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Ten-year Changes in Health-Related Quality of Life after Biliopancreatic Diversion with Duodenal Switch (BPDDS)

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Short title: Quality of life after bariatric surgery

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Abstract

Background: Long term data of health-related quality of life (HRQL) after Biliopancreatic diversion with duodenal switch (BPDDS) procedure is scarce, and the aim of this study was to evaluate changes in HRQL from baseline to 10 years in patients who had undergone BPDDS.

Methods: We included 50 patients who underwent BPDDS for severely obesity at Førde Central Hospital in a prospective cohort study. HRQL was measured with a self-report questionnaire, the Short-Form-36. Main outcomes were the "physical component score" (PCS) and the "mental component score" (MCS). HRQL was assessed before surgery and after 1, 2, 5 and 10 years. Linear mixed effect models were applied to evaluate changes over time.

Results: A total of 35 patients (70%) completed the 10 years follow-up of the HRQL study. The mean BMI at baseline was 51.7 (95 % CI, 50.0, 53.5) and 34.3 (95% CI, 32.4, 36.2) at 10 years. The PCS score improved significantly from 32.6 (95% CI, 29.7, 35.5) at baseline to 44.2 (95% CI, 40.9, 47.5) at the 10-year follow-up (P<0.001). MCS also improved significantly from 37.8 (95% CI, 34.2, 41.3) at baseline 46.0 (95% CI, 41.9, 50.0) at the 10-year follow-up (P< 0.001). However, the scores at 10-year follow-up were significantly lower than the Norwegian norm data.

Conclusion: Ten years after BPDDSs the patients` HRQL was significantly improved from preoperative values and approximately 60% of the improvements seen at the one-year follow-up were maintained.

Keywords: Obesity; Obesity surgery; Bariatric surgery; Health-related quality of life; Short Form -36; SF-36; Health status survey Body mass index; BMI.

Introduction

Severe obesity is a chronic, lifelong, multifactorial disease that is associated with a range of serious health complications and reduced health-related quality of life (HRQL) [1-4]. The desire for an improved HRQL is often a major motivation for seeking bariatric surgery [5, 6]. We have previously reported two- and five-year HRQL outcomes in patients who underwent biliopancreatic diversion with duodenal switch (BPDDS) [7-9]. Compared to gastric bypass, BPDDS is associated with higher loss and remission rates for metabolic diseases [10]. A recent systematic review identified seven prospective cohort studies reporting HRQL both preoperatively and > five years after bariatric surgery [11]. Of these studies, only one reported 10-year HRQL data, but no studies included BPDDS [12]. Thus, there is a need for knowledge about long-term changes in HRQL after BPDDS.

The aim of this study was to evaluate changes in HRQL from baseline to 10 years after surgery in patients who had undergone BPDDS. We hypothesized that significant improvements would occur in HRQL.

Methods

Study design and patients

The first 51 patients who were accepted for BPDDS at Førde Central Hospital in Norway were invited to participate in a prospective cohort study. The criteria for having surgery included BMI \geq 40.0 or 35.0-39.9 with obesity-related co-morbidities, no active psychosis, no alcohol or drug problems, age 18-60, and failure to lose weight through other methods. Written informed consent was obtained from the participants. Patients were included consecutively from 2001 to 2004. The patients were assessed at baseline and 1, 2, 5 and 10 years after surgery when they also completed self-reported questionnaires as described below.

Patients completed the Short Form -36 (SF-36) questionnaires at home and brought completed questionnaires to their hospital appointments at baseline (date of surgery) and follow-up visits. The Obesity Related Problem Scale (OP scale) was sent to patients prior to the 10-year follow-up visit only.

A priori power calculation was performed using a two-sided paired test (predicted effect size = 0.6, providing 90% power, p<0.05) indicating that at least 32 paired observations would be required to detect changes in the health related quality of life scores. To ensure that the study was robust concerning missing data, 51 patients were recruited.

The treatment: Biliopancreatic Diversion with Duodenal switch.

The BPDDS combines longitudinal gastric resection (creating restriction) with upper small bowel exclusion (creating malabsorption). Different grades of restriction and malabsorption can be combined. Restriction and malabsorption can be modified at later stages if found necessary; a re-resection of the stomach can be performed for inadequate weight loss or weight regain, and reentering a part of the small bowel can be performed for excessive malabsorption[13, 14].

Demographic characteristics and clinical data

The patients' age, gender, marital status and educational level were recorded. Body mass index (BMI) was calculated as weight divided by height squared (kg/m²) and body weight was measured in light clothing without shoes to the nearest 0.1 kg. Height was measured in a standing position without shoes to the nearest 0.01 m. The percent excess body mass index loss (%EBMIL) and percent total weight loss (%TWL) from baseline to the ten year follow-up were calculated [15].

Outcome variables

The SF-36 (Norwegian version *1.2*) measures general HRQL [16], and it has demonstrated good validity and reliability [17]. SF-36 consists of eight dimensions of physical and mental functioning, ranging from 0 (poorest) to 100 (optimal). The subscales bodily pain, physical functioning and role-physical reflect physical functioning, and mental health and roleemotional reflect mental functioning. The subscales vitality, social function and general health reflect both physical and mental functioning. The SF-36 can be factor-analyzed and reduced to two summary scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). Both PCS and MCS are constructed so that in the general US population they have a mean of 50 and SD of 10, where a higher score indicates better HRQL. [18]. **A PCS and MCS score of 8 points can be considered as a large negative deviation of the average Norwegian norm scores [19, 20]. PCS and MCS scores are standardized so that a difference in 2- 4.9 points can be interpreted as a small effect size, 5-7.9 points as a medium effect size and 8+ points as a large effect size[19, 21]. The two summary scores of the SF-36: PCS and MCS were the primary outcomes of this study. Data from the study participants were compared to SF-36 norm scores from the Norwegian population (2002, N=5,396)[20].**

The OP scale, Version 2, a measure of the impact of obesity on psychosocial functioning [22], has demonstrated good validity and reliability [7, 23]. A score = 0 indicates the best possible state and 100 the worst possible state. Scores < 20 indicate no/or very mild impairment, 20 to 39.99 mild impairment, 40 to 59.99 moderate impairment, 60 to 79.99 severe impairment, and > 80 extreme impairment [23].

The patients were also asked how satisfied they were, all things considered, with the treatment results after surgery. This question had four response choices: very satisfied, satisfied, uncertain or dissatisfied.

Statistical analysis

Clinical and sociodemographic data, as well as the question on treatment satisfaction, are described in terms of frequency and percentages or means \pm standard deviation (SD). We also report baseline data in those with 10-year data (responders) separate from those who dropped out (non-responders). Comparison of characteristics at baseline between responders and non-responders were tested by independent t-test (continuous variables) and the chi-squared test (categorical variables).

We used linear mixed effect models based on restricted maximum likelihood estimation with random intercept for subjects to estimate changes over time. Time was included as a categorical variable. Ten years changes of PCS and MCS from baseline were the main outcomes. Effect sizes were interpreted according to Cohen. A value of < 0.2 was considered as trivial, 0.2- <0.5 as small, 0.5 - <0.8 as moderate and >0.8 as large [19]. Differences between the patients SF-36 scores and the normative scores at the 10-year follow-up were first adjusted for age, gender, and then also for BMI, to reflect the same distributions as that of our study sample using analysis of covariance (ANCOVA).

Correlations between postoperative weight loss in BMI units and change in PCS and MCS over the 10-year period were studied using partial correlations (baseline versus 10-year follow up and 5-year follow-up versus 10-year follow up, adjusted for baseline values of PCS or MCS).

Statistical analysis was performed with SPSS for Windows version 23.0. Two-sided P-values < 0.05 were considered statistically significant.

Ethics

The investigation conforms to the principles outlined in the Declaration of Helsinki. The study was approved by the Regional Committee of Ethics in Medicine, West-Norway.

Results

All 51 patients who were invited participated and gave written informed consent. One patient died two years after surgery and was excluded from the study. Seven patients were re-operated--five due to weight regain and two as a result of inadequate weight loss. Two of the seven re-operated patients completed the 10-year follow-up. These two patients had a resection of the stomach nine years after the BPDDS due to weight regain after initial weight loss.

The characteristics of the patients are presented in table 1. At the 10-year assessment we received complete weight data from 38 patients, SF-36 data from 35 patients, and OP Scale data from 36 patients. We found no significant differences either in demographic characteristics, BMI, nor SF-36 scores (data not shown) at baseline or at 5-year follow-up between those who submitted 10-year SF-36 data and those who did not.

The mean BMI for the 38 patients with weight data at 10-year follow-up was reduced from 51.7 (95 % CI; 50.0, 53.5) to 34.3 (95 % CI; 32.4, 36.2), P < 0.001 (Fig 1 a). The mean %EBMIL was 66.2 (SD, 22.2) and the average %TWL was 33.4 (SD, 11.3).

The mixed effect model analysis showed that PCS improved from baseline to the 10-year follow-up (P< 0.001, ES = 1.1), [52.1 (49.4, 55.8) at 1 y, 52.6 (49.8, 55.4) at 2 y, 50.0 (46.8, 53.3) at 5y, 44.2 (40.9, 47.5) at 10 y] (Table 2 and fig. 1b).

The effect size for PCS compared to the norm population adjusted for BMI, age and gender was large after ten years (P< 0.001). The MCS also improved significantly from baseline to the 10-year follow-up (P< 0.001), [52.2 (49.0, 55.3) at 1 y, 50.7 (47.0, 54.4) at 2 y, 47.1 (43.1, 51.1) at 5 y, 46.0 (41.9, 50.0) at 10 y](Table 2, Figure 1c), and the effect size compared to the norm population adjusted for BMI, age and gender was moderate (P< 0.001). SF-36 subscale-scores also improved significantly from baseline to 10-year follow-up (Table 2). Although the improvements in SF-36 scores over time were substantial, the scores were still below norm values even after adjusting for BMI.

We found that 84% of the patients had a PCS score 8 point below the average Norwegian population norm before surgery compared to 43% after 10 years. For MCS 62% had a score 8 points below the population norm before surgery compared to 42.9% after 10 years. The corresponding percentages in the norm population are 18% for PCS and 16% for MCS.

Changes in BMI from baseline to the 10-year follow-up were not significantly correlated with changes in PCS (r = -0.14, P = 0.424) and MCS (r = -0.06, P = 0.749). However, an increase in BMI from the 5-year follow-up to the 10-year follow-up were correlated with reductions in PCS (r = 0.53, P = 0.004) and MCS (r = 0.40, P = 0.041).

The mean OP score at the 10-year follow-up was 33.3 (SD, 29.2). Twenty-four (68.6%) of the patients were very satisfied with the treatment, 7 (20%) patients were satisfied and 4 (11.4%) were uncertain. No one was dissatisfied.

Discussion

This is to the best of our knowledge the first study that has prospectively evaluated 10-year changes in HRQL after BPDDS. We evaluated changes in HRQL among 35 patients with severe obesity and found statistically significant and clinically important long-term improvement from baseline. The improvements in HRQL from baseline to two years were dramatic, followed by moderate declines from two to five years. From five to ten years the PCS score declined further, while the MCS remained stable. To date, the SOS-study (using Vertical Banded Gastroplasty, Gastric Banding and Gastric Bypass) is **one of two studies** that has prospectively evaluated 10-year changes after bariatric surgery, finding similar 10-year HRQL trajectories [12]. **Our findings are consistent with other studies that have measured HRQL only after surgery [24-26]. The second study that evaluated 10-year changes in HRQL found improvement in PCS but not for MCS[27].**

When comparing our 10-year results with the normative Norwegian population we found that both the PCS scores and MCS scores were significantly lower than norm scores adjusted for age and gender. The statistical differences were still significant after adjustment for BMI. Thus, the differences in HRQL between the patient and norm sample are not related to differences in BMI. However, the differences in SF-36 scores may be related to factors such as redundant skin, change in bowel habits, fear of weight regain or losing control over food or overeating [28-30].

The OP scale was constructed to measure the impact of obesity on psychosocial function, which was a key domain in assessing HRQL in the SOS-study [12]. The mean OP score at 10years in our study indicated a mild impairment, almost similar to what was found in the SOSstudy. In addition to the OP scale we asked patients to rate their satisfaction with treatment results. Nearly all patients were satisfied/very satisfied with the treatment, which corresponds to the report by Hess et al. in patients who had undergone BPDDS [14].

Karlsson et al. showed that weight loss, weight regain and weight stability corresponded with changes in HRQL, with small to moderate correlations reported [12]. Unlike Karlsson et al., we found no significant correlations between weight loss and 10-year change in HRQL in our study. However we found that an increase in BMI from the 5 to the 10- year follow-up correlated significantly with a reduction in HRQL. Thus, it seems that weight regain after a period of weight loss and weight stability negatively influences HRQL. This is a finding that corresponds to results from a qualitative study with patients from the same study population; the qualitative study found that patients experienced that weight regain was connected with emotional stress, shame and self-contempt [30]. If, however, the weight remains low it gives a potential for life long improvement in HRQL [31]. Although these emotional factors may play a role in long-term HRQL, we cannot draw any conclusions about these factors on the basis of our study.

A strength of our study is the long follow-up with an acceptable response rate (70%). In addition we used well-validated HRQL instruments (both generic and obesity-specific) that allowed us to compare the results with population norms and the SOS study. Lack of a control

group could be considered a limitation, but we believe that prospective, long-term cohort studies with careful monitoring of the patients is an appropriate design [32].

Conclusion

Ten years after BPDDS the patients' HRQL was significantly improved from preoperative values, and approximately 60% of the improvements seen at the one-year follow-up were maintained. Given the scarcity of long-term studies of HRQL after bariatric surgery, especially those studying BPDDS, further studies should be performed to confirm these findings.

Disclosures

The authors claim no commercial associations that might be a conflict of interest in relation to

this article.

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Table 1. Demographic characteristics and body mass index at baseline.

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Variable	All (n=50)	Group A (n=35)	Group B (N=15)
Age (y), mean ± SD	37.8 ± 8.1	38.1 ± 8.6	37.0 ± 6.1
Gender, woman, n (%)	27 (54)	16 (45.7)	11 (73.3)
Body mass index (kg/m ²),	51.7 ± 7.5	51.7 ± 8.0	51.7 ± 7.3
mean ± SD			
Marital status, n (%)			
Married/cohabitants	25 (50)	19 (54.3)	6 (40)
Live alone	25 (50)	16 (45.7)	9 (60)
Education, n (%)			S
Primary school	11 (22)	7 (20.0)	4 (26.7)
High school	26 (52)	19 (54.3)	7 (46.6)
University ≤ 4 y	9 (18)	5 (14.3)	4 (26.7)
University ≥ 4 y	4 (8)	4 (11.4)	0 (0)

Group A = patients who completed the questionnaires at 10 year. Group B = patients who did not complete the questionnaires at 10 years. Y = year, SD = standard deviation. There were no significant differences (P<0.05) between group A and B.

Table 2. HRQL before and ten years after surgery compared with a general Norwegian population sample.

Scores SF-36	Security of the stars and	P-value of	Difference from	n andre fan
Scores SF-50	Surgical treatment Mean (95 % CIs), and effect	change	Difference from adjusted norm score at	p-value for comparison
	sizes	change	10 y	with norm data
	51205		Mean and 95% CI	with horm data
PCS				
Before surgery	32.6 (29.7, 35.5)			
5 y follow-up	48.5 (45.4, 51.6)			
10 y follow-up	44.2 (40.7, 47.6)			
5-10 y change	-4.3 (-8.0, -0.7)	0.019		
ES of change 5-10 y	-0.4		-7.7 ^a (-10.7, -4.6)	<0.001 ^a
0-10 y change	11.6 (8.0, 15.1)	< 0.001	-4.8 ^b (-7.9, 1.6)	0.003 ^b
ES of change 0-10 y	1.2			
MCS				
Before surgery	37.8 (34.2, 41.3)			
5 y follow-up	45.7 (42.0, 49.5)			
10 y follow-up	45.9 (41.8, 50.0)			
5-10 y change	-0.2 (-4.1, 4.6)			
ES of change 5-10 y	-0.0	0.936	$-6.5^{a}_{b}(-9.5, -3.4)$	<0.001 ^a
0-10 y change	8.1 (3.9, 12.4)	< 0.001	-5.5 ^b (-8.7, -2.3)	<0.001 ^b
ES of change 0-10 y	0,8			
SF-36 subscales				
Physical functioning	42.7 (28.0.40.2)			
Before surgery	43.7 (38.0, 49.3)			
5 y follow-up	83.5 (77.4, 89.6)			
10 y follow-up	79.7 (73.2, 86,3)	0.273	-8.1 ^a (-13.4, -2.8)	0.003 ^a
5-10 y change 0-10 y change	-3.7 (-10.5, 3.0)	<0.001	-8.1 (-13.4, -2.8) -2.0 ^b (-7.5, 3.4)	0.003 0.463 ^b
	36.0 (29.4, 42.7) 1.5	<0.001	-2.0 (-7.3, 3.4)	0.405
ES of change 0-10 y Role physical	1.5			
Before surgery	26.0 (15.8, 36.2)			
5 y follow-up	68.3 (57.4, 79.1)			
10 y follow-up	56.5 (44.6, 68.3)			
5-10 y change	-11.8 (-25.3, 1.7)	0.087		
0-10 y change	30.5 (17.2, 43.8)	< 0.001	$-21.8^{a}(-32.8, -10.8)$	<0.001 ^a
ES of change 0-10 y	0.9	<0.001	$-16.9^{b}(-28.3, -5.5)$	0.004 ^b
Bodily pain				
Before surgery	38.8 (31.2, 46.5)			
5 y follow-up	65.9 (57.9, 73.9)			
10 y follow-up	53.5 (44.9, 62.2)			
5-10 y change	-12.4 (-21.8, -3.0)	0.010	$-19.1^{a}_{b}(-27.1, -11.0)$	< 0.001 ^a
0-10 y change	14.7 (5.4, 24.0)	0.002	-13.6 ^b (-21.9, -5.3)	0.001 ^b
ES of change 0-10 y	0.5			
General health				
Before surgery	42.4 (36.6, 49.3)			
5 y follow-up	65.6 (58.4, 72.8)			
10 y follow-up	57.7 (49.8, 65.7)	0.000		0.0013
5-10 y change	-7.8 (-16.6, 1.0)	0.080	$-17.3^{a}(-24.2, -10.5)$	$< 0.001^{a}$
0-10 y change	15.3 (6.6, 24.0)	0.001	-10.3 ^b (-17.3, -3.2)	0.004 ^b
ES of change 0-10 y	0.6			
Vitality Deferse surgery	215 (247 282)			
Before surgery	31.5 (24.7, 38.3)			
5 y follow-up 10 y follow-up	53.6 (46.6, 60.7) 48.9 (41.2, 56.7)			
5-10 y change	48.9 (41.2, 56.7) -4.7 (-13.5, 4.1)	0.294	-14.6 ^a (-21.2, -8.0)	<0.001 ^a
0-10 y change	-4.7 (-13.5, 4.1) 17.4 (8.8, 26.1)	<0.001	-14.6 (-21.2, -8.0) -10.4^{b} (-17.2, -3.6)	<0.001 0.003 ^b
ES of change 0-10 y	0.8	~0.001	-10.4 (-17.2, -3.0)	0.005
Social functioning	0.0			
Before surgery	56.1 (49.1, 63.0)			
5 y follow-up	77.9 (70.6, 85.3)			
10 y follow-up	71.6 (63.5, 79.6)			
5-10 y change	-6.4 (-15.8, 3.0)	0.183		
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0-10 y change	15.5 (6.3, 24.7)	0.001	-15.7 ^a (-22.1, -9.2)	<0.001 ^a		
ES of change 0-10 y	0.5		-14.2 ^b (-20.9, -7.6)	<0.001 ^b		
Role emotional						
Before surgery	44.7 (33.9, 55.4)					
5 y follow-up	65.2 (53.9, 76.5)					
10 y follow-up	72.3 (60.1, 84.4)					
5-10 y change	7.1 (-6.0, 20.1)	0.287	-15.2 ^a (-24.5, -5.8)	0.001 ^a		
0-10 y change	27.6 (14.4, 40.4)	< 0.001	-12.8 ^b (-22.4, -3.1)	0.010^{b}		
ES of change 0-10 y	0.7					
Mental health						
Before surgery	60.5 (54.5, 66.4)					
5 y follow-up	70.3 (64.1, 76.5)					
10 y follow-up	71.3 (64.5, 78.0)					
5-10 y change	1.0 (-6.1, 8.1)	0.781	-9.6 ^a (-14.6, -4.6)	< 0.001 ^a		
0-10 y change	10.8 (3.9, 17.8)	0.002	-9.0 ^b (-14.1, -3.8)	0.001 ^b		
ES of change 0-10 y	0.5					

^a Based on adjusted norm scores for age and gender. ^bBased on adjusted norm scores for age, gender and BMI. Y = year. ES = effect size, PCS = physical component summary, MCS = mental component summary

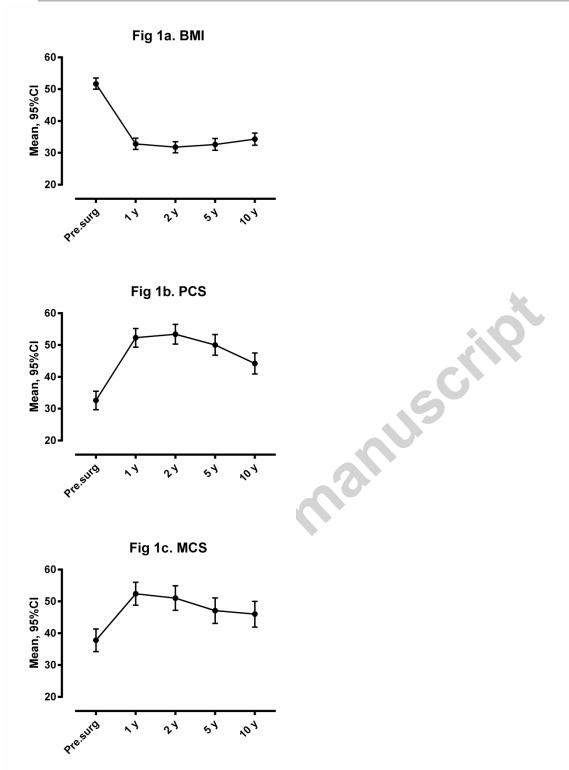


Fig 1a Body mass index (BMI) % Follow-up at; 1 y (100%), 2 y (100%), 5 y (78%), 10 y (76%)
Fig 1b Physical component summary (PCS) % Follow-up at; 1 y (94%), 2 y (82%), 5 y (92 %), 10 y (70%)
Fig 1c Mental component summary (MCS) % Follow-up at; 1 y (94%), 2 y (82%), 5 y (92 %), 10 y (70%)