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Original article

# Safety and effectiveness of REALIZE adjustable gastric band: 5-year prospective study

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## Abstract

**Background:** The long-term safety results of the REALIZE (Ethicon Endo-Surgery, Inc., Cincinnati, OH) adjustable gastric band collected in this prospective, multicenter study in patients with morbid obesity are presented.

**Objectives:** To determine the reoperation rate, including band revisions, replacements, and explants, resulting from a serious adverse device-related event through years 4 and 5. Various efficacy measures were also assessed as secondary objectives.

**Setting:** Nine academic and/or private institutions.

**Methods:** The participating institutions enrolled 303 patients, who were then assessed on an annual basis, with 231 patients completing 5 years of follow-up. The study parameters included reoperation rates, changes in percentage of excess weight loss (%EWL), and changes in body mass index (BMI), as well as parameters of diabetes and dyslipidemia. Quality of life was assessed using the Short Form (SF)-36 and the Impact of Weight on Quality of Life-Lite questionnaires.

**Results:** The reoperation rate due to a serious adverse event in this population at 5 years after implantation with the REALIZE gastric band was 8.9%. The most common serious adverse event was band slippage, which affected 6.9% of the study population. The mean %EWL was 35.6% ± 26.84%, and the decrease in mean BMI was  $-7.01 \pm 5.45 \text{ kg/m}^2$  at 5 years. Patients experienced improvements in mean glycated hemoglobin and serum lipid levels, in addition to improvements in the quality of life measures.

**Conclusion:** No new safety concerns were identified during the 5 years of follow-up. Although the results of this study did not meet the predefined safety criteria of 8% or less, the safety profile and long-term effectiveness observed in this study are consistent with those in the current literature. (Surg Obes Relat Dis 2021;17:956–962.) © 2021 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

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**Keywords:** Morbid obesity; Bariatric surgery; Gastric band; Weight loss; REALIZE adjustable gastric band; Laparoscopic adjustable gastric band

According to the World Health Organization, the world-wide prevalence of obesity has tripled since 1975 [1]. It is estimated that there were 1.9 billion adults (age 18+ years) who were overweight and 650 million adults who were obese in 2016 [1]. Obesity is associated with a wide variety of undesirable health outcomes. Being overweight or obese substantially raises an individual's risk of mortality and morbidity from hypertension, dyslipidemia, type 2 diabetes (T2D), coronary heart disease, stroke, gall bladder disease, osteoarthritis, sleep apnea, respiratory problems, and endometrial, breast, prostate, and colon cancers [2]. In a more recent development, obesity, especially for those patients with a body mass index (BMI)  $\geq 35$  kg/m<sup>2</sup>, is a contributing factor to the severity of severe acute respiratory syndrome coronavirus 2 and the need for invasive mechanical ventilation [3].

Evidence has demonstrated that various strategies to reduce weight in overweight and obese individuals can successfully reduce the risks of mortality and morbidity [2,4–6]. Weight loss surgical procedures, including gastric bypass, sleeve gastrectomy, and adjustable gastric banding, exhibit the most substantial and durable responses among the available weight loss interventions. However, weight loss procedures are major operations with certain limitations and with both short- and long-term complications.

The purpose of this study is to present 5-year safety and effectiveness data for the REALIZE gastric band (manufactured by Ethicon Endo-Surgery, Inc.), as directed by the United States Food and Drug Administration (FDA). The primary objective was to assess the 5-year REALIZE gastric band reoperation rate, including band revisions, replacements, and explantations, resulting from serious adverse device-related events. The secondary (effectiveness) objectives were to evaluate changes in excess weight, quality of life, glycated hemoglobin (HbA1C) levels, and serum lipid levels 5 years after implantation of the REALIZE gastric band.

## Methods

### *Study centers*

We selected 9 academic and/or private practice clinical sites to participate in the study, based on their laparoscopic surgery experience and multidisciplinary team approach. All study centers followed a common protocol approved by their respective institutional review boards.

### *Study population*

This was a prospective, single-arm, multicenter study to fulfill the FDA requirement to perform a postapproval study to evaluate the long-term safety and effectiveness of the

REALIZE adjustable gastric band (clinicaltrials.gov: NCT 00543140). The initial study included 140 patients who had the device implanted under the original premarket approval (PMA) protocol (clinicaltrials.gov: NCT 00166205) and who consented to participate in the extended study. An additional 163 patients enrolled in a parallel protocol, for a total of 303 patients in the intent-to-treat population (ITT). Data were pooled from both protocols and data collection was conducted under similar conditions using the same device to assess safety and efficacy during the same assessment periods. A total of 231 (76.2%) patients completed the 5-year follow-up visit. The final study visit was completed on January 12, 2015. Male and female patients between 18 and 60 years of age (inclusive) who were considered appropriate candidates for a surgical weight loss intervention (body mass index [BMI] of  $>40$  kg/m<sup>2</sup> and  $\leq 55$  kg/m<sup>2</sup>, or a BMI  $\geq 35$  kg/m<sup>2</sup> and  $<40$  kg/m<sup>2</sup> with  $\geq 1$  co-morbid conditions) were considered for inclusion in both the initial PMA and extension cohorts, as well as the parallel postmarket study cohort.

Key exclusion criteria for the PMA extension group included:

1. Prior REALIZE explantation.

Key exclusion criteria for the parallel protocol included:

1. Women who were currently pregnant or not practicing birth control;
2. A previous malabsorptive or restrictive bariatric procedure;
3. The presence of inflammatory disease or congenital or acquired anomalies of the gastrointestinal (GI) tract;
4. Severe cardiopulmonary disease or other serious organic disease;
5. Upper GI bleeding disorders;
6. Gastroesophageal reflux disease;
7. Use of long-term steroid treatment or steroids within 15 days of surgery;
8. Being unable or unwilling to comply with the dietary restrictions required by this procedure;
9. Having a known allergy to materials contained within the band or its injection port;
10. The presence of a terminal illness with a life expectancy of  $\leq 5$  years;
11. An inability to refrain from use of anticoagulants or aspirin within 15 days before surgery; or
12. Acute or chronic infection (localized or systemic).

### Surgical technique

The REALIZE adjustable gastric bands, also known as the Swedish adjustable gastric bands or the curved adjustable gastric bands (Ethicon Endo-surgery, Cincinnati, OH), were implanted in accordance with their respective Instructions for Use. The surgical technique has been previously described by Phillips et al. [7].

### Statistical analyses

The sample size was selected to provide greater than 80% power, based on a 1-sided exact binomial test and a .05 significance level, to detect a significant difference from the performance goal of 8% after 4 and 5 years of implantation. The performance goal of 8% was based upon the safety results of the initial 3 years of this study, with input from the FDA. The reoperation rate in years 1–3 was ~2% per year and was projected to be 4% for years 4 and 5. Doubling this rate established a 8% performance goal based upon an inferiority margin factor of 2. Secondary effectiveness parameters were summarized by postimplantation year. For continuous parameters, we used descriptive statistics, including means, standard deviations, medians, minimums, maximums, and 95% confidence intervals (CIs) of the means. Changes from baseline were summarized in a similar manner, with baseline defined as the last available measurement on or before the date of implantation. An analysis of results from the Short Form (SF)-36 Questionnaire and the

Impact of Weight on Quality of Life (IWQOL-Lite) was consistent with the recommendations for these surveys, and the significance of changes from baseline was assessed using the matched-pairs *t* test. Categorical parameters were calculated as summaries with counts and percentages.

### Ethical approval and informed consent

All procedures performed in this study were in accordance with the ethical standards of the institution and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

### Results

The disposition of patients showing the merging of the 2 cohorts is presented in Fig. 1. Protocol CI-02-006 represents cohort from the PMA with the 2-year extension, and CI-07-006 represents the parallel cohort added as part of the post-approval study.

There were 9 participating institutions that contributed to this study. Table 1 lists the site numbers, the number of patients enrolled, and the number of patients who completed 60 months of follow-up.

Of the 303 patients, 72 did not complete a 5-year visit. The reasons for study discontinuation are listed in Table 2.

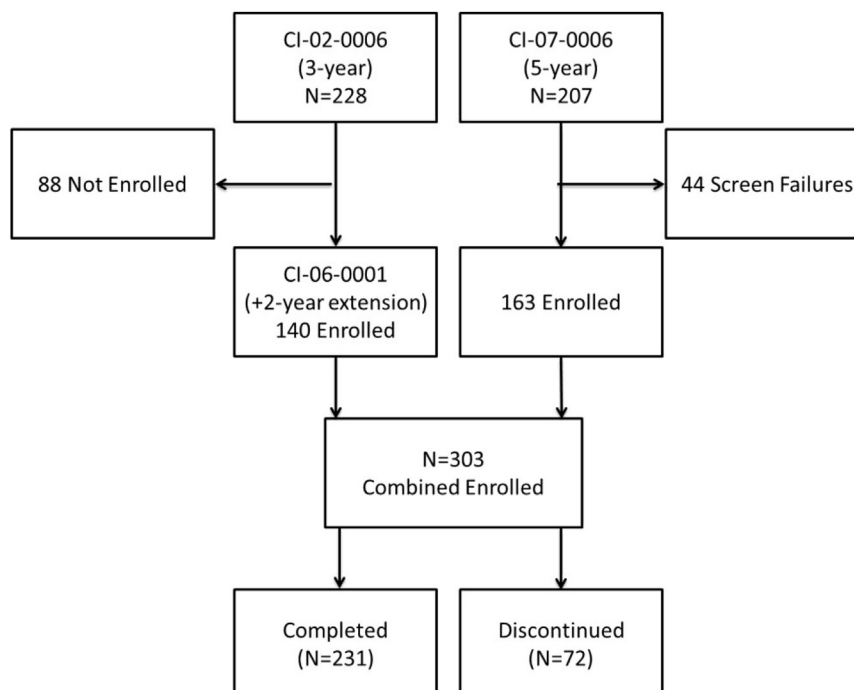


Fig. 1. Disposition of patients.

Table 1  
Site listing and number of participating patients

Site no.	Enrolled	Completed
1	22	12
2	76	52
3	14	8
4	81	59
5	20	18
6	13	13
7	19	18
8	29	28
9	29	23
Total	303	231

The complications or serious adverse events prompting device removal included device-related infections, band slippage, erosive gastritis due to band erosion, and impaired gastric emptying. There was 1 subject death in the study, during the second year of follow-up, due to myocardial infarction deemed unrelated to the study device or procedure. The demographic characteristics and baseline characteristics of the combined study population are presented in Table 3. The majority of patients were female and Caucasian, not of Hispanic origin, with a mean age of 40.5 years. The combined study population had a mean weight of 272.2 pounds, the mean BMI was 44.1 kg/m<sup>2</sup>, and the mean waist circumference was 49.2 inches.

Of the 303 patients enrolled, 76 (25.1%) experienced at least 1 serious adverse event over the course of the study. Table 4 lists the most common serious adverse events reported over the 5 years of follow-up and the numbers of patients affected.

### Reoperation rate

The primary safety endpoint was the reoperation rate, defined using the number of patients for whom reoperations were performed during years 4 and 5 as the numerator and the number of ITT patients as the denominator. For the purpose of this study, reoperations were defined as band

Table 2  
Reasons for study discontinuation

Reason for discontinuation	Intent-to-treat population, n = 303, n (%)
Lost to follow-up	33 (45.8)
Withdrawal of consent	13 (18.1)
Protocol violation	10 (13.9)
Early band removal due to a complication	9 (12.5)
SAE leading to removal of gastric band	3 (4.2)
Lack of effectiveness leading to explant or additional obesity surgical procedure	1 (1.4)
Death	1 (1.4)
Other	2 (2.8)
Total	72

SAE = serious adverse event.

explantations, band revisions, and band replacements resulting from a serious adverse device-related event. There were 27 qualified reoperations that fit the protocol definition, for a rate of 8.9% (27 of 303) with a 95% CI range of 6.0% to 12.7% ( $P = .6919$  for comparison to the goal of <8%). As mentioned previously, 1 death occurred during this study, owing to myocardial infarction considered unrelated to the REALIZE gastric band device or procedure.

### Secondary endpoints

While not the focus of this study, effectiveness parameters were collected and are summarized in Table 5.

Of the 303 enrolled patients, at the beginning of the study 16.2% (49 of 303) met the definition of having diabetes, with an HbA1C level  $\geq 6.5$  percent or a medical history diagnosis of T2D, and over the duration of the study the proportion with diabetes decreased to 8.6%. The mean HbA1C level of this diabetic subgroup was 7.8 percent (range, 6.4–11.9 percent) at baseline, decreasing to 7.2 percent (range, 5.4–11.5 percent) at the last evaluable visit. Of these 49 patients, 46.9% (23 of 49) experienced a drop in HbA1C to <6.5 percent, from an average of 7.5 percent to 5.85 percent. Another 14 patients (28.6%) showed improvement but remained at or above the 6.5 percent threshold at the last evaluable study visit. The remaining 24.5% (12 of 49) of patients showed an increase in the HbA1C level over the study period, with a mean baseline value of 7.4 percent increasing to 9.1 percent. The follow-up compliance for this group of patients was good. The mean follow-up duration, measured from the implant date to the final study visit, among the 49 patients with diabetes was 4.8 years, and ranged from 1.98

Table 3  
Demographic and baseline characteristics (n = 303)

Characteristic	n (%)
Sex	
Male	61 (20.1)
Female	242 (79.9)
Race	
Caucasian, not of Hispanic origin	205 (67.7)
Asian/Pacific Islander	8 (2.6)
Black, not of Hispanic origin	27 (8.9)
Hispanic	55 (18.2)
Other	8 (2.6)
Age, yr	
Mean $\pm$ SD	40.5 $\pm$ 9.90
Range	18–61
Weight, pounds	
Mean $\pm$ SD	272.2 $\pm$ 40.78
Range	187–412
BMI, kg/m <sup>2</sup>	
Mean $\pm$ SD	44.1 $\pm$ 4.76
Range	35–55
Waist circumference, in	
Mean $\pm$ SD	49.2 $\pm$ 5.67
Range	37–72

SD = standard deviation; BMI = body mass index.

Table 4  
Most common serious adverse events

Serious adverse event	ITT patients, n (%)
Band slippage	21 (6.9)
Erosion into gastrointestinal tract	4 (1.3)
Port displacement	3 (1.0)
Catheter-related complication	14 (4.6)
Gastric dilation <sup>a</sup>	7 (2.3)
Vomiting <sup>b</sup>	5 (1.6)
Hiatal hernia <sup>c</sup>	5 (1.6)

ITT = intent-to-treat.

<sup>a</sup> Gastric dilation was synonymous with pouch dilation, pouch enlargement, or prolapsed pouch.

<sup>b</sup> Vomiting was defined as a forcible loss of stomach contents deemed related to the study device.

<sup>c</sup> Hiatal hernia was defined as a protrusion of the upper stomach through the diaphragm into the chest cavity.

to 5.23 years. In total, 45 (91.8%) patients with diabetes had at least 4 years of follow-up, 3 (6.1%) had 2 to 4 years of follow-up, and 1 (2.0%) had <2 years of follow-up.

### Quality of life scores

Patients observed a general improvement in their quality of life, as measured by the SF-36 and IWQOL-Lite questionnaires, at every postsurgery visit. A higher number indicates a higher quality of life for both questionnaires. The SF-36 scores improved from baseline to 5 years in both dimensional components. The physical component summary increased significantly, from  $41.8 \pm 9.7$  to  $50.1 \pm 9.8$  ( $P < .0001$ ). The mental component summary increased, but not enough to reach statistical significance (from  $50.6 \pm 10.0$  to  $52.0 \pm 9.5$ ;  $P < .1507$ ). Results of the IWQOL-Lite questionnaires were also significant, with the mean transformed score increasing from  $46.6 \pm 20.0$  at baseline to  $79.1 \pm 19.3$  at 5 years ( $P < .0001$ ).

The secondary effectiveness results seen in this study demonstrate that there is a reasonable assurance that the use of the device for its intended use and conditions of use will provide clinically significant effectiveness results in a significant portion of the target population.

Table 5  
Weight loss and lab value results

Variable	1 yr, n = 295, mean (SD)	2 yr, n = 276, mean (SD)	3 yr, n = 271, mean (SD)	4 yr, n = 160, mean (SD)	5 yr, n = 240, mean (SD)
%EWL	39.0 (19.29)	42.6 (22.29)	41.2 (24.87)	37.4 (27.44)	35.6 (26.84)
Reduction in BMI, kg/m <sup>2</sup>	-7.80 (3.94)	-8.46 (4.52)	-8.21 (4.96)	-7.59 (5.57)	-7.01 (5.45)
Reduction in absolute weight, kg	-49.36 (26.16)	-52.30 (28.02)	-50.46 (30.52)	-46.74 (33.80)	-43.13 (32.49)
% With total weight reduction	17.86 (8.70)	19.24 (9.85)	18.58 (10.93)	17.02 (12.11)	16.04 (11.92)
Reduction in HbA1C	-.40 (.69)	-.41 (.75)	-.27 (.67)	-.43 (.57)	-.22 (.82)
Increase in HDL, mg/dL	7.6 (9.12)	11.4 (9.46)	10.2 (10.02)	9.4 (11.44)	9.3 (11.51)
Reduction in LDL, mg/dL	-3.8 (27.31)	-6.7 (27.68)	-8.2 (29.14)	-12.2 (31.17)	-7.3 (31.90)
Reduction in triglycerides, mg/dL	-42.0 (85.54)	-43.4 (89.63)	-41.6 (83.71)	-25.1 (122.66)	-28.2 (110.15)

SD = standard deviation; EWL = excess weight loss; BMI = body mass index; HbA1C = glycated hemoglobin; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

### Discussion

The need for additional surgical intervention is of high concern when considering the long-term utility of an adjustable gastric band for weight loss. The primary goal of this study was to determine the reoperation rate (band revisions, band replacements, and explantations resulting from serious adverse events) of gastric banding at years 4 and 5 after implantation. The safety success criterion for this study was an observed device-related reoperation rate that was 8% or less for years 4 and 5 of the study. This postmarket safety study had a reoperation rate of 8.9%, with a 95% CI range of 6.0% to 12.7%. Even though this study failed to meet its safety success criterion, the safety performance of the REALIZE gastric band was acceptable and consistent with the reoperation rates found in literature. Gastric band complications, such as removals and revisions, have been researched and are well documented. The overall 14.2% (43 of 303) reoperation rate at 5 years in this investigation aligns with the reoperation rate of 13.5% at 5 years in a similar population studied by Biertho et al. [8]. Furbetta et al. [9] followed 1840 laparoscopic adjustable gastric band (LAGB) patients over a 5-year period, finding a reoperation rate of 5.9% through 3 years and a cumulative rate of 10% at 5 years. In a large study, Ibrahim et al. [10] reported that 18.5% of patients required a reoperation due to band complications at 4.5 years.

No new safety concerns were identified in this study; as such, all safety events were consistent with previously published data for at least 5 years of follow-up.

Secondary endpoints included an evaluation of the REALIZE band's effectiveness. The REALIZE gastric band was effective in reducing excess weight loss in morbidly obese patients up to 5 years after implantation of the device, based on a percentage of excess weight loss (%EWL) of  $35.6 \pm 26.84\%$  at 5 years post surgery. In this multicenter study, the mean %EWL across all sites ranged from  $22.58 \pm 14.54$  to  $52.44 \pm 27.20$ . Table 6 shows the number of patients per site who completed the 5 year follow-up, and the corresponding mean %EWL.

No discernible trends were apparent regarding the mean %EWL at 60 months and the percentage of patients completing

Table 6  
Percentage of excess weight lost per site for completers at 60 months

Site no.	No. ITT patients	No. patients completed 60 mo	% LTF	Mean %EWL at 60 mo	SD
1	22	12	18.2	22.585	14.539
2	76	52	26.3	39.424	25.642
3	14	8	50	42.749	26.323
4	81	59	25.9	23.303	25.666
5	20	18	10	52.442	27.197
6	13	13	0	39.84	22.526
7	19	18	5.3	39.083	19.656
8	29	28	3.4	43.753	31.897
9	29	23	24.1	38.684	27.513
Total	303	231			

ITT = intent-to-treat population; EWL = excess weight loss; SD = standard deviation; LTF = lost to follow up.

the study. In the original PMA study, the mean %EWL at 3 years postsurgery was 41.2% [7], which is similar to the percentage seen in this postmarket extension study (i.e., 41.2%). This and other similarities are an indication of the validity of merging the populations reported herein. Table 4 lists the complete weight loss and lab value results. In the present study, the mean reduction in absolute weight at 5 years post surgery was  $-43.1 \pm 32.5$  pounds, while the mean percentage in weight reduction at 5 years post surgery was  $16.0 \pm 11.9\%$ . This translated to a mean reduction in BMI of  $-7.0 \pm 5.45$  kg/m<sup>2</sup> at 5 years post surgery.

In comparison to similar studies, the 5-year postsurgery mean %EWL of 35.6 with a BMI change of  $-7.0$  kg/m<sup>2</sup> suggests that the benefits of LAGB are durable as well as repeatable. Similarly, Vitiello et al. [11], noted a mean % EWL of 40.5% and a BMI change of  $-9.36$  kg/m<sup>2</sup> at 5 years. O'Brien et al. [12], in a large, long-term LAGB population study (n = 5235), showed a mean %EWL of 47.7% and a reduction in BMI of 8.5 points at 5 years.

Improvements in various metabolic factors were maintained at 5 years post surgery. Mean reductions in HbA1C; reductions in low-density lipoprotein, total cholesterol, and triglycerides; and a mean increase in high-density lipoprotein were all maintained at 5 years post surgery, with similar results as those described in the 3-year study. In the 49 patients meeting the definition of being diabetic due to an HbA1C level of  $\geq 6.5$  percent or a medical history diagnosis of T2D, almost half (46.9%) reduced their HbA1C to nondiabetic levels during the study.

In addition to an acceptable reoperation rate, an acceptable %EWL, and improvements in metabolic factors, these changes were accompanied by lasting improvements in the quality of life at 5 years postsurgery, based on SF-36 Physical Component and domain scores and the IWQOL-Lite total transformed score and domain scores.

There were several limitations in this investigation. There was no comparison group, but the subject functioned as his/her own control, with results pre- and posttreatment. The results of this study may not be generalizable to clinical practice, as the study was done in specialized centers and may

not represent all sites of care. For various reasons, with the most common being loss to follow-up, 24% (72 of 303) of our patient group did not complete the entire study.

## Conclusions

This postmarket safety study had a reoperation rate of 8.9%, which did not meet the arbitrary, predetermined safety success criterion of 8%. Even so, the general safety profile, reoperation rate, and effectiveness endpoints that were observed in this study are consistent with those reported in current literature. No unexpected findings were observed.

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## Disclosures

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## References

- [1] World Health Organization. Fact sheet on Obesity and Overweight. 2020. Here is the link: <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>.
- [2] Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults—the evidence report. National Institutes of Health. *Obes Res* 1998;6(Suppl 2):51S–209S.
- [3] Simonnet A, Chetboun M, Poissy J, et al., LICORN and the Lille Coronavirus Disease 2019 (COVID-19) and Obesity study group. High prevalence of obesity in severe acute respiratory syndrome

- coronavirus 2 (SARS-CoV-2) requiring invasive mechanical ventilation. *Obesity (Silver Spring)* 2020;28(7):1195–9.
- [4] Cuneen SA. Review of meta-analytic comparisons of bariatric surgery with a focus on laparoscopic adjustable gastric banding. *Surg Obes Relat Dis* 2008;4(3 Suppl):S47–55.
- [5] Korenkov M, Shah S, Sauerland S, Duenschede F, Junginger T. Impact of laparoscopic adjustable gastric banding on obesity co-morbidities in the medium- and long-term. *Obes Surg* 2007;17:679–83.
- [6] O'Brien PE, McPhail T, Chaston TB, Dixon JB. Systematic review of medium-term weight loss after bariatric operations. *Obes Surg* 2006;16:1032–40.
- [7] Phillips E, Ponce J, Cunneen SA, et al. Safety and effectiveness of REALIZE adjustable gastric band: 3 year prospective study in the United States. *Surg Obes Relat Dis* 2009;5(5):588–97.
- [8] Biertho L, Steffen R, Branson R, et al. Management of failed adjustable gastric banding. *Surgery* 2005;137(1):33–41.
- [9] Furbetta N, Gragnani F, Flauti G, Guidi F, Furbetta F. Laparoscopic adjustable gastric banding on 3566 patients up to 20-year follow-up: long-term results of a standardized technique. *Surg Obes Relat Dis* 2019;15(3):409–16.
- [10] Ibrahim AM, Thumma JR, Dimick JB. Reoperation and Medicare expenditures after laparoscopic gastric band surgery. *JAMA Surg* 2017;152(9):835–42.
- [11] Vitiello A, Piloni V, Ferraro L, Forestieri P. Is the sleeve gastrectomy always a better procedure? Five-year results from a retrospective matched case-control study. *Obes Surg* 2018;28(8):2333–8.
- [12] O'Brien PE, Hindle A, Brennan L, et al. Long-term outcomes after bariatric surgery: a systematic review and meta-analysis of weight loss at 10 or more years for all bariatric procedures and a single-centre review of 20-year outcomes after adjustable gastric banding. *Obes Surg* 2019;29(1):3–14.