OAGB vs RYGB-Data from a RCT made in Switzerland

Dr Th Köstler

Leiter Adipositas Zentrum; Schlieren-ZH

(No disclosure)

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Bariatric surgery in Switzerland 2023

4.2.1 Basiseingriffe

(Definition: Etablierte Primär-Eingriffe)

- Magenband (Adjustable Gastric Banding, AGB)
- Schlauchmagen (Sleeve Gastrectomy, SG)
- Proximaler Roux-Y Magen-Bypass (Gastric Bypass, RYGBP; alimentärer Schenkel ≤150 cm)

4.2.2 Komplexe Eingriffe

- Bilio-pankreatische Diversion (Bilio-Pancreatic Diversion, BPD)
- Bilio-pankreatische Diversion mit Duodenal Switch (BPD-DS)
- Zweizeitiges Vorgehen (Ersteingriff Schlauchmagen, Zweiteingriff Duodenal Switch, oder proximaler Magen-Bypass)
- Re-Do-Operationen (Verfahrenswechsel)
- Primäreingriffe bei Patienten mit St n nach Antireflux-Chirurgie
- Revisions-Operationen (Wiederherstellung der Anatomie, Eingriffe an Magenpouch, exakte Definitionen vgl Liste der CHOP-Codes auf: www.smob.ch)
- Eingriffe bei Diabetes Typ 2 und BMI >= 30

4.2.3 Experimentelle Eingriffe

Experimentelle Eingriffe dürfen nur im Rahmen einer vom lokalen ethischen Komitee akzeptierten, prospektiven Studie durchgeführt werden (gemäss „Verordnung über klinische Versuche mit Ausnahme klinischer Versuche mit Medizinprodukten" ab 1.1.2013).

- Distaler Roux-Y Magen-Bypass (Common Channel ≤100 cm)
- Magenplikatur (Gastric Plication/Greater Curvature Plication)
- Magenstimulation (IGS/Implantable Gastric Stimulation)
- Vagusblockade (VBLOC/Vagal Block for Obesity Control)
- Ileales Interponat (Ileal Transposition)
- Omega-Loop Magen-Bypass (Mini-Gastric Bypass)
- Duodeno-jejunaler Bypass mit/ohne Magenschlauch (Duodeno-Jejunal Bypass m/o Sleeve Gastrectomy)
- Endoskopische interventionelle Verfahren
- Alle anderen Verfahren, welche nicht in den Punkten 4.2.1 und 4.2.2 erwähnt sind.

permitted bariatric procedures

- Proximal Roux-en Y gastric bypass
- Gastric Sleeve,
- Gastric Banding
- Biliopancreatic Diversion (Scopinaro)

Not permitted bariatric procedures

- **OAGB**
- Endoscopic procedures……

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OAGB vs RYGB-Data from a RCT made in Switzerland

The study is conducted as a **non-inferiority trial** with the sample-size calculations performed accordingly.

EWL 12 months after surgery is the primary endpoint, whereas

-3-year EWL,

-morbidity, mortality, remission of obesity related comorbidities,

-quality of life (QOL)

-and hormonal and lipid profile changes are secondary endpoints.

Prospective Randomized Controlled Trial of Laparoscopic Roux-Y-Gastric Bypass Versus Laparoscopic One-Anastomosis Gastric Bypass for Obesity: One-year results of weight loss, and metabolic changes

Tarik Delko[*,1,2 +], Marko Kraljević[*,1,2], Ioannis Lazaridis[2], Thomas Köstler[1], Anne Jomard[3,4], Amy Taheri[3,5], Thomas Lutz[5], Elena Osto[3,4], Urs Zingg[1]

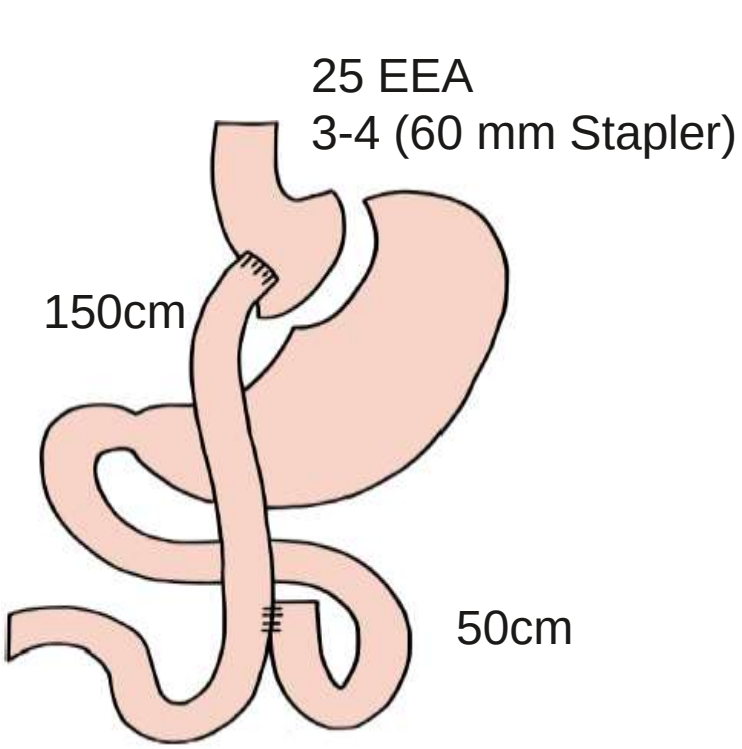
October 2016 to Avril 2018 at the Obesity & Bariatric Surgery Centre Limmattal,

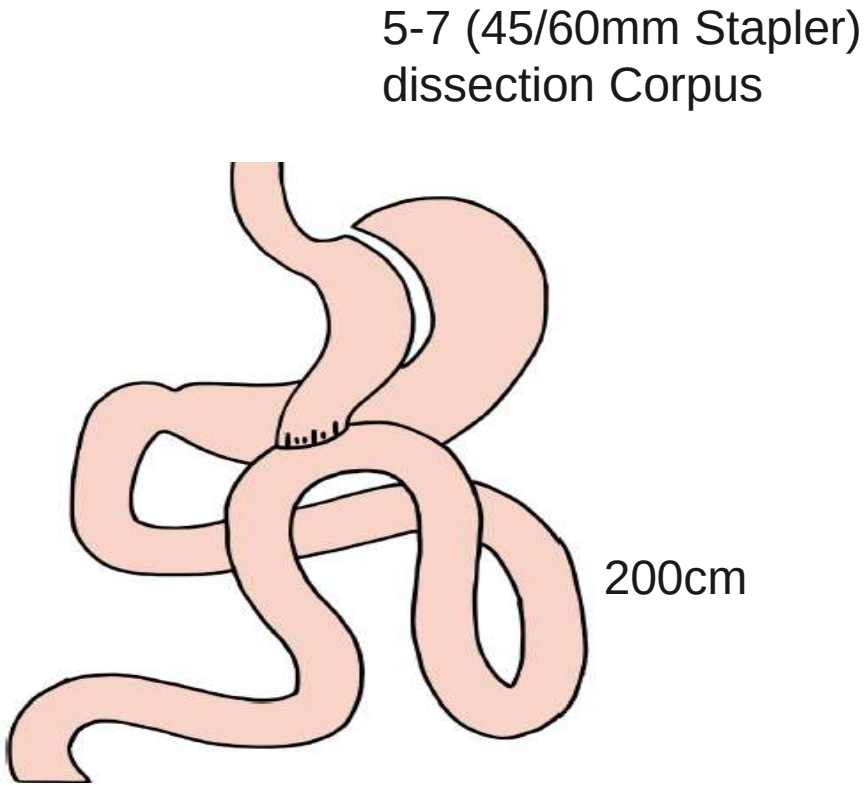
Using a block-randomization method with a **1:1 ratio**, 80 eligible patients were assigned to undergo RYGB or OAGB

All patients were randomized and operated on by **one surgeon**

Surgical experience prior to study entry: RYGB>2000, OAGB<15

Prospective Randomized Controlled Trial of Laparoscopic Roux-Y-Gastric Bypass Versus Laparoscopic One-Anastomosis Gastric Bypass for Obesity: One-year results of weight loss, and metabolic changes





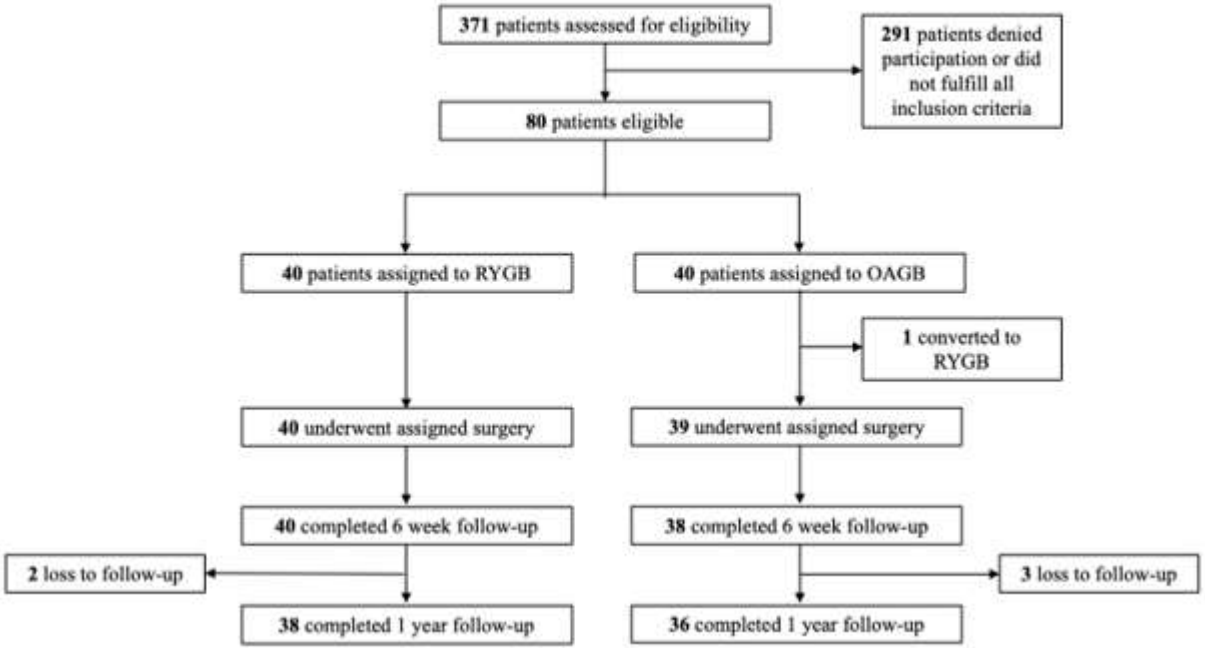
Prospective Randomized Controlled Trial of Laparoscopic Roux-Y-Gastric Bypass Versus Laparoscopic One-Anastomosis Gastric Bypass for Obesity: One-year results of weight loss, and metabolic changes

	per protocol population	RYGB group	OAGB group
n	79	40	39
age, y	40.2 (11.5)	40.4 (12.1)	39.9 (10.9)
sex			
male, n	9 (11.4)	7 (17.5)	2 (5.1)
female, n	80 (88.6)	33 (82.5)	37 (94.9)
weight, kg	109.6 (14.2)	111.2 (15.9)	107.9 (12.2)
BMI, kg/m²	39.8 (3.2)	39.7 (2.8)	39.9 (3.6)
T2DM/prediabetes, n	18 (22.8)	11 (27.5)	7 (17.9)
HbA1c, %	5.6 (0.6)	5.6 (0.6)	5.5 (0.6)
with antidiabetics, n	7 (8.9)	6 (15.0)	1 (2.6)
with insulin, n	1 (1.3)	1 (2.5)	0 (0.0)
arterial hypertension, n	41 (51.9)	20 (50.0)	21 (53.8)
with medication, n	18 (22.8)	9 (22.5)	9 (23.1)
hyperlipidemia, n	37 (46.8)	21 (52.5)	16 (41.0)
with medication, n	5 (6.3)	5 (12.5)	0 (0.0)
reflux, n	42 (53.2)	18 (45.0)	24 (61.5)
with medication, n	28 (35.4)	10 (25.0)	18 (46.2)
sleep apnea, n	21 (26.6)	11 (27.5)	10 (25.6)

There were no statistically significant differences in patients' characteristics in the two study groups at baseline

Prospective Randomized Controlled Trial of Laparoscopic Roux-Y-Gastric Bypass Versus Laparoscopic One-Anastomosis Gastric Bypass for Obesity: One-year results of weight loss, and metabolic changes

Figure 1



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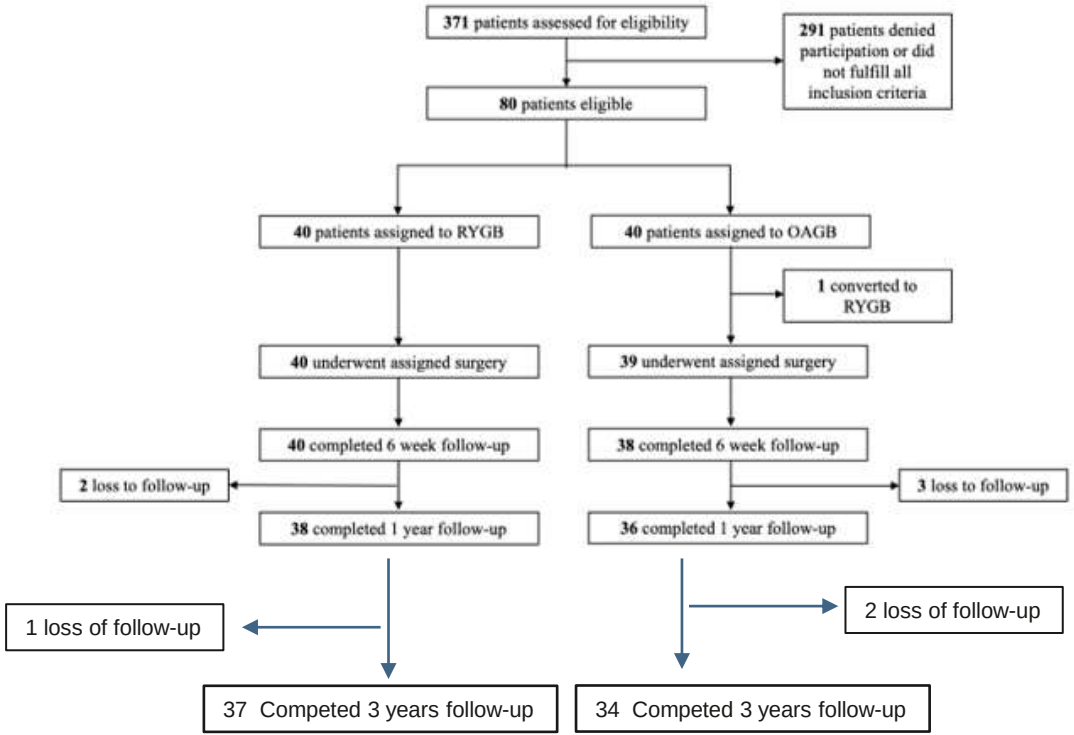
Prospective Randomized Controlled Trial of Laparoscopic Roux-Y-Gastric Bypass Versus Laparoscopic One-Anastomosis Gastric Bypass for Obesity: One-year results of weight loss, and metabolic changes

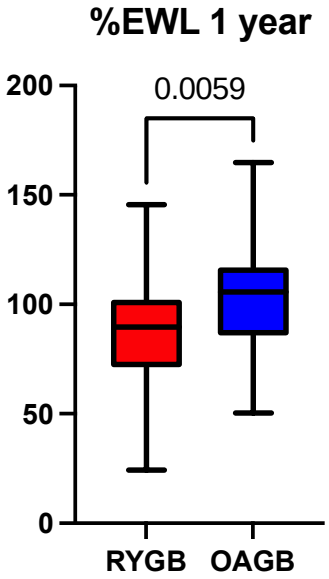
284 **Figure 1**

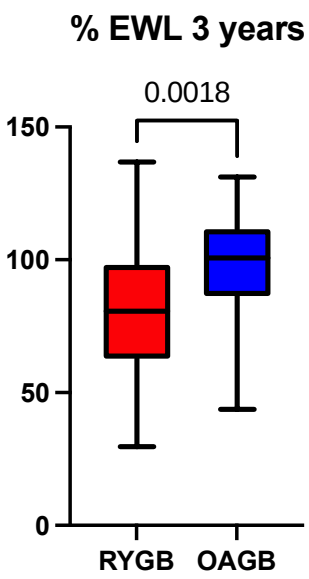


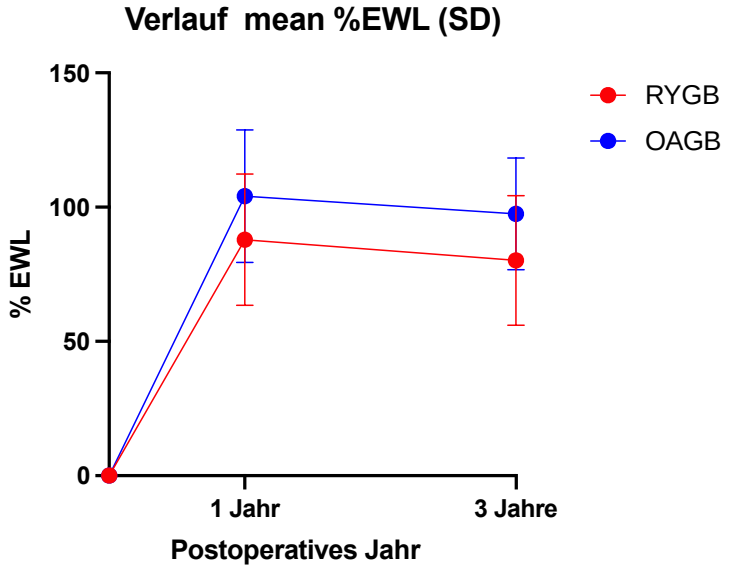
Results:

primary endpoint : excess weight loss (EWL) at one and three years after surgery

	RYGB	OAGB	P
% EWL 1y	87.9 (24.4)	104.1 (24.6)	**0.0059**
% EWL 3y	80.2 (24.1)	97.5 (20.8)	**0.0018**



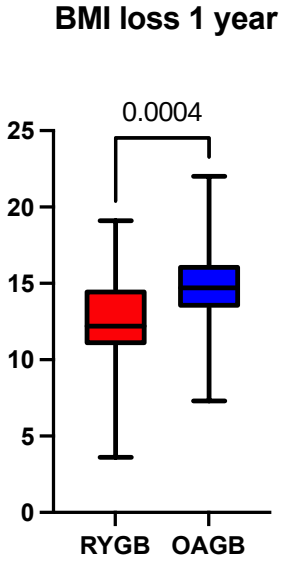


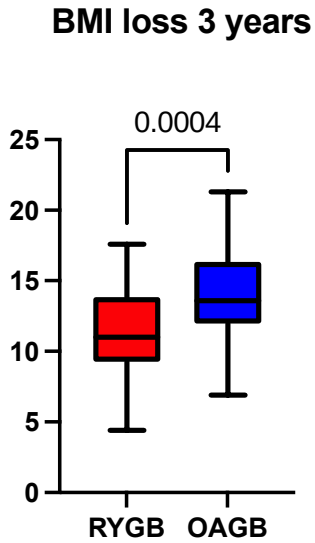


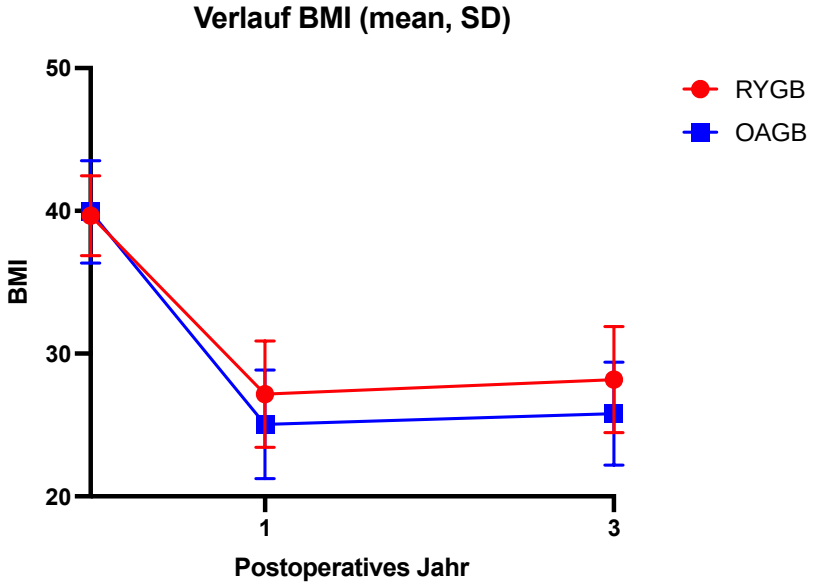
Results

primary endpoint : Mean BMI loss (SD) at one and three years after surgery

	RYGB	OAGB	P
BMI loss 1 y	12.4 (2.8)	14.8 (2.6)	**0.0004**
BMI loss 3 y	11.4 (3.1)	14.2 (3.3)	**0.0004**



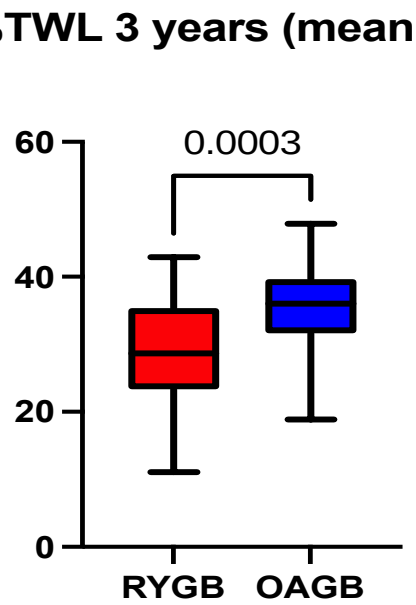




Results:

primary endpoint : % TWL (SD) at one and three years after surgery

	RYGB	OAGB	P
%TWL 1y	31.5 (7.1)	37.4 (6.1)	**0.0004**
%TWL 3y	28.8 (7.7)	**35.4 (6.8)**	**0.0003**



Results

Secondary endpoint: Early postoperative morbidity (<30 days)

	RYGB (n=40)	OAGB (n=39)	
length of stay	3,5 days	3,3 days	
«Leak»	0	0	
Obstruction	0 (1)	0	
Bleeding	2	4	P = 0.3844
Infection	2	0	P = 0.1613
Clavien-Dindo 3-4	4	4	P = 0.9704

After changing to Staple line Reinforcement: No more bleedings

Results

Secondary endpoint : late morbidity 3 Years

	RYGB	OAGB	P
small bowel obstruction	1 (2.5)	0 (0)	1.000
anastomotic stenosis	2 (5)	3 (7.7)	**0.675**
marginal ulcer	4 (10)	11 (28.2)	**0.048**
internal hernia	2 (5)	0 (0)	**0.439**
dumping	5 (12.5)	3 (7.7)	0.712
Insufficient weightloss/weight regain -inadequate weight loss: EWL < 50% and/or BMI > 35 kg/m2 -weight regain: 15% of the lowest post-operative weight	4 (10)	0 (0)	**0.116**
chronic abdominal pain	1 (2.5)	1 (2.6)	1.000
de novo reflux symptoms	1 (2.5)	4 (10.3)	0.200
total	**19**	**22**	

6 W. 40 mg Pantoprazol

Results Late complications (3 years) > **Clavien- Dindo III (%)**

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	RYGB	OAGB
Small bowel obstruction	1	0
Marginal ulcer (Pouch resection and Oesophagojejunostomy)	1	1
Internal Hernia	2	0
Weight regain (Pouch resizing + Minimizer" banding")	1	0
Chronic abdominal pain	1	1
Reflux (Biliary reflux, RYGB reconstraction)	0	3
Dumping (reversal into normal anatomy)	0	1
Total	6	6

Results

Secondary endpoint : early and late morbidity (3 Years)

Mean albumin (g/l) (SD)

	RYGB	OAGB	P
Baseline	45 (3.2)	44 (3.5)	0.132
1 y	43 (2.9)	41.7 (3.6)	0.093
3 y	41.9 (2.8)	41.3 (2.6)	0.377

Mean prealbumin (g/d) (SD)

	RYGB	OAGB	P
Baseline	307 (34.2)	313 (45.6)	0.556
1 Jahr	257 (57.7)	212 (65.2)	**0.003**
3 Jahre	234 (40.9)	208 (35.6)	**0.008**

Mean vitamin D3 nmol/l (SD)

	RYGB	OAGB	P
Baseline	17 (6.7)	17 (7.5)	0.939
1 y	29 (9.8)	22 (8.3)	**0.006**
3 y	28 (9.7)	25 (8.9)	0.278

Mean parathyroid hormon (PTH) (pg/ml) (SD)

	RYGB	OAGB	P
Baseline	39 (13.5)	44 (15.3)	0.353
1 y	28 (11.6)	38 (16.5)	**0.005**
3 y	34 (12.5)	53 (26.5)	**0.001**

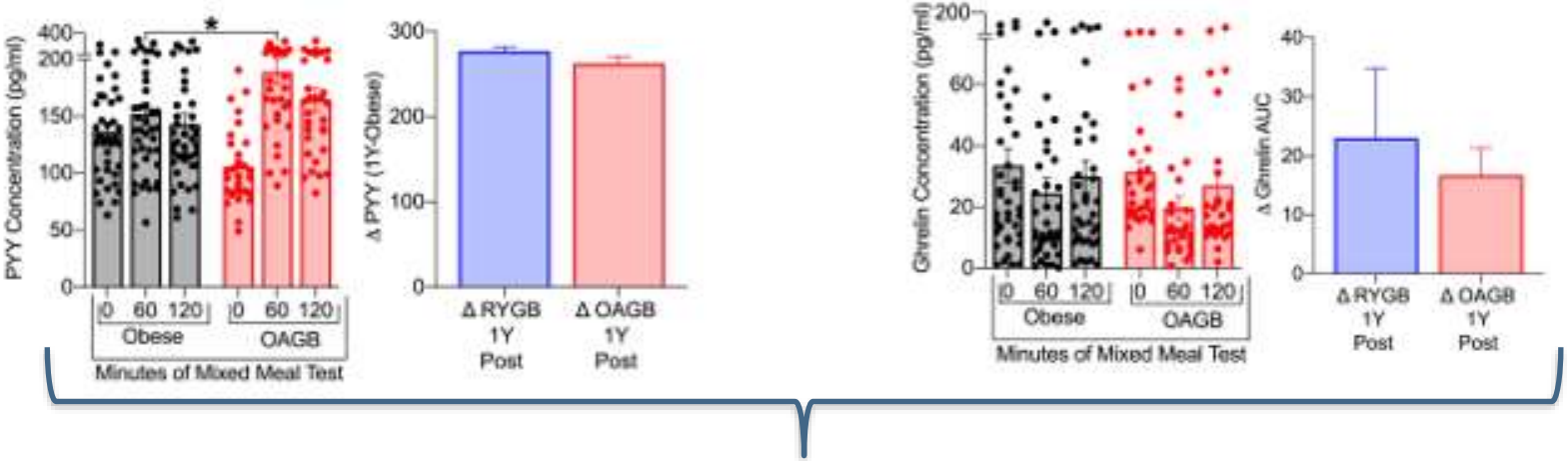
Mean hemoglobin (g/d) (SD)

	RYGB	OAGB	P
Baseline	144 (14.7)	139 (11)	0.132
1 y	131.7 (13.6)	136 (13.4)	0.189
3 y	134.3 (18.2)	126.5 (12.8)	**0.044**

Results

Secondary endpoint : hormonal changes (peptide YY **[PYY]** and **ghrelin**).

1 Year

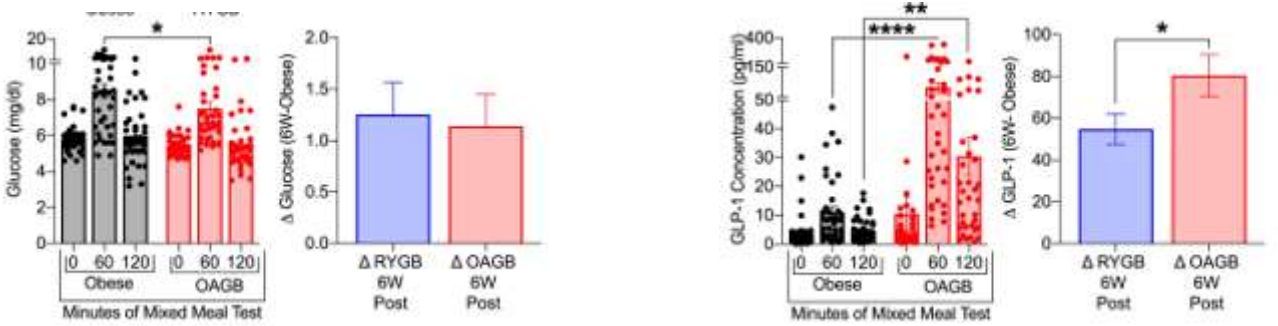


No difference in Ghrelin and PYY between RYGB and OAGB

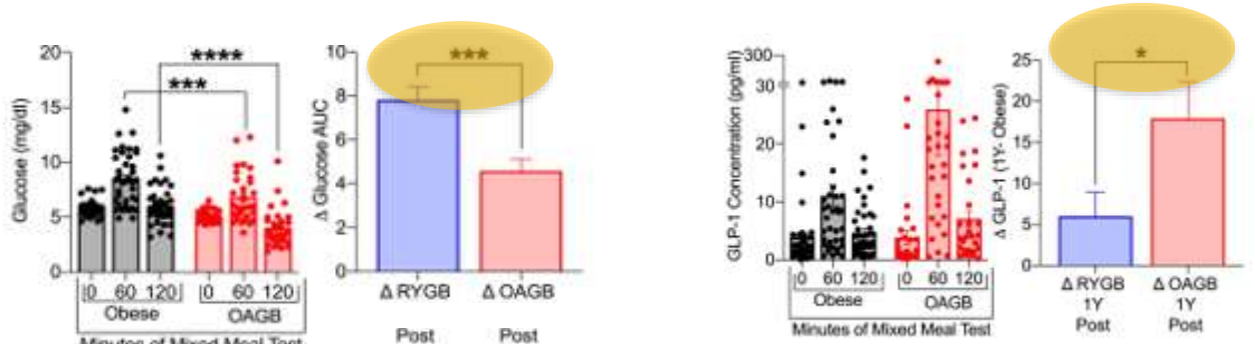
Results

Secondary endpoint : hormonal changes (glucagon like peptide-1 **[GLP-1])**

6 Weeks



1 Year



OAGB improves glucose regulation significantly better compared to the RYGB

Results

Secondary endpoint : quality of life

GIQLI: abdominal pain, diarrhea

		Preop.		1 Year postop.						
RYGB (31)		mean	SD	mean	SD		p value			p value
	Pain	17.1	5.3	13.2	7.2	pain	0.04		pain	0.01
	Diarrhea	13.7	4.1	15.7	5.9	Diarrhea	0.59		Diarrhea	0.11
OAGB (23)		mean	SD	mean	SD		p value			p value
	Pain	16.7	4.9	12.0	7.9	pain	0.07		pain	0.01
	Diarrhea	12.8	3.6	14.9	6.4	Diarrhea	0.13		Diarrhea	0.11
		p value			p value					
	pain	0.74		pain	0.56					
	Diarrhea	0.32		Diarrhea	0.64					

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Our Conclusion

TWL% after 3 years OAGB better than PRYGB

Short and long-term problems at the foot point anastomosis are eliminated with the OAGB

OAGB improves glucose regulation significantly better compared to PRYGB by hormone mesurements

More anastomotic ulcers OAGB vs PRYGB at 3 years

More reflux complications OAGB vs PRYGB at 3 years

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Results:

Secondary Endpoint: Remission comorbidities after 1y

Table 2

	RYGB		OAGB		
	12 months	remission	12 months	remission	p
T2DM/prediabetes, n	0/11	11/11	0/6	6/6	NA
arterial hypertension, n	2/19	17/19	3/19	16/19	1.000
hyperlipidemia, n	2/20	18/20	2/15	13/15	1.000
reflux, n	0/18	18/18	6/24	16/24	0.024
sleep apnea, n	0/11	11/11	0/9	9/9	NA

No difference

No difference

French Study YOMEGA (multicenter)

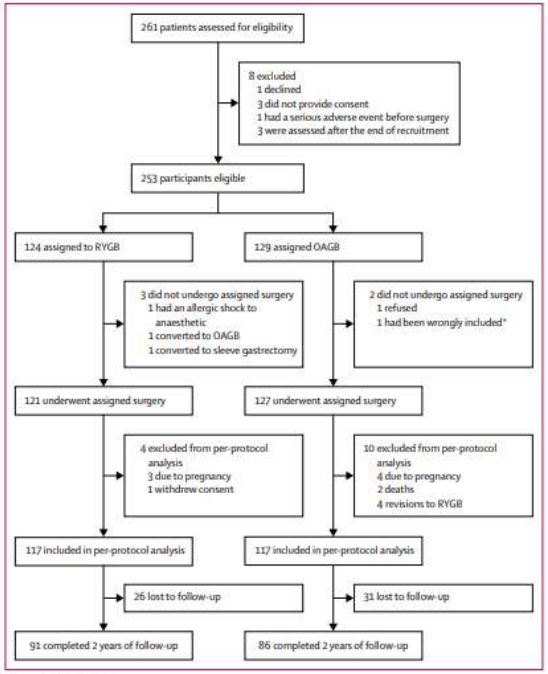
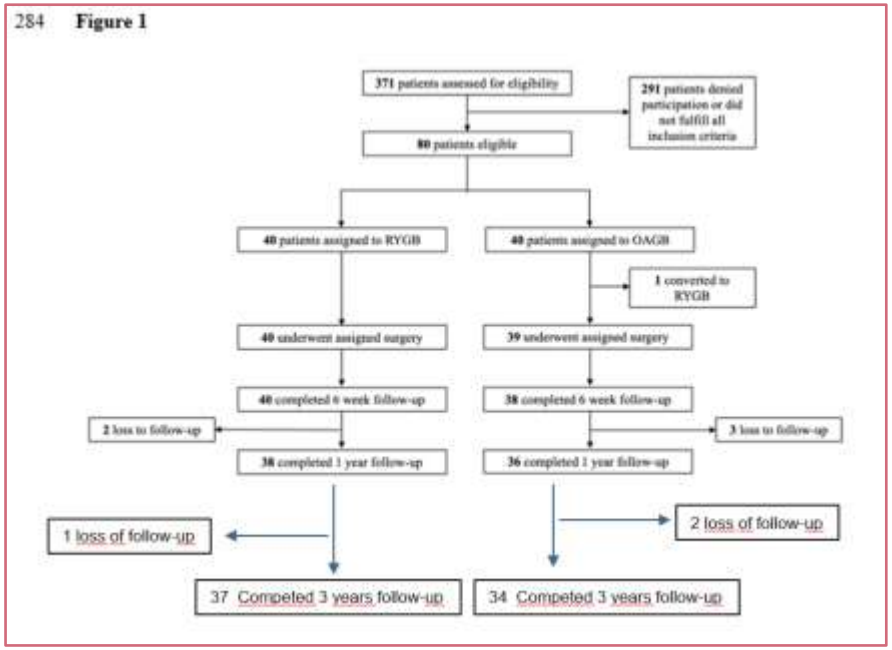


Figure 2: **Study profile**
*Patient had a history of gastric banding.

2y Follow up; RYGB 77.7%
OAGB 73.5%

Swiss Study (single center Limmattal)



3y Follow up; RYGB 92.5%
OAGB 87.2%

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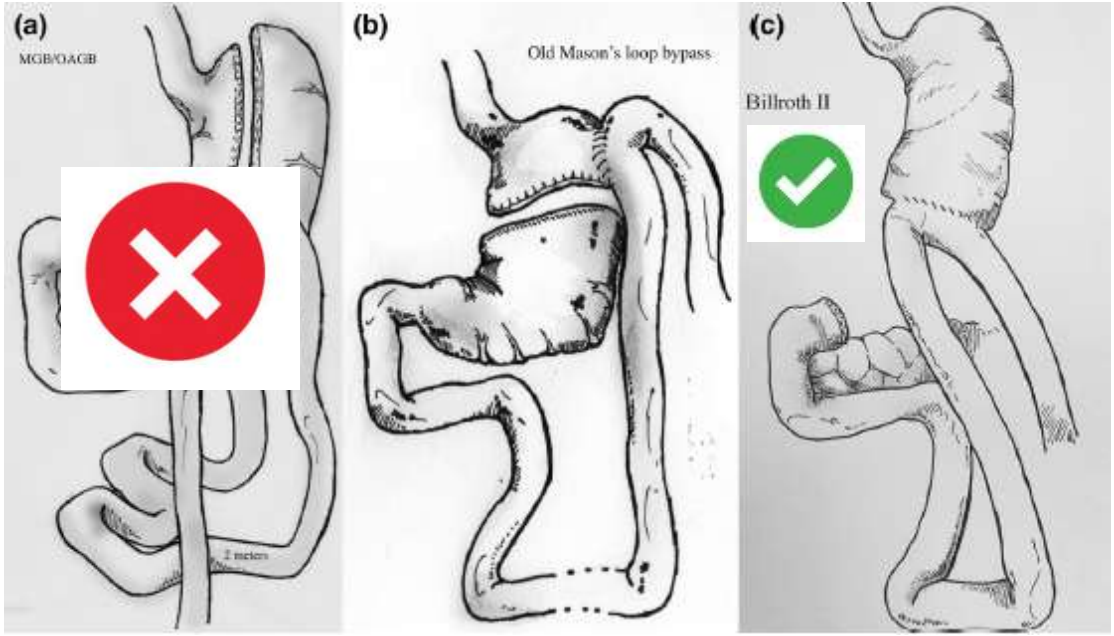
Bariatric surgery in Switzerland 2023

But…..



- **43.71** Partielle gastrektomie mit Anastomose zum Jejunum
  - > 43.71.11 Partielle gastrektomie (2/3-Resektion) mit Anastomose zum Jejunum
  - > 43.71.21 Partielle gastrektomie (4/5-Resektion) mit Anastomose zum Jejunum

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The primary endpoint : % TWL (SD) at one, two and three years after surgery

Swiss Study (single center Limmattal)

	RYGB	OAGB	P
%TWL 1y	31.5 (7.1)	37.4 (6.1)	**0.0004**
%TWL 3y	28.8 (7.7)	**35.4 (6.8)**	**0.0003**

French Study YOMEGA (multicenter)

	RYGB	OAGB	P
%TWL 2y	35.4 (8.1)	37.1 (10.3)	

No difference in OAGB

Late complications > **Clavien- Dindo III (%)**

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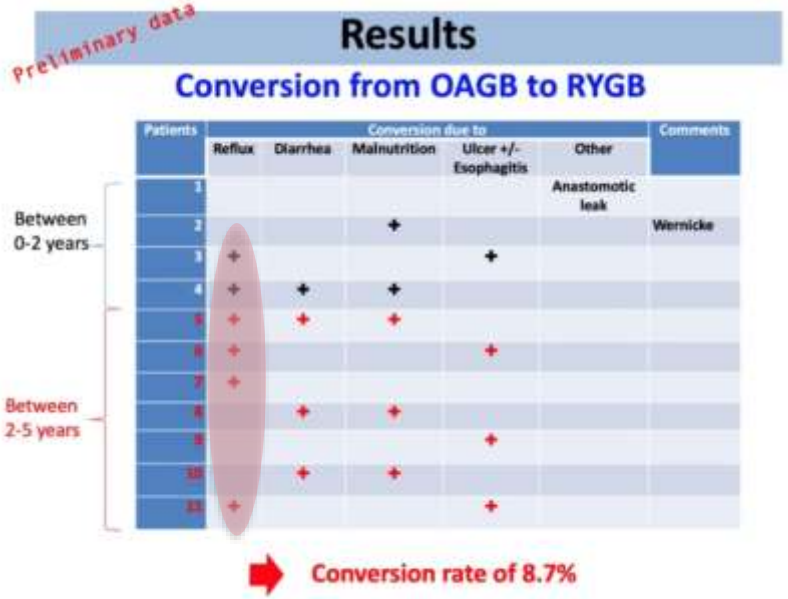
	OAGB 2Y	OAGB 3Y
Small bowel obstruction	**1 (1,2%)**	0
Marginal ulcer (Pouch resection and Oesophagojejunostomy)	1(1,2%)	1 (2,9%)
Internal Hernia	**0**	0
Anastomotic leak	1 (1,2%)	0
Chronic abdominal pain	0	1 (2,9)
Reflux (Biliary reflux, RYGB reconstraction)	**2 (2,4%)**	**3 (8.8%)**
Dumping (reversal into normal anatomy)	0	1 (2,9%)
Malnutrition (Wernicke)	**2 (2,4%)**	**0**
Total	**6**	**6**

the missing data

28.6% of lost to follow-up at 5 years



Reoperation of patients with avialable Follow up

Conversion OAGB to RYGB	OAGB (5Y)	OAGB (3Y)
Reflux	7,1%	8.8%
Malnutrition	3,5%	0%
Ulcer GE	2,3%	2,9%

Functional Changes in the Stomach and Esophagus after 1 One Anastomosis Gastric Bypass- OAGB-BiFlux Trial

Primary Endpoint

Ulcer rate in the area of the gastrointestinal anastomosis, and the analysis of predictive factors for the development of an ulcer after 2 and 5 years

Secondary Endpoints

-weight loss % at 2 and 5 years

-changes in the esophagus or stomach detected by gastroscopy (macroscopic characterization using Los Angeles classification), tissue Biopsies, high-resolution manometry and impedance multi-channel pH metry

-Mortality , Morbidity

Functional Changes in the Stomach and Esophagus after 1 One Anastomosis Gastric Bypass- OAGB-BiFlux Trial

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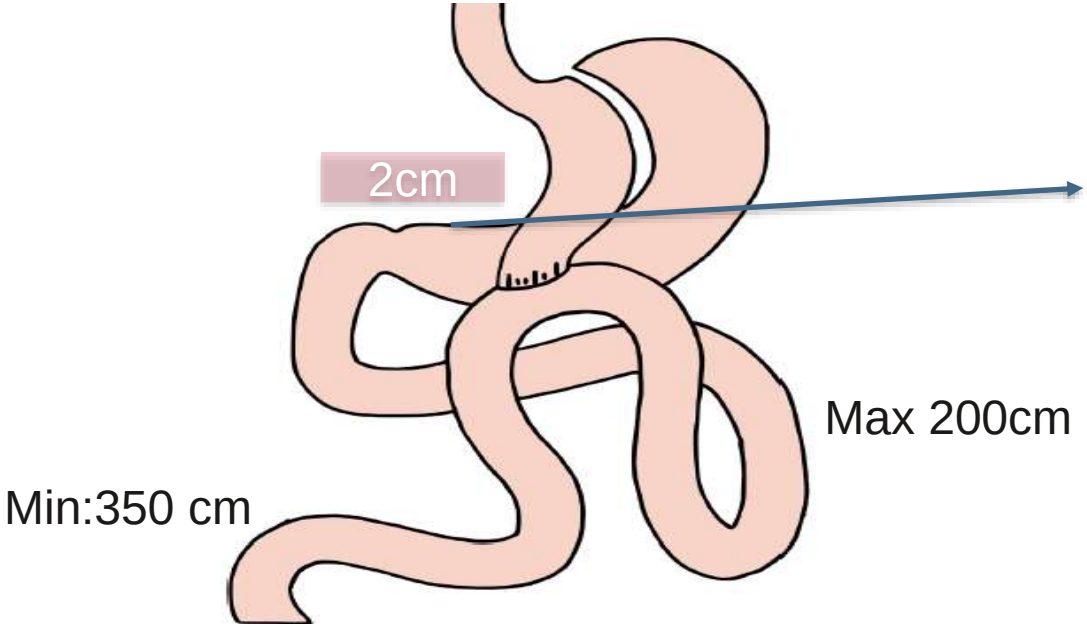
Exclusion criteria:
Reflux disease

- -Hiatal hernia > 4cm
- -Barrett's esophagus according to biopsy Esophagitis grade C or D)
- -Acid exposure time > 6% (Lyon criteria)
- -Reflux episodes > 80/24h (Lyon criteria)
- -Insufficiency of the lower esophageal sphincter according to manometry
- -Pathological acidic and non-acidic reflux according to impedance pH-metry

Functional Changes in the Stomach and Esophagus after 1 One Anastomosis Gastric Bypass- OAGB-BiFlux Trial

5-7 (45/60mm Stapler)
dissection Antrum



Workshop Spital- Limmattal

Wann

Dienstag 06. Dezember 2022, 7.30–16.00 Uhr

Programm

07.30–08.10 Uhr	**Komplexe und Standard-bariatrische Operationsverfahren**, **inklusive Omega-Magenbypass**	Dr. Thomas Köstler Dr. Diana Mattiello
08.10–08.50 Uhr	Opioidfreie Anästhesie	Dr. Corina Labitzke Dr. Isabel Marcolino
09.00–14.00 Uhr	Vier Live-Operationen	
14.00–15.00 Uhr	Mittagspause	
15.00–15.30 Uhr	Q&A	
15.30–16.00 Uhr	Patientenvisite	
16.00 Uhr	Ende des Workshops	

Questions, Des questions ,Fragen?

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