinical problems; rather, they are subject to many changes that are all the more drastic given the pace of the emergence of new knowledge. For these reasons, we intend to continually update these guidelines, which will always be available on the two organizations’ websites.

In addition, although the book does not address the complex issue of complications arising from obesity, it is also appropriate to distinguish between generic clinical decisions manageable through the guidelines and complex decisions typical for the elderly patient with multiple pathologies or with a pathology like obesity that brings with it a wide range of other conditions, which these days require the doctor to be capable of directly managing the scientific knowledge available (knowledge management).

The key to understanding how the world works is to question its nature, being always ready to give up previous ideas if the answers contradict what we think.

It is in this spirit that *Clinical Management of Overweight and Obesity: Recommendations of the Italian Society of Obesity (SIO)* is published. The drafting of these guidelines, as stated above, is and will be founded on a continuous collaboration with those who feel a need to revise, correct, supplement, and implement these operational suggestions. In this context, we would like to cite the words that spoken by Winston Churchill in a rather more dramatic predicament, but which seem eminently applicable here, too: “This is not the end, not even the beginning of the end. But it is perhaps the end of the beginning.”

*The Editors,
Paolo Sbraccia
Enzo Nisoli
Roberto Vettor*

Introduction

Although it was only in 1950 that obesity was introduced into the international classification of diseases (currently code ICD-10 E66), it has already reached epidemic proportions before the end of the century, becoming one of the leading causes of death and disability worldwide. In 2014, 2 billion adults (over 20 years of age) were overweight, and it was estimated that 500 million adults worldwide were obese: over 200 million men and nearly 300 million women. About 65% of the world's population currently live in countries where overweight and obesity kill more than underweight ones. The number of people afflicted is growing without any decline, and more than 40 million children under 5 years old proved to be overweight in 2010. According to the WHO, "Obesity is one of the greatest public health challenges of the twenty-first century. Its prevalence has tripled in many countries of the WHO European Region since the 1980s, and the numbers of those affected continue to rise at an alarming rate. In addition to causing various physical disabilities and psychological problems, excess weight drastically increases a person's risk of developing a number of noncommunicable diseases (NCDs), including cardiovascular disease, cancer and diabetes."

The recommendation to reduce body weight in overweight or obese individuals is therefore mandatory. However, long-term treatment is a challenging task and requires an integrated approach using all the available instruments in a complementary way, drawing on diverse professional skills but all sharing the same therapeutic objective.

The first aim of *Clinical Management of Overweight and Obesity: Recommendations of the Italian Society of Obesity (SIO)* is to serve as a practical point of reference for all the many professionals responsible for treating people with obesity; however, this is also for researchers, students, and the patients themselves who intend to, in the context of a therapeutic education program, explore aspects linked to their own condition.

Each chapter begins with a schematic sequence of statements together with notes as the level of scientific proof and strength of the recommendation as indicated by "Methodological Manual – How to produce, spread and update recommendations for clinical practice" drawn up under "The National Program for

Guidelines” now changed to “National System for Guidelines” (http://www.snlg-iss.it/manuale_metodologico_SNLG) (Table 1). A commentary follows, exploring the scientific basis for the proofs and the recommendations complete with bibliographical notes.

Table 1 Levels of proof and strength of the recommendation

<i>Levels of proof</i>
<i>Level I:</i> Evidence obtained from two or more properly designed randomized controlled trials
<i>Level II:</i> Evidence obtained from one well-designed randomized controlled trial
<i>Level III:</i> Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
<i>Level IV:</i> Evidence obtained from multiple time series designs with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence
<i>Level V:</i> Evidence obtained by uncontrolled studies
<i>Level VI:</i> Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees
<i>Strength of the recommendation</i>
<i>Level A:</i> Good scientific evidence suggests that performing the procedure or diagnostic test is strongly recommended
<i>Level B:</i> At least fair scientific evidence suggests that the benefits of the clinical service may outweigh the potential risks. Clinicians should discuss the service with eligible patients
<i>Level C:</i> At least fair scientific evidence suggests that there are benefits provided by the clinical service, but the balance between benefits and risks is too close for making general recommendations. Clinicians need not offer it unless there are individual considerations
<i>Level D:</i> The procedure or diagnostic test is not recommended
<i>Level E:</i> It is strongly suggested to refrain from performing the procedure or diagnostic test

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Part I

General Remarks

Lucio Lucchin

1.1 Management of Obesity-Affected People

Obesity is a chronic disease with a complicated etio-pathogenesis [1, 2]. This means that the factors that make it up interact together via linear and non-linear equations, thus making the estimate of the results not precise. These factors interact and adapt themselves to the environment and culture and evolve in time. Because there is not any efficient unidirectional strategy, particularly in the long term, it is fundamental to try to give answers to questions that are not necessary in other pathologies.

1.2 Is It Strategic to Communicate Preliminarily the Typology of Treatment to the Obese Patient?

Yes, in order to limit the disorientation and the attraction towards the commercial therapeutic illusions and towards little or not competent professionals. This involves negative consequences for the obese patient, both psychologically and clinically. Doctors, *in primis*, and the other health workers who are involved in this clinical condition, have the ethical and deontological need to make their professional background transparent (especially non-doctors), besides the intervention model they are willing to adopt [3]. The Medical Deontological Italian Code (version 18 May 2014) must be considered in art. 16: diagnostic procedures and therapeutic interventions; 21: professional competence; 33: information and communication to the patient; 35: informed consensus and dissent; 55: sanitary information. The criterion

L. Lucchin

Medical Director of the Clinical Nutrition Unit Health, District of Bolzano, Bolzano Hospital, Boehler street 5 39100, Bolzano, Italy

e-mail: lucio.lucchin@sabes.it

of transparency of the services provided is required also at a legislative level by the Italian law ‘Decreto Presidente Consiglio dei Ministri’ 19 May 1995 – GU number 125: ‘General reference framework of public service charter’. Even though this document is addressed to the healthcare companies, its spread is recommended to the single operative units that deal with chronic pathologies. The expectations of obese patients in terms of weight loss, which are at least 20–30 % per year [4, 5], have to be discussed ab initio. The unrealistic expectations seem not to have negative consequences [6]. In order to communicate preliminarily the treatment typology to the obese patient, it is desirable to specify:

1. Entity, organisation chart and qualifications of the operator/s
2. Way of access into the structure
3. Privacy safeguard
4. Quality standard of the unit (number of treatments per year, drop-outs after 6/12/24 months, average weight loss after 6/12/24 months, etc.)
5. Therapeutic model used with relative informed consent [7].

A preliminary meeting with everyone who has requested a reservation in a determinate time period may result useful [8]. (*Level of evidence VI, Strength of recommendation B*)

1.3 How Long Should the First and the Control Visits Last?

This aspect is underestimated, exception made for the economic aspect. In order to be efficient, the treatment of a chronic pathology needs to be clear in its contents so as to define the time needed for the medical control. In literature reports, the duration of a medical examination for an obese patient ranges between 15 and 20 min (15 min in Italian public services) [4–9]. At the present time, with an obese patient, the doctor does not modify the duration of the examinations but he modifies the contents of the examination. Most of the time is used to measure the *clinical-anthropometrical parameters* [10] and for the therapy of the complications, and just a few minutes are devoted to the finding of the strategy for changing lifestyle. The specialists in this field are used to increase the duration of the examination [11]. In order to have a good bond between efficiency and efficacy, what has to be considered to quantify the medical visit duration is:

1. Decide the minimum number of visits per year per patient (first visit+control visits).
2. Identify the components of the intervention (clinical, psychological and weight anamnesis; objective visit; patient’s motivation and expectations to define targets and therapeutic strategy; prescription of the nutritional plan; etc.) and quantify their duration.
3. Plan how much information has to be given, considering that the patient remembers only a little percentage of what is said. After 30 min, the attention is at its lowest point

and 40–60 % of what the doctor said is forgotten in a couple of days. What is remembered increases to 30 % by repeating the most important concepts [12]. It is important not to give too much information all at once. Besides, it is important to remember that the patient wants to be more informed about the prognosis and about the lifestyle modification [13]; (*Kindelan and Kent in British general practice 1987*).

4. Verify the possibility of using informatics-based therapy strategies, which could be very useful and efficient if personalised and interactive [14].

In order to optimise the examination timing for the obese patient, the doctor needs to know the therapeutic education: problem solving, semantic map, empathic communication (active listening) and a good capability in understanding the non-verbal communication [1, 15, 16]. From the experience of specialists, it emerges that the average time for the first medical examination should be between 45 and 75 min, whereas the average time for a normal medical control should be between 20 and 30 min. (*Level of evidence VI, Strength of recommendation B*)

1.4 How Important Is Health Worker Example?

Health professionals should promote prevention-based strategies and encourage correct lifestyles [17]. The difficulty in becoming competent and the fact that a lot of health workers have risk factors and/or chronic pathologies that they should treat make the proposed therapeutic strategies less efficient. A part of them puts the responsibility on the patient [18], and at least one third (with growing trend) has difficulties in the proposal of adequate lifestyles due to a weak self-esteem, which is caused by the incongruence between what they do and what they suggest to the patients [19]. Literature shows how just if the doctor has a normal weight, suggest therapeutic strategies to the obese patient [20–22]. The patient as well better follows the suggestions from normal weight doctors [23]. It is also important in terms of public health that health workers are the first ones to contrast the negative stigma associated with this condition [24]. The example of the modern health worker is important for the contrast to chronicity. In order to be convincing and reassuring, it is important to improve the personal coherence level. (*Level of evidence VI, Strength of recommendation B*)

1.5 Individual or Group Therapy: Which Is the Best One?

Studies show how the individual psychological-educational intervention or the counselling one are weak in terms of efficiency as too many resources are required [25]. The group therapy (cognitive-behavioural therapy that modifies the lifestyle) seems more efficient compared to the individual treatment, especially if associated with physical activities [26]. The most favourable outcomes are related to the size of weight loss, the fat mass [27] reduction, the drop-outs, the young age, a better looking self-image [28] and a better control of food assumption after 12 months

[23]. The group therapy for the care of obesity is therefore useful, especially in public services. (*Level of evidence III, Strength of recommendation B*)

1.6 How Much Pedagogical Time Is Needed for the Obese Patient?

The complexity of obesity needs a multidimensional approach [2], based on the intervention in different fields: biological (clinical-nutritional and physical activity), psychological and socio-cultural. There are many scientific publications that state how the emotional relationship of the health worker regarding the obese patient is less than in other pathologies [29]. The loss of weight should not be considered the principal goal of the treatment of the obese patient. Weight stabilisation in a certain amount of time is linked with the pedagogical education to the pathology self-management. It has been esteemed that at the moment of the medical examination the patient has one, two–three, nine problems. The doctor finds out more or less 50 % of these problems [30]. These difficulties to identify the patients' problems are well supported in literature [31]. The perception of the consequences of overweight or obesity on the health changes from person to person but especially on the basis of the ethnic group. In order to educate the patient, it is important to improve the communication techniques that nowadays are too often inadequate [32]. The health personnel often overestimates the cognitive capacity of the patients who often say they have understood even though they have not. A patient with a chronic pathology, especially if over 65 years, has a reduced level of text comprehension (fifth level out of 12 instead of an average of eighth–ninth level) [33]. This means that the written or spoken language used has to be tested preliminarily. To remember the common learning problems: anger, denial, fright, anxiety, thoughts about health, differences of language, physical disabilities, pain, cognitive imitations, religion, age, comorbidity, economic situation, distance from the health centre. Another important factor is the therapeutic adherence that is inversely proportional to the number of pharmacological doses and to the entity of the lifestyle modification [34]. The attention to the communication methods [35] is addressed principally to language terms and style [36]. Medical practitioners are still using little systematic analysis as regards their patient's lifestyle [37]. No more than the 30 % of them motivate the patient to lose weight [38]. Scientific evidence relating to the effect of solicitation by scientific societies and/or institutions for the screening of obesity is weak [39]. An adequate counselling improves the weight loss in the long term in at least one third of the patients. The pedagogical time for the obese patient has to be esteemed in a few years and has to be included in the therapeutic strategy. The doctors who deal with obesity are recommended the implementation of:

1. Psychometric tests such as BISA (Body Image and Satisfaction Assessment), PBIA (Pictorial Body Image Assessment), HR-QoL (Health-Related Quality of Life) [40]
2. Models such as AAR (Ask, Advise and Refer) [31], FRAMES (Feedback, Responsibility, Advice, Empathy, Self-efficacy) [41] or 5A (Assess-Advise-Agree-Assist-Arrange) [9]

In the end, it results strategic to identify the various categories of obese people and, among them, the ones that could use electronic health records. (*Level of evidence III, Strength of recommendation A*)

1.7 How to Evaluate Patient Appreciation?

The detection of the treatment appreciation by the patient is fundamental in terms of quality of the service provided. The improvement of the obese patient's quality of life, which is worse than normal weight people's, is one of the primary goals of the treatment, but it should be properly supervised. The obese people are more satisfied with the treatment compared to non-obese [34]. Recently a specific survey for obesity, the Laval Questionnaire [42], has been validated. The appreciation of the treatment received and the life quality are strictly related. If there are a lot of scientific publications about the quality of life, there are not as many regarding the perceived quality of the treatment and the few existing documentations are related to the bariatric treatment [43, 44]. In this case, satisfaction has been observed from both social and physical points of view. It is recommended to predispose a systematic survey of the treatment appreciation, with adequate samples and frequency, which is fundamental for the professional improvement. (*Level of evidence V, Strength of recommendation A*)

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Part II

Lifestyle Modifications