Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

A Randomized Controlled Trial of Reflux Esophagitis and Other Late Postoperative Complications: 3-Year Follow-Up Results in the FundoRingOAGB Trial

Oral Ospanov
Astana Medical University
Scott Shikora
Brigham and Women's Hospital
Bakhtiyar Yelembayev
Astana Medical University
Venera Rakhmetova
Astana Medical University
Kuandyk Zhumankulov
Myrzabek Rysbekov
Astana Medical University
Shakhizada Ospanova
Galymjan Duysenov
kazbareo@gmail.com

Astana Medical University

Research Article

Keywords: Obesity, Bariatric surgery, One-anastomosis gastric bypass, Reflux Esophagitis, Late Complications, Fundoplication, FundoRing

Posted Date: March 24th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9027575/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Version of Record: A version of this preprint was published at Obesity Surgery on June 30th, 2026. See the published version at https://doi.org/10.1007/s11695-026-08769-0.

Abstract

Background/Objectives:

The new FundoRing gastric bypass method demonstrates improved antireflux effects after one year of follow-up compared to standard one anastomosis gastric bypass (OAGB). However, the longer-term impact of this innovation on adverse effects remains unclear.

The aim of this study was to compare three-year follow-up of reflux esophagitis and other late postoperative complications between the FundoRing method and standard one anastomosis gastric bypass.

Methods: This was a single-center, prospective, interventional, open-label (no masking) RCT (FundoRing Trial) with a 3-year follow-up period. The endpoints were assessment of reflux esophagitis, and other late postoperative complications.

Results: Overall, 1000 patients (n=500 FundoRing One-anastomosis gastric bypass [f-OAGB] vs. n=500 standard OAGB [s-OAGB]) with complete follow-up data were included in the study. No mortality occurred in either group.

The DeMeester index 3- years after surgery was significantly lower in the f-OAGB group (3.97 ± 1.8 versus 7.2 ± 7.4; difference 3.23; 95% CI: 1.82–4.64; p<0.001).

At 3-year follow-up FundoRingOAGB significantly decrease dumping syndrome symptoms, marginal ulcer and other late complications.

Conclusions:

A three-year follow-up of the FundoRing method compared to standard one anastomosis gastric bypass confirms improved results of surgery, including 24-hour pH impedance monometry, and a reduction of late complications.

Key Points

• FundoRingOAGB improved results of 24-hour pH impedance manometry.

• Impedance pH monitoring is important to determine the acid or bile(non-acid) reflux esophagitis.

• FundoRingOAGB significantly decrease dumping syndrome symptoms, marginal ulcer and other late complications

Introduction

Background and rationale

Obesity and its complication a threat to health, and the global health burden associated with high body mass index has increased significantly in the last three decades [1].

Metabolic bariatric surgery (MBS) is an evidence-based, superior option for treating obesity and its negative consequences [2]. However, there are currently no ideal surgical methods for MBS, so the search for new solutions is essential. One controversial method is the one anastomotic gastric bypass (OAGB). At the same time OAGB is a simpler and is non-inferior to RYGB in terms of remission of type 2 diabetes mellitus, weight loss, and early and late complications with a shorter operating time [3]. The absence of a second anastomosis (enteroenterostomy) eliminates complications associated with it and reduces the likelihood of internal hernias [4].

Also advantages of OAGB is the lower incidence of dumping syndrome (DS) [5]. A previous study reported that the incidence of DS was 42.9% after OAGB compared to 56.4% after RYGB. However, the incidence of marginal ulcers was significantly higher in patients who underwent OAGB than in those who underwent RYGB [6]. Studies have also shown that lengthening the gastric pouch reduces the incidence of DS from 60% to 49%; however, it simultaneously increases the incidence of anastomotic ulcers from 2.6% to 12.4% [7]. OAGB are as effective as RYGB for weight loss, but OAGB have lesser complications [8]. OAGB was an "acceptable mainstream surgical option" and it could no longer be regarded as a new or experimental procedure [9].

One-year results of RCT the new Fundoring (FundoRingOAGB) method demonstrated reducing of the incidence of reflux esophagitis [10] and dumping syndrome [11]. But thise results and other outcomes at three-year follow-up was not clear.

Objectives

This study aimed to compare the three-year follow-up of reflux esophagitis and other late postoperative complications using FundoRing versus standard one anastomosis gastric bypass.

Materials and Methods

Patients, trial design and setting

This an open-label RCT (FundoRingOAGB Trial) was conducted at Medical University. A single surgeon performed all the procedures.

The study protocol was published previously and registered in the ClinicalTrials.gov database.

The CONSORT checklist and flow diagram for RCTs were used to guide the reporting of this study [12].

Eligibility criteria

The inclusion criteria

- - Patients with metabolic syndrome.
- - Class I– III obesity (30.0–50.0 body mass index [BMI, kg/m2]).
- - Acceptable operative risk (ASA 1–2)
- - Patients aged 18–60 years.

The exclusion criteria

- -Patients with previous hiatal herniorrhaphy and fundoplication.
- - Giant hiatal hernia (HH) > 5 cm (or ≥ 30.0% of the stomach residing in the chest).
- - Reflux esophagitis C or D (by Los Angeles [LA] classification).
- -Patients after bariatric surgery.

Intervention and comparator

All the procedures were performed laparoscopically.

The investigational metabolic/bariatric surgery (MBS) procedure was characterized as FundoRing OAGB (f-OAGB) [13.14]. The procedure included a laparoscopic OAGB incorporating total fundoplication of the OAGB-excluded stomach with gastric pouch long 10 cm. The control procedure was standard OAGB (s-OAGB) with gastric pouch long 15–18 cm [15]. The f-OAGB and s-OAGB methods are shown in Fig. 1.

Outcome measures Although the primary registered endpoint was weight loss, for this analysis of 3-year outcomes, the main focus is on the assessment of reflux and late complications, as key indicators of the long-term efficacy and safety of the new technique.

Primary outcome measure

- Body mass index (BMI, kg/m2) and 1 and 3-year follow-up change BMI (ΔBMI).
- Postoperative evaluation DeMeester score with use 24-hour pH impedance monitoring of esophagus at 3-year follow-up.
- Late postoperative complications at > 30 days -<1 year follow-up, 1 and 3-year follow-up.

Sample size determination

An appropriate sample size for detecting a difference between the means of the two samples was calculated [16].

The equation for calculating sample size is shown below (Fig. 2). His means 385 measurements are needed to have a confidence level of 95% that the evaluation DeMeester score (primary outcome) is

within ± 5% of the measured value.

For 95% confidence, and a margin of error of 5%. A proportion of 0.5, and unlimited population size. Z for a 95% confidence level is 1.96. Thus, for the case above, a sample size of at least 385 people would be necessary. We used a standard formula for a large population to estimate the sample size needed to assess the primary outcome—the DeMeester score. The calculation showed that at least 385 patients per group are required to achieve a 95% confidence level with a 5% margin of error. We decided to increase the group size to 500 patients, which substantially exceeds the minimum required 385. This decision was made deliberately for several reasons:

- Compensation for potential loss to follow-up: We anticipated that a proportion of patients might be lost during the 3-year follow-up period. Increasing the sample size allowed us to maintain statistical power even with a retention rate of approximately 80–85%, which was ultimately observed.
- Improved precision of estimates: A larger sample size enables narrower confidence intervals and more robust estimates of the intervention effect, particularly for rare adverse events.

Randomization and group allocation

Patients who met the inclusion criteria and did not meet the exclusion criteria were consecutively included and randomized into one of the two study arms by the study statistician, who participated only in the randomization and statistical analysis. The randomization list was maintained in a strictly confidential manner, and allocation concealment was ensured using sequentially numbered, identical, opaque, sealed envelopes. The intervention was randomly assigned to each patient during the pre-procedure visit by a nurse who did not participate in patient enrollment or assessment.

Statistical methods

Statistical analyses were performed using Microsoft Excel for Mac StatPlus MacPro (AnalystSoft Inc., Walnut, CA, USA). Normal distribution of the variables was tested using the Kolmogorov–Smirnov test. Quantitative demographic and outcome variables were reported as means and SD, and qualitative variables were reported as counts and percentages. Between-group comparisons of quantitative variables were performed using an independent samples t-test, and within-group comparisons were performed using a paired-samples t-test. Between-group differences in qualitative variables were assessed using the chi-square test. Statistical significance was set at $p < 0.05$.

Results

Patient allocation

Between January 2021 and December 2024, 1000, patients were randomly allocated to either the f-OAGB experimental group (n = 500) or the s-OAGB control group (n = 500). No significant differences were

found between the f-OAGB and s-OAGB groups in terms of distribution of age, sex, preoperative BMI (Table 1).

Table 1
Distribution of age, sex, BMI

Characteristics	f-OAGB n = 500	s-OAGB n = 500	p-value/statistic
Age (years)	37 ± 7.7*	40 ± 9.2	0.6. t = 0.45
Female (n)	421 (84.2%)	407 (81.4%)	0.2. **X^2 = 1.37
BMI*** (kg/m2) preop	40.04 ± 5.49	40.49 ± 5.72	0.2. t = 1.27
BMI*** (kg/m2) postop	25.92 ± 2.03	27.53 ± 3.25	0.001. t = 8.61

*Values are presented as mean ± one standard deviation (SD).

** X2 -Pearson Chi-Square

***BMI = body mass index

The change of BMI between baseline and 3 - year follow-up in the f-OAGB group was 40.04 ± 5.49 kg/m2 vs 25.92 ± 2.03 kg/m2 respectively. And the change of BMI between baseline and 3 - year follow-up in the f-OAGB group was 40.49 ± 5.72 kg/m2 vs 27.53 ± 3.25 kg/m2 respectively.

Flow diagram of the randomized controlled allocation of the FundoRingOAGB Trial shown in Fig. 3.

Postoperative reflux esophagitis evaluation with use monitoring of pH impedance

Monitoring of 24-hour pH impedance was performed 3 years after the surgical procedures (Table 2). we use the Digitrapper™ Recorder and disposable Digitrapper™ pH & Impedance Catheter 900003 VersaFlex™ ZNID15 + 8R catheters and Reflux Software v6.1 (Medtronic, USA) (Fig. 4.) provided detailed data on acid/non-acid reflux episodes and their duration after three years, using parameters such as the total number of reflux episodes, the percentage of time when pH < 4, and the DeMeester score.

Table 2
The results of 24-hour pH impedance 3 years follow up monitoring with use Digitrapper™ & Catheter 900003 VersaFlex™ ZNID15 + 8R.

Variable	f-OAGB (n = 175)	s-OAGB (n = 175)	Mean difference (95% CI) **	P-value
Acid exposure time (< 4.2%)	1.05 ± 0.6*	1.85 ± 1.1	0.80 (0.52–1.08)	< 0.001
Number of acid reflux episodes pH < 4	5.01 ± 4.1	9.3 ± 7.8	4.29 (2.84–5.74)	< 0.001
Number of episodes of weakly acidic reflux 4 < pH < 7	31.47 ± 14.1	39.64 ± 23.1	8.17 (3.62–12.72)	< 0.001
Number of episodes of alkaline reflux pH > 7	1.35 ± 0.4	5.61 ± 5.3	4.26 (3.24–5.28)	< 0.001
DeMeester index (≥ 14.72)	3.97 ± 1.8	7.2 ± 7.4	3.23 (1.82–4.64)	< 0.001

*Values are presented as mean ± standard deviation. **Mean differences are given with 95% confidence interval.

A 24-hour pH impedance measurement 3- years after surgery showed that the acid exposure time was 1.05 ± 0.6% in the f-OAGB group and 1.85 ± 1.1% in the s-OAGB group (difference 0.80; 95% CI: 0.52–1.08; $p < 0.001$). The number of acid reflux episodes (pH < 4) was significantly lower after f-OAGB (5.01 ± 4.1 vs. 9.3 ± 7.8; difference 4.29; 95% CI: 2.84–5.74; $p < 0.001$). Similarly, the frequency of weakly acidic refluxes (4 < pH < 7) was lower in the f-OAGB group (31.47 ± 14.1 vs. 39.64 ± 23.1; difference 8.17; 95% CI: 3.62–12.72; $p < 0.001$). The number of alkaline refluxes (pH > 7) was also significantly lower after f-OAGB (1.35 ± 0.4 vs. 5.61 ± 5.3; difference 4.26; 95% CI: 3.24–5.28; $p < 0.001$). The DeMeester index was significantly lower in the f-OAGB group (3.97 ± 1.8 versus 7.2 ± 7.4; difference 3.23; 95% CI: 1.82–4.64; $p < 0.001$).

Late postoperative complications

No mortality occurred in either group. Late postoperative complications include incidence of dumping syndrome, marginal ulcer, bile reflux-esophagitis, food intolerance, protein malnutrition, anemia and thiamine (B1) deficiency.

Incidence of dumping syndrome 3-year follow-up

In the Table 3 demonstrate Incidence of complications.

Table 3
Incidence of complications

Outcomes	groups/ statistic	(> 30 days -<1 year follow-up	1-year follow-up	3-years follow-up
Patient retention rate (follow-up rate)	f-OAGB	n = 500 (100%)	n = 500 (100%)	n = 415 (83%)
	s-OAGB	n = 500 (100%)	n = 500 (100%)	n = 435 (87%)
Dumping syndrome (n (%))	f-OAGB	-	98 (19.6%)	57 (13.7%)
	s-OAGB	-	175 (35%)	159 (36.5%)
	p-value	-	$\chi2 = 6.3$, $p = 0.012$	$\chi2 = 15.4$, $p = 0.001$
Marginal ulcer (GEA) (n)	f-OAGB	1	3	1
	s-OAGB	3	14	15
	p-value	$\chi2 = 1.0$, $p = 0.31$	$\chi2 = 7.2$, $p = 0.007$	$\chi2 = 11.8$, $p < 0.001$
Bile reflux-esophagitis (n)	f-OAGB	0	1	1
	s-OAGB	29	36	41
	p-value	$\chi2 = 29.8$, $p < 0.001$	$\chi2 = 34.4$, $p < 0.001$	$\chi2 = 38.1$, $p < 0.001$
Food intolerance (n)	f-OAGB	27	4	2
	s-OAGB	12	3	3
	p-value	$\chi2 = 7.4$, $p = 0.007$	$\chi2 = 0.14$, $p = 0.7$	$\chi2 = 0.16$, $p = 0.69$
Protein malnutrition (n)	f-OAGB	1	7	19
	s-OAGB	2	9	16
	p-value	$\chi2 = 0.33$, $p = 0.56$	$\chi2 = 0.25$, $p = 0.6$	$\chi2 = 0.43$, $p = 0.5$
Anemia (B12, iron, ferritin deficiency) (n)	f-OAGB	48	78	88
	s-OAGB	43	69	83
	p-value	$\chi2 = 0.3$, $p = 0.58$	$\chi2 = 0.64$, $p = 0.42$	$\chi2 = 0.59$, $p = 0.44$
Thiamine (B1) deficiency	f-OAGB	4	15	18
	s-OAGB	3	11	17

Outcomes	groups/ statistic	(> 30 days -<1 year follow-up	1-year follow-up	3-years follow-up
	p-value	$\chi 2 = 0.14$, $p = 0.7$	$\chi 2 = 0.63$, $p = 0.43$	$\chi 2 = 0.09$, $p = 0.75$

* X2 -Pearson Chi-Square

Dumping syndrome

A comparative analysis of the incidence of dumping syndromes revealed that in the first group, the incidence of dumping syndromes decreased from 19.6% to 13.7% ($p = 0.25$), while in the second group, it remained at the almost same percentage, amounting to 35% in the first year and 36.5% at 3 years postoperatively ($p = 0.84$). These The results obtained in the comparison groups were not statistically significant in the f-OAGB (3 years and 1 year of follow-up) and s-OAGB (3 years and 1 year of follow-up) groups, which are indicated in the table as: A vs. B and C vs. D. But as the table shows, differences between f-OAGB and s-OAGB were statistically significant (0.012 (X2 = 6.3) at 1 -year follow up (A vs C in table) and were statistically significant (0.001 (X2 = 15.4) at 3 -year follow up (B vs D in table)

The proportion of patients with early symptoms in the first group increased from 24.49% in the first year to 33.3% by the third year. The proportion of patients with late dumping symptoms increased from 32.7% to 42.1%. The combination of early and late dumping symptoms decreased from 42.8% in the first year to 24.6% by the third year.

The proportion of patients with early symptoms in the second group was 28% in the first year and 25.8% by the third year. The proportion of patients with late dumping symptoms also decreased slightly from 42.86% to 39%. The proportion of patients with a combination of early and late dumping symptoms increased slightly from 29.14% in the first year to 35.2% by the third year.

Marginal ulcer (GEA)

During the observation period “≥30 days - <1 year follow-up”, there were 3 cases of marginal ulcer in the s-OAGB group versus 1 case in the f-OAGB group ($p = 0.31$). These cases of marginal ulcer were associated with irregular use of PPIs for prophylactic purposes. At the 1-year follow-up, a statistically significant difference was noted between the groups, with 14 marginal ulcers in the gastroenteroanastomosis area being endoscopically diagnosed in the s-OAGB group, while only 3 marginal ulcers were detected in the f-OAGB group out of 500 patients ($p = 0.007$). We associate these results with a longer and more voluminous gastric pouch in the s-OAGB group. A similar trend persisted at the 3-year follow-up period. During this period, 15 marginal ulcers were diagnosed in the s-OAGB group at the gastrojejunostomy, while only 1 marginal ulcer was detected in the f-OAGB group ($p < 0.001$).

All marginal ulcers were treated with therapeutic doses of PPIs without the need for surgery.

Bile reflux-esophagitis

Bile reflux esophagitis is the "Achilles heel" of OAGB, and therefore this late complication significantly impacted the evaluation of different one-anastomosis gastric bypass methods.

In the ≥ 30 days - <1-year follow-up period, there were 29 cases of bile reflux esophagitis in the s-OAGB group versus 0 cases in the f-OAGB group ($p < 0.001$). These cases of bile reflux esophagitis were associated with absent fundoplication of the OAGB component. At the 1-year follow-up, a statistically significant difference was noted between the groups, with 36 cases of bile reflux esophagitis diagnosed in the s-OAGB group, while only 1 case of bile reflux esophagitis was detected in the f-OAGB group out of 500 patients ($p < 0.001$). A similar trend persisted at the 3-year follow-up period. During this period, 41 bile reflux esophagitis were diagnosed in the s-OAGB group at the gastrojejunostomy, while only 1 bile reflux esophagitis was detected in the f-OAGB group ($p < 0.001$). 24-hour pH-impedance monitoring was performed on a representative sample of patients due to the invasive nature and complexity of the method, and this subsample was balanced between the groups to ensure the reliability of the comparison. Bile reflux esophagitis was diagnosed based on a combination of clinical symptoms (bitter taste in the mouth, burning sensation), endoscopic findings, and was confirmed by the presence of alkaline reflux episodes (pH > 7) during 24-hour pH-impedance monitoring. All patients with bile reflux esophagitis were treated without the need for surgery.

Food intolerance

In the ≥ 30 days - <1-year follow-up period, there were 27 cases of food intolerance in the f-OAGB group versus 12 cases in the s-OAGB group ($p = 0.007$). These cases of food intolerance were associated with fundoplication of the OAGB component. But the 1-year follow-up, a food intolerance was not statistically significant difference between the groups, 4 cases of food intolerance diagnosed in the f-OAGB group versus 3 cases was detected in the s-OAGB group ($p < 0.07$). At the 3-year follow-up period in f-OAGB group were diagnosed 2 cases of food intolerance versus 3 cases in the s-OAGB group ($p = 0.69$). All patients with food intolerance were treated without the need for surgery.

Protein malnutrition

Protein malnutrition in the ≥ 30 days - <1-year follow-up period, there were 1 cases of food intolerance in the f-OAGB group versus 2 cases in the s-OAGB group ($p = 0.56$). At the 1-year follow-up, a protein malnutrition was 7 cases of protein malnutrition in the f-OAGB group versus 9 cases was in the s-OAGB group ($p < 0.6$). At the 3-year follow-up period in f-OAGB group were 19 cases of protein malnutrition versus 16 cases in the s-OAGB group ($p = 0.5$). All patients with protein malnutrition were treated without the need for surgery.

Anemia

Anemia was most often caused by deficiencies of B12, iron, ferritin [17].

Anemia in the ≥ 30 days - <1-year follow-up period, there were 48 cases in the f-OAGB group versus 43 cases in the s-OAGB group ($p = 0.58$). At the 1-year follow-up, anemia was 78 cases in the f-OAGB group versus 69 cases was in the s-OAGB group ($p < 0.42$). At the 3-year follow-up period in f-OAGB group were

88 cases of anemia versus 83 cases in the s-OAGB group (p = 0.44). All patients with anemia were treated without the need hemotransfusion.

Thiamine (B1) deficiency

Thiamine (B1) deficiency this is a typical late complication of bariatric surgery.Thiamine deficiency in the ≥ 30 days - <1-year follow-up period, there were 4 cases in the f-OAGB group versus 3 cases in the s-OAGB group (p = 0.7). At the 1-year follow-up, thiamine deficiency was 15 cases in the f-OAGB group versus 11 cases was in the s-OAGB group (p < 0.43). At the 3-year follow-up period in f-OAGB group were 18 cases of thiamine deficiency versus 17 cases in the s-OAGB group (p = 0.75). All patients with thiamine deficiency were treated with use vitamine B1.

Discussion

Unlike sleeve gastrectomy, gastric bypass surgery offers the opportunity to use the remnant (exclusion) part of the stomach as an excellent, readily available plastic material to improve results and enhance the reliability of gastric bypass [18]. This is especially important for correction disadvantages of OAGB. Postoperative bile reflux esophagitis after OAGB is a common finding in scintigraphy and endoscopy [19]. A Systematic review and meta-analysis demonstrated that almost all diagnoses of bile reflux resolved after revision from OAGB to RYGB [20]. An alternative to converting OAGB to RYGB is to perform a revision procedure such as Nissen fundoplication [21]. But an additional combination of gastric bypass with fundoplication may also be necessary for RYGB [22]. The use of fundoplication for reflux esophagitis after previous Roux-en-Y gastric bypass was described by Kawahara N.T. et al. [23]. Maurissen J. et al. use fundoplication as a revision procedure after bariatric surgery to treat dumping syndrome [24].

Unfortunately, this procedure was typically performed by the authors in revision bariatric procedures. We stated that one anastomosis gastric bypass is the primary procedure in our bariatric metabolic surgical practice and primary simultaneous surgery using of modified fundoplication for gastric bypass during OAGB had the benefits of greater reduction of acid reflux and effectively prevented bile reflux esophagitis compared with the OAGB without fundoplication [25].

The FundoRing method is standardized and described in detail [26]. It differs significantly from the Nissen method, which is the prototype [27].

This randomized controlled trial with a 3-year follow-up provides important data on the impact of wrapping the fundus (fundoplication) of the excluded part of the stomach for OAGB on preventing reflux esophagitis, dumping syndrome and other complications.

The FundoRing-OAGB modification exerted a significant anti-dilatation effect on the gastric pouch after 3 years follow up, as confirmed reliably by using endoscopic ultrasound (EUS) [28].

Other improved results, for example antireflux outcomes are also due to FundoRing. Monitoring of 24-hour pH impedance was performed 3 years after the surgical procedures using Digitrapper™. The compare results f-OAGB group vs s-OAGB group shown better data in first group on the acid exposure time and number of reflux episodes when pH < 4, number of episodes of weakly acidic reflux 4 < pH < 7, number of episodes of alkaline reflux pH > 7. The DeMeester index was significantly lower in the f-OAGB group (3.97 ± 1.8 versus 7.2 ± 7.4; difference 3.23; 95% CI: 1.82–4.64; p < 0.001). Acid reflux seems to be as common as bile reflux in patients presenting with GERD after OAGB [31]. Nehmeh et all. (2021) write that out of the 43 patients who underwent 24-h impedance pH monitoring, acid reflux was diagnosed in 13 (30.2%) patients, non-acid (biliary) in 12 (27.9%), and mixed in 5 (11.6%) patients.

These authors indicated that the median DeMeester score was 48.95 (27.67) in patients with acid reflux, 2.8 (7.4) in patients with bile reflux, and 28.7 (5.6) in patients with mixed reflux. In this study, the median time interval between surgery and 24-hour impedance pH monitoring was 64 (56) months. The high median DeMeester score of 48.95 and 9.65% of the distal esophageal acid exposure time at pH < 4 in patients confirm that patients after OAGB surgery may be exposed to acid [29]. The large difference in 24-hour impedance pH monitoring results in the study by Nehmeh et al. (2021) and in the s-OAGB group in our study, because, firstly, that our study design relied on random sampling versus in the other study 24-hour pH-impedance measurement was used only in patients complaining of reflux after OAGB. Furthermore, the authors were not specified the device used for 24-hour pH impedance monitoring.

Late postoperative complications include incidence of dumping syndrome, marginal ulcer, bile reflux-esophagitis, food intolerance, protein malnutrition, anemia and thiamine (B1) deficiency.

Modified fundoplication of the OAGB-excluded stomach (FundoRingOAGB) significantly decreased DS symptoms more effectively than standard OAGB (f-OAGB (19.6%) versus 35% in s-OAGB group) at 1-year follow-up [11]. The 3-year follow-up DS symptoms in our study also significantly decreased in f-OAGB (13.7%) versus 36.5% in s-OAGB group.

The incidence of marginal ulcers after OAGB varies from 2 to 3% [30].

According to the standardization of the surgical technique for performing FundoRing OAGB, in the first group, the gastric pouch length did not exceed 10 cm and the volume was 20 ml, while in the second group, the gastric pouch length was 15–18 cm and the volume was 40–50 ml. This influenced the incidence of marginal ulcers in the groups. At the 1-year follow-up and at the 3-year follow-up, the incidence of ulcers was 3 cases (f-OAGB) vs 14 cases (s-OAGB) and 1cases vs 15 cases for f-OAGB and s-OAGB, respectively. This confirms the opinion of many authors about the influence of gastric pouch size as a major factor in the occurrence of marginal ulcers [31, 32]. Therefore, it is important to be able to accurately calculate the volume of the gastric pouch, which is recommended to be approximately 20 ml. [33].

We observed food intolerance more frequently in the f-OAGB group (27 cases) versus 12 in the s-OAGB group, with a particularly significant difference in the > 30 days to < 1 year follow-up period. We attribute

the higher prevalence of food intolerance in the f-OAGB group to a greater restrictive effect due to the presence of a fundoplication wrap.

Differences in the incidence of anemia and thiamine deficiency between groups were not statistically significant across the various observation periods.

Strengths and Limitations

This study has limitations. Trial did not include patients with reflux esophagitis C or D grade (by Los Angeles [LA] classification) and patients after bariatric surgery.

Conclusions

A three-year follow-up of the FundoRing method compared to standard one anastomosis gastric bypass confirms improved results of 24-hour pH impedance monometry, and a reduction of other late complications.

Declarations

Ethical approval

The study protocol was approved by the Ethics Committee of the medical center. Patient safety and well-being were ensured throughout the study in accordance with the Declaration of Helsinki. Informed consent was obtained from each participant before enrolment in the study.

Conflicts of interest

The authors declare no competing interests.

Contributions

OO was the principal investigator; he conceived the study. VR, MR contributed to the study design and to the development of the proposal. GD, BY, GY led the trial methodologists. BY, GD, K.Zh was involved in patient recruitment and acquisition of data. SSh and OO were involved in review of the scientific literature. All authors approved the final version of the manuscript to be submitted.

Author Contribution

OO was the principal investigator; he conceived the study. VR, MR contributed to the study design and to the development of the proposal. GD, BY, GY led the trial methodologists. BY, GD, K.Zh was involved in

patient recruitment and acquisition of data. SSh and OO were involved in review of the scientific literature. All authors approved the final version of the manuscript to be submitted.

Data Availability

Data furnished upon request.

References

1. Zhou XD, Chen QF, Yang W, Zuluaga M, Targher G, Byrne CD, Valenti L, Luo F, Katsouras CS, Thaher O, Misra A, Ataya K, Oviedo RJ, Pik-Shan Kong A, Alswat K, Lonardo A, Wong YJ, Abu-Abeid A, Momani A, Zheng H. M. H. (2024). Erratum: Burden of disease attributable to high body mass index: an analysis of data from the Global Burden of Disease Study 2021 (eClinicalMedicine (2024) 76, (S2589537024004279), (10.1016/j.eclinm.2024.102848)). eClinicalMedicine, 78, Article 102958. https://doi.org/10.1016/j.eclinm.2024.102958.
2. De Luca M, Shikora S, Eisenberg D, et al. Scientific Evidence for the Updated Guidelines on Indications for Metabolic and Bariatric Surgery (IFSO/ASMBS). OBES SURG. 2024;34:3963–4096. https://doi.org/10.1007/s11695-024-07370-7.
3. Singh B, Saikaustubh Y, Singla V, et al. One Anastomosis Gastric Bypass (OAGB) vs Roux en Y Gastric Bypass (RYGB) for Remission of T2DM in Patients with Morbid Obesity: a Randomized Controlled Trial. OBES SURG. 2023;33:1218–27. https://doi.org/10.1007/s11695-023-06515-4.
4. Musella M, Susa A, Manno E, De Luca M, Greco F, Raffaelli M, Cristiano S, Milone M, Bianco P, Vilardi A. и др. Осложнения после мини/одиного анастомозного шунтирования желудка (MGB/OAGB): Межучрежденческий опрос 2678 пациентов с промежуточным (5 лет) наблюдением. Ожиреные. Хирург. 2017;27:2956–2967. 10.1007/s11695-017-2726-2
5. Hailstone L, Tovmassian D, Nguyen CL, et al. Medium-term outcomes from a series of 1000 one anastomosis gastric bypass in Australia: a case series. Obes Surg. 2024;34:2111–5. https://doi.org/10.1007/s11695-024-07213-5.
6. Ahmed Y, Ataya K, Almubarak A, et al. One anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity: an updated meta-analysis and systematic review of randomized controlled trials. Obes Surg. 2025;35:1438–46. https://doi.org/10.1007/s11695-025-07776-x.
7. Bühler G, Schneider R, Kraljević M, et al. More anastomotic ulcers, less dumping, and equal weight loss in long vs. short gastric pouch in laparoscopic Roux-en-Y gastric bypass. Obes Surg. 2025;35:450–8. https://doi.org/10.1007/s11695-024-07645-z.
8. Balamurugan G, Leo SJ, Sivagnanam ST, Balaji Prasad S, Ravindra C, Rengan V, Arora E, Bindal V. Comparison of Efficacy and Safety Between Roux-en-Y Gastric Bypass (RYGB) vs One Anastomosis Gastric Bypass (OAGB) vs Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S): a Systematic Review of Bariatric and Metabolic Surgery. Obes Surg. 2023;33(7):2194–209. 10.1007/s11695-023-06602-6.

9. Mahawar KK, Himpens J, De Shikora SA, et al. The first consensus statement on one anastomosis/mini gastric bypass (OAGB/MGB) using a modified Delphi approach. Obes Surg. 2018;28:303–12.
10. Ospanov O, Yeleuov G, Buchwald JN, Zharov N, Yelembayev B, Sultanov K. A Randomized Controlled Trial of Acid and Bile Reflux Esophagitis Prevention by Modified Fundoplication of the Excluded Stomach in One-Anastomosis Gastric Bypass: 1-Year Results of the FundoRing Trial. Obes Surg. 2023;33(7):1974–83. 10.1007/s11695-023-06618-y. Epub 2023 Apr 26.
11. Ospanov O, Danyarova L, Sultanov K, Duysenov G, Zharov N, Yelembayev B, Ospanova S. Comparison of Dumping Syndrome After FundoRing and Standard One-anastomosis Gastric Bypass: A Randomized Controlled Trial. Obes Surg 2025 Dec 4. 10.1007/s11695-025-08416-0. Epub ahead of print.
12. BMJ. 2025;389:e081123.
13. Ospanov O. The Surgical Technique of Primary Modified Fundoplication Using the Excluded Stomach with Simultaneous Gastric Bypass. Obes Surg. 2023;33:1311–3. https://doi.org/10.1007/s11695-023-06505-6.
14. Ospanov OB. Surgical technique of laparoscopic mini-gastric bypass with obstructive stapleless pouch creation: A case series. Int J Surg. 2019;67:70–5. 10.1016/j.ijsu.2019.05.011. Epub 2019 Jun 1.
15. Carbajo MA, Luque-de-León E, Jiménez JM, Ortiz-de-Solórzano J, Pérez-Miranda M, Castro-Alija MJ. Laparoscopic One-Anastomosis Gastric Bypass: Technique, Results, and Long-Term Follow-Up in 1200 Patients. Obes Surg. 2017;27:1153–67. https://doi.org/10.1007/s11695-016-2428-1.
16. Serdar CC, Cihan M, Yücel D, Serdar MA. Sample size, power and effect size revisited: simplified and practical approaches in pre-clinical, clinical and laboratory studies. Biochem Med (Zagreb). 2021;31(1):010502. Epub 2020 Dec 15.
17. Weng T, Chang C, Dong Y, et al. Anaemia and related nutrient deficiencies after Roux-en-Y gastric bypass surgery: a systematic review and meta-analysis. BMJ Open. 2015;5:e006964. 10.1136/bmjopen-2014-006964.
18. Ospanov O, Ospanova S, Laparoscopic. Endoscopic Robotic Surg. 2025;8:156–9. https://doi.org/10.1016/j.lers.2025.06.002.
19. Saarinen T, Pietiläinen KH, Loimaala A, et al. Bile reflux is a common finding in the gastric pouch after one anastomosis gastric bypass. OBES SURG. 2020;30:875–81. https://doi.org/10.1007/s11695-019-04353-x.
20. Sargsyan N, Das B, Robb H, et al. Outcomes of One-Anastomosis Gastric Bypass Conversion to Roux-en-Y Gastric Bypass for Severe Obesity: A Systematic Review and Meta-analysis. OBES SURG. 2024;34:976–84. https://doi.org/10.1007/s11695-023-07050-y.
21. Werapitiya SB, Ruwanpura SP, Coulson TR. Laparoscopic fundoplication using the excluded stomach as a novel management option for refractory bile reflux following one anastomosis gastric bypass (OAGB). Obes Surg. 2022;32(2):561–6. https://doi.org/10.1007/s11695-021-05804-0.

22. Colpaert J, Horevoets J, Maes L, Uijtterhaegen G, Bruno Dillemans. Surgical treatment of therapy-resistant reflux after Roux-en-Y gastric bypass. A case series of the modified Nissen fundoplication. Acta Chir Belg. 2019. https://doi.org/10.1080/00015458.2019.1696028.
23. Kawahara NT, Alster K, Maloof-Filho F, et al. Modified Nissen fundoplication: laparoscopic antireflux surgery after Roux-en-route gastric bypass in obesity. Clin (Sao Paulo). 2012;67(5):531–3. https://doi.org/10.6061/clinics/2012(05)23.
24. Maurissen J, Yercovich N, Van Aelst P, et al. Modified Nissen fundoplication in the syndrome of late discharge after gastric bypass according to Roux. Obes Surg. 2021;31:2353–5. https://doi.org/10.1007/s11695-021-05310-3.
25. Ospanov O. Regarding Revision/Conversion Surgeries After One Anastomosis Gastric Bypass—An Experts' Modified Delphi Consensus. OBES SURG. 2025;35:2021–2. https://doi.org/10.1007/s11695-025-07912-7.
26. Ospanov O. Standardization of surgical technique of the fundoring method for laparoscopic gastric bypass. Sci Rep. 2025;15(1):44941. 10.1038/s41598-025-29153-5. PMID: 41462511; PMCID: PMC12750015.
27. Ospanov O, Zharov N, Yelembayev B, Duysenov G, Volchkova I, Sultanov K, Mustafin AA, Three-Arm. Randomized Controlled Trial of Primary One-Anastomosis Gastric Bypass: With FundoRing or Nissen Fundoplications vs. without Fundoplication for the Treatment of Obesity and Gastroesophageal Reflux Disease. Med (Kaunas). 2024;60(3):405. 10.3390/medicina60030405.
28. Ospanov O, Yelembayev B, Buchwald JN, Sultanov K, Rakhmetov M, Duysenov G, Tuleuov B. Comparative endoscopic ultrasound assessment of the gastric pouch after FundoRing-OAGB and OAGB. BMC Surg. 2025;26(1):23. 10.1186/s12893-025-03386-7.
29. Nehmeh WA, Baratte C, Rives-Lange C, et al. Acid Reflux Is Common in Patients With Gastroesophageal Reflux Disease After One-Anastomosis Gastric Bypass. OBES SURG. 2021;31:4717–23. https://doi.org/10.1007/s11695-021-05542-3.
30. Parmar CD, Mahawar KK. One anastomosis (mini) gastric bypass is now an established bariatric procedure: a systematic review of 12,807 patients. Obes Surg. 2018;28:2956–67.
31. Salame M, Jawhar N, Belluzzi A, Al-Kordi M, Storm AC, Abu Dayyeh BK, Ghanem OM. Marginal Ulcers after Roux-en-Y Gastric Bypass: Etiology, Diagnosis, and Management. J Clin Med. 2023;12(13):4336. 10.3390/jcm12134336.
32. Gao X, Dai S, Wang G, Li W, Song Z, Su Z, Zhu S, Zhu L, Li P. Large Versus Small Gastric Pouch for Roux-en-Y Gastric Bypass in Individuals With Type 2 Diabetes and a Body Mass Index < 35 kg/m2: Six-Year Outcomes. Front Endocrinol. 2022;13:913062. 10.3389/fendo.2022.913062.
33. Ospanov O. The Theoretical Calculation with Laparoscopic and 3D-MSCT Validation of the Volume Measurement Method for a Gastric Pouch in Gastric Bypass Surgery. https://www.frontiersin.org/journals/surgery/articles/10.3389/fsurg.2026.1708352/abstract.

Figures

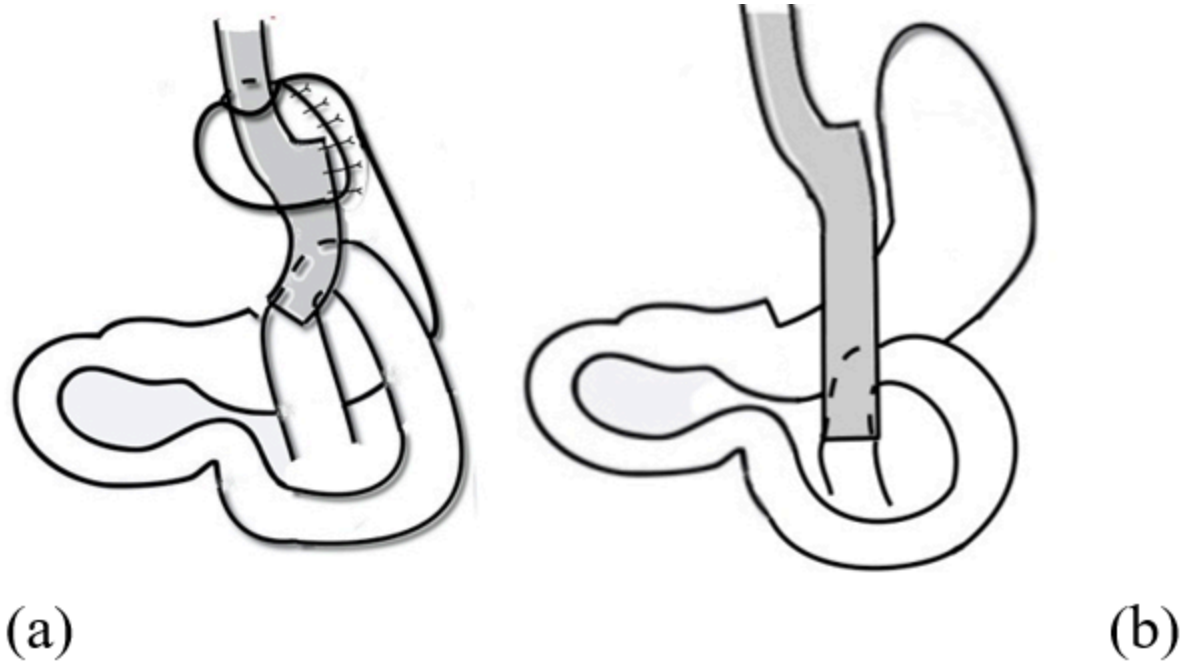


Figure 1

Schemes of one anastomosis gastric bypass (OAGB): (a) Investigational intervention - FundoRingOAGB (f-OAGB), (b) Comparator - standard OAGB (s-OAGB). Ó 2023. Oral Ospanov

$$\text{Unlimited population: } n = \frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2} \qquad n = \frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2}$$

$$\text{Finite population: } n' = \frac{n}{1+\frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2 N}} \qquad n = \frac{1.96^2 \times 0.5(1-0.5)}{0.05^2} = 384.16$$

Figure 2

Sample size calculation formulas for large population, where z is z-score (1.96), ε is the margin of error, n is the population size, $\hat{p}$ is the population proportion (0.5).

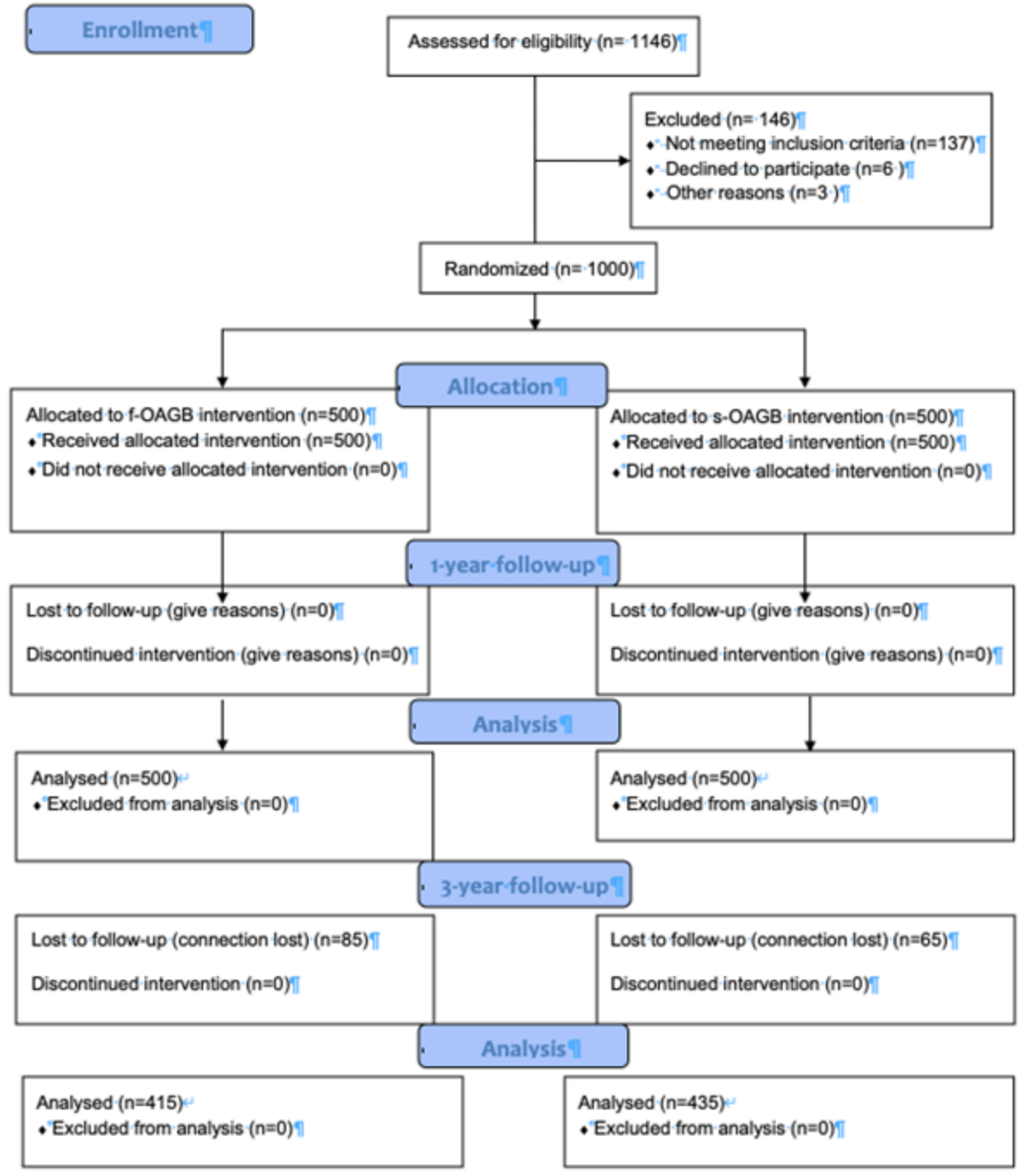


Figure 3

CONSORT flow diagram of patient enrollment, randomization, and analysis in the trial

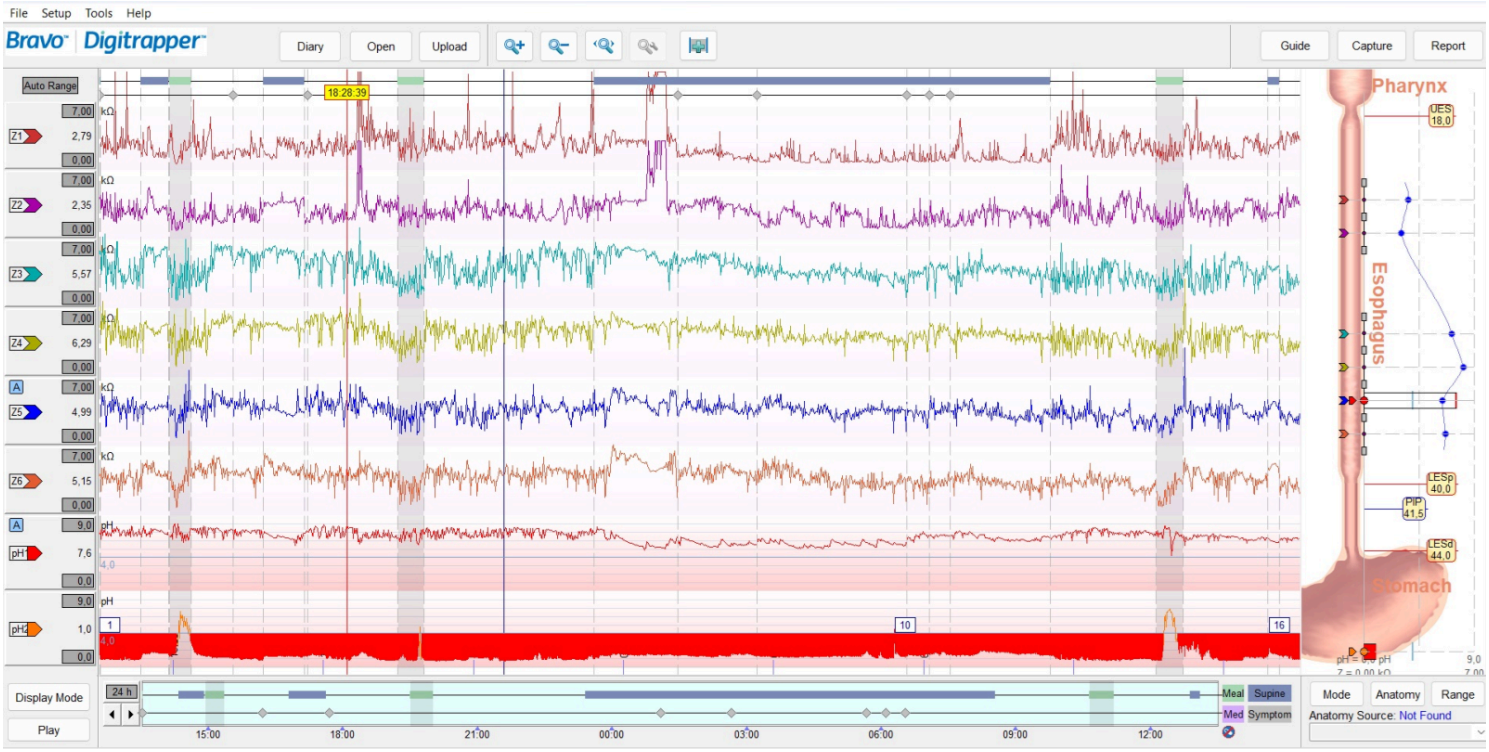


Figure 4

The demonstration of case of 24-hour pH impedance measurement 3- years follow-up after surgery in f-OAGBgroup with use Digitrapper™ Recorder, ZNID15+8R catheters and Reflux Software v6.1 (Medtronic, USA)