



Published in final edited form as:

*Surg Obes Relat Dis.* 2009 ; 5(2): 250–256. doi:10.1016/j.soard.2009.01.009.

## Two-Year Changes in Health-Related Quality of Life in Gastric Bypass Patients Compared to Two Severely Obese Groups

Ronette L Kolotkin, Ph.D., Ross D Crosby, Ph.D., Richard E Gress, M.A., Steven C Hunt, Ph.D., and Ted D Adams, Ph.D.

### Abstract

**Background**—Few weight loss surgery trials evaluate changes in health-related quality of life (HRQOL) relative to obese individuals not participating in weight loss interventions.

**Objectives**—In a prospective study we evaluated two-year changes in HRQOL in gastric bypass patients compared to two separate severely obese groups not undergoing weight loss intervention.

**Setting**—Bariatric surgery practice.

**Methods**—421 surgery patients (GBP) were compared with 405 individuals who sought but did not have bariatric surgery (No GBP) and 319 population-based obese individuals (Pop OB) on obesity-specific (IWQOL-Lite) and general (SF-36) HRQOL at baseline and two-years.

**Results**—Weight loss was 34.2% for GBP, 1.4% for No GBP and a gain of 0.5% for Pop OB. Both measures of HRQOL showed greater improvements for the GBP group ( $p < 0.001$ ), even after controlling for baseline differences. Effect sizes for changes in physical and weight-related HRQOL were very large for GBP, but small to medium for the two comparison groups. Effect sizes for changes in psychosocial aspects of HRQOL were moderate to very large for the GBP, but small for comparison groups. Ninety-seven percent of surgery patients reported meaningful improvements on IWQOL-Lite total score, versus 43% of the No GBP group and 30% of the Pop OB group ( $p < 0.001$ ).

**Conclusions**—Dramatic improvements occurred in both obesity-specific and physical health-related quality of life for gastric bypass surgery patients two-years post-surgery compared to two severely obese groups not enrolled in weight loss intervention. Changes in the psychosocial aspects of HRQOL were medium to large and more variable across domains.

### Keywords

gastric bypass surgery; health-related quality of life (HRQOL); cohort trial; IWQOL-Lite; SF-36

### Introduction

Weight loss surgery has been associated with major and durable reductions in excess body weight<sup>1, 2</sup>, total mortality<sup>3, 4</sup>, co-morbid conditions<sup>1, 5, 6</sup>, and improvements in health-related quality of life (HRQOL)<sup>7–9</sup>. A number of controlled trials have been designed to compare

various bariatric surgery procedures with one another<sup>10–13</sup>, but few have investigated HRQOL outcomes in patients receiving weight loss surgery relative to non-surgically treated obese individuals.

The Swedish Obese Subjects (SOS) study, a prospective nonrandomized intervention trial, compared obese individuals (BMI ≥ 34) undergoing three types of bariatric surgery with non-surgically treated individuals undergoing conventional weight loss treatment<sup>14</sup>. HRQOL, assessed using a battery of general and obesity-specific measures, improved dramatically in surgical patients, while only minor fluctuations in HRQOL scores were observed in controls. In a randomized controlled trial by O'Brien and colleagues<sup>15</sup> patients with BMI = 30–35 were randomly assigned to either laparoscopic adjustable gastric banding or a very-low calorie diet that included pharmacotherapy and lifestyle change. At two-years patients receiving surgery reported improved general HRQOL in all eight domains of HRQOL, whereas non-surgical patients reported improvements in three domains (physical functioning, vitality, and mental health).

The present study was a prospective two-year, cohort study comparing patients who had Roux-en-Y gastric bypass surgery with two groups of severely obese individuals who did not receive weight loss intervention — (1) individuals who sought gastric bypass surgery but did not have the surgery, and (2) severely obese community subjects derived from a population study. The objective was to evaluate two-year changes in HRQOL in the gastric bypass patients relative to the two comparison groups, thus adding to a sparse literature of prospective trials investigating HRQOL outcomes in gastric surgery patients versus obese individuals not enrolled in weight loss interventions.

## Materials and Methods

### Participants

Study participants were recruited for the Utah Obesity Study<sup>16</sup>, an ongoing, prospective study comparing gastric bypass surgery patients with individuals who sought but did not have gastric bypass surgery as well as severely obese subjects randomly chosen from a population database representing over one million first-degree relatives from 120,000 Utah families<sup>17–19</sup>. The sample for the current study consisted of 421 gastric bypass surgery patients, 405 individuals who sought but did not have surgery, and 319 severely obese population-based subjects. Patients seeking gastric bypass surgery were recruited from a partnership of bariatric surgeons of the Rocky Mountain Associated Physicians (Salt Lake City, UT). Gastric bypass participants had a reported BMI ≥ 40 kg/m<sup>2</sup> or ≥ 35 kg/m<sup>2</sup> and two comorbidities, which primarily included cardiovascular, sleep apnea, uncontrolled type 2 diabetes or weight induced physical problems that interfered with daily functioning. Exclusion criteria for all study participants included: previous gastric surgery for weight loss, gastric or duodenal ulcers in the previous six months, active cancer within the past five years (except for non-melanoma skin cancer), myocardial infarction in the previous six months, and history of alcohol or narcotic abuse. Participants included in the current paper were all those who had a valid HRQOL assessment at baseline.

## Procedures

This study was approved by the University of Utah IRB. Informed consent was obtained for all participants. Upon initial evaluation and again at two-years, participants' heights and weights were obtained by the study personnel. Body mass index (BMI) was calculated as kilograms/meters<sup>2</sup>. Participants also completed questionnaires at baseline and two-year follow-up that included demographic information and two measures of HRQOL.

## Measures

**Impact of Weight on Quality of Life-Lite (IWQOL-Lite)**—The IWQOL-Lite<sup>20</sup> is a 31-item measure of weight-related quality of life. There are five domain scores (Physical Function, Self-Esteem, Sexual Life, Public Distress and Work) and a Total score. Scores for all domains and Total score range from 0–100, with lower scores indicating greater impairment. The IWQOL-Lite has demonstrated excellent reliability and validity<sup>20, 21</sup>.

**Medical Outcomes Study Short-Form-36 (SF-36)**—The SF-36<sup>22</sup> is a 36-item measure of general HRQOL, consisting of eight subscales (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health) and two summary scores [Physical Component Summary (PCS) and Mental Component Summary (MCS)]. The two summary scores represent independent (orthogonal) indices based on factor analysis of subscale scores using the Medical Outcomes Study data<sup>22</sup>. Scores on all subscales and PCS and MCS range from 0 to 100, where 100 represents the best HRQOL. Scores for PCS and MCS are norm-based, with a mean of 50 and a standard deviation of 10. Estimates of internal consistency for the SF-36 typically have exceeded 0.80 for all subscales across diverse patient groups<sup>23, 24</sup>.

## Statistical Analyses

Groups were compared on baseline characteristics using chi-square analysis for categorical measures and analysis of variance (ANOVA) for continuous measures using a two-tailed alpha of .05. Post-hoc tests for categorical measures were based upon pairwise Bonferroni-corrected<sup>25</sup> chi-square comparisons ( $\alpha = .05/3 = .017$ ) and for continuous measures were based on Tukey's honestly significant difference (hsd)<sup>26</sup> to control for multiple comparisons. Groups were compared on baseline HRQOL scores using analysis of covariance (ANCOVA), controlling for BMI and gender. Groups were compared on changes in HRQOL at two-year follow-up using ANCOVA, controlling for baseline score, gender, and baseline BMI using a Bonferroni-corrected two-tailed alpha of .003 (.05/16) to control for multiple comparisons. Pair-wise post-hoc comparisons were based upon covariate-adjusted Bonferroni-corrected contrasts using a significance of .001 (.003/3). Within group effect sizes were calculated as the difference between scores at endpoint and baseline divided by the baseline standard deviation. Additionally, we computed the number and percent of participants in each group that demonstrated meaningful improvement in IWQOL-Lite total score using the algorithm described by Crosby and colleagues<sup>27</sup>. Based on this algorithm, scores have shown meaningful improvement if they have increased 7–12 points, depending upon baseline severity. The percent of patients demonstrating meaningful improvement/no

change /deterioration was compared across groups using chi-square analysis. All analyses were conducted using SPSS Version 16.0.1<sup>28</sup>.

## Results

### Demographic and Weight Characteristics

Table 1 presents baseline demographic and weight characteristics by group. Those who sought but did not have surgery were less likely to be married than surgery patients (52.3% vs. 61.8%), but did not differ from surgery patients in terms of other demographic and weight characteristics. In contrast, obese population-based subjects were older, weighed less, and had a higher proportion of males and Caucasians than both surgery patients and those who sought but did not have surgery.

### Baseline HRQOL

Baseline comparisons between groups in IWQOL-Lite and SF-36 scores are presented in Table 2. Surgery patients were more impaired than those who sought but did not have surgery on physical HRQOL (including Physical Function and Sexual Life from the IWQOL-Lite and Physical Functioning, Role Physical, and PCS from the SF-36) but did not differ on psychosocial components. In contrast, surgery patients were more impaired than population-based obese subjects on all scales and total scores from both the IWQOL-Lite and the SF-36.

### Two-Year Follow-up Rates

Two-year valid HRQOL assessments (IWQOL-Lite and/or SF-36) were obtained for 308 (73.2%) surgery patients, 253 (62.5%) individuals who sought but did not have surgery, and 272 (85.3%) obese community participants ( $\chi^2_{(2)} = 36.42, p < .001$ ). Bonferroni-corrected post hoc comparisons revealed that follow-up rates were significantly higher for obese community participants than surgery patients, which were in turn significantly higher than follow-up rates for those who sought but did not have surgery. Participants who failed to complete the two-year assessment were younger, less likely to be married, more likely to be a minority, had fewer years of education, higher BMI, and reported poorer quality of life at baseline on most IWQOL-Lite (all except Sexual Life) and SF-36 (all except Physical Function, Role Physical, Vitality, and PCS) scales.

### Two-Year Weight Loss

The percent weight loss at two years among surgery patients averaged 34.2% (SD = 10.0, range = 65.4% loss to 1.0% gain), compared to 1.4% (SD = 8.6, 31.7% loss to 20.3% gain) for individuals who sought but did not have surgery and a 0.5% gain (SD = 9.3, 57.4% loss to 27.0% gain) for obese population-based participants ( $F_{(2,802)} = 1235.54, p < .001$ ).

### Two-Year Changes in HRQOL

Two-year changes in IWQOL-Lite and SF-36 scores by group are presented in Table 3. Gastric bypass patients showed significantly greater improvement than both those who sought but did not have surgery and population-based obese individuals on all measures.

HRQOL changes in the group who sought and did not have surgery were comparable to those in the population-based obese group except for IWQOL-Lite Sexual Life and Work, where greater improvement was observed in the group that sought but did not have surgery. Within-group effect size changes in the surgery group for the IWQOL-Lite ranged from 1.73 (Work) to 3.31 (total score) and for the SF-36 ranged from .60 (Role Emotional) to 2.04 (Physical Functioning).

### Meaningful Changes in IWQOL-Lite Total Score

Ninety-seven percent (97%) of surgery patients experienced meaningful improvements, compared to only 43% of those who sought but did not have surgery and 30% of population-based obese individuals ( $\chi^2_{(4)} = 299.20$ ,  $p < 0.001$ ). This difference remained significant ( $p < .001$ ) after controlling for baseline BMI. No surgery patients reported meaningful deteriorations in IWQOL-Lite total score over the two-year period, compared to nearly one in five individuals in the group that sought but did not have surgery (18.9%) and population-based obese (17.2%) groups.

### Discussion

Quality of life is “an essential parameter in measuring the effectiveness of bariatric surgery and should be assessed objectively as a valid outcome measure in clinical trials<sup>29</sup>.” The current study adds to the sparse literature on HRQOL outcomes in prospective trials of bariatric surgery versus non-surgically treated obese groups<sup>14, 15</sup> and is unique in that two separate severely obese comparison groups were used, both of which did not receive weight loss intervention. The group that sought but did not have surgery is more like the surgical group at baseline (as both groups qualified for and desired surgery) and provides a direct test of the effectiveness of gastric bypass surgery on HRQOL. The severely obese community comparison group was randomly selected from a population study and thus is representative of the general population of severely obese individuals not seeking bariatric surgery. The significant two-year post-surgical differences in HRQOL relative to two comparison groups reinforces the findings of the effectiveness of gastric bypass surgery on improving HRQOL and may have implications for policy development regarding reimbursement. The unique inclusion of the two comparison groups provides an opportunity to test what happens to the HRQOL of severely obese individuals if they are left to their own devices regarding weight loss treatment and directly addresses the beneficial effects of gastric bypass surgery versus no intervention.

Statistically significant improvements were observed in all aspects of HRQOL for the surgery patients at two-years compared to the group that sought but did not have surgery. In addition, 97% of the surgical patients experienced meaningful improvements in IWQOL-Lite total score versus 43% of the group that did not have surgery. Dramatic changes in HRQOL occurred at two-years for the surgical patients. For example, IWQOL-Lite total score changed over three standard deviations, SF-36 PCS changed nearly two standard deviations, and SF-36 MCS changed just over half a standard deviation, whereas improvements in HRQOL were much more modest in the group that did not have surgery (IWQOL-Lite total score changed a little more than half a standard deviation, and SF-36

PCS and MCS scores changed less than a third of a standard deviation). The greater changes observed in the obesity-specific measure (IWQOL-Lite) than in the general measure of HRQOL (SF-36) are consistent with previous reports of greater sensitivity of disease-specific measures of HRQOL<sup>30</sup>.

We also found large and statistically significant differences between bariatric surgery patients and the population-based severely obese control group. For this group, two-year changes in HRQOL were quite modest (IWQOL-Lite total score changed less than a third of standard deviation, SF-36 PCS and MCS scores showed almost no change from baseline), in stark contrast to the dramatic changes observed in the surgical group. Although the severely obese population-based group did not perfectly match the gastric bypass cases on a number of variables, use of this group allowed us to compare changes in HRQOL two-years after surgery with those reported by a general sample of obese individuals not seeking obesity surgery.

One of the limitations of this study is that groups were not comparable in all variables at baseline. Although the surgical patients and the participants who sought but did not have surgery were drawn from the same population (i.e. seekers of gastric bypass surgery), the group who sought but did not have surgery differed from the surgical group with respect to fewer HRQOL impairments at baseline (particularly with respect to the physical and sexual aspects of HRQOL) and they were less likely to be married. It is possible that better baseline physical HRQOL contributed to their not having gastric bypass surgery (i.e. the more physically impaired individuals were deemed more eligible by insurance companies). When subjects were seeking but did not receive surgery, it was primarily due to the insurance company with which the subject was insured; some companies did not cover gastric bypass surgery as part of their insurance plan. None of the subjects were denied surgery because they were too sick. However, some subjects who initially were denied surgery because their insurance did not cover it paid for it out of their own pockets and later had surgery. Thus, socioeconomic factors may have been different at baseline (although there were no differences between the groups on number of years of education). Furthermore, the groups may have differed with respect to insurance company requirements regarding the necessity of undergoing behavioral or other interventions prior to approval for surgery as well as other variables not assessed in this study (e.g. presence of social support). Unfortunately, we lack the data that would allow us to address these issues.

Both comparison groups experienced modest improvements in HRQOL, perhaps due to their participation in a research study. It is likely that the greater changes observed in the seeking surgery but denied controls versus the community controls were a result of their poorer baseline HRQOL, which allowed more opportunity for improvement. Our finding of better HRQOL at baseline in the obese community controls than in subjects who sought but did not have surgery is consistent with previous research comparing HRQOL in bariatric surgery seekers versus obese community volunteers<sup>31</sup>. We speculate that the presence of better HRQOL among the obese community participants may account for their lack of interest in seeking bariatric surgery in spite of having clinically severe obesity.



Strengths of the current study included the unique design of comparing patients who received gastric bypass surgery with two different comparison groups. Additionally, the comparison groups were not samples of convenience, but consisted of a naturally occurring group of surgery seekers who did not have surgery (primarily due to denial by insurance providers) as well as severely obese subjects randomly selected from a population study. Furthermore, both general and obesity-specific measures were used to assess HRQOL as recommended in a critical review of controlled weight loss trials<sup>32</sup>. Of the two prospective, controlled trials of bariatric surgery in the literature, the SOS study also used both types of HRQOL measures<sup>14</sup>, while the study by O'Brien et al. used only a general measure<sup>15</sup>.

Follow-up rates were better in the O'Brien et al. study (98% of 40 surgical patients and 83% of 40 nonsurgical patients at two-years) and the Karlsson et al. SOS study (98% of 487 surgical patients and 84% of 487 nonsurgical patients at two-years) than in the present study (73.2% of surgical patients, 62.5% of denied controls, and 85.3% of obese community controls). Incomplete participation in follow-up assessments may have resulted in bias. Additionally, there were differences in subject characteristics as well as baseline HRQOL scores between participants who completed follow-up HRQOL assessments and those who did not, which created a bias in favor of participants with better baseline HRQOL and lower BMI, as well as those who were older, married, more educated and Caucasian. It is also unknown whether participants in the comparison groups sought nonsurgical weight loss treatment during the course of this study, which if they had, may have contributed to improvement in HRQOL.

In conclusion, at two-year follow-up dramatic improvements in two types of HRQOL were found for patients who received gastric bypass surgery compared to patients who sought but did not have gastric bypass surgery and severely obese volunteers from a population sample. Patients undergoing gastric bypass surgery lost an average of 34.2% of their body weight. The large weight reduction is likely responsible for observed improvements in HRQOL. However, it is possible that similar changes in HRQOL would occur in patients achieving this same degree of weight loss through non-surgical means.

## References

1. Buchwald H, Avidor Y, Braunwald E, Jensen MD, Pories W, Fahrbach K, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA*. 2004; 292:1724–37. [PubMed: 15479938]
2. O'Brien PE, McPhail T, Chaston TB, Dixon JB. Systematic review of medium-term weight loss after bariatric operations. *Obes Surg*. 2006; 16:1032–40. [PubMed: 16901357]
3. Adams TD, Gress RE, Smith SC, Halverson RC, Simper SC, Rosamond WD, et al. Long-term mortality after gastric bypass surgery. *N Engl J Med*. 2007; 357:753–61. [PubMed: 17715409]
4. Sjostrom L, Narbro K, Sjostrom CD, Karason K, Larsson B, Wedel H, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med*. 2007; 357:741–52. [PubMed: 17715408]
5. Pories WJ, Swanson MS, MacDonald KG, Long SB, Morris PG, Brown BM, et al. Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. *Ann Surg*. 1995; 222:339–50. discussion 50–2. [PubMed: 7677463]
6. Sjostrom L, Lindroos AK, Peltonen M, Torgerson J, Bouchard C, Carlsson B, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med*. 2004; 351:2683–93. [PubMed: 15616203]

7. Dixon JB, O'Brien PE. Changes in comorbidities and improvements in quality of life after LAP-BAND placement. *Am J Surg.* 2002; 184:51S–54S. [PubMed: 12527352]
8. O'Brien PE, Dixon JB, Brown W, Schachter LM, Chapman L, Burn AJ, et al. The laparoscopic adjustable gastric band (Lap-Band): a prospective study of medium-term effects on weight, health and quality of life. *Obes Surg.* 2002; 12:652–60. [PubMed: 12448387]
9. Wadden TA, Sarwer DB, Fabricatore AN, Jones L, Stack R, Williams NS. Psychosocial and behavioral status of patients undergoing bariatric surgery: what to expect before and after surgery. *Med Clin North Am.* 2007; 91:451–69. xi–xii. [PubMed: 17509389]
10. Sugerman HJ, Starkey JV, Birkenhauer R. A randomized prospective trial of gastric bypass versus vertical banded gastroplasty for morbid obesity and their effects on sweets versus non-sweets eaters. *Ann Surg.* 1987; 205:613–24. [PubMed: 3296971]
11. Nguyen NT, Goldman C, Rosenquist CJ, Arango A, Cole CJ, Lee SJ, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. *Ann Surg.* 2001; 234:279–89. discussion 89–91. [PubMed: 11524581]
12. Hell E, Miller KA, Moorehead MK, Norman S. Evaluation of health status and quality of life after bariatric surgery: comparison of standard Roux-en-Y gastric bypass, vertical banded gastroplasty and laparoscopic adjustable silicone gastric banding. *Obes Surg.* 2000; 10:214–9. [PubMed: 10929151]
13. Muller MK, Wenger C, Schiesser M, Clavien PA, Weber M. Quality of Life After Bariatric Surgery-A Comparative Study of Laparoscopic Banding vs. Bypass. *Obes Surg.* 2008
14. Karlsson J, Sjostrom L, Sullivan M. Swedish obese subjects (SOS)—an intervention study of obesity. Two-year follow-up of health-related quality of life (HRQL) and eating behavior after gastric surgery for severe obesity. *Int J Obes Relat Metab Disord.* 1998; 22:113–26. [PubMed: 9504319]
15. O'Brien PE, Dixon JB, Laurie C, Skinner S, Proietto J, McNeil J, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. *Ann Intern Med.* 2006; 144:625–33. [PubMed: 16670131]
16. Adams TD, Avelar E, Cloward T, Crosby RD, Farney RJ, Gress R, et al. Design and rationale of the Utah obesity study. A study to assess morbidity following gastric bypass surgery. *Contemp Clin Trials.* 2005; 26:534–51. [PubMed: 16046191]
17. Hunt SC, Williams RR, Barlow GK. A comparison of positive family history definitions for defining risk of future disease. *J Chronic Dis.* 1986; 39:809–21. [PubMed: 3760109]
18. Williams RR, Hunt SC, Barlow GK, Chamberlain RM, Weinberg AD, Cooper HP, et al. Health family trees: a tool for finding and helping young family members of coronary and cancer prone pedigrees in Texas and Utah. *Am J Public Health.* 1988; 78:1283–86. [PubMed: 3421383]
19. Williams RR, Hunt SC, Heiss G, Province MA, Bensen JT, Higgins M, et al. Usefulness of cardiovascular family history data for population-based preventive medicine and medical research (the Health Family Tree Study and the NHLBI Family Heart Study). *Am J Cardiol.* 2001; 87:129–35. [PubMed: 11152826]
20. Kolotkin RL, Crosby RD, Kosloski KD, Williams GR. Development of a brief measure to assess quality of life in obesity. *Obes Res.* 2001; 9:102–11. [PubMed: 11316344]
21. Kolotkin RL, Crosby RD. Psychometric evaluation of the Impact Of Weight On Quality Of Life-Lite Questionnaire (IWQOL-Lite) in a community sample. *Qual Life Res.* 2002; 11:157–71. [PubMed: 12018739]
22. Ware, J., Snow, K., Kosinski, M., Gandek, B. *SF-36 Health Survey: Manual and Interpretation Guide.* The Health Institute, New England Medical Center; Boston: 1993.
23. McHorney CA, Ware JE Jr, Lu JF, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care.* 1994; 32:40–66. [PubMed: 8277801]
24. McHorney CA, Ware JE Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care.* 1993; 31:247–63. [PubMed: 8450681]
25. Miller, RG. *Simultaneous statistical inference.* Second. Springer Verlag; New York: 1981.



26. Winer, BJ. *Statistical Principles in Experimental Design*. Second. McGraw-Hill; New York: p. 1971
27. Crosby RD, Kolotkin RL, Williams GR. An integrated method to determine meaningful changes in health-related quality of life. *J Clin Epidemiol*. 2004; 57:1153–60. [PubMed: 15567631]
28. SPSS. *Statistical package for the social sciences (Version 16.0.1)*. SPSS Inc; Chicago: p. 1989-2007.
29. Nguyen N, Varela EJ, Nguyen T, Wilson SE. Quality of life assessment in the morbidly obese. *Obes Surg*. 2006; 16:531–3. [PubMed: 16687017]
30. Guyatt, GH., Jaeschke, R., Feeny, DH., Patrick, DL. Measurements in clinical trials: Choosing the right approach. In: Spilker, B., editor. *Quality of Life and Pharmacoeconomics in Clinical Trials*. 2nd. Lippincott-Raven; Philadelphia: 1996. p. 41-48.
31. Kolotkin RL, Crosby RD, Williams GR. Health-related quality of life varies among obese subgroups. *Obes Res*. 2002; 10:748–56. [PubMed: 12181383]
32. Maciejewski ML, Patrick DL, Williamson DF. A structured review of randomized controlled trials of weight loss showed little improvement in health-related quality of life. *J Clin Epidemiol*. 2005; 58:568–78. [PubMed: 15878470]

**Table 1**

Baseline characteristics by group.

Characteristic	Gastric Bypass Surgery (n = 421)	Seeking But Did Not Have Surgery (n = 405)	Population-based Obese (n = 319)	Significance
Female gender (n, %)	355 (84.3) <sup>a</sup>	344 (84.9) <sup>a</sup>	243 (76.2) <sup>b</sup>	$\chi^2_{(2)} = 11.32, p = .003$
Age, yrs. (mean, SD)	42.1 ± 10.8 <sup>a</sup>	42.5 ± 11.4 <sup>a</sup>	48.8 ± 10.9 <sup>b</sup>	$F_{(2, 1142)} = 39.98, p < .001$
Married (n, %)	260 (61.8) <sup>a</sup>	212 (52.3) <sup>b</sup>	222 (69.6) <sup>a</sup>	$\chi^2_{(2)} = 22.60, p < .001$
Caucasian race (n, %)	376 (89.3) <sup>a</sup>	367 (90.6) <sup>a</sup>	310 (97.2) <sup>b</sup>	$\chi^2_{(2)} = 16.74, p < .001$
Education, yrs. (mean, SD)	14.1 ± 2.2	13.9 ± 2.4	13.8 ± 2.3	$F_{(2, 1073)} = 1.49, p = .227$
Weight, lbs. (mean, SD)	292.6 ± 61.1 <sup>a</sup>	284.9 ± 57.0 <sup>a</sup>	269.8 ± 54.8 <sup>b</sup>	$F_{(2, 1142)} = 14.04, p < .001$
BMI, kg/m <sup>2</sup> (mean, SD)	47.3 ± 7.8 <sup>a</sup>	46.5 ± 7.7 <sup>a</sup>	43.9 ± 6.4 <sup>b</sup>	$F_{(2, 1142)} = 20.35, p < .001$

Cells without common superscripts are different  $p < .05$  based upon Tukey's hsd (F test) or Bonferroni (chi-square) correction.

**Table 2**

Baseline IWQOL-Lite and SF-36 scores by group adjusted for BMI and gender.

<b>IWQOL-Lite Score</b>	<b>Gastric Bypass Surgery (n = 382–416)</b>	<b>Seeking But Did Not Have Surgery (n = 360–400)</b>	<b>Population-based Obese (n = 286–314)</b>	<b>Significance</b>
Physical Function	26.9 ± 18.5 <sup>a</sup>	31.1 ± 20.8 <sup>b</sup>	48.2 ± 21.2 <sup>c</sup>	F <sub>(2, 1124)</sub> = 81.07, p < .001
Self-Esteem	22.6 ± 20.8 <sup>a</sup>	24.3 ± 22.0 <sup>a</sup>	45.7 ± 25.9 <sup>b</sup>	F <sub>(2, 1125)</sub> = 95.20, p < .001
Sexual Life	39.5 ± 30.4 <sup>a</sup>	46.6 ± 32.5 <sup>b</sup>	65.7 ± 29.7 <sup>c</sup>	F <sub>(2, 1023)</sub> = 46.75, p < .001
Public Distress	36.3 ± 23.2 <sup>a</sup>	39.4 ± 24.9 <sup>a</sup>	62.0 ± 24.8 <sup>b</sup>	F <sub>(2, 1124)</sub> = 83.33, p < .001
Work	46.2 ± 26.5 <sup>a</sup>	47.5 ± 27.1 <sup>a</sup>	68.0 ± 23.8 <sup>b</sup>	F <sub>(2, 1113)</sub> = 56.08, p < .001
IWQOL-Lite Total	31.5 ± 16.5 <sup>a</sup>	34.8 ± 18.5 <sup>a</sup>	54.5 ± 19.6 <sup>c</sup>	F <sub>(2, 1125)</sub> = 127.02, p < .001
<b>SF-36 Score</b>				
Physical Functioning	37.1 ± 21.8 <sup>a</sup>	41.8 ± 24.5 <sup>b</sup>	56.6 ± 23.2 <sup>c</sup>	F <sub>(2, 1113)</sub> = 43.84, p < .001
Role Physical	32.7 ± 35.8 <sup>a</sup>	39.7 ± 39.1 <sup>b</sup>	58.6 ± 38.7 <sup>c</sup>	F <sub>(2, 1121)</sub> = 32.35, p < .001
Bodily Pain	41.0 ± 21.6 <sup>a</sup>	41.7 ± 21.0 <sup>a</sup>	56.5 ± 22.2 <sup>b</sup>	F <sub>(2, 1121)</sub> = 41.11, p < .001
General Health	43.3 ± 14.4 <sup>a</sup>	44.5 ± 15.2 <sup>a</sup>	54.9 ± 16.3 <sup>b</sup>	F <sub>(2, 1121)</sub> = 49.80, p < .001
Vitality	25.9 ± 17.4 <sup>a</sup>	28.1 ± 19.0 <sup>a</sup>	41.6 ± 20.7 <sup>b</sup>	F <sub>(2, 1121)</sub> = 58.04, p < .001
Social Functioning	48.8 ± 25.6 <sup>a</sup>	51.5 ± 26.9 <sup>a</sup>	72.5 ± 24.5 <sup>b</sup>	F <sub>(2, 1121)</sub> = 72.47, p < .001
Role Emotional	47.6 ± 43.1 <sup>a</sup>	45.3 ± 42.9 <sup>a</sup>	65.4 ± 40.0 <sup>b</sup>	F <sub>(2, 1121)</sub> = 20.05, p < .001
Mental Health	59.2 ± 19.2 <sup>a</sup>	57.1 ± 20.9 <sup>a</sup>	70.4 ± 18.9 <sup>b</sup>	F <sub>(2, 1121)</sub> = 38.31, p < .001
PCS	31.5 ± 8.8 <sup>a</sup>	33.7 ± 9.2 <sup>b</sup>	39.1 ± 9.6 <sup>c</sup>	F <sub>(2, 1113)</sub> = 42.90, p < .001
MCS	41.4 ± 11.6 <sup>a</sup>	40.4 ± 12.1 <sup>a</sup>	47.8 ± 11.5 <sup>b</sup>	F <sub>(2, 1113)</sub> = 37.13, p < .001

Cells represent unadjusted means ± SD.

Cells without common superscripts are different, p &lt; .017 based upon covariate adjusted Bonferroni contrasts.

**Table 3**

Two-year changes in IWQOL-Lite and SF-36 scores by group.

IWQOL-Lite Score	Gastric Bypass Surgery (n = 260298)		Seeking But Did Not Have Surgery (n = 203244)		Population-based Obese (n = 226262)		Significance
	Mean, SD	Effect Size	Mean, SD	Effect Size	Mean, SD	Effect Size	
Physical Function	58.8 ± 20.6 <sup>a</sup>	3.13	13.8 ± 25.8 <sup>b</sup>	0.65	4.9 ± 17.6 <sup>b</sup>	0.24	F <sub>(2, 798)</sub> = 463.02, p < .001
Self-Esteem	56.7 ± 26.5 <sup>a</sup>		13.1 ± 23.1 <sup>b</sup>		8.3 ± 18.4 <sup>b</sup>		F <sub>(2, 798)</sub> = 340.80, p < .001
		2.75		0.58		0.34	
Sexual Life	47.8 ± 31.8 <sup>a</sup>		7.2 ± 29.4 <sup>b</sup>		5.0 ± 26.4 <sup>c</sup>		F <sub>(2, 687)</sub> = 148.44, p < .001
		1.62		0.22		0.17	
Public Distress	52.2 ± 23.4 <sup>a</sup>		11.6 ± 26.0 <sup>b</sup>		4.6 ± 19.3 <sup>b</sup>		F <sub>(2, 797)</sub> = 335.92, p < .001
		2.25		0.45		0.19	
Work	44.0 ± 26.8 <sup>a</sup>		9.5 ± 25.9 <sup>b</sup>		4.6 ± 20.4 <sup>c</sup>		F <sub>(2, 789)</sub> = 210.12, p < .001
		1.73		0.35		0.19	
IWQOL-Lite Total	54.0 ± 19.4 <sup>a</sup>		12.0 ± 21.7 <sup>b</sup>		5.5 ± 15.1 <sup>b</sup>		F <sub>(2, 798)</sub> = 468.95, p < .001
		3.31		0.63		0.29	
<b>SF-36 Score</b>							
Physical Functioning	45.4 ± 26.1 <sup>a</sup>		6.7 ± 22.0 <sup>b</sup>		0.8 ± 21.2 <sup>b</sup>		F <sub>(2, 744)</sub> = 247.65, p < .001
		2.04		0.28		0.04	
Role Physical	47.4 ± 45.5 <sup>a</sup>		11.6 ± 42.8 <sup>b</sup>		2.9 ± 39.8 <sup>b</sup>		F <sub>(2, 755)</sub> = 71.37, p < .001
		1.33		0.29		0.07	
Bodily Pain	27.4 ± 25.4 <sup>a</sup>		4.3 ± 23.0 <sup>b</sup>		-0.4 ± 20.4 <sup>b</sup>		F <sub>(2, 752)</sub> = 96.57, p < .001
		1.25		0.20		-0.02	
General Health	22.6 ± 16.9 <sup>a</sup>		5.4 ± 17.5 <sup>b</sup>		2.1 ± 13.9 <sup>b</sup>		F <sub>(2, 752)</sub> = 117.86, p < .001
		1.59		0.36		0.13	
Vitality	31.6 ± 24.0 <sup>a</sup>		6.2 ± 20.6 <sup>b</sup>		4.7 ± 16.4 <sup>b</sup>		F <sub>(2, 752)</sub> = 122.84, p < .001
		1.84		0.32		0.23	
Social Functioning	29.5 ± 28.4 <sup>a</sup>		6.0 ± 29.0 <sup>b</sup>		1.7 ± 23.9 <sup>b</sup>		F <sub>(2, 753)</sub> = 60.63, p < .001
		1.17		0.22		0.07	

IWQOL-Lite Score	Gastric Bypass Surgery (n = 260298)		Seeking But Did Not Have Surgery (n = 203244)		Population-based Obese (n = 226262)		Significance
	Mean, SD	Effect Size	Mean, SD	Effect Size	Mean, SD	Effect Size	
Role Emotional	25.5 ± 50.3 <sup>a</sup>	0.60	12.8 ± 51.7 <sup>b</sup>	0.29	6.9 ± 42.4 <sup>b</sup>	0.17	F <sub>(2, 755)</sub> = 11.73, p < .001
	14.8 ± 19.6 <sup>a</sup>	0.80	2.4 ± 19.8 <sup>b</sup>	0.12	1.3 ± 16.5 <sup>b</sup>	0.7	
Mental Health	16.9 ± 10.0 <sup>a</sup>	1.88	2.7 ± 9.0 <sup>b</sup>	0.29	0.4 ± 8.3 <sup>b</sup>	0.04	F <sub>(2, 742)</sub> = 232.49, p < .001
	7.0 ± 13.1 <sup>a</sup>	0.62	2.4 ± 12.6 <sup>b</sup>	0.20	1.7 ± 10.5 <sup>b</sup>	0.15	
PCS							F <sub>(2, 742)</sub> = 13.19, p < .001
MCS							

Cells without common superscripts are significantly different based upon covariate-adjusted Bonferroni-corrected contrasts with  $p < .017$ .

Cell entries represent mean (SD) change from baseline and within-group effect size.