Why Quality of Life Measures Should Be Used in the Treatment of Patients with Obesity

Marianne Sullivan, Jan Karlsson, Lars Sjöström and Charles Taft

Sahlgrenska University Hospital, Göteborg, Sweden

The aims of this chapter are

• To introduce a new discipline—quality of life assessment: its development, purposes, concepts, definitions, and basic tools
• To describe the current status of quality of life research in obesity
• To illustrate the usefulness of quality of life assessment in obesity

BACKGROUND AND RATIONALE

This section looks at health-related quality of life: its past, present and future status, what it is and the reasons for measuring it.

How the Need for Quality of Life Measures in Medicine Evolved

From Negative to Positive Health Concepts

The mission of health care services today is not only to cure disease, restore function, and alleviate ailment, but also to prevent disease and promote health. After World War II the ‘academic world’ tried to reorient the concept of health by broadening its definition. The net result of these efforts was that the patient perspective in medical care was emphasized by WHO in their 1948 definition of health, which included not only absence of disease or infirmity, but also a state of complete physical, mental and social well-being. The first attempts to quantify the new health definition began about a decade later. The principal focus in the 1960s on the physical aspects of health, primarily activities of daily living, later shifted to incorporate mental and social aspects, resulting in comprehensive health status questionnaires. During that decade the clinical trial (randomized or controlled) was proffered as the pre-eminent experimental model in clinical research. It was noteworthy that it took about two decades before this model was fully recognized by the medical profession (the Society of Clinical Trials was inaugurated in 1978), a fact that should be taken into account by those who complain that the integration of quality of life in medicine is moving slowly. The International Society for Quality of Life Research was created in 1994.

Classification of Medical Care by Level of Knowledge and Relation to Quality of Life

The need for quality of life assessment in medicine should be considered in relation to several key components of medical care: level of knowledge, efficiency, costs and evaluation. It may therefore be
helpful to view today’s clinical medicine along a continuum from cure to supportive therapy.

1. **Therapy with genuinely conclusive knowledge (top level)**, i.e. treatment where the cause of the disease is known and can be influenced or eliminated. Long and intense basic research characterizes the scientific breakthroughs making causal therapy and prophylactic measures possible. Such therapy is very inexpensive compared with earlier treatments. Examples include a number of virogenic (e.g., polio, childhood viroses) and bacterial epidemics (e.g., tuberculosis, syphilis), now treated by immunization and antibiotics or chemotherapy, respectively. Another example is substitution therapy used when a certain substance is lacking or insufficient, e.g., in pernicious anaemia, hypothyroidism and diabetes. Apart from the last condition, the cost/benefit ratio at this level is very beneficial, the need for alternative therapies in principle is little, and the need for quality of life measures minimal. Diabetes is, however, not easily classified along the continuum despite the life-saving insulin therapy. Long-term features call for multimodal treatments to prevent negative sequelae and quality of life assessments are thus useful endpoints.

2. **Therapy with a certain biological long-term effect (intermediate level)**, i.e. treatment that reduces morbidity and mortality despite incomplete knowledge of the underlying disease mechanisms. Large and significant groups of diseases are represented here, e.g., non-generalized tumour diseases, kidney failure and coronary heart disease. Treatment at this level is often technically sophisticated and expensive but primitive from a biological perspective. Genuine cure for the disease is not the issue, rather the aim of treatment is to try to save a life at any cost. Treatment comprises a series of multimodal efforts with an increasing number of more and more specialized members of the treatment team at each rung up the treatment ladder, where surgical intervention is the precipitating first-order action available (e.g., tumour surgery, transplantation surgery). Today’s treatment team is exemplified by the chain of care providers for patients with coronary heart disease from intensive care unit to outpatient rehabilitation and check-ups: ambulance staff, surgeons, cardiologists, nurses, psychologists, dieticians, physiotherapists, etc.

Outcome assessment is also multidisciplinary, often with improvements differing in various domains. The final common pathway from the multicausal aetiology to the pathogenic mechanism is not yet available, i.e. the moncausal model exemplified at level 1 does not apply. The cost/benefit ratio is not beneficial, largely independent of the calculation method, e.g., cost/utility measures such as QALYs (quality-adjusted life years). A substantial and wide array of research attempts contribute to improved and safer therapy, e.g., improvement in transplantation outcome due to increasing knowledge about the immune system. The comprehensive evaluation of results often applied nowadays includes quality of life measures as secondary endpoints.

3. **Therapy with no certain biological long-term effect (bottom level)**, i.e. treatment of diseases where the cause is basically unknown and probably not possible to influence in the long run. This level comprises a great number of chronic diseases or conditions which place extreme demands on societal resources from an economic as well as humanitarian point of view. Among the many examples of such diseases are degenerative processes in the nervous system and supportive tissue, chronic pain conditions, many cancer diseases and mental diseases, degenerative diseases of ageing, and severe obesity. The goal of caretaking is effective symptom control and palliation, and the primary outcome is optimal quality of life. The health care system can offer a wide range of alternatives and combinations of treatments. Apart from providing transient symptom relief, traditional medical treatment is usually not applicable at this level; rather treatment is concerned with creating a psychologically positive therapeutic environment. Therapeutic teams provide functional training, compensation for functional impairments, physical conditioning, diet, supportive therapy to infuse hope, console, deal with psychosocial problems, etc.

Despite the availability of a vast number of therapeutic options, the benefits from treatments according to currently available clinical measures are more marginal than at level 2. The total effects of care are difficult to evaluate in all respects because there is no standardized way of weighing transient ‘objective’ and varying ‘subjective’ improvements in clinically applicable terms. The impact on quality of
life typically needs to be measured by an extensive battery of generic and condition-specific measures to be satisfactorily understood. A cost/benefit ratio would probably be very high, i.e. disadvantageous, if such calculations were found to be feasible. Cost/ utility measures, sometimes supplementing the evaluation system of level 2, are also tested here. Although hard to validate, they offer new ways of thinking about resource allocation and ethics.

The need for quality of life assessment is naturally dependent on the relations between the key components of medical care, i.e. the lower the level of knowledge, the more complicated the evaluation will be. Treatment effects are dependent on the experienced change per se and people’s expectations before, during and after therapy. It is thus necessary to include various patient-based measures in order to interpret treatment benefits versus placebo and adaptation effects.

How Quality of Life Measures Were Introduced in Clinical Trials

Early Milestones

Early studies (mid-1960s) in rehabilitation medicine used one social criterion (return to work) as central evidence of wisely spent resources. Later, evaluation of specialized medical care, e.g. coronary bypass surgery, also defined treatment success in terms of return to work, often labelled quality of life. The health-related, or rather illness/sickness-related, quality of life assessment was introduced as an emerging research area in medicine in the 1970s, when today’s methods were created and field-tested for the first time. During the 1980s a few large-scale clinical trials specified secondary quality-of-life aims. A well-known example of this trend was the COPD (chronic obstructive pulmonary disease) intervention study by McSweeney et al. (1), where different expectations of quality of life were linked to the alternative treatment options under examination. A frequently cited trial from oncology (limb-sparing vs. amputation in patients with soft tissue sarcoma) showed that inclusion of comprehensive quality of life measurements added new and valuable knowledge for subsequent clinical practice (2). Clinical cancer trials have recognized and incorporated quality of life measures increasingly ever since (3,4). Cardiology and rheumatology were also among the early application areas. For example, the first recognized international demonstration of the need for quality of life research in clinical medicine took place in the cardiovascular field, i.e. the 1983 workshop under the auspices of the National Heart, Lung and Blood Institute (5) and the well-known multicentre study of antihypertensive therapy and quality of life (6). In rheumatology, the attempts to document patient-based effects of treatment in rheumatoid arthritis moved from mere registration of functional aspects of daily living to the use of the multidimensional self-report measures in the early 1980s (7).

Evidence-based Medicine and the Patient’s Viewpoint

It was not until the WHO meeting in 1986, however, that health promotion objectives were made explicit and the health promotion hospital movement was launched to supplement disease orientation with health development. The importance of this goal was strongly emphasized and evaluation of health gains therefore expanded to include selfrated health/quality of life as an important endpoint. Methodological meta-analyses and evidence-based medicine were introduced to the medical establishment, all directed toward improving the arsenal of therapeutic measures. First, the traditional outcomes, readily understood by the medical profession, were evaluated; e.g. tumour response in cancer trials and walking distance in trials from rheumatology, pulmonary medicine and cardiology. Quite recently, this development has enabled us to approach outcome assessment from a different vantage point, the patient’s (8,9). The validity and usefulness of assessing people’s own perceptions of their health have now been documented in a multitude of studies (10). For example, self-rated global health has proved a more powerful predictor of mortality than traditional clinical measures, such as diagnostic criteria or laboratory measurements (11).

Current Status and Future

The Rationale of Quality of Life Outcomes: ‘Why Measure It?’

The rationale behind measuring quality of life in health care concerns the ‘paradox of health’, i.e.
better health state according to traditional indicators is not automatically accompanied by improved well-being or perceived health gain (12). Quality of life outcome evaluation is especially important in incurable conditions, when the self-evident and realistic goal of care is to make the patient’s life as comfortable, functional, and satisfactory as possible. Although traditional clinical outcome measures of signs and symptoms, together with data on survival, disease-free survival and time without symptoms of disease and toxicity of treatment, are certainly important in evaluating benefits of interventions, all this says little about people's overall health and the quality of their lives. Such information can be obtained only from the patient him/herself. It cannot be emphasized enough that quality of life studies should be conducted to get new information of clinical value, information that can be applied in further research and eventually in clinical practice.

Toward an Operational Definition of Health-related Quality of Life: ‘What It Is’

Since the inception of quality of life research in medicine about 30 years ago, a controversy has existed concerning the potentials of quality of life questionnaires. Advocates have pointed to the centrality of these measures in all outcome assessments in chronic conditions. Others have thought of quality of life data as mainly qualitative, not amenable to meaningful statistical analysis and interpretation. So, when quality of life research first attracted attention in clinical studies it was met by a series of challenges: conceptual and methodological barriers to be overcome as well as attitudinal and practical hindrances due to lack of experience (3,13). It took several decades of conceptual analysis, pragmatic definitions and development and testing of basic tools before the current multidimensional, psychometrically sound measures became available.

It is not possible to define all aspects of health or quality of life distinctly; these concepts are truly subjective and situational. If the concepts are considered solely unidimensionally and globally, they become practically undefined; e.g. 'how would you rate your quality of life?' Indicators like this are of questionable value because it is hard to interpret them; they do not provide the specific information needed to evaluate effects of treatment, to assist medical decisions, or to improve care. Problems in defining quality of life have paved the way for a joint behavioural/clinical effort to agree on operational definitions of a set of core dimensions that incorporates both broader and narrower elements, most often called health-related quality of life (Table 33.1) (14–16). The rationale behind this pragmatic solution may be readily understood through Figure 33.1. In the figure the dimensions are summarized in relation to obesity to reflect functional limitations and well-being along the continuum from condition-specific to general aspects of physical and mental health. Examples of specific and generic instruments currently used in obesity research are shown.

‘Consensus’ on concepts and definitions has led to the development of standardized questionnaires with well-established psychometric properties. Quality of life outcome measures in medicine are thus multidimensional, quantitative, and developed in accordance with psychometric theory to form multi-item scales, profiles and indexes. Most often clinical research questions require a combination of condition-specific and generic questionnaires. Condition-specific measures are often designed for clinical use and to be sensitive to changes after treatment. On the other hand, generic measures capture dimensions that are not specific to the condition and enable comparisons to be made between groups. Their central points concern health-related

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Table 33.1 Core dimensions of health-related quality of life in clinical research

<table>
<thead>
<tr>
<th>Concepts</th>
<th>Definitions</th>
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<tbody>
<tr>
<td>Physical complaints/well-being</td>
<td>For example, disease- and treatment-related symptoms, general symptoms, fitness</td>
</tr>
<tr>
<td>Psychological distress/well-being</td>
<td>For example, anxiety and depressive symptoms, positive affect, cognitive disturbance</td>
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<tr>
<td>Functional status</td>
<td>For example, activities of daily living</td>
</tr>
<tr>
<td>Role functioning</td>
<td>For example, occupational and housework activities</td>
</tr>
<tr>
<td>Social functioning/well-being</td>
<td>For example, interpersonal relations, quantity and quality of social interaction, leisure</td>
</tr>
<tr>
<td>Health/quality of life perception</td>
<td>For example, global ratings</td>
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</tbody>
</table>

Reproduced from Sullivan (77) with permission.
<table>
<thead>
<tr>
<th>Concepts: condition-specific and generic</th>
<th>Instruments: obesity-related and generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition-specific</td>
<td>IWQOL</td>
</tr>
<tr>
<td>Complaints/consequences</td>
<td>• Health</td>
</tr>
<tr>
<td></td>
<td>• Social/Interpersonal</td>
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<tr>
<td></td>
<td>• Work</td>
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<td></td>
<td>• Mobility</td>
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<td></td>
<td>• Self-esteem</td>
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<td></td>
<td>• Sexual life</td>
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<td></td>
<td>• Activities of daily living</td>
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<tr>
<td></td>
<td>• Comfort with food</td>
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<tr>
<td>Functional health: generic</td>
<td>TFEQ</td>
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<tr>
<td>Physical/mobility oriented consequences</td>
<td>• Restraint eating</td>
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<tr>
<td></td>
<td>• Disinhibition</td>
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<tr>
<td></td>
<td>• Hunger</td>
</tr>
<tr>
<td>Social/emotional/cognitive consequences</td>
<td>OP</td>
</tr>
<tr>
<td></td>
<td>• Obesity-related psychosocial problems</td>
</tr>
<tr>
<td>Mental health: generic</td>
<td></td>
</tr>
<tr>
<td>Distress/well-being</td>
<td></td>
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<tr>
<td>Overall quality of life</td>
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<td></td>
<td>Global ratings</td>
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</table>

**Figure 33.1** Conceptual and measurement model of health-related quality of life assessment in obesity: a continuum of concepts and instruments. IWQOL: Impact of Weight on Quality of Life (40); TFEQ: Three-Factor Eating Questionnaire (54); OP: Obesity-related Problem scale from the SOS Quality of Life Survey (39); SIP: Sickness Impact Profile (69); SF-36: Short Form-36 Health Survey (34); HAD: Hospital Anxiety and Depression scale (72). Reproduced from Sullivan et al. (78) with permission.

functioning and behaviour in everyday life. Thus, they usually include items related to aspects of physical functioning, e.g. mobility, but also to role and social functioning, and other common dimensions of health status such as pain, sleep, sexual functioning, general health perceptions and aspects of well-being, e.g. mood. It should be noted, however, that despite close points of similarity among generic instruments, they tend to vary widely in their focus on core dimensions of health as well as in their capacity to detect relevant differences between study populations and within treatment groups over time.

Quality of life measures play an increasingly important role in evidence-based medicine since information from patients is not highly correlated with ratings of care professionals and significant others or with laboratory tests and other surrogate clinical
outcomes. The inclusion of quality of life endpoints in intervention studies of obese persons is, however, a more recent phenomenon than in several other disciplines such as rheumatology, cardiology, and oncology, and has yet to gain wide acceptance among scientists and clinicians involved in the progress of obesity research (17–19). The most recent, comprehensive text on quality of life and phar-macoeconomics in clinical trials (20) addresses research activities from a wide variety of areas, but not obesity. In line with a general trend in health care, however, new standards proposed for evaluating the success of obesity interventions include quality of life assessments (21).

**Authorized Measures: Psychometric Criteria**

A summary of all the basic requirements of standardized quality of life questionnaires in medicine was formally established in the 1990s (22). By making the instrument criteria presented in Table 33.2 publicly available (23), the Medical Outcomes Trust contributes to quality assurance of outcome instruments, as the standards may be used: (a) to choose appropriate measures; (b) to assess the adequacy of findings, e.g., in the peer review of publications; and (c) to evaluate claims for new pharmaceutical agents where major focus is placed on quality of life.

Authorization of instruments today includes, beyond a clear conceptual and measurement model, evidence of reliability, validity, responsiveness, interpretability, practicality and cross-cultural applicability (Table 33.2). There are now well-established and feasible methods available to perform careful construction of questionnaires and determine their psychometric properties to ensure interpretability of results (16,24–26). This methodology is also helpful for shortening instruments (27,28) and for cultural and language adaptations (29–31). The availability of computer services such as The On-Line Guide to Quality-of-Life Assessment, OLGA (32) helps today’s selection and application of standardized instruments.

The process of instrument development thus implies many different steps of analysis to determine if the questionnaire measures the presumed constructs or dimensions of health status/quality of life (Table 33.2). Evidence of the construct validity of questionnaires is of particular importance when quality of life methods are being developed and incorporated in a new research field, as is now the case in obesity. It should be especially recognized that basic psychometric testing goes beyond the traditional calculation of Cronbach’s alpha coefficients, which gives an estimate of the reproducibility of a measure. Modern testing is now more focused on the internal structure of an instrument, e.g., convergent and discriminant validity. A good example of this process is found in the Medical Outcomes Study approach, representing a broad range of self-reported functioning and well-being measures from which the Short Form 36-item Health Survey is derived (33–36). The increasing use of quality of life assessments as major endpoints in clinical trials places certain demands on instruments to demonstrate satisfactory responsiveness (37,38). The sensitivity of instruments to detect change in health over time has been studied far less than other aspects of validity (19).
Clinical Relevance

While the use of quality of life data in clinical trials is dictated by the research questions or hypotheses specified in the protocol, the clinical value may differ. In general, quality of life data may help care providers in: (a) evaluating the total burden of a disease; (b) estimating the effects of different treatment options; (c) detecting morbidity, psychosocial problems and special needs; (d) improving quality of care (communication, clinical decision-making and caretaking); and (e) educating staff, patients, families and others. With self-report questionnaires, patients have a better opportunity to selectively perceive and evaluate important symptoms and signs, impacts and side effects of therapy, and thus become responsible partners in the treatment process. Compliance rates may also improve. Outside the inner circle of medical care, health planners may find guidance in prioritizing and developing new care programmes.

In summary, quality of life measures today are

- Standardized, with cross-cultural applicability
- Established part of technology assessment in clinical research
- Newly introduced in treatment evaluation in obesity research

HEALTH-RELATED QUALITY OF LIFE (HRQL) AND OBESITY: WHAT DO WE KNOW?

Current ‘State of the Art’ in Obesity

As obesity is considered a chronic and incurable disease, the outcome of treatment can only be measured through changes in the degree of overweight and its consequences, not in terms of cure rate. The primary goal of treatment could be expressed in terms of controlling concomitant diseases, symptoms and complaints, and minimizing psychosocial adverse effects by reducing weight. Under these circumstances, the obvious outcome of therapy is the effect it has on the patients’ everyday life and well-being. Health-related quality of life assessment in intervention studies of obesity, and the potential clinical value of such data, will thus be focused on below. Primary prevention of obesity will certainly benefit from knowledge about the self-report methods discussed (Figure 33.1), although this issue is beyond the scope of this chapter.

An indication of the current state of HRQL in obesity research may be obtained by examining the published literature. Table 33.3 presents a list of publications obtained from a recent Medline search of quality of life methods used in obesity research. Studies were included if quality of life was approached in a multidimensional way, research questions were distinctly addressed and assessments accounted for in the methods section.

In a nutshell, this summary of main purposes and methods of the papers substantiates: (a) the newness of the field; (b) the scarcity of controlled studies; (c) the variety of selected instruments; and (d) the rapidly growing number of epidemiological and clinical studies using HRQL methods. It is also notable that most clinical studies have been conducted to evaluate the effects of weight-reduction surgery, while only two or three have been carried through to assess quality of life change during non-surgical weight loss treatment. To date, only a few attempts have been made to develop and validate HRQL methods in obese populations (39–43). Further careful evaluations of instrument properties are needed in longitudinal field studies, where the contribution of specific questionnaires vis-a-vis generic ones can be clarified. This process will take several years to complete. A number of recent publications have measured health status in the obese using the generic SF-36 Health Survey. Due to its well-documented high psychometric standards and multinational applicability, the SF-36 will undoubtedly be increasingly used, with or without other condition-specific measures (44).

HRQL and Obesity: Interpretation Strategies

Proposed strategies for interpreting quality of life data are multifaceted (37,45) and various illustrative examples related to obesity will be presented below. Statistical significance testing should not be used as the sole criterion for interpreting the clinical meaning of quality of life findings. For example, content-based interpretation strategies are a useful means to communicate the basic meaning of questionnaire scores. Elaborate examples of this approach can be
-found in the interpretation guidelines for the SF-36 Health Survey (35).

Since quality of life measurement scores have no direct commonly understood meaning, the clinical significance of different scale levels may be difficult to interpret for the inexperienced user. To be more user-friendly scores are sometimes transformed into a 0-to-100 scale, which facilitates the understanding of differences in scores and also enables scores of different measures within an instrument to be compared along a uniform scale (cf. SF-36 health profiles in Figures 33.2 and 33.3). A common way to evaluate the impact on quality of life is to relate patient scores to the scores of reference groups.

### Table 33.3  Health-related quality of life (HRQL) studies in obesity: study design, main purpose and methods

<table>
<thead>
<tr>
<th>Main purpose</th>
<th>Study</th>
<th>HRQL assessment/method</th>
</tr>
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<tbody>
<tr>
<td>Review article</td>
<td>HRQL assessment in obesity</td>
<td>Sullivan <em>et al.</em> (17), Kral <em>et al.</em> (18), Sarlio-Lähteenkorva <em>et al.</em> (79)</td>
</tr>
<tr>
<td>Validation study</td>
<td>Development of obesity-specific HRQL instruments</td>
<td>Sullivan <em>et al.</em> (39), Kolotkin <em>et al.</em> (40), Kolotkin <em>et al.</em> (41), Mathias <em>et al.</em> (42), Le Pen <em>et al.</em> (43)</td>
</tr>
<tr>
<td>Cross-sectional study</td>
<td>Impact of obesity on HRQL</td>
<td>Sullivan <em>et al.</em> (39), Fontaine <em>et al.</em> (57), Fontaine <em>et al.</em> (58), Han <em>et al.</em> (51), Le Pen <em>et al.</em> (43), Mathias <em>et al.</em> (42), Brown <em>et al.</em> (52)</td>
</tr>
<tr>
<td>Retrospective study</td>
<td>Treatment effects of weight-reduction surgery</td>
<td>Carr <em>et al.</em> (80), Hafner <em>et al.</em> (81)</td>
</tr>
<tr>
<td>Controlled retrospective study</td>
<td>Treatment effects of weight-reduction surgery</td>
<td>Isacsson <em>et al.</em> (82), Van Gemert <em>et al.</em> (83)</td>
</tr>
<tr>
<td>Prospective study</td>
<td>Treatment effects of weight-reduction surgery</td>
<td>Larsen (84), Choban <em>et al.</em> (85), Chan and Villar (86), Lavie and Milan (87)</td>
</tr>
<tr>
<td>Controlled clinical trial</td>
<td>Effects of weight-reduction surgery vs. conventional treatment</td>
<td>Karlsson <em>et al.</em> (19)</td>
</tr>
<tr>
<td>Randomized controlled trial</td>
<td>Prediction and effects of long-term dieting in moderately obese women randomized to a lacto-vegetarian vs. regular diet</td>
<td>Karlsson <em>et al.</em> (55)</td>
</tr>
<tr>
<td></td>
<td>Effects of a combined 12-week weight loss programme in moderately obese women</td>
<td>Rippe <em>et al.</em> (65)</td>
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</table>
‘Known group’ comparisons may include norm-based interpretation linked to the analysis of score distributions in characterized clinical as well as general populations (cf. SIP category and index scores of severely obese vs. those of healthy subjects and cancer survivors in Figures 33.4 and 33.6, respectively). It is also useful to calculate the percentage of the study sample with no reported limitation on the different functional health scales, versus proportions with small-to-moderate and large dysfunction. Among other distribution-based interpretation methods to convey differences in quality of life scores, calculation of effect sizes should be mentioned. Effect size estimates allow direct comparisons across different measures regardless of scoring system and the clinical significance of differences between groups may be judged against standard criteria proposed by Cohen (46).

The clinical meaning of change in intervention studies is another important issue. To arrive at meaningful interpretations, quality of life change scores may be compared, or anchored to other established criteria for clinical change. Obviously, effects of obesity interventions on quality of life may be related to weight change and to reductions in morbidity. It should be noted, however, that initial weight loss or participation per se in weight management programmes is likely to produce unrealistic short-term changes, and repeated post-treatment assessments, including long-term follow-up of quality of life, are strongly recommended (19,47). The issue of clinically meaningful change could also be elucidated by calculating effect sizes of change (48). Standardized response means, SRM (49), is one of several methods used to estimate the responsiveness of measures in intervention studies (cf. SOS Quality of Life Survey change over time in Figure 33.8). Changes in score levels can also become meaningful by comparing them with ‘normality’ defined by population norms or with the impact of observed life events, such as being laid off from work.

Understanding individual scores sometimes requires thresholds indicating current or future morbidity, e.g. to estimate the prevalence of mood disorder in obese populations (cf. HAD scale and probabilities of depression in Figure 33.10). These well-established means of interpretation are all the more important in the field of obesity where the experience of quality of life measures is scanty.

**HRQL and Obesity I: Obese Subjects vs. General Population Norms**

The impact of obesity on quality of life has mainly been studied in clinical investigations where it is not known if samples are representative of the total obese population. It has been shown that obese subjects who seek treatment for their obesity report greater psychopathology than those who do not seek treatment (50). Both obese groups in that study, however, reported more distress than did normal weight controls. In the Swedish Obese Subjects (SOS) study, the severely obese who chose surgical treatment had generally lower levels of quality of life before treatment than their matched obese controls (19). Thus, it is crucial to perform population studies that include generic questionnaires in order to determine the extent and nature of the burden of obesity in relation to general population norms. Recently, three studies have used the SF-36 Health Survey to study the impact of obesity on quality of life in general population samples. The SF-36 is a widespread, generic short-form instrument, which comprises eight core domains of health-related quality of life: physical functioning, role functioning-physical, bodily pain, general health, vitality, social functioning, role functioning-emotional, and mental health (35,36,44).

Le Pen et al. (43) compared the SF-36 health profiles of subjects classified as non-obese (BMI < 27), overweight (BMI 27–30) or obese (BMI ≥ 30) in a French community sample. The overweight group did not differ from the non-obese except for a slight but significant decrease in physical functioning. The obese group, however, showed impaired quality of life compared to the non-obese on five of eight SF-36 scales: physical functioning, role functioning-physical and bodily pain (scales which mainly reflect physical health aspects) and in general health and vitality (scales reflecting both physical and mental health aspects). Unexpectedly, no differences between groups were observed on the mental health scales (social functioning, role functioning-emotional, and mental health).

Han et al. (51) used the SF-36 to evaluate the impact of abdominal fat (large waist circumferences) as well as generalized obesity (high BMI) on quality of life in a Dutch population sample. The total sample was divided by sex and tertiles of waist circumference and BMI. Odds ratios were cal-
Figure 33.2  SF-36 health profiles in relation to body mass index (BMI) in a Swedish population study. A higher score (range 0–100) on the SF-36 scales represents better health status. Subjects are grouped in five categories of BMI: underweight (BMI < 18.5), normal weight (18.5 ≤ BMI < 25), overweight (25 ≤ BMI < 30), obesity (30 ≤ BMI < 40) and massive obesity (BMI ≥ 40). Calculations of BMI are based on self-reported height and weight. PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

Brown et al. (52) presented SF-36 data from a large (n = 14,431) population-based study of Australian women 45–49 years of age. Around half of the sample had a BMI > 25. The study corroborated earlier findings that the physical aspects of HRQL (physical functioning, bodily pain and general health) and vitality deteriorate with increasing BMI. Furthermore, even after adjusting for area of residence, education, smoking, exercise and menopausal status they found both high and low BMI to be associated with worse HRQL. The study provided additional support from the HRQL perspective for an optimal BMI range of 20–25.

We will use SF-36 data from two Swedish population studies to further illustrate this type of norm-based interpretation. In the first example, SF-36 health profiles from subjects with underweight and increasing degrees of overweight are compared with the normal weight persons in a 1997 population study in a Swedish county (Figure 33.2; Ulf Larsson et al., unpublished data). The total postal survey comprised a random sample of the adult population (n = 8751, 72% response rate). We used a subsample of subjects between 16 and 65 years of age to avoid confounding physical health with increasing age.

As shown in Figure 33.2 the pattern of impact is quite clear; the more overweight the worse the health profile and more so for physical aspects of health (physical functioning, role-physical, bodily pain and general health) than mental. There is a dramatic negative impact on all aspects of health when obesity is massive (BMI ≥ 40). The difference, expressed in effect sizes, between the massively obese and normal weight subjects, was particularly...
Figure 33.3 Comparison of SF-36 health profiles and summary scores between an obese (BMI ≥ 30) population sample and age- and sex-matched Swedish population norms. Calculations of BMI are based on self-reported height and weight. A higher score on the SF-36 scales (range 0–100) and summary components represents better health status. The physical (PCS) and mental (MCS) component summary scores are weighted indexes (mean 50, SD 10) of the eight scales. The physically oriented scales (PF, RP, BP and GH) have the highest impact on PCS, while the mentally oriented scales (MH, RE, SF and VT) have the highest impact on MCS. A score of 50 on PCS and MCS represents the mean of the general Swedish population. PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health; PCS, physical component summary score; MCS, mental component summary score. Differences between groups were tested by Fisher’s non-parametric permutation test: 

\[ * P < 0.05, ** P < 0.01, *** P < 0.001, **** P < 0.0001 \]

large on physical functioning and general health, and moderate on social functioning, bodily pain, vitality and mental health (data not shown). A lower health profile compared with the normal weight group can also be seen in the physical areas for obese persons (BMI 30–39.9) and for those with overweight (BMI 25–29.9). Vitality and social functioning are affected in the obese group (BMI 30–39.9) but, unexpectedly, not mental health. It is also notable that underweight persons (BMI < 18.5) report worse mental health in all aspects compared with the obese and overweight groups and worse physical health than the normal weight group.

Mental health scores among the normal weight, overweight and obese in the French, Dutch, Australian and Swedish population samples were unexpectedly similar. This finding indicates that the prevalence of mood disorders in a random population sample of overweight and obese persons does not, unlike the massively obese (BMI ≥ 40.0), differ from that of the general population. However, the sensitivity of the mental health scale of the SF-36 to detect mental disturbances in overweight and obese samples should be further investigated.

In Figure 33.3, an obese population group (BMI ≥ 30) is compared with a perfect age- and sex-matched Swedish SF-36 norm population (53), i.e. reference values representing the general population. The accuracy of comparisons with norm values requires that known systematic differences in self-rated health by demographics be taken into consideration. For example, physical health in particular decreases with age and women show generally lower health profiles than men. Thus, the advantage of a perfectly matched reference group is obvious. As shown in Figure 33.3, the health profile of the obese is clearly worse in all respects than the population norm. The SF-36 physical and mental summary scores are displayed to further emphasize
the large differences between groups. It should be noted though that the health profile of the obese sample in Figure 33.3 is worse than that of the corresponding group (BMI 30–39) in Figure 33.2. The reasons for this are probably related to sample differences and thus more research is needed to clarify the impact of obesity on quality of life in general population samples.

There is no ‘gold standard’ quality of life instrument by which to assess the burden of obesity. On the contrary, since obesity is associated with a wide range of chronic conditions it would most likely be advantageous to compare results from different generic instruments. In the next example, the Sickness Impact Profile (SIP) is used to assess functional health in a sample of severely obese subjects. The SIP is a well-established self-report measure of health-related limitations in 12 defined areas of everyday life: body care and movement, mobility, ambulation, sleep and rest, eating, home management, work, recreation and pastimes, social interaction, communication, alertness behaviour and emotional behaviour. A physical, psychosocial, and overall index is also calculated.

In Figure 33.4, SIP dimension and index scores in a group of severely obese subjects from the SOS methods study (27) are compared with healthy reference subjects (39). The main features of the SOS registry and intervention studies can be seen in Figure 33.5.

The severely obese report more functional limitations in nearly all aspects of everyday life. Mobility-oriented areas are the most affected (body care and movement, mobility, and ambulation) together with home management, work, recreation and pastimes, social interaction, communication, alertness behaviour and emotional behaviour. A physical, psychosocial, and overall index is also calculated.

A disadvantage of the SIP is that eating problems of significance to obese people are not covered by the eating category. Rather SIP items comprise problems associated with poor nutrition due to lack of appetite, impairment, dexterity difficulties, etc. As an alternative to the SIP eating category, the Three-Factor Eating Questionnaire (TFEQ, Figure 33.1) is an appropriate and comprehensive measure of eating behaviour related to overweight and obese subjects (19,54–56).

**Summary: How Obese Persons Differ From the General Population**

- Poorer functioning and well-being, more in physical than mental aspects
- The more overweight, the worse HRQL
- Both physical and mental aspects affected in the massively obese
- Poorer HRQL in massive obesity than in underweight

**HRQL and Obesity II: Obese Subjects Seeking Treatment vs. Other Groups of Chronically Ill and Disabled**

In a US study, Fontaine et al. (57,58) used the SF-36 to assess quality of life in a consecutive sample of obese subjects seeking outpatient treatment. The obese scored significantly worse on all of the eight SF-36 scales compared with general US population norms. The largest differences were noted for the bodily pain and vitality scales. Further comparisons with reference values for other chronic medical conditions indicated that the impact of pain among obese subjects seeking treatment is considerable, equivalent to that of chronic migraine patients. This finding is of clinical importance and the effect of weight loss on chronic pain should be investigated.

In the next example, SIP category and index scores of the severely obese are compared with cancer survivors. As can be seen in Figure 33.6a, functional limitations in everyday life are in most areas worse in the severely obese than in an unselected group of cancer survivors 2–3 years after diagnosis (59). The differences are significant for several of the SIP categories and for all three summary indexes: physical, psychosocial, and overall. Restrictions are as common among the obese as in cancer survivors in areas representing mobility, sleep and rest, home
Figure 33.4(a) Mean scores of SIP categories and indexes for severely obese subjects (SOS) vs. reference subjects from the general population. High scores on SIP categories and indexes represent dysfunction.

BCM, body care and movement; M, mobility; A, ambulation; SR, sleep and rest; E, eating; HM, home management; W, work; RP, recreation and pastimes; SI, social interaction; C, communication; AB, alertness behaviour; EB, emotional behaviour; PH, physical index (mean of BCM, M and A); PS, psychosocial index (mean of SI, C, AB and EB); Overall, total SIP index (mean of all 12 categories).

Differences between groups were tested by Fisher’s non-parametric permutation test. ****P < 0.0001, ***P < 0.001, **P < 0.01, *P < 0.05, NS, not significant.

(b) Effect sizes of SIP categories and indexes for severely obese subjects (SOS) vs. reference subjects from the general population. Effect size was calculated as the mean scale score difference between groups divided by the pooled standard deviation.
The SOS study is an ongoing nationwide, multicentre project which comprises a registry study and an intervention trial. Since its start in October 1987 about 7000 severely obese persons have been accepted in the registry study. Inclusion criteria are age at accrual (37–57 years) and BMI $\geq 34$ kg/m$^2$ for males and BMI $\geq 38$ kg/m$^2$ for females.

The intervention study is a controlled clinical trial designed to test if the negative effects of severe obesity on mortality, morbidity and quality of life are reduced during long-term weight reduction. The outcomes of surgical vs. conventional weight reduction treatment will include 2000 surgical cases and their matched controls followed for 10 years.

Health-related quality of life, HRQL. A battery of study-specific and generic questionnaires was designed to assess quality of life in the SOS study (see Appendix). Well-established HRQL measures, assumed to cover a broad range of health impacts of obesity, were supplemented by condition-specific parts, all suitable for large-scale mailout–mailback data collection.

Figure 33.5  The Swedish Obese Subjects (SOS) study

management, work, and communication. Effect size calculations (Figure 33.6b) further illustrate the relative strength of functional impacts in the obese versus cancer survivors. The recreation and pastimes and social interaction domains are most negatively affected by obesity, although effect sizes are small to moderate (interval 0.20–0.50). Additional comparisons showed that the impact of obesity was equal to that of a subgroup of cancer survivors with one or more known recurrences. Only limitations in mobility were significantly worse in the recurrence group (data not shown).

In contrast, the level of impact of obesity on functional health is modest compared with disabling conditions such as rheumatoid arthritis or chronic pain syndrome, where limitations according to SIP overall index are three to four times greater (60). However, the severely obese report worse mental well-being (Mood Adjective Check List; see Appendix) than a number of chronically ill or injured patient populations such as rheumatoid arthritis sufferers, cancer survivors with no recurrence 2–3 years after diagnosis, and people with spinal cord injuries several years after injury (39). The well-being of obese persons matches that of cancer survivors with recurrence and people with spinal cord injuries less than 2 years after injury. Only non-responders to treatment among patients with chronic pain syndrome score lower. Moreover, the severely obese report more symptoms of anxiety and depression (Hospital Anxiety and Depression scale; see Appendix) compared with spinal cord injured and disease groups such as generalized malignant melanoma and intermittent claudication.
Figure 33.6(a) Mean scores of SIP categories and indexes for severely obese subjects (SOS) vs. unselected cancer survivors. High scores on SIP categories and indexes represent dysfunction. BCM, body care and movement; M, mobility; A, ambulation; SR, sleep and rest; E, eating; HM, home management; W, work; RP, recreation and pastimes; SI, social interaction; C, communication; AB, alertness behaviour; EB, emotional behaviour; PH, physical index (mean of BCM, M and A); PS, psychosocial index (mean of SI, C, AB and EB); Overall, total SIP index (mean of all 12 categories). Differences between groups were tested by Fisher’s non-parametric permutation test. ****P < 0.0001; ***P < 0.001; **P < 0.01; *P < 0.05; NS, not significant.

(b) Effect sizes of SIP categories and indexes for severely obese subjects (SOS) vs. unselected cancer survivors. Effect size was calculated as the mean scale score difference between groups divided by the pooled standard deviation.
Table 33.4 Obesity-related psychosocial problems (OP) in everyday life in severely obese men and women. Answers to the question: ‘Are you bothered because of your obesity as regards the following activities?’ (Scale range: definitely not bothered, not so bothered, mostly bothered, definitely bothered)

<table>
<thead>
<tr>
<th>Items in OP scale</th>
<th>Percentage mostly or definitely bothered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30.0–34.9</td>
</tr>
<tr>
<td></td>
<td>Men (n=596)</td>
</tr>
<tr>
<td>Private gatherings in my own home</td>
<td></td>
</tr>
<tr>
<td>Private gatherings in a friend’s or relative’s home</td>
<td></td>
</tr>
<tr>
<td>Going to restaurants</td>
<td></td>
</tr>
<tr>
<td>Going to community activities, courses, etc.</td>
<td></td>
</tr>
<tr>
<td>Holidays away from home</td>
<td></td>
</tr>
<tr>
<td>Trying on and buying clothes</td>
<td></td>
</tr>
<tr>
<td>Bathing in public places (beach, public pool, etc.)</td>
<td></td>
</tr>
<tr>
<td>Intimate relations with partner</td>
<td></td>
</tr>
<tr>
<td>OP scale score* (mean and 95% CI)</td>
<td>37.0</td>
</tr>
<tr>
<td></td>
<td>34.9–39.1</td>
</tr>
</tbody>
</table>

*OP scores are transformed to a 0–100 scale. A higher score indicates greater problems.

Summary: How Obese Patients Differ From other Chronic Populations

- Poorer functioning and mental well-being than unselected cancer survivors 2–3 years after diagnosis; comparable to those with recurrence
- The more overweight, the worse HRQL
- Better functioning than patients with disabling conditions, e.g. rheumatoid arthritis, chronic pain conditions
- Poorer mental well-being than the disabled, e.g. those with rheumatoid arthritis or with spinal cord injuries more than 2 years after injury

HRQL and Obesity III: Psychosocial Functioning

Impairment in psychosocial functioning among obese subjects has been documented in several reports during the last decades (18,61). Most studies, however, have been conducted in small samples of severely obese subjects before and after surgical treatment for obesity and generalizations are therefore uncertain. The validity of these studies is further hampered by the high dropout rates and their failure to include control subjects, long-term follow-ups and standardized instruments, which greatly jeopardize the interpretability of the data.

Psychosocial dysfunction related to overweight is probably not well covered by generic instruments and an obesity-specific scale (Obesity-related Problem scale, OP; see Appendix) was developed in the SOS study to assess the impact of obesity on psychosocial functioning. The module comprises eight questions on how bothered patients are by their obesity in everyday life activities. Psychometric properties were shown to be satisfactory in the first 1743 subjects examined (39), later cross-validated in more than 2000 consecutive SOS subjects (62). The OP scale showed only moderate correlations \((r=0.41–0.54)\) with other HRQL measures and thus provides unique information on the quality of life of obese subjects. Table 33.4 illustrates that the psychosocial burden of obesity is substantial. Women perceived markedly more problems in every area regardless of degree of overweight, while men reported more problems the higher their BMI. As expected, the general trend for both men and women pointed to more concerns regarding activ-
ties in public places, such as trying on and buying clothes and bathing in public places. It has also been documented in the SOS intervention study that obese who choose surgical treatment report markedly more psychosocial dysfunction at baseline than do matched obese controls (19).

**Summary: How Obesity-related Psychosocial Problems are Perceived**

- Worst in public places, e.g. trying on and buying clothes, bathing
- Women much worse than men
- In men, the more overweight, the more psychosocial problems

**HRQL and Obesity IV: Responsiveness to Weight Loss**

Surprisingly little is known about the influence of weight reduction on psychosocial functioning and well-being in overweight or obese persons (63), and very few studies have measured the effects of weight loss on physical functioning, role functioning, vitality or other important aspects of health status. It is also unclear how weight gain which occurs after initial weight loss during the course of treatment affects the quality of life of the obese patients (64). Some recent studies that have used standardized self-report instruments for outcome assessment suggest that weight loss in obese subjects (e.g. after diet and lifestyle modification treatment) is mostly associated with improvements in mood (63). Positive long-term changes in functional health (Sickness Impact Profile) in moderately obese women were found after compliance in a 2-year weight loss programme (55). In a recent study, the SF-36 Health Survey was used to assess quality of life change in moderately obese women after a 12-week weight loss programme (65). Significant improvements in physical functioning, vitality and mental health were found in the intervention group, while no such improvements were noted in the control group.

Several studies on the outcome of weight-reduction surgery in severely obese subjects have reported very positive effects on psychosocial functioning and well-being (18). Responsiveness to weight loss after obesity surgery on the different quality of life domains is, however, still unclear, especially in the long-term perspective. Obviously, it would be of great clinical value to clarify how the magnitude of weight loss affects quality of life, e.g. how much weight reduction is required to improve the general health perceptions of the patient. With regular use of well-established, standardized HRQL instruments in obesity research it would be possible to calculate a dose–response relation between weight loss and the various quality of life parameters.

**HRQL Change in the SOS Intervention Study: the SOS Quality of Life Survey**

The following examples are based on severely obese patients followed for 4 years in the SOS intervention study (Karlsson et al., unpublished data). A battery approach was applied in the SOS study to assess quality of life. The SOS Quality of Life Survey (see Appendix) is intended to tap a broad range of health impacts of obesity, and generic instruments or subscales on functioning and well-being are supplemented by obesity-specific modules.

Poor HRQL at baseline was dramatically improved after obesity surgery, while stable ratings over time were observed in the control group. Powerful improvements after 6 and 12 months in the surgical group were followed by a slight to moderate decline at 2- 3- and 4-year follow-ups. It was demonstrated that improvements in HRQL after 6 months were weakly related to weight loss, while this association was strengthened at 2-year follow-up (19). Thus, short-term change on HRQL indicators in weight loss studies should be interpreted with caution. Long-term follow-up is most likely necessary to confirm the effects of obesity interventions on quality of life.

In Figure 37.7, the percentage bothered on each item of the Obesity-related Problem scale (OP) are shown at baseline and at 2- and 4-year follow-ups. Great improvements can be seen from baseline to intermediate (2-year) and long-term (4-year) follow-ups in all activities covered by the OP scale. The OP scale has proved the most responsive HRQL measure in relation to weight loss over 4 years in the SOS intervention study (19,66). The results are strengthened by the fact that the dropout rate in the surgery group was extremely low even after 4 years (about 17%).

To enable comparisons of the effect of obesity
surgery on the different quality of life domains, change scores from baseline to follow-ups were transformed to standardized response means (SRM; Mean_{diff}/SD_{diff}) (49). Effect sizes of HRQL change after 6, 24 and 48 months are displayed in Figure 37.8. SRMs for weight change were also calculated as a point of reference and, as expected, the effect size after gastric surgery was large (data not shown). SRM for weight loss was largest after 6 months (2.75) but declined after 2 years (1.95) and 4 years (1.60). A similar trend was noted for the HRQL measures. Great changes in eating behaviour (TFEQ) were observed after surgical intervention, i.e. patients reported more restrained eating (RE) and less disinhibition (DI) and hunger (HU). The early changes, however, declined slightly over time. Improvements in functional health (SIP) were largely in leisure activities (RP) and social interaction (SI). Relatively small improvements (SRMs around 0.20 to 0.50) were seen in the general health (GHRI-CH) and mental health (MACL, HAD, SE) domains as well as in global quality of life (QL).

HRQL Improvements in Relation to Weight Loss After Surgical Treatment

HRQL changes 4 years after obesity surgery were related to the magnitude of weight loss; improvements were stable over time in patients with substantial weight loss ( > 30 kg; around 30%), while a regression was observed in patients with less weight reduction. If weight loss was minor ( < 10 kg), patients tended to return to their baseline levels.

A dose–response relation was observed between weight loss and improvements in psychosocial functioning (OP). The surgically treated subjects were grouped by amount of weight loss (kg) 4 years after surgery and the mean OP-scale scores were calculated for each measurement time point. There were no significant differences between groups at baseline. After 6 months, levels of psychosocial problems were substantially reduced in all groups, with a more positive trend seen in subjects with major long-term weight reduction. A distinct pattern of change among groups was observed, namely, subjects with more favourable long-term weight...
reduction reported significantly lower levels of obesity-related psychosocial problems.

As shown in Figure 33.9, effect sizes of long-term change in quality of life were associated with the amount of weight loss at 4-year follow-up (66). Where there was substantial weight reduction (≥25% of preoperative body weight), large effects (>0.8 SRM) were noted for obesity-related measures reflecting eating pattern and psychosocial problems but also for general health and functional health domains such as ambulation, recreation and pastimes, and social interaction. Interpretation of effect sizes proved that long-term effects of major weight loss on mental well-being were beneficial. Moderate effect sizes (0.5 < SRM < 0.8) were noted for depressive symptoms (HAD-D), self-esteem (SE), and overall mood (MACL), while the effect on anxiety symptoms was minor (0.2 < SRM < 0.5).

The matched control group, conventionally treated in primary health care, improved their eating pattern (decreased Disinhibition and Hunger scores) as well as their obesity-related psychosocial problems; however, the effects were small. Neither generic measures nor body weight changed beyond the trivial level in controls (Figure 33.8). They had gained 1.7 kg on average (SD 10.3) at 4 years.

Is poor HRQL reversible after substantial weight loss, i.e. to levels of a group of healthy subjects? Are improvements maintained over time? In most instances the answer seems to be yes and definitely so regarding psychosocial functioning and mental well-being. Whether impacts on physical functioning are permanently reversed needs more attention, particularly concerning how weight loss affects concomitant conditions. The SOS study will shed more light on this issue.
Summary: How Improvements are Evaluated and Related to Weight Loss

- Key to success: need for both condition-specific and generic measures, long-term follow-up, large samples, matched controls
- Poor quality of life is mostly reversible if weight loss is substantial
- Obesity-specific measures most responsive to weight reduction

HRQL and Obesity V: Detecting Mood Disorders

Studies of the prevalence of psychopathology in obese persons have yielded inconsistent results (61). The reasons for this are probably related to differences in study populations as well as assessment methods. Obese men and women in the SOS registry study showed significantly more self-assessed psychiatric morbidity than reference subjects and other patient groups (39), emphasizing the high distress level associated with severe obesity. Self-assessment measures are of potential use in clinical practice for detecting mood disorders. For example, the Hospital Anxiety and Depression scale (HAD; see Appendix) could be used in the assessment of HRQL to increase attention to mental health aspects. The instrument was designed to detect mood disorders, particularly in the somatically ill. Therefore, the HAD does not involve any somatic items frequently found in similar instruments assessing psychiatric morbidity, e.g. Beck’s Depression Inventory (67). The latter measure includes questions about appetite loss and weight change, which may be accurate indicators of depression in normal...
weight individuals but are likely to confound the occurrence of depression in obese populations.

The two cut-offs of the HAD scale for possible and probable clinical cases of anxiety or depression have proved clinically valid in a number of studies within our research programme. Figure 33.10 illustrates the prevalence figures for depression in the SOS surgery group by amount of weight loss after 4 years compared with corresponding data in the control group. Baseline, 2- and 4-year values are given. The conclusion is clear: patients who choose surgery more frequently showed distress levels indicating depression than those who served in the control group. Degree of improvement neatly followed amount of weight loss. Controls showed slight weight gain on average after both 2 and 4 years but prevalence figures indicating possible disorder were somewhat lower regarding the lower cut-off.

Questionnaires with validated thresholds like the HAD scale are well suited for the clinical setting and can thus aid specialists, GPs, dieticians and other allied health professionals in detecting mood disorders among the obese. Further, other condition-specific measures such as the OP scale and the TFEQ (see Appendix) should be of value to care providers once the relevant threshold values have been established. Progress in this area is foreseen within the SOS study.

**Summary: Detecting Psychiatric Morbidity**

- HAD scale thresholds effective in the obese
- High prevalence of depression reversible if weight loss is substantial

**CONCLUSIONS**

Resource allocations for the management of obesity and other so-called lifestyle disorders demonstrating small or uncertain treatment effects have diminished concurrently with increasing health care service costs. At the same time obesity is growing to pandemic proportions and costs for treating diseases associated with obesity are consuming more and more of health care budgets. Obesity has become 'a time bomb to be defused' (68). If attention is paid to the total burden of overweight, both in terms of personal suffering and healthcare expenditures, there is probably enough strong evidence to demand allocation of resources for serious clinical action to fight obesity.

The introduction of health-related quality of life (HRQL) to obesity research, prevention and clinical management may further strengthen the evidence. First, since the goals of weight reduction interventions are not only to normalize metabolic risk factors, reduce morbidity, prolong life, but also to restore or enhance functioning and well-being, HRQL endpoints must be included when evaluating treatments. Second, it has become increasingly recognized in clinical epidemiology and evidence-based medicine that systematic and comprehensive documentation of treatment efficacy should incorporate HRQL outcome measures. Third, pharmaceutical regulatory agencies, such as the FDA in the USA and EMEA in Europe, are currently integrating HRQL assessment into their clinical development plan. Fourth, new guidelines and recommendations will move pharmaceutical claims, also for severe obesity, towards a more ‘fair balance’ between clinical findings/surrogate measures and the patient’s viewpoint, i.e. HRQL.

**Summary: Quality of Life and Obesity—What Do We Know?**

- Health-related quality of life—a useful concept in research, prevention and clinical medicine
- Methodological ‘know how’ readily available
APPENDIX: SWEDISH OBESE SUBJECTS (SOS) QUALITY OF LIFE SURVEY

Conceptual and measurement model of health-related quality of life in obesity

<table>
<thead>
<tr>
<th>Concepts: condition-specific and generic</th>
<th>Instruments: obesity-related and generic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition-specific</strong></td>
<td><strong>TFEQ</strong></td>
</tr>
<tr>
<td>Complaints/ consequences</td>
<td>• Restraint eating</td>
</tr>
<tr>
<td><strong>Generic</strong></td>
<td><strong>OP</strong></td>
</tr>
<tr>
<td>Functional health</td>
<td>• Obesity-related psychosocial problems</td>
</tr>
<tr>
<td>Physical/ mobility oriented consequences</td>
<td>• Disinhibition</td>
</tr>
<tr>
<td><strong>Social/ emotional/ cognitive consequences</strong></td>
<td><strong>SIP</strong></td>
</tr>
<tr>
<td><strong>General health perceptions</strong></td>
<td>• Ambulation</td>
</tr>
<tr>
<td><strong>Mental health</strong></td>
<td>• Home management</td>
</tr>
<tr>
<td>Distress/ well-being</td>
<td>• Work</td>
</tr>
<tr>
<td></td>
<td>• Recreation and pastimes</td>
</tr>
<tr>
<td><strong>Overall quality of life</strong></td>
<td><strong>SIP</strong></td>
</tr>
<tr>
<td></td>
<td>• Social interaction</td>
</tr>
<tr>
<td><strong>TFEQ</strong>: Three-Factor Eating Questionnaire (54, 55)</td>
<td><strong>GHRI</strong>: General Health Rating Index (39, 71)</td>
</tr>
<tr>
<td><strong>OP</strong>: Obesity-related Problem scale from the SOS Quality of Life Survey (39)</td>
<td><strong>HAD</strong>: Hospital Anxiety and Depression scale (39, 72)</td>
</tr>
<tr>
<td><strong>SIP</strong>: Sickness Impact Profile (69, 70)</td>
<td><strong>MACL</strong>: Mood Adjective Check List (39, 73)</td>
</tr>
<tr>
<td><strong>GHRI</strong>: General Health Rating Index (39, 71)</td>
<td><strong>SE</strong>: Self-Esteem scale (74, 75)</td>
</tr>
<tr>
<td><strong>HAD</strong>: Hospital Anxiety and Depression scale (39, 72)</td>
<td><strong>Global rating</strong>: Overall quality of life (76)</td>
</tr>
</tbody>
</table>

TFEQ: Three-Factor Eating Questionnaire (54, 55); OP: Obesity-related Problem scale from the SOS Quality of Life Survey (39); SIP: Sickness Impact Profile (69, 70); GHRI: General Health Rating Index (39, 71); HAD: Hospital Anxiety and Depression scale (39, 72); MACL: Mood Adjective Check List (39, 73); SE: Self-Esteem scale (74, 75); Global rating: Overall quality of life (76).
Brief description of the SOS Quality of Life Survey

**Self-assessment of eating behaviour.** The three-factor eating questionnaire (TFEQ) includes 36 statements with an agree/disagree response format, 14 questions on a four-point response scale, and one rating on a 0–10-point scale. Responses are dichotomized and summed into three factors: restrained eating, disinhibition, and hunger. A short-form version is developed within the SOS Study.

**Obesity-related psychosocial problems.** A study-specific module was created (OP) to assess how bothered obese persons are in everyday life because of their obesity. It contains eight items on a four-point response scale to cover the perceived impact of obesity on selected activities known central to obese persons. Responses are summed into one score.

**Physical and role functioning.** Ambulation (A), home management (HM), work (W), and recreation and pastimes (RP), four categories from the Sickness Impact Profile (SIP), were selected to cover limitations in daily life activities. They contain 12, 10, 9 and 8 statements, respectively. Respondents simply agree to those statements that describe a limitation related to their health. Items agreed to are summed according to predetermined weights, divided by the sum of all weights in each category and multiplied by 100.

**Psychosocial functioning.** Social interaction (SI), the main psychosocial category from the SIP, was chosen to assess health-related dysfunction in social life; quality and quantity of social contacts within the family, among friends, and in the community. It has 20 statements with the same format as described above.

**General health perceptions.** Overall health was measured by the current health scale (CH) selected from the General Health Rating Index (GHRI). The scale aggregates nine statements on a four-point response format.

**Mood disorders/distress.** The Hospital Anxiety and Depression scale (HAD) was used to describe levels of psychological distress, screening for possible or probable mood disorder in the somatically ill. The instrument has 14 questions on a four-point response scale, summed to anxiety and depression scores with cut-offs for clinical cases.

**Mental well-being.** Mental well-being was measured by the short version of the Mood Adjective Check List (MACL) comprising 38 adjectives on a four-point response scale, summed into pleasantness, activation and calmness dimension scores and an overall index. A self-esteem scale (SE) comprising 10 questions on a four-point response scale was added to include the psychological self-image.

**Overall quality of life.** A global question was posed in accordance with a standardized wording using a seven-point response scale with anchors ‘very poor’ and ‘excellent’.

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REFERENCES


