Bodø, May -16

# Complications, comorbidities and quality of life after duodenal switch operation at Nordland hospital 2006-2010.

Student: Vegard Slettvold MK-11
Supervisors: Torunn Nestvold, MD, PhD and Knut Tore Lappegård, MD, PhD.


MED-3950 5th year assignment. Proffesional study in medicine at University of Tromsø.

## Preface

This project report is a 5th year thesis at the professional study in medicine at the University of Tromsø, Norway. It is a mandatory assignment ensuring students learn how to do literary research, writing of a scientific paper and handling statistical data.

The background for choosing this project is the student`s interest in general surgery, surgical methods for weight loss and related complications. Nordland hospital has received accreditation as a Bariatric surgery center by the European association for the study of obesity, and is an excellent base for such a project.

The patient data used in the project was already enrolled in research made by head of bariatric surgery Torunn Nestvold MD, PhD who has been supervisor of the project together with Knut Tore Lappegård MD, PhD at Nordland hospital Bodø. They have been very helpful with advice and guidance concerning collection of data, analysis and writing of the project report. A big thank you goes to them for sharing their time and expertise.

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# 1. Abstract

**Project aims and objectives**

We investigated the duodenal switch procedure performed at Nordland hospital in the period 2006 – 2010. Weight and comorbidities before and after surgery, complications, re-operations, department learning curve and quality of life after surgery were assessed.

**Introduction**

Obesity is an increasing health problem worldwide and it is associated with serious comorbidities such as diabetes mellitus type II, hypertension and obstructive sleep apnea. Treatment options include lifestyle intervention, medications and bariatric surgery. Duodenal switch is one of the bariatric surgery procedures in use today, it results in weight loss and reduction in comorbidities, but carries risks of complications.

**Material and methods**

41 patients were enrolled in this retrospective study. Data were collected searching the electronic health record DIPS, and quality of life scores were collected through a questionnaire. All data were analyzed using SPSS for Mac IOS.

**Results**

Mean weight loss 1 year after surgery was 72,6 kg. At last control after surgery comorbidity rates were reduced from 36,6% to 0% for diabetes, from 43,9% to 12,2% for hypertension and from 46,3% to 4,9% for OSAS. 24,4% suffered an early complication. 39% suffered a late complication. 26,8% was re-operated. Mean quality of life score was 3 out of maximum 4. No learning curve for the department was observed.

**Discussion and conclusion**

Duodenal switch procedure for obesity seems to be a highly effective treatment resulting in substantial weight loss and a nearly resolution of comorbidities one year after surgery. At last control (in average 44 months after surgery) these results were stable. The procedure for this group of patients probably carries a high risk of early and late complications, re-operations, iron- and vitamin D-deficiency and need for plastic surgery.

# 2. Project aims and objectives

In this project we investigated comorbidities, complications and quality of life (QoL) - patient reported outcomes, following bariatric surgery with the bileopancreatic diversion with duodenal switch procedure (BPDDS) performed at Nordland hospital in the period 2006 – 2010. We investigated both early and late complications after surgery. We wanted to find the rate of complications after this type of surgery at a regional center for bariatric surgery, the rate of comorbidities before and after surgery, and quality of life after surgery.
Finally we plotted the complications on a timeline to detect if there was a decreasing rate of complication over time, indicating a possible learning curve for the department as a bariatric surgery center. A learning curve would be an interesting finding because studies show an inverse correlation between post-operative complications and surgical skills (1).

Though it would have been interesting, we did not compare the effect of the BPDDS with the Roux-en-Y Gastric bypass procedure (RYGB). Our focus has been on this particular BPDDS-procedure performed at Nordland hospital.

# 3. Introduction

## 3.1 Obesity

Obesity is an increasing health problem in the world, and particularly in the developed world. The WHO states that in 2014, 39% of the adult world population (adult > 18 years old) was overweight, 13% suffered from obesity (2) and the trend is increasing (3).

The WHO has defined obesity as ”a condition of abnormal or excessive fat accumulation that may impair health” (4). The parameter most widely used to measure and categorize obesity is the body mass index (BMI) (a person’s weight in kilograms, divided by the square of his/her height in meters ($kg/m^2$)). Many have questioned the use of BMI as a measure of obesity (5, 6), but it remains the measure of choice, probably because of its simplicity.

The classification of adult weight with BMI is as follows (4):

- Underweight: BMI < 18,5
- Normal weight: BMI 18,5 – 24,99

- Overweight: BMI > 25
- Obese: BMI > 30

  Further classification of obesity can be made

  Class I: BMI 30 – 34,99

  Class II: BMI 35 – 39,99

  Class III: BMI > 40

Waist circumference in combination with BMI is often used to assess risk for disease. This assessment used by the National Heart, Lung and Blood Institute, states that people with BMI > 25 has a higher risk of comorbidities if their waist circumference is > 88 cm for women and > 102 cm for men (7).

Overweight and obesity lead to a higher rate of comorbid diseases such as diabetes mellitus type II (DM type II), hypertension, dyslipidemia, obstructive sleep apnea syndrome (OSAS) and cardiovascular disease. The benefits of weight reduction are reduction or even resolution of these comorbidities (8-10). It also reduces overall mortality (11, 12).

### 3.2 The gut-brain-axis

The concept of gut-brain-axis refers to the neuroendocrine signaling pathways that exist between the gastrointestinal tract (GI-tract) and the central nervous system (CNS). From the GI-tract afferent pathways signals information to the CNS, both by vagal and non-vagal signaling. Gut hormones via blood stream also affect the CNS in response to food consumption and other stimuli. Both the neural and the endocrine signaling are influenced by food entering the stomach, which affects mechanical stretch receptors and chemical receptors (13, 14). Likewise there are descending neural pathways through the vagal nerve that affect the gut, the best example being the *cephalic phase* of digestion where visualization, smell and expectations of food increases gastric acid secretions.

### 3.3 Comorbidities

Several conditions and diseases are related to overweight and obesity (15). The most frequent are; DM type II, cardiovascular disease, OSAS, asthma and musculoskeletal pain, in addition obesity is found to increase the general risk of cancer (15) and even mortality (16). The association between obesity and mental health problems like depression should also be mentioned (17), but are not assessed further in this report.

### 3.3.1 Pathogenesis of comorbidities

The pathogenesis of the obesity-related comorbidities is uncertain, but considerable research has been done on the subject. Most research is done regarding cardiovascular disease and DM type II as comorbidities associated with obesity. Obesity, excess adipose tissue and intra-abdominal adipose tissue in particular, are known to cause an increase in the secretion of adipocytokines. Adipocytokines cause an increased level of general low-grade chronic inflammation in the body through an increase in inflammatory cytokines. This low-grade chronic inflammation is thought to contribute to both atherosclerosis and insulin resistance (18, 19). The role of the gut microbiota has recently also become an interesting field in medicine, and it may also play a part in the pathogenesis of obesity-related comorbidities (19, 20).

Other comorbidities have a more obvious pathogenesis, like OSAS where the fat deposits cause difficulties breathing-in when the patient is in a supine position and asleep, causing restrictive respiratory dysfunction and a decrease in oxygen level in the blood (21).
In osteoarthritis it is thought that increased biomechanical load is the main cause, but also general inflammation may play a part (22). The reduction or resolution of almost all of these comorbidities following weight loss is indicative that they are in fact related to the overweight itself.

## 3.4 Treatment

The treatments available for obesity can be categorized into:

- Lifestyle intervention (diets, exercise and behavioral treatment)
- Medications (fat digestion-altering drugs, serotonin-agonists, etc.)
- Surgery (restrictive surgery, malabsorptive surgery)

### 3.4.1 Lifestyle intervention

Lifestyle intervention includes dietary counseling, increase in physical activity and behavioral/cognitive therapy. Lifestyle intervention is the most important part of obesity treatment whatever treatment option chosen, and is necessary to achieve long lasting/permanent weight loss. There are no complications associated with the treatment but patient participation and motivation is obligate. Lifestyle intervention alone has been shown to have some effect (23, 24), but the weight loss tends to be modest, and difficult to maintain for a longer time (25).

### 3.4.2 Medications for treatment of obesity

Drug therapy for obesity does not yet offer a wide variety of options. There are currently three anti-obesity drugs in use, Orlistat (pancreatic lipase inhibitor), Lorcaserin (5HT2c-agonist) and Phentermine (TAAR1-agonist) (26), of which only Orlistat is approved for use in Norway. They all cause a modest amount of weight loss (26), but they are also known to have side effects (27).

### 3.4.3 Bariatric surgery

Bariatric surgery can be categorized into two different types, according to the mechanism that leads to weight loss; restrictive and malabsorptive bariatric surgery. The most frequent procedures combine these two methods. Bariatric surgery is considered the treatment most effective in causing sustained weight loss, resolution of comorbidities and decrease in overall mortality (11, 12). It is also known to improve QoL for patients (28).

Indications for bariatric surgery as treatment of obesity are set by The American Society for Bariatric and Metabolic Surgery; BMI > 40, or BMI > 35 with comorbidities (29). Number and types of comorbidities necessary to fill the criteria can be different among departments and operators. The RYGB is now the most widely used procedure, and the preferred procedure in most bariatric surgery centers. Indications for BPDDS as preferred procedure is a BMI > 50, because for these patients BPDDS has shown a better long term weight loss (30). These criteria were also used at Nordland hospital.

#### Restrictive bariatric surgery

The principle of a restrictive procedure is that a smaller ventricle volume will make the patients unable to consume big meals. The main goal is to decrease the amount of calories consumed. The mechanism for this decrease in food-intake is not fully understood, although both vagal neural signaling via stretch-receptors and modulation of hormonal signaling has been proposed (the gut - brain axis)(31).

Primarily two methods are used in the world today. One is **gastric banding** which is surgical placement of an adjustable band in the upper portion of the ventricle just below the cardia, compartmentalizing it from the bigger lower portion (this procedure is currently not in use in Norway) (32). Another method is the **sleeve gastrectomy,** which involves partial gastrectomy, removing approximately 70-80% of the ventricle, making a tube-shaped ventricle (32). A sleeve gastrectomy has an increased impact on the gut-brain-axis compared to gastric banding.

The advantages of restrictive procedures are that the intervention on the gastrointestinal tract is limited to the ventricle and there are minimal malabsorptive side effects in comparison to the malabsorptive procedures (33).

### Malabsorptive bariatric surgery

Malabsorptive procedures involves shortening of the active absorptive part of the small intestine, decreasing the length and surface area for both digestion of food and absorption of already digested food (33), therefore the procedure is in fact both malabsorptive *and* maldigestive. The malabsorptive procedures used today divide the intestine into three limbs; alimentary limb, bileopancreatic limb and common limb. The lengths of the limbs are different according to the procedure chosen (33).

Among malabsorptive procedures, there are mainly two different procedures in use today. The first, and definitely the most popular procedure performed is the **Roux-en-Y gastric bypass (figure 1)**, which is a combined restrictive and malabsorptive procedure. In this operation the ventricle is divided beneath the cardia, making a proximal gastric pouch. The jejunum is divided 30-50 cm distal to the ligament of Treitz and the distal end is attached to the proximal gastric pouch through a gastrojejunostomy. The distal portion of the ventricle and the following proximal end of the jejunum is attached to the jejunum in a jejunojejunostomy 75-150 cm distal from the gastrojejunostomy creating an alimentary limb for food. Distal to this anastomosis (the rest of the intestine) is called the common channel, and the digestion and absorption of nutrients takes place in this part.

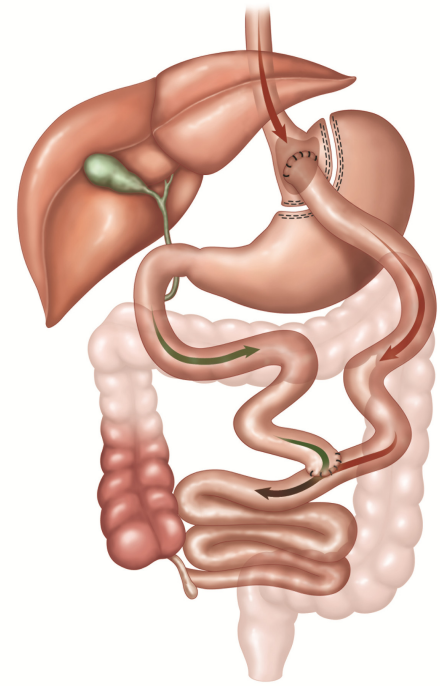

Figure 1. Gastric bypass (Adapted from Neff. KJ et al [120] The illustration is the property of Johnson & Johnson and Ethicon Endo-Surgery (Europe). It is reproduced here with their kind permission.

Second is the **bileopancreatic diversion with duodenal switch (BPDDS) (figure 2)**, also a combined restrictive and malabsorptive procedure. The operation consists of a vertical gastrectomy removing approximately 70-80% of the ventricle, similar to the sleeve gastrectomy mentioned above. The duodenum is divided below the pylorus; the duodenum distal to the resection is the beginning of the bileopancreatic limb. The ileum is then divided 2,5 meters from the ileocecal valve, and the distal end is attached to the proximal duodenum through a duodenoileostomy. The proximal end of the jejunum is anastomosed 50-100 cm from the ileocecal valve (32), creating a common limb for food, bile and pancreatic juice.

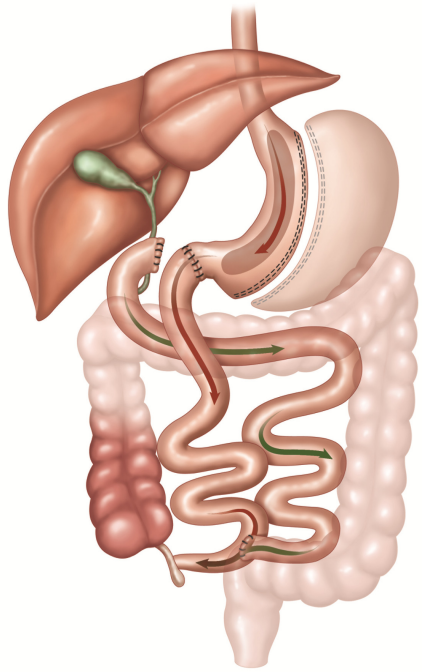

Figure 2. Duodenal switch (Adapted from Neff KJ et al [120]) The illustration is the property of Johnson & Johnson and Ethicon Endo-Surgery (Europe). It is reproduced here with their kind permission.

The mechanism by which malabsorptive bariatric surgery causes weight loss is not fully understood. The anatomical malabsorption is important in causing weight loss. Studies also show that the gut-brain-axis probably plays a part in the weight-loss mechanism following malabsorptive surgery. A possible reduction in serum ghrelin levels is thought to be play a role, and lately an increase in levels of the anorexigenic hormones PYY and GLP-1 are found to be important for the post-surgical weight loss (13, 34-36).

A very important effect in favor of bariatric surgery is not only the weight loss per se, but the reduction or even resolution of comorbidities associated with overweight and obesity (37, 38).

### 3.5 Complications to BPDDS-surgery

Complications to BPDDS can be divided into early surgical (< 30 days post-surgery) and late surgical (> 30 days post-surgery) (39). They can be more procedure specific like internal herniation, or they can be procedure non-specific – like anastomotic leakage, wound-infection or hematoma.

Internal herniation is a complication not very common after other surgical procedures of the GI-tract. It happens because of the loss of mesentery fat leading to increased mobility of the intestine and increasing diameter of the defect in the mesentery in the area of the entero-

entero anastomosis and in the *Petersen`s space*. It can cause episodes of subileus, ileus or intestinal ischemia.

Diarrhea and vomiting are well known complications to BPDDS (40), and are thought to be an effect of the anatomical change after surgery, diarrhea being caused by the malabsorptive effect, and vomiting by the restrictive effect.

### 3.6 Related literature

There has been and is still ongoing research on the subject, often aiming to compare the outcomes and complications between BPDDS to the now more widely used RYGB (41-43). Some have focused only on the BPDDS-outcomes and complications (44). Concerning QoL-scores among BPDDS-patients, there has mostly been research comparing it with RYGB, or not distinguishing between the two. Some articles showed better QoL-scores after BPDDS compared to RYGB (43, 45, 46). One Norwegian paper focused mainly on QoL-outcome after BPDDS-operation, and showed improved but fading QoL-score 5 years after operation (47). Complications and adverse effects are more frequent after BPDDS than RYGB, especially diarrhea, bloating and malnutrition (41-43, 48).

## 4. Material and methods

### 4.1 Patient data

We have collected data from all patients operated with the duodenal switch procedure at Nordland hospital 2006 – 2010, a total of 42 patients. 41 patients were still alive and were included in the study.

All relevant patient data including clinical parameters were obtained from the hospitals electronic health record DIPS. Some parameters were easily available as they were previously obtained systematically during an ongoing study; the remaining parameters were obtained by searching the patients' records for pre-defined clinical end-points.

### 4.2 QoL-score

The QoL-score questionnaire form used was PROSURG – Patient reported outcomes in obesity surgery (Figure 3 - Appendix), an obesity specific questionnaire currently under development by researchers at Høgskolen i Sogn og Fjordane/Helse Førde (49). It is aiming to be a questionnaire based on the Swedish Op-scale, adjusted for Norwegian conditions (50).

The questionnaire has not previously been used in research, but has been validated against the widely used SF-36 and our results can be compared to SF-36-scores and Op-scale. This is still unpublished data (49).

The questionnaire/PROSURG-forms were sent by ordinary mail to the patients, who then filled out forms and returned them. Patients were asked to score their health in general, their weight`s influence on activities of daily life - ADL (subdivided in 8 parameters), side effects and overall satisfaction. Scores for every parameter ranged 1 – 4 (Figure 3 - appendix). The questionnaires were sent to the address registered in the electronic health record DIPS, containing the survey form, information about the research project, an acceptance form and a pre-stamped return-envelope. A second round of questionnaires was sent to those who didn't return the first one. A total of 16 (39%) patients filled out and returned the survey form.

All the data concerning complications and QoL-scores were plotted into an Excel-file. Mean scores were calculated by dividing sum of each score by number of responders (n=16). Daily life influence scores were first calculated by dividing the sum of 8 sub-parameters by 8. The data were analyzed using SPSS Statistics program for Mac IOS.

### 4.3 Work process

Contact was established with the supervisors Torunn Nestvold, MD, PhD and Knut Tore Lappegård, MD, PhD December 2014. Project description was made and submitted March 2015. Literature search and writing of most of the introduction to the project report was done August 2015. Literature search was done primarily online searching PubMed, but also textbooks available online through the University library were used for this work.

Selection of questionnaire form for the QoL-score was made in September 2015 and was mailed to the patients October 2015. Answers were collected continuously from then until start of January after a second round of questionnaires were mailed to those who did not respond the first round. This work was delayed relative to the plan made in the project description.

Data collection from the electronic health record DIPS was made in the period January – March 2016. Data were analyzed using SPSS for Mac IOS and the project report was written April - May 2016. Throughout the period there were regular meetings between the student

and one or both supervisors, from April 2016 to completion in the end of May 2016 there were weekly meetings. Supervisors contributed with advice and guidance. Data collection, analysis and writing of the report is done entirely by the student.

### 4.4 Definitions

**Diarrhea:** ≥ 3 loose stools per day, or the patient experiencing diarrhea as a problem.

**DM type II**: diagnosed and medically treated.

**Early complication**: any unexpected complication related to the operation occurring within 30 days after surgery.

**Hypertension:** diagnosed and medically treated.

**Iron deficiency:** biochemically measured iron-levels below reference at last control, or more than once on previous controls.

**Last control:** last visit at the regional center for treatment of morbid obesity.

**Late complication**: any complication related to the operation occurring later than 30 days after surgery. Diarrhea and vomiting are registered as a late complication if present at last control.

**Late surgical complication:** same as above but excluding diarrhea and vomiting.

**Malabsorption:** Need for parenteral nutrition or need for nutritional supplements exceeding the recommended post-surgery supplements.

**OSAS:** elevated apnea-hypopnea-index (AHI-index) on nocturnal pulse oxymetry and indication for nocturnal continuous positive airway pressure or bilevel positive airway pressure (CPAP/BiPAP).

**Plastic surgery:** one or more plastic surgeries related to post-bariatric condition.

**Protein deficiency:** low S-Albumin in combination with hair loss or edema.

**Re-operation:** one or more operations for conditions directly related to the duodenal switch procedure. Re-operation may have been done after both early and late complication.

**Time of follow-up:** number of months between surgery and last control

**Vitamin B12-deficiency:** biochemically measured Vitamin B12-levels below reference at last control, or more than once on previous controls.

**Vitamin D-deficiency:** biochemically measured Vitamin D-levels below reference at last control, or more than once on previous controls.

**Vomiting:** regular vomiting after eating small portions of food.

**Weight loss:** we have measured the total weight loss (TWL), and percentage of total weight loss (%TWL). Many articles operate with percentage excessive weight loss as a parameter,

but %TWL is considered most representative (51). %TWL is TWL as percentage of the patients weight at first admission.

# 5. Results

## 5.1 Baseline characteristics (table 1)

Out of 41 patients there were 25 (61%) women and 16 (39%) men.

Mean age at surgery was 39,8 years ranging from 26 – 58 years.

Mean weight at first admission was 166,7 kg, ranging from 118,4 – 254,8 kg.

Mean time of follow-up was 44 months postoperatively, ranging from 10 – 102 months.

| Women | Men | Age (years) | Weight (kg) | Follow-up (Months) |
|---|---|---|---|---|
| **25 (61%)** | **16 (39%)** | **39,8** | **166,7** | **44** |

Table 1. Baseline data for the patient group.

## 5.2 Weight loss (table 2)

Mean weight loss one year after surgery was 72,6 kg, ranging from 35,4 – 110,9 kg.

Mean weight one year after surgery was 94,2 kg, ranging from 69 – 159,6 kg.

Mean weight at last control was 90,4 kg, ranging from 61,4 – 140,3 kg.

| | Weight (kg) | Weight loss (kg) | TWL (%) |
|---|---|---|---|
| **First admission** | **166,7** | **-** | **-** |
| **1 year after surgery** | **94,2** | **72,6** | **43,3** |
| **Last control** | **90,4** | **76,3** | **45,8** |

Table 2. Weight loss results.

## 5.3 Comorbidities (table 3)

15 (36,6%) patients had DM type II before surgery, 1 patient (2,4%) one year after surgery and no patients (0%) at last control.

18 (43,9%) patients had hypertension before surgery, 5 patients (12,2%) one year after surgery and 5 patients (12,2%) at last control.

19 patients (46,3%) patients had OSAS with CPAP/BiPAP before surgery, 4 patients (9,8%) one year after surgery and 2 patients (4,9%) at last control.

| | DM type II (%) | Hypertension (%) | OSAS (%) |
|---|---|---|---|
| **First admission** | **36,6** | **43,9** | **46,3** |
| **1 year after surgery** | **2,4** | **12,2** | **9,8** |
| **Last control** | **0** | **12,2** | **4,9** |

Table 3. Comorbidity results.

## 5.4 Complications

21 patients (51,2%) suffered complication(s) after surgery (figure 4).

5 patients (12,2%) suffered both early and late complication(s).

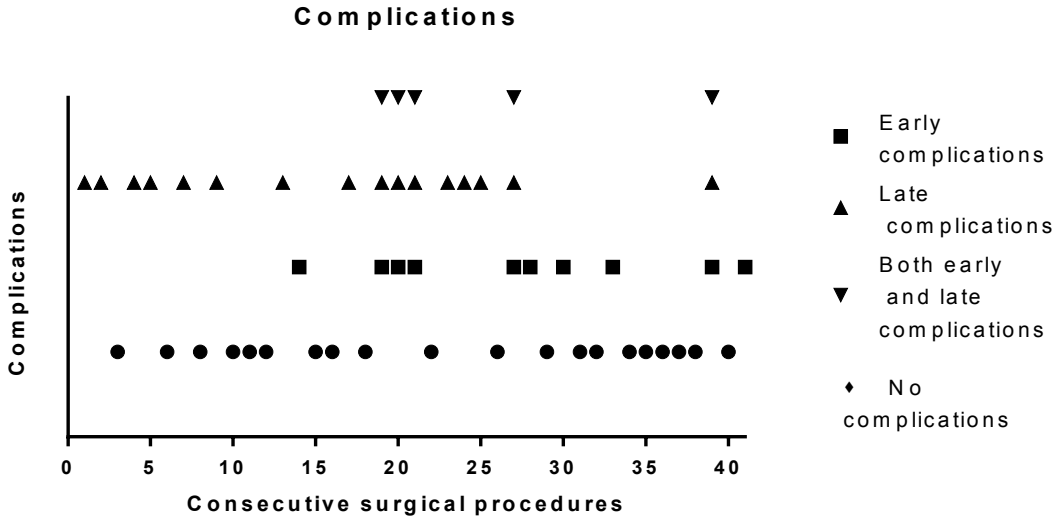


Figure 4. Complete overview of complications.

10 patients (24,4%) suffered a total of 14 early complications after surgery, of which anastomotic leakage and surgical wound-infection were the most common (Table 4).

| Anast. leakage | Wound - infection | Hematoma | Seroma | Kidney failure | Fistula |
|---|---|---|---|---|---|
| **4 (9,8%)** | **5 (12,2%)** | **2 (4,9%)** | **1 (2,4%)** | **1 (2,4%)** | **1 (2,4%)** |

Table 4. Early complications after BPDDS.

16 patients (39%) suffered a total of 26 late complications, of which malnutrition/malabsorption was most common. Diarrhea and vomiting were registered as late complications if present at last control (Table 5).

29,3% suffered a late surgical complication.

19,5% suffered from diarrhea one year after surgery.

19,5% suffered from diarrhea at last control.

12,2% suffered from vomiting one year after surgery.

4,9% suffered from vomiting at last control.

| Ventral hernia | Malab-sorption | Diarrhea | Vomiting | Fistula | Internal herniation | Stricture |
|---|---|---|---|---|---|---|
| **5 (12,2%)** | **6 (14,6%)** | **8 (19,5%)** | **2 (4,9%)** | **2 (4,9%)** | **2 (4,9%)** | **1 (2,4%)** |

Table 5. Late complications after BPDDS.

11 patients (26,8%) were re-operated at some point for a total of 16 conditions, including elongation of the common channel, anastomotic leakage and internal herniation (Table 6).

| Common channel elongation | Ventral hernia | Ileus | Wound - revision | Dilated alimen. limb | Hema-toma | Internal hern. | Anast. leak. | Fistula |
|---|---|---|---|---|---|---|---|---|
| **2** | **3** | **1** | **2** | **1** | **1** | **1** | **4** | **1** |

Table 6. Re-operation after BPDDS.

## 5.5 Deficiencies and plastic surgery

51,2% had iron deficiency after surgery

43,9% had vitamin D-deficiency

2,4% had vitamin B12-deficiency.

22,0% underwent plastic surgery related to the weight loss.

## 5.6 QoL-scores (table 7)

Mean PROSURG-score was 3,00 on a scale from 1 – 4.

Mean *overall health* score was 2,44 on a scale from 1 – 4.

Mean *ADL-influence* score was 3,1 on a scale from 1 – 4.

Mean *Side effects* score was 2,81 on a scale from 1 – 4.

Mean *satisfaction* score was 2,94 on a scale from 1 – 4.

| | PROSURG | Health | ADL-influence | Side effects | Satisfaction |
|---|---|---|---|---|---|
| **Av. score** | **3,0** | **2,44** | **3,1** | **2,81** | **2,94** |

Table 7. PROSURG-results.

### 5.7 Learning curve

Concerning early complications there was no obvious pattern. In fact the longest period of no early complications was the first 14 patients operated (Figure 4).

Concerning late complications there was no obvious pattern, though there were less late complications in the last 10-15 patients operated (Figure 4).

## 6. Discussion

One of the main goals of this assignment was to investigate how the patients having undergone BPDDS-surgery are doing 5 – 10 years after surgery. We wanted to assess this by making them score their outcomes through a QoL-questionnaire, and further correlate these scores to complications and effect on comorbidities. Unfortunately our method of data collection on the QoL-score was inadequate and only 39% of the patients filled out the PROSURG-questionnaire. The results limit the possible outcomes of the project report, and the main focus is therefore the complications after and comorbidities before and after surgery.

### 6.1 Weight loss

The most obvious finding in this report is the substantial weight loss seen in patients operated with BPDDS. In our patient group, the mean loss was 72,6 kg one year after surgery. This is expected, and on the same level as seen after BPDDS worldwide (52, 53).

### 6.2 Comorbidities

Concerning obesity-related comorbidities we compared the prevalence before and after surgery. Of the relevant comorbidities, DM type II, hypertension and OSAS were the comorbidities most frequently reported in the electronic patient record DIPS. All of the patients operated had a follow-up control one year after surgery, while only 25 (61%) five year after. Status concerning comorbidity and complications one year after surgery is therefore most used in this report. However, in some parameters we have used *last control* as an end-point, since mean time of follow-up was 44 months.

The results on comorbidities are in line with other comparable projects (45, 52). They are convincing that BPDDS is in fact an effective treatment for obesity-related comorbidities, and probably an explanation why this surgery and bariatric surgery in general has expanded as a treatment for obese patients worldwide.

## 6.3 Complications

The possible complications seen after BPDDS are also present in our patient material. A *complication* is an inaccurate term. It can be on a range from life threatening conditions to mild symptoms. Complications can also be highly subjective; as an example can different patients experience the same amount and frequency of diarrhea in different ways. Especially complications like diarrhea and vomiting can be due to non-compliant post-surgical eating habits. These are challenges in computing rates of complications in our report.

For diarrhea and vomiting we have set objective criteria (see definitions in 5.3), but we have also tried to adjust for subjective patient experience by listing diarrhea as a complication if the patient reports diarrhea as a problem, even though there may not be more than 3 loose stools per day. Likewise regular vomiting after meals are not listed as complication if patients are eating larger portions than recommended. Since diarrhea and vomiting are common complications, and are more difficult to measure than other complications, we have chosen not to include diarrhea and vomiting when reporting *late surgical complications*.

The rates of complications in this report indicate that a surgical procedure is not a "quick fix" for obesity and related comorbidities. The patients undergoing a BPDDS should be aware of the risks of both early and late complications. There is also a high risk of needing a re-operation and/or plastic surgery following BPDDS.

The complication rates seen in our study are similar to rates in other similar studies regarding diarrhea, vomiting and malnutrition (41, 44, 48), anastomotic leakage and wound-infection (54). For ileus (52), and internal herniation the rates were also approximately at the same level (55).

## 6.4 Quality of life

The response on PROSURG was disappointingly low. The mean overall score among the 16 patients who filled out the questionnaire was 3,00 out of 4,00.
Mean scores on influence on activities of daily life were 3,05, meaning **mildly distressed by their weight or body shape** after surgery. These results are comparable to post-surgery results on the SF-36 score (56).

It is difficult to draw any conclusions from these scores. It may be that the patients filling out the form were more satisfied then the ones not filling out the form, though we found no correlations between PROSURG-response and complications.

### 6.5 Learning curve

The BPDDS-procedures were performed by one head surgeon, one assisting surgeon and a standard surgical team of two surgical nurses, one anesthesiology-nurse and one anesthesiologist. A total of 5 surgeons performed BPDDS at Nordland hospital during this period, all of them with different experience in bariatric surgery. In this small cohort of 41 patients there were no consistency concerning learning curve theory. The first early complication appeared on patient number 14. It should be mentioned that the head surgeon participating in most of the procedures had experience in doing BPPDS before attending our hospital.

We found no obvious learning curves. This may indicate that individual variations between patients and between surgeons are of greater importance than department experience when it comes to risks for complications.

### 6.6 Project limitations

The patient material in our study is small with only 41 patients. It is a retrospective study with the possibility of recall-bias, especially concerning the QoL-score. We have no control group to compare results with.

When collecting complication data, we have searched through the patient records, mainly discharge reports and outpatient controls. This means that the registering of an incidence as a complication depends on it being registered in the patient record. This is a source of uncertainty, for example some incidents like a self-limiting wound-infection, hematoma or seroma might go unmentioned in the record by one surgeon, and not by another. We lack an objective standard for some of the complications registered, and rely only on the health record descriptions. This should be taken into account when interpreting the complication rates.

Some of the patients may have received follow-up treatment at a hospital other than Nordland hospital, and health records of such treatment have not been available for us in this study, especially for plastic surgery this is a source of uncertainty.

For the QoL-scores it would have been interesting to collect scores before and after surgery to see a possible change. Because our study is retrospective, this was not possible for us. Our results are limited to giving post-surgery information about quality of life. As our response on the PROSURG-questionnaire was low, it cannot give any significant information about quality of life after BPDDS at Nordland hospital. We should have considered using a QoL-questionnaire that has been used in research before, making it easier to compare our post-surgery scores with previous studies.

Our learning curve data do not take into account variables like surgeon-experience, patient health status, operating schedule etc., and can only give information about the department as a unit.

Our patients have an average follow-up time of 44 months. Some patients had no follow-up after one year. Our report cannot give information on long-term outcomes exceeding one year. This is a limitation as the first year after such a procedure involves a significant change in GI-function and life style.

### 6.7 Project strengths

We have done a monocenter study. The patients are a homogeneous group selected for treatment by the same objective criteria. One person has collected data, and therefore there is no inter-individual variability in data collection.

Patients had already been enrolled in another research project, and many data like weight, medications and comorbidities was systematically collected. The data have been collected exclusively from medical health records and not from medical registers; this reduces the risk of missing relevant data or errors in data collection.

## 7. Conclusion

Based on our findings, BPPDS seems to be a highly effective treatment for obesity and obesity-related comorbidities.

The expected weight loss one year after surgery is substantial. At last control, which in our study was average 44 months after surgery, the weight loss was maintained.

The improvements in the comorbidities DM type II, hypertension and OSAS are as substantial as the weight loss, and at last control it is close to total resolution.

Our findings indicate that the procedure carries a high risk of both early and late complications, re-operation and need for plastic surgery. For example diarrhea, a late complication, is present in 1 out of 5 operated patients.

This retrospective study did not reveal any changes in complication rate in the study period, indicating that the hypothesis of a learning curve effect did not occur.

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# 9. Appendix

**Patient Reported Outcomes in Obesity Surgery (PROSURG)**

- Hvordan er *helsa* di for tida?

| Dårlig | Ikke helt god | God | Svært god |
|---|---|---|---|
| ○ | ○ | ○ | ○ |

- Føler du at din *vekt eller kroppsform* plager deg innenfor områdene nedenfor?
(kryss av det alternativet som passer best for deg i dagens situasjon)

| Områder | Betydelig plaget | Moderat plaget | Mildt plaget | Ikke plaget |
|---|---|---|---|---|
| 1. Vanlige fysiske aktiviteter (spasere, gå opp trapper og lignende) | ○ | ○ | ○ | ○ |
| 2. Smerter i kroppen | ○ | ○ | ○ | ○ |
| 3. Diskriminering eller ufin oppførsel | ○ | ○ | ○ | ○ |
| 4. Søvn | ○ | ○ | ○ | ○ |
| 5. Seksualliv | ○ | ○ | ○ | ○ |
| 6. Vanlig sosial omgang | ○ | ○ | ○ | ○ |
| 7. Arbeid, skolegang eller andre daglige gjøremål | ○ | ○ | ○ | ○ |
| 8. Selvfølelse | ○ | ○ | ○ | ○ |

- Er du plaget med *bivirkninger* i forhold til at du har gjennomgått overvektskirurgi?

| Betydelig plaget | Moderat plaget | Mildt plaget | Ikke plaget |
|---|---|---|---|
| ○ | ○ | ○ | ○ |

- Hvor fornøyd er du, alt tatt i betraktning, med *behandlingsresultatet* etter overvektskirurgi?

| Svært fornøyd | Fornøyd | Usikker | Misfornøyd |
|---|---|---|---|
| ○ | ○ | ○ | ○ |

Figure 3. PROSURG-questionnaire (Norwegian translation).