Tailoring Limb length based on total small bowel length in omega-loop gastric bypass

Published: 02-12-2019
Last updated: 18-07-2024

To investigate whether adjusting the length of the BP-limb of the OAGB based on measured total small bowel length leads to more weight loss, resolution of co-morbidities with less development of micronutrient deficiencies and bowel movements...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52591

Source
ToetsingOnline

Brief title
Limb Length OLGB based on small bowel length

Condition

- Other condition
- Malabsorption conditions
- Gastrointestinal therapeutic procedures

Synonym
bariatric surgery, weight reduction surgery

Health condition

obesitas behandeling

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: FitForMe BV,Stichting CON-VOLUME research

Intervention

Keyword: bp-limb, length, OLGB, small bowel

Outcome measures

Primary outcome

Percent total weight loss (%TWL) at 5 years.

Assumptions : Control group : TWL of 35% (SD 12%)

Experimental group : TWL of 40% (SD 12 or 9%)

(Absolute difference TWL 5% with possible smaller SD)

Definition : TWL = ([initial weight - attained weight]/ initial weight) * 100

Secondary outcome

1) Percent of total weight loss (%TWL) at 1,2,3,and 4 years.

2) Percent excess weight loss (%EWL) at 1,2,3, 4 and 5 years.

Definition: %EWL (Initial Weight - Postop Weight) / (Initial Weight -

Ideal Weight)

(ideal weight is defined by the weight corresponding to a BMI of 25

kg/m2)

3) Percent excess BMI loss (%EBMIL) at 1,2,3, 4 and 5 years.

Definition: %EBMIL (ΔBMI / (Initial BMI - 25)) * 100]

4) Proportion of patients with 22 <= BMI <= 30 Kg/m2 at 1,2,3, 4 and 5 years

5) Mean number of daily bowel movements in the last two weeks at 6 months, 1,2,3, 4 and 5 years.

6) Mean number of days with daily bowel movements > 3 in the last two weeks at 6 months, 1,2,3, 4 and 5 years.

6) Quality of life measured by the RAND-36 questionnaire at 6 months, 1,2,3, 4 and 5 years.

7) percentage of patients experiencing moderate to severe dumping symptoms defined by the Dumping Severity Score (DSS) at 6 months, 1,2,3, 4 and 5 years. Moderate to severe is defined as 3 or more dumping symptoms with a severity score of 2 or 3 on a 4-point Likert scale. Symptoms are divided in two categories, e.g. early and late,
as described by Emous et.al. (7)

8) percentage of patients who have neither deficiencies of iron, nor vit. D, nor vit B12 without extra suppletion, at 6 months, 1,2,3, 4 and 5 years . Deficiencies are based on the local normal laboratory values.

9) Proportion of patients who have a deficiency at 6 months, 1,2,3, 4 and 5 years, or received extra suppletion for:

- iron (ferritin)

- vitamin B12

- vitamin D3

- Vitamin B1

- Vitamin B6

- Folic acid

- Vitamin A

- Vitamin D

- Calcium

- Phosphate

- Albumin

- Zinc

- Copper

- Selenium

10)Proportion of patients at 1,2,3, 4 and 5 years without diabetes, both with remission and without de novo, defined as an HbA1c less than 48 mmol/mol without diabetes medication in the last 6 months.

11)Proportion of patients at one year and two years with improvement of diabetes, defined as a reduction of HbA1c of 10mmol/mol or more but not reaching remission criteria and/or less anti-diabetic medication.

12)Proportion of patients at 1,2,3, 4 and 5 years with remission of hypertension, defined as a blood pressure of 140/90 mmHg or less without antihypertensive medication.

13)Proportion of patients at 1,2,3, 4 and 5 years with improvement of

hypertension, defined as a lower blood pressure and/or less antihypertensive

medication (not reaching the criterion of remission).

14)Proportion of patients at 1,2,3, 4 and 5 years with resolution of sleep

apnea, defined by cessation of CPAP or other devices use, documented by

their own pulmonologist

15)

Study description

Background summary

One-anastomosis gastric bypass (OAGB) is currently one of the most effective treatment options for morbid obesity. It is technically a more simple procedure compared to the RYGB and has proven in some studies to have a better outcome in terms of weight loss and reduction of co-morbidities.
The aim of the weight loss surgery is to achieve an optimum weight loss aiming at a BMI of 25 kg/m2 in combination with a minimum of side effects, like vitamin, macronutrient, mineral deficiencies and diarhea.
There is substantial variation in the determination of the biliopancreatic (BP) limb length of the anastomosis with some surgeons using a fixed length and some a length based on the initial BMI. The length varies between less than 150 cm to more than 250 cm. A recent retrospective study by Charalampos et.al. adjusting limb length from 200 to 300 cm depending on BMI resulted in on average comparable EWL when corrected for initial BMI. The average BMI after 36 months was 27.5 Kg/m2 (± 5.3). This strategy of BP based on initial BMI results in 16% of patients with a final BMI > 33 and 16% with less than 22.
Furthermore despite (over-the-counter) multivitamin suppletion 20% or more patients developed de novo deficiencies of iron, vit B12, vit D, and/or minerals in the first postoperative year (1).
Ahuja et.al. adjusted the limb length from 150 to 250 cm depending on BMI and also found increasing number of deficiences of micro-nutrients with increasing BP length (2). In this study patients were advised to use a multivitamin supplement, however no specific brand was used.
In RYGB surgery there is some evidence for a role of length of the BP limb on weight loss. Nergaard et al. performed a RCT comparing a BP limb of 200 to 60 cm with a alimentary limb of 60 and 150 cm respectively. The longer limb length led to more weight loss but also to more bowel movements and micronutrient

deficiencies (3). Total small bowel length was measured in their whole patient population and varied between 480 and 870 cm but was not taken in to account in terms of stratification.
Zorilla et.al performed a systematic review on limb length in RYGB and found 13 studies meeting adequate quality (4). Weight loss on the whole was better in patients with longer BP limbs.
There is evidence in the RYGB literature that the length of the common channel plays a role in the outcome of surgery both in weight loss and in micronutrient deficiencies. It is known that the length of the total small bowel can vary considerably with measured values between 350 to more than 1000 cm (5).
In this study in 443 patients TSB median length was 690 cm (women 678±92, men 728±85 cm) with a SD of 94 cm. In males 3% had a bowel length < 400 cm and 15% > 800, in females 2% had a length of < 400 cm and 5% > 800 cm.
In current practice in OAGB surgery surgeons use a fixed BP-limb length or adjust the length to the initial BMI. Total weight loss varies in literature between 30-35 % with SD up to 8.5%, aiming at a BMI result between 23 and 30 Kg/m2
The contribution of the length of the residual small bowel, total minus the BP-limb, on weight loss and deficiencies has up till now not been studied in OAGB surgery

Study objective

To investigate whether adjusting the length of the BP-limb of the OAGB based on measured total small bowel length leads to more weight loss, resolution of co-morbidities with less development of micronutrient deficiencies and bowel movements compared a to standard limb length in OAGB in patients using a standardized multivitamin supplement (FitForMe Primo).

Primary Objective:
To compare the percent total weight loss (%TWL) at 5 years between the group with the standard BP-length and the group with a adjusted BP-length .

Secondary Objective(s):
1) To compare the percent of total weight loss (%TWL) between the groups at 1,2,3 and 4 years.

2) To compare the percent excess weight loss (%EWL) between the groups at 1,2,3, 4 and 5 years.
Definition: %EWL (Initial Weight - Postop Weight) / (Initial Weight - Ideal Weight)
(ideal weight is defined by the weight corresponding to a BMI of 25 kg/m2)

3) To compare the percent excess BMI loss (%EBMIL) between the groups at 1,2, 3, 4 and 5 years.
Definition: %EBMIL (ΔBMI / (Initial BMI - 25)) * 100)

4) To compare the proportion of patients with 22 <= BMI <= 30 between the groups at 1,2 3, 4 and 5 years.

5) To compare the mean number of daily bowel movements and number of days with daily bowel movements > 3 over in the last two weeks at 6 months, between the groups at 1,2, 3, 4, and 5 years.

6) To compare the Quality of life measured by the RAND-36 questionnaire between the groups at 6 months, 1,2, 3, 4 and 5 years

7) To compare the percentage of patients experiencing moderate to severe dumping symptoms defined by the Dumping Severity Score (DSS) (see Emous et.al.) at 6 months, year 1, 2, 3, 4 and 5 between the groups.

8) To compare the proportion of patients in the two groups who have neither deficiencies of iron, nor vit. D, nor vit B12 without extra suppletion, at 6 months, 1, 2, 3, 4 and 5 years. Deficiencies are defined by the lower border of the local normal laboratory values.

9) To compare the proportion of patients in the two groups who have a deficiency at 6 months, 1, 2, 3, 4 and 5 years, or received extra suppletion for :
- Vitamin B1
- Vitamin B6
- Folic acid
- Vitamin A
- Vitamin D
- Calcium
- Phosphate
- Albumin
- Zinc
- Copper
- Selenium

Deficiencies are defined by the lower border of the local normal laboratory values.

10)To compare the proportion of patients between the groups at 1, 2, 3, 4 and 5 years without diabetes, both those with remission of diabetes and those without de novo diabetes, defined as an HbA1c less than 48 mmol/mol without diabetes medication in the last 6 months.
11) To compare the proportion of patients between the groups at 1, 2, 3,4 and 5 years with improvement of diabetes, defined as a reduction of HbA1c with at least 10 mmol/mol, but not reaching remission criteria and/or less anti-diabetic medication.
12) To compare the proportion of patients between the groups at 1, 2, 3, 4 and 5 years with remission of hypertension, defined as a blood pressure of 140/90 mmHg or less without antihypertensive medication.

13) To compare the proportion of patients between the groups at 1, 2, 3, 4 and 5 years with improvement of hypertension, defined as a lower blood pressure of at least 10 mm Hg systolic and/or 5 mmHg diastolic, and/or less antihypertensive medication (not reaching the criterion of remission).
14) To compare the proportion of patients between the groups at 1, 2, 3, 4 and 5 years with resolution of sleep apnea, defined by cessation of CPAP or other devices use, documented by their own pulmonologist
15) To perform analysis of the above parameters in the subgroups with TSBL 500-700 and >700.
16) To compare within the standard group of patients with an allocated BP-limb length of 150 cm those with a TSBL < 500 to those with a TSBL 500-700 and to those with TSBL >700 cm on the above mentioned parameters.
17) to perform regression analysis on other factors possibly contributing to the primary or secondary outcomes.

Study design

This is a double-blind randomized 5 year study with two arms. Patients who are scheduled for primary OLGB surgery are eligible when during the surgery total small bowel length can be measured and if they are able to swallow the Fitforme WLS primo multivitamin capsule. Patients will be allocated to one of the two surgical treatment arms by randomization at the beginning of the operation. Only the operating surgeon is aware of the allocation and will document total small bowel length, treatment allocation and BP-length in a coded database. Both the TSBL and the length of the BP-limb will not be documented in the patient file. The investigators and the patient will not be informed on the BP-limb length during the study.
Patients with a TSBL of less than 500 cm will recieve the same treatment whether they are allocated to the standard arm or to the alternative arm. For logistic reasons they will also be randomized and those with the experimental arm will be combined with the standard group for the analysis. Based on literature the percentage patients with a TSBL < 500 cm will be probably less than 5, not causing statistical issues (5).
Patients with a small bowel that could not be measured during surgery will be treated according to the current daily practice and will not enter the study.

Intervention

Patients will be randomly allocated to one of the two treatment arms :
- 1. A standard BP-limb length of 150 cm
- 2. A BP-limb length depending on total small bowel length (TSBL) measured during the surgical procedure :
- TSBL : < 500 cm : 150 cm
- TSBL : 500-700 cm : 180 cm
- TSBL : > 700 cm : 210 cm

Study burden and risks

burden and risks :
1. a full measurement of the small bowel length during surgery includes a small risk of laceration of the bowel. The surgeons are experienced in this technique of measuring as they need to measure the distance from Treitz to the planned anastomosis during the standard procedure of the OAGB.
2. the adjusted lengths of the biliopancreatic limb based on total small bowel length are within the currently used lengths in literature and are considered safe. Whether this leads to less or more adverse events in the patients after the surgery is part of the investigation. However, all expected side effects are treatable.

Potential benefits are a better outcome of weight reduction compared to current usual care without increases in vitamin and/or micronutrient deficiencies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

obesity class II with co-morbidity or clas III in accordance with IFSO criteria
agreed to have a OLGB

Exclusion criteria

BMI > 50 kg/m2
pregnancy planning
non-compliant
\addiction behaviour
history of bowel disease
intolerance of FitForMe multivitamin

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2020
Enrollment:	212
Type:	Actual

Ethics review

Approved WMO Date:	02-12-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	27-01-2020
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	28-11-2022
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27559
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71064.099.19