

Health-related quality of life and paid work participation after duodenal switch

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ABSTRACT

Background

Morbid obesity can reduce the health-related quality of life (HRQL) and paid work participation, and the duodenal switch (DS) can induce large weight loss in patients suffering from this disease. However, data about HRQL combined with paid work participation after duodenal switch are lacking. The aim of this study was to provide longitudinal data of these issues.

Methods

Fifty-one consecutive morbidly obese patients accepted for DS gave their informed consent to participate in the study. Mean age was 37.7 years (SD, 8.0), and 54.9% were women. HRQL was assessed using the “Short-Form 36 Health Status Survey”. Eight subscores, the physical component summary (PCS), and the mental component summary (MCS) were calculated. Paid work participation was assessed as performing or not performing paid work. Data were assessed before DS (T0), one year after DS (T1), and two years after DS (T2).

Results

All the SF-36 scores improved significantly from T0 to T1 and T2 ($p < 0.001$), when they were in the normal range compared to the population norm. The number of patients performing paid work increased from 28 (54.9%) at T0 to 34 (66.7%) at T2, $p = 0.031$. The patients who performed paid work had significantly better PCS and MCS scores than those who did not before, but not after, DS.

Conclusion

Our data indicate that the SF-36 scores of the patients were normalized after DS.

A marked improvement in the paid work participation was also observed.

Introduction

The impact of morbid obesity (body mass index (BMI) > 40 or ≥ 35 with obesity-related comorbidities) on the health-related quality of life (HRQL) is often devastating [1]. Work is also an important aspect of quality of life, and morbid obesity has been associated with decreased participation in paid work [2]. Improving the HRQL and paid work participation are therefore important treatment goals, not only for the well-being of the individuals suffering from morbid obesity [1] but also for the reduction of the financial burden on society [2].

The only current treatment documented to provide sustained weight loss in patients with morbid obesity is bariatric surgery [3]. Studies have suggested that different bariatric procedures can lead to significant weight loss and improve HRQL [1, 4]. A few studies also suggest that paid work participation may increase after bariatric surgery [2, 5-7]. One of the most powerful types of bariatric surgery for inducing weight loss is the duodenal switch (DS) [8]. Few studies have examined how this procedure affects HRQL, but the results so far have been promising [9-11]. Furthermore, to our knowledge, no one has ever studied changes in paid work participation after DS. Since different bariatric procedures may give rise to different treatment effects, the effects of each procedure should be carefully documented longitudinally.

The aim of this study was therefore to study HRQL and paid work participation before and after DS. For HRQL, our primary outcome measures were the summary scores of the “Short-Form 36 Health Status Survey” (SF-36). For the paid work participation, our primary outcome was defined as performing versus not performing paid work. Other results in this paper are secondary

outcomes. We hypothesized that we would observe a substantial improvement in the HRQL and a small improvement in paid work participation after DS.

Methods

Study design and patients

The first 51 patients with morbid obesity who were accepted for DS at Førde Central Hospital were invited to participate in the study. Our bariatric surgery program was initiated in 2001, and the inclusion criteria for participation were BMI ≥ 40.0 or ≥ 35.0 - 39.9 with obesity-related comorbidities, age 18-60, no alcohol or drug problems, no active psychosis, and failure to lose weight through other methods. Power calculations were done using a two-sided paired t-test (predicted effect size = 0.6, providing 90% power, $p < 0.05$) indicating that 32-paired observations would be needed to detect changes in the SF-36 scores. To ensure that the study was robust concerning missing data, 51 patients were recruited. Data were assessed before DS (T0), one year after DS (T1), and two years after DS (T2).

The treatment: Duodenal switch

The duodenal switch is performed by resecting the greater curvature of the stomach, leaving a narrow gastric tube of 100 to 120 ml along the lesser curvature. The pylorus is left intact, and the duodenum is divided 3 to 4 cm distal to the pylorus. The small bowel is usually divided 250 cm above the coecum, and the proximal end of the distal small bowel is anastomosed to the proximal end of duodenum (alimentary limb). The distal end of the proximal small bowel is usually anastomosed to the alimentary limb 75 to 100 cm above the coecum

(common limb). Due to the malabsorption induced, patients are encouraged to eat a high protein diet and to take prescribed daily doses of vitamins and minerals.

Sociodemographics and clinical variables

Age, gender and the educational level were noted. 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. BMI was calculated as weight divided by height squared (kg/m^2). The percent excess BMI loss (%EBMIL) was calculated as: $100 - (\text{follow-up BMI} - 25 / \text{beginning BMI} - 25) \times 100$.

Health-related quality of life

HRQL refers to the aspects of quality of life that specially relate to a person's health and can be defined as self-perceived multidimensional health status [12, 13]. To measure HRQL, we used the SF-36 (Norwegian version 1.2), which is a well-established self-administrated generic measure of the health burden of chronic diseases [14]. The SF-36 has demonstrated good validity and reliability [15]. SF-36 assesses eight dimensions of physical and mental health, each ranging from 100 (optimal) to zero (poorest). The subscales are physical functioning, physical role functioning, bodily pain, and general health, which all reflect physical health. The subscales of vitality, social functioning, emotional role functioning, and mental health reflect mental health. The eight SF-36 subscales can be factor-analyzed and reduced to two summary scores, the physical component summary (PCS) and the mental component summary (MCS) [16]. To calculate the PCS and MCS, we used the oblique method, which allows for the correlation of physical and mental health [17]. A higher score on both these scales

represents better health. Norm data on the SF-36 were obtained from the Short Form 36 (SF-36) health survey in Norway 1998 (n=2323) [18].

Work participation

Data on paid work participation were based on self-reports. The patients were asked if they performed paid work at the time of the questioning. This was assessed on a continuous scale ranging from zero to 100% (i.e., 100% was defined as full-time in paid work). For descriptive purposes the patients were classified as “not working” (not performing paid work), “working-part-time” (less than 100%), and “working full-time” (100%). We also estimated the average weekly hours in paid work (full-time = 37.5 hours per week). Norm data on paid work participation (performing versus not performing paid work) were obtained from the “Labor Force Survey” in Norway 2004 (n=96000) [19].

Statistics

The population norm data for the SF-36 and paid work participation were adjusted by age and gender to reflect the same distribution as in our study sample. The patients’ SF-36 data are presented as means and standard deviations and as means for the population norm. We calculated effect sizes to illustrate the differences in SF-36 scores between the patients and the population norm by subtracting the mean scores of the population norm from the mean scores of the patient group divided by the standard deviations of the patient group at T0, T1, and T2. Effect sizes were judged against the standard criteria proposed by Cohen [20]: trivial (<0.2), small (0.2 to <0.5), moderate (0.5 to <0.8), and large (≥ 0.8). Mixed-effect models were used to calculate repeated mean changes and 95% CIs for the SF-36

scores from T0 to T1 and T2 [21]. By performing these analyses, data from all 51 patients were included. Simple and multiple regression analysis were used to study if the change in BMI from T0 to T2 was predictive for changes in the PCS and MCS from T0 to T2. In the multiple regression analysis, the initial SF-36 summary score was entered as a covariate to account for the fact that those with a higher level on this score had less room for improvement (ceiling effect) and to control for regression to the mean [22]. The McNemar's test was used to explore longitudinal changes in paid work participation (performing versus not performing paid work). The Wilcoxon-test was used to study the average paid work participation per week before and after DS. Differences in the PCS and MCS in the patients, who performed versus not performed paid work before and after DS, were studied using multiple regression analysis (adjustments were done for age, gender and educational level). In the regression analysis, the unstandardized regression coefficients (B) are reported. A paired t-test was used to explore changes in BMI. A two tailed p-value of <0.05 was considered statistically significant. The SF-36 scores were calculated with the SF Health Outcomes™ Scoring Software, basic version (Quality Metric Inc. Lincoln, USA). The mixed linear analyses were conducted with the package nlme in the statistical program R (the R Foundation for Statistical Computing, Vienna, Austria). The remaining analyses were performed using the statistical program SPSS for Windows, version 15.0 (SPSS Inc. Chicago, USA).

Ethics

Informed consent was obtained from all participants. This investigation conforms to the principles outlined in the Declaration of Helsinki. The study was approved

by The Norwegian Social Science Data Services and by the Regional Committee of Ethics in Medicine, West-Norway.

Results

Characteristics of the study participants

All 51 patients who were invited agreed to participate in the study. The mean age was 37.7 years (SD, 8.0), 28 patients (54.9%) were women and 38 patients (74.5%) had less than 13 years of education. We had complete data on all patients for changes in BMI. All completed the SF-36 at T0, 48 (94%) at T1, and 42 (82%) at T2. Eight of the incomplete SF-36 datasets at T2 were caused by an error at the hospital that lead to omissions of several items in some of the questionnaires. The nine patients who did not complete the SF-36 at T2 had practically identical sociodemographic characteristics, BMI and SF-36 summary scores at T0. Furthermore their weight loss was similar to the rest of the sample (data not shown). Regarding paid work participation, we lacked data at T2 for two patients. For these patients, we used the available data collected at T1 and at follow-up control 18-months after surgery.

Weight loss

Mean BMI at T0 was 51.9 (SD, 7.5). At T1, it was 32.8 (SD, 5.8), ($p < 0.001$, compared to T0), and at T2, it was 31.8 (SD, 5.6) ($p < 0.001$, compared to T0). The mean %EBMIL at T2 was 74.8% (SD, 22.1%), and 88.3% of the patients had a %EBMIL $> 50\%$.

SF-36 scores

The effect sizes at T0 indicated that there were large impairments in all the SF-36 scores compared to the population norm (Table 1). Effect sizes at T1 and T2 indicated that the scores had changed considerably and were in the normal range (Table 1). This was reflected by statistically significant improvements in all the SF-36 subscores ($p < 0.001$) and SF-36 summary scores in the mixed-effect analysis (Table 2).

Using simple regression, the degree of BMI unit change from T0 to T2 was significantly correlated to the degree of change in the PCS ($B = 0.57$ (95% CI, 0.08 to 1.06), $p = 0.026$). No significant association was however found when we adjusted for the initial PCS score ($B = 0.28$ (95% CI, -0.10 to 0.66), $p = 0.145$). We found no association between the degree of BMI unit change and change in the MCS (data not shown).

Work participation

The number of patients who performed paid work was unchanged from T0 to T1 (Table 3). However, the number increased from 28 (54.9%) at T0 to 34 (66.7%) at T2, $p = 0.031$. The percentage of the patients performing paid work at T2 was still somewhat lower than the age and gender adjusted population norm (82.7%). The average paid work participation per week in those who performed paid work both before and after DS ($n = 28$) was 31.2 hours at T0 and 32.8 hours per week at T2, $p = 0.505$. The average paid work participation in the six patients (two women and four men), who started to perform paid work after DS, was 26.9 hours per week at T2.

Paid work participation and the SF—36 summary scores

At T0, the patients who performed paid work (n=28) had significantly better scores on the PCS (B=8.4 (95% CI, 2.8 to 14.0), p<0.004) and the MCS (B= 8.6 (95% CI, 1.5 to 15.6), p<0.018), than those who did not (n=23). At T2, no significant differences were found in the PCS (B= 4.1 (95% CI -1.6 to 9.9), p=0.157) or MCS (B= -1.1 (95% CI -9.2 to 7.0), p=0.782) in those who performed (n=26) versus not performed paid work (n=16). The B-values were adjusted for age, gender and educational level. These covariates showed no statistically associations with the PCS or MCS (data not shown). Due to small sample size, we were unable to perform meaningful analyzes of changes in the PCS and MCS in patients who improved their workability versus those who did not.

Discussion

This study shows that the patients' SF-36 scores normalized after DS. A marked improvement in paid work participation was also observed.

There are now several studies showing excellent improvements of HRQL after a range of bariatric surgery procedures [4, 23-26]. It is likely that that the procedure associated with the best long-term weight loss maintenance (>5 to 10 years), and having few side-effects, also will have the best long-term effect on HRQL [4]. Longer follow-up is therefore needed to study this issue.

However, our results are promising and support the previous findings in the studies on DS, HRQL, and other patient-reported outcomes. Thus, Weiner et al. described 23 patients one year after DS and found large improvements in HRQL measured with the SF-12v2, the Gastrointestinal Quality of Life Index and the Bariatric Quality of Life Score [9]. Marceau et al. conducted a 15-year follow-

up on 1423 patients [11]. The patients' level of overall satisfaction with the treatment results, taking all factors into consideration, was good at the 5-year follow-up (95% were satisfied). However, as some patients experienced some weight gain over the years, the level of satisfaction tended to decrease somewhat with time.

In our study, 67% of patients were still obese ($BMI \geq 30$) at T2, while the prevalence in the general adult Norwegian population is approximately 20% [27]. Our finding that the SF-36 scores at T2 were practically identical to those of the population norm is therefore somewhat better than expected. Similar findings have also been reported by others [24, 26]. Differences in most SF-36 sub-domains are usually 5 to 10 points lower in individuals from the general population with a BMI between 30 and 34.9 compared to persons with a BMI < 30 [28, 29]. Such differences are therefore what we would expect in studies like the present one. Some have suggested that this discrepancy may be related to some short-term euphoria and relief due to a long-term disability having finally been relieved ("the honeymoon effect") [26]. It has been shown that this effect is probably temporary and that there is a small fallback to "expected values" after a longer follow-up period [26]. However, several studies suggest that a relatively good HRQL can be maintained as long as 10 to 25 years after bariatric surgery [4, 30, 31].

Our finding that the degree of change in BMI was not a significant predictor of changes of PCS and MCS, is partly in agreement with previous research, which shows only small associations between the degree of weight loss and a range of HRQL measures [4, 26]. Our study does not seem to have enough power to detect small associations. Furthermore, we suggest that most patients in

our study had a weight loss that exceeded a threshold above which little difference in generic HRQL is observed. Thus, longitudinal data after DS suggest that most patients with an initial BMI above 50 will be fairly satisfied if they maintain a long-term BMI less than 40 and that most patients with an initial BMI less than 50 will be fairly satisfied with a long-term BMI less than 35 [32]. The association between HRQL and changes in BMI in our cohort may therefore be strengthened after prolonged follow-up, when some patients may regain some weight. Another explanation may be that procedures like the DS may change an individuals' relationship to food by increasing a perception of control over eating behavior [33-35]. This effect may in turn affect some aspects of HRQL favorably without being strongly related to the degree of weight loss.

Most previous studies indicate that bariatric surgery improves paid work participation [2, 5-7]. Even small increases in paid work participation can be important, since patients having bariatric surgery often have decades of working life ahead of them. Although the number of patients who performed paid work in this study increased significantly, the rate was still lower than the population norm. However, at T2, many of the patients had just reached a plateau of weight loss, and some needed a panniculectomy. It is therefore reasonable to expect that the paid work participation in this cohort may continue to increase. Some possible confounders could have caused the increase in the paid work participation. The youngest patients in our study could have started to perform paid work during the follow-up period for natural reasons, and improved economics could have lead to higher paid work participation. However, only one patient was less than 25 years old at the start of the study, and that patient performed paid work before and after

DS. Furthermore, the paid work participation in Norway showed a small reduction during the follow-up period [19].

Our finding that not performing paid work was associated with a poorer PCS and MCS scores was expected, since similar findings have been reported by others [6, 36]. The association between performing paid work and HRQL is likely bidirectional. Performing paid work may influence HRQL positively, and having poor HRQL may lead to inability to perform paid work. At T2, there were no differences in the PCS and MCS scores between those who performed versus not performed paid work. This observation is most likely related to the large improvements in the PCS and MCS scores from T0 to T2.

Some limitations of the study should be considered. First, the data on paid work participation were based on self-reports, and recall bias may have occurred. Second, since we lacked data on sick-leave days, it was not possible to calculate an exact estimate of the participation in paid work. Third, we lacked SF-36 data in nine patients at T2. However, we consider this to be a random error. Finally, we acknowledge that using an obesity-specific HRQL measure could have been complementary.

In conclusion, our data support the hypothesis that DS can normalize generic HRQL and increase paid work participation in patients with morbid obesity. However, studies with a longer follow-up period are warranted.

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Table 1. SF-36 data in the patient group before and after duodenal switch (DS) and in the population norm. Effect sizes are for differences between the patient group and the population norm.

SF-36 scores	T0 (n = 51)	T1 (n = 48)	T2 (n = 42)	Population norm (n=2323)
Physical functioning	43.0 (24.8)	87.6 (19.2)	91.0 (13.3)	91.4
Effect size	-1.95	-0.20	-0.03	
Physical role functioning	25.5 (33.7)	74.8 (36.8)	81.0 (31.6)	84.2
Effect size	-1.74	-0.26	-0.10	
Bodily pain	38.5 (27.3)	73.3 (26.7)	77.1 (22.8)	77.5
Effect size	-1.43	-0.16	-0.02	
General health	42.0 (23.7)	81.0 (20.7)	78.8 (23.8)	79.9
Effect size	-1.60	0.05	-0.05	
Vitality	31.1 (22.3)	64.7 (22.7)	63.7 (22.4)	59.9
Effect size	-1.29	0.21	0.17	
Social functioning	55.7 (29.7)	86.7 (18.1)	83.6 (21.5)	86.3
Effect size	-1.03	0.02	-0.13	
Emotional role functioning	45.8 (42.7)	78.5 (36.1)	77.8 (36.6)	84.3
Effect size	-0.90	-0.16	-0.18	
Mental health	60.1 (21.3)	80.5 (18.7)	76.9 (20.1)	78.5
Effect size	-0.86	0.11	-0.08	

Table 1 cont.

SF-36 scores	T0	T1	T2	Population
	(n = 51)	(n = 48)	(n = 42)	norm (n=2323)
Physical component summary	32.3 (10.2)	52.3 (9.4)	53.5 (8.5)	53.7
Effect size	-2.10	-0.15	-0.02	
Mental component summary	37.8 (12.7)	52.0 (11.4)	50.3 (12.2)	51.3
Effect size	-1.06	0.06	-0.08	

The patients SF-36 data before DS (T0), one year after DS (T1), and two years after DS (T2) are presented as means and standard deviations, and as means for the norm population, which is adjusted for age and gender [18]. Effect size is calculated by subtracting the mean score of the population norm from the mean score of the patient group divided by the standard deviation of the patient group. Effect sizes <0.2 is considered trivial compared to the population norm. Effect sizes from 0.2 to <0.5 is considered as small, from 0.5 to <0.8 as moderate, and ≥ 0.8 as large. The effects size of the SF-36 can be either neutral (identical score in both populations), positive (better score than the norm population) or negative (worse score).

Table 2. Mixed effect model estimates: mean changes (95% confidence intervals) in the SF-36 summary scores after duodenal switch (DS)

Measure	T1: change from T0	T2: change from T0
Physical component summary	19.9 (17.0 to 22.7), p<0.001	20.6 (17.6 to 23.6), p<0.001
Mental component summary	14.1 (10.3 to 17.8) p<0.001	12.5 (8.5 to 16.4) p<0.001

T0: before DS (n=51). T1: one-year after DS (n=48). T2: two-years after DS (n=42).

Table 3. Paid work participation before duodenal switch (DS) (T0), one-year after DS (T1) and two-years after DS (T2)

Groups	T0, n (%)	T1, n (%)	T2, n (%)
All (n=51)			
Not working	23 (45.1)	23 (45.1)	17 (33.3)
Working part-time	8 (15.7)	9 (17.6)	11 (21.6)
Working full-time	20 (39.2)	19 (37.3)	23 (45.1)
Women (n=28)			
Not working	13 (46.4)	13 (46.4)	11 (39.3)
Working part-time	7 (25.0)	8 (28.6)	9 (32.1)
Working full-time	8 (28.6)	7 (25.0)	8 (28.6)
Men (n=23)			
Not working	10 (43.5)	10 (43.5)	6 (26.1)
Working part-time	1 (4.3)	1 (4.3)	2 (8.7)
Working full-time	12 (52.2)	12 (52.2)	15 (65.2)