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# Improvement in health-related quality of life following Roux-en-Y gastric bypass

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# ABSTRACT

**INTRODUCTION:** This study explored whether health-related quality of life (HRQOL) changes following Roux-en-Y gastric bypass surgery were associated with identifiable socio-demographic or clinical characteristics, and it examined the impact on health outcomes of changes in the Danish criteria for bariatric surgery.

**MATERIAL AND METHODS:** Participants (n = 55) completed the Short Form Health Survey v2 (SF-36) before and  $22 \pm 4.2$ months after surgery. Information on socio-demographics, body mass index (BMI), co-morbidity and satisfaction with surgery were collected through patient questionnaires and hospi-tal records.

**RESULTS:** There was overall improvement on all SF-36 subscales and in the mean physical score (PCS) and mean mental score (MCS) (p = 0.001). A total of five patients had lower PCS and 13 patients had lower MCS after surgery, but we identified no particular characteristics associated with this poorer outcome. Co-morbidity and preoperative PCS/ MCS showed a strong correlation with change in PCS/MCS score.

**CONCLUSION:** Gastric bypass had a positive overall effect on HRQOL, but further investigation of indivi-dual variations is needed. We found no significant differences in HRQOL outcome between those patients who would be accepted for bariatric surgery under the current Danish criteria for bariatric surgery and those patients who only fulfilled the criteria for bariatric surgery before 2011.

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A central goal of health care is to maximise patient functioning and well-being. This has prompted measurement of health-related quality of life (HRQOL) that encompasses physical, psychological and social functioning [1, 2]. Obese people generally have an impaired HRQOL [3, 4]. However, people seeking bariatric surgery for obesity appear to have a poorer HRQOL than obese individuals seeking non-surgical treatment and obese individuals not seeking weight-loss treatment [4].

HRQOL improves significantly after bariatric surgery, but individual variations in outcome are often large [5-8]. As gastric bypass is an invasive procedure with an irreversible effect on eating behaviour and in some cases with serious adverse events [9], it is important to identify potential risk factors for poor long-term outcome. In Denmark, bariatric surgery is free of charge for patients fulfilling the Health and Medicines Authority's criteria, which until 2011 were in line with international criteria [10]. However, in 2011 access to surgery was restricted dramatically, and the annual number of operations fell from 0.9 per 1,000 inhabitants (2010) to 0.2 per 1,000 inhabitants (2012) [11]. The restrictions involved a tightening of the criteria for patients without manifest obesity co-morbidities, which raised the lower body mass index (BMI) threshold from 40 to 50 kg/m<sup>2</sup> and increasing the lower age limit from 18 to 25 years [11]. It is not known whether patients fulfilling the tighter criteria benefit more from surgery than patients who only met the previous criteria.

This study assessed HRQOL changes associated with Roux-en-Y gastric bypass with follow-up over an average of 22 months. The aim was to explore whether postoperative HRQOL variations were associated with identifiable socio-demographic or clinical characteristics and, in particular, whether HRQOL changes differed between patients fulfilling the current Danish criteria and patients only fulfilling the criteria for bariatric surgery before 2011.

# MATERIAL AND METHODS Subjects

The initial sample comprised 121 consecutive patients treated with Roux-en-Y gastric bypass bet-ween 1 January 2008 and 31 December 2010 at Odense University Hospital, Denmark. Preoperatively, patients were obliged to lose 8% body weight through diet and exercise and to participate in a programme providing information about potential risks and complications of bariatric surgery, expected results, vitamin substitution and dumping symptoms. In accordance with the recommendations from the Danish Centre for Health Technology Assessment [12], the operation was not offered to patients with severe psychological problems (e.g. severe depression or personality disorder), mental retardation or addiction to alcohol or illegal drugs. The patients attended a follow-up consultation which involved assessment of vitamin status and medical complications. Of the initial 121 patients, 72 (59.5%) completed a followup questionnaire and 49 patients declined participation

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### 🖌 🛛 FIGURE 1



Median Short Form (SF) 36 scores<sup>a</sup> for patients undergoing bariatric surgery according to eligibility under current Danish criteria (n = 12) (**A**) and under the pre-2011 criteria (n = 55) (**B**).



10-PF RP BP GH VT SF RE MH PCS MCS -40 -→ Preoperative → Post-operative BP = bodily pain; GH = general health; MCS = mental component summary; MH = mental health; PCS = physical component summary; PF = physical functioning; RE = role emotional; RP = role physical; SF = social functioning; VT = vitality.

a) A higher SF-36 score indicates a better health-related quality of life.

in the study. Preoperative HRQOL data were unavailable for 17 patients, which left data for 55 patients for further analysis.

# **Data collection**

HRQOL was assessed using the Danish version of the generic Medical Outcomes Study (MOS) 36-Item Short Form Health Survey v2 (SF-36) [13], which was completed by patients at the start of the pre-surgical programme and after surgery. The SF-36 assesses function in eight life domains and gives two summary scores: a physical component summary (PCS) and a mental component summary (MCS). Higher SF-36 scores indicate better HRQOL. Scores are standardised such that the (US) general population mean is 50; thus scores under 50 reflect a functioning inferior to that of the general population. The SF-36 has previously been used in bari-

# 🖌 FIGURE :

Individual change scores in Short Form 36 physical component summary (PCS) (A) and mental component summary (MCS) (B) for 55 patients undergoing bariatric surgery.



atric patients [14], but not in a Danish patient sample. Data on weight (kg), BMI and obesity-related diseases (type 2 diabetes, hypertension, osteoarthritis, sleep apnoea, and polycystic ovary syndrome) were extracted from hospital records. The post-operative questionnaire included the SF-36 items and questions on civil status, education, current weight and satisfaction with the surgical procedure. Patients completed it anonymously either by post or on the Internet. The study was registered on the open web site clinicaltrials.gov and was given the identification number NCT02032199.

### Statistical analyses

Analyses were conducted using SPSS version 21. Kolmogorov-Smirnov tests showed that whereas *change* scores for PCS and MCS were normally distributed, many of the pre- and post-operative do-main or summary scores were non-normally distributed. Due to this and the relatively small sample size, most HRQOL analyses used non-parametric tests. We used Wilcoxon signedrank tests to com-pare SF-36 scores before and after surgery, and independent-samples Mann-Whitney tests to explore potential effect on change scores of gender, civil status (married/with partner versus single/ widowed), highest education (10th class and under versus higher), co-morbidity (any co-morbidity versus none) and eligibility for bariatric surgery (current criteria, i.e. BMI > 50 kg/m<sup>2</sup> if no associated diseases and ≤ 25 years versus previous criteria, i.e. BMI > 40 kg/m<sup>2</sup> if no associated diseases and ≤ 18 years).

Spearman rank correlations were used to investigate the relationship between PCS/MCS changes and age, preoperative BMI, time since operation and baseline PCS/MCS. Surgical eligibility and variables significantly related to PCS/MCS change scores were entered into multiple linear re-gression analysis to test their independent contribution to changes in PCS/MCS. Statistical significance was set at  $p \le 0.05$ .

*Trial registration:* ClinicalTrials.gov identifier: NCT02032199.

### RESULTS

The 55 patients with full HRQOL data were not significantly different from the initial sample (n = 121) with respect to age (mean 43 ± 9.7 years, range 35-61 years versus  $43 \pm 9.4$ ), gender (85% women in both groups) and preoperative BMI (46.1  $\pm$  5.3 kg/m² versus 46.0  $\pm$  5.2 kg/m<sup>2</sup>). Information on civil status and education was not available for the initial sample. The mean follow-up time after bariatric surgery was 22 ± 4.2 months (range 14-30 months). Of the 55 patients, 76% were very satisfied with the surgical outcome, 14% were satisfied, 6% were a little dissatisfied and 4% were very dissatisfied. Participants experienced a significant weight loss after surgery (preoperative BMI 46.1 ± 5.3 kg/m<sup>2</sup> versus 29.6  $\pm$  5.1 kg/m<sup>2</sup> post-operatively). The median PCS score showed improvement after surgery (M = 36.7, interquartile range (IQR) = 19.1 versus M = 56.0, IQR = 11.8, p = 0.000), as did the median MCS score (M = 45.1, IQR = 22.6 versus M = 55.4, IQR = 13.1, p = 0.002). All eight SF-36 subscales also showed post-operative improvement (p < 0.05, Figure 1).

Only co-morbidity and baseline score had a significant relationship with overall *change* in PCS or MCS score. Patients with co-morbidity (n = 29, 53%) showed greater improvement in PCS (median change 16.4 (IQR 16.8) versus 6.6 (IQR 14.8) for those without co-morbidity, p = 0.013). Lower baseline PCS or MCS was also associated with a greater score improvement (Spearman correlation coefficient -0.791, p = 0.000 for PCS and -0.635, p = 0.000 for MCS).

Although median HRQOL scores improved after surgery, five patients had a lower PCS (i.e. worse overall physical health) and 13 patients had a lower MCS (i.e. worse overall psychological health) at follow-up than before surgery (**Figure 2**). We could not identify any particular variables that might explain this poorer outcome at follow-up. These patients were mostly women, both younger and older, had a range of civil and educational statuses, all had lost weight after operation and only two were unsatisfied with the surgical outcome.

Regression analysis suggested that co-morbidity influenced the PCS score change through lower baseline scores (**Table 1**). The eligibility criteria of preoperative BMI (40/50 kg/m<sup>2</sup>) and age (the youngest patient was 35 years) contributed little to the variation in PCS and MCS change scores. Thus, HRQOL outcome was similar for patients who fulfilled the current and earlier criteria for bariatric surgery (Figure 2). Whereas the regression model for PCS explained 64% of the variance in change scores, less than 40% of the variance in MCS change scores was explained, which suggests a certain influence of other variables that were not measured in this study.

### DISCUSSION

Patient-reported HRQOL scores showed significant improvement in the obese patients undergoing bariatric surgery, and the improvement in physical and psychological functioning was sustained 22 months post-surgery. Some patients had a poorer HRQOL at follow-up, but we could identify no par-ticular socio-demographic or clinical characteristics that singled them out from the other patients.

Patients with co-morbidity showed a greater improvement in SF-36 physical functioning, which is in line with a previous study [15]. We found no significant HRQOL differences between patients who were eligible for bariatric surgery under the current Danish criteria

## TABLE 1

Logistic regression models for change in Short Form 36 physical component summary and mental component summary health scores for 55 patients undergoing bariatric surgery.

Beta coefficient	Standard error	p-value	R square
-	-	-	0.64
-0.734	0.090	0.000	
0.037	2.274	0.684	
0.137	2.695	0.128	
-	-	-	0.37
-0.592	0.138	0.000	
-0.195	3.518	0.087	
0.080	4.250	0.476	
	- -0.734 0.037 0.137 - -0.592 -0.195 0.080	Beta         Standard           coefficient         error           -         -           -0.734         0.090           0.037         2.274           0.137         2.695           -         -           -0.592         0.138           -0.195         3.518           0.080         4.250	Standard         Product           coefficient         error         p-value           -         -         -           -0.734         0.090         0.000           0.037         2.274         0.684           0.137         2.695         0.128           -         -         -           -0.592         0.138         0.007           -0.195         3.518         0.087           0.080         4.250         0.476

MCS = mental component summary; PCS = physical component summary. Patients seeking bariatric surgery have a reduced quality of life. After 22 months of follow-up, all dimensions of generic quality of life have improved. This applies both to patients meeting the current restrictive criteria for publicly funded surgery and to patients only meeting the less restrictive criteria, which were in place until 2011. Photo: Shutterstock.



and those patients eligible under the Danish criteria for bariatric surgery before 2011. Instead, outcome was most strongly related to preoperative physical and mental health, as also reported in a study on gastric banding [6]. This study was limited to a self-selected group who were willing to complete a follow-up questionnaire on HRQOL and post-operative outcome. Although the study patients were representative of pati-ents presenting to our department for Roux-en-Y bypass surgery with respect to age, gender and preoperative BMI, we were unable to compare them with the patients not participating in the study in terms of other potentially important socio-demographic variables such as civil status and education. This introduces the risk of sampling bias, and the results may therefore not be representative of all patients undergoing bariatric surgery in Denmark. Furthermore, this study is limited to use of a generic instrument to measure HRQOL, and this may mean that issues of special relevance to obese persons have not been assessed. Kushner & Foster [16] note that generic HRQOL instruments do not ask about issues such as preoccupation with food or hatred of one's body, which may be important aspects of quality of life for people undergoing interventions for obesity. The addition of an obesityspecific instrument could help to further investigate HRQOL issues relevant to bariatric surgery patients. Previously, however, SF-36 scores have shown significant correlation with scores on the Impact of Weight on Quality of Life (IWQOL) questionnaire [17], which suggests that the SF-36 is sensitive enough to identify at least some of the HRQOL effects of obesity.

### CONCLUSION

Patient-reported HRQOL showed significant overall improvements in this group of obese patient undergoing bariatric surgery. The observed improvement in physical and psychological functioning was sustained 22 months post-surgery. We found no significant differences in HRQOL outcome bet-ween the patients who would be accepted for bariatric surgery under the current Danish criteria for bariatric surgery and the patients who only fulfilled the criteria for bariatric surgery before 2011. Some patients had a poorer HRQOL at follow-up. Although, we could not identify particular socio-demographic or clinical characteristics associated with this poorer outcome, we recommend that clinicians be aware of potential individual variations in the postoperative course.

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