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# Efficacy of transoral outlet reduction in Roux-en-Y gastric bypass patients to promote weight loss: a systematic review and meta-analysis



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## ABSTRACT

**Background and study aims** Transoral outlet reduction (TORe) is an endoscopic procedure used in patients with weight gain post Roux-en-Y gastric bypass (RYGB). We performed a systematic review and meta-analysis to evaluate the efficacy and safety of TORe with a full-thickness suturing device for treating patients with weight regain after RYGB.

**Patients and methods** We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, Google-Scholar, MEDLINE, SCOPUS, and Web of Science databases (earliest inception to March 2020). The primary outcomes assessed were technical success, absolute weight loss (AWL) and percent of total weight loss (% TWL) at 3, 6, and 12 months after the procedure. The secondary outcomes assessed were pooled rate of adverse events (AEs), adverse event subtypes and association of size of gastrojejunal anastomosis (GJA) and percent TWL.

**Results** Thirteen studies on 850 patients were included. The pooled rate of technical success was 99.89 %. The absolute weight loss (kg) at 3, 6, and 12 months was 6.14, 10.15, and 7.14, respectively. The percent TWL at 3, 6, and 12 months was 6.69, 11.34, and 8.55, respectively. The pooled rate of AE was 11.4 % with abdominal pain being the most common adverse event. The correlation coefficient (r) was –0.11 between post TORe GJA size and weight loss at 12 months.

**Conclusion** TORe is an endoscopic procedure that is safe and technically feasible for post RYGB with weight gain.

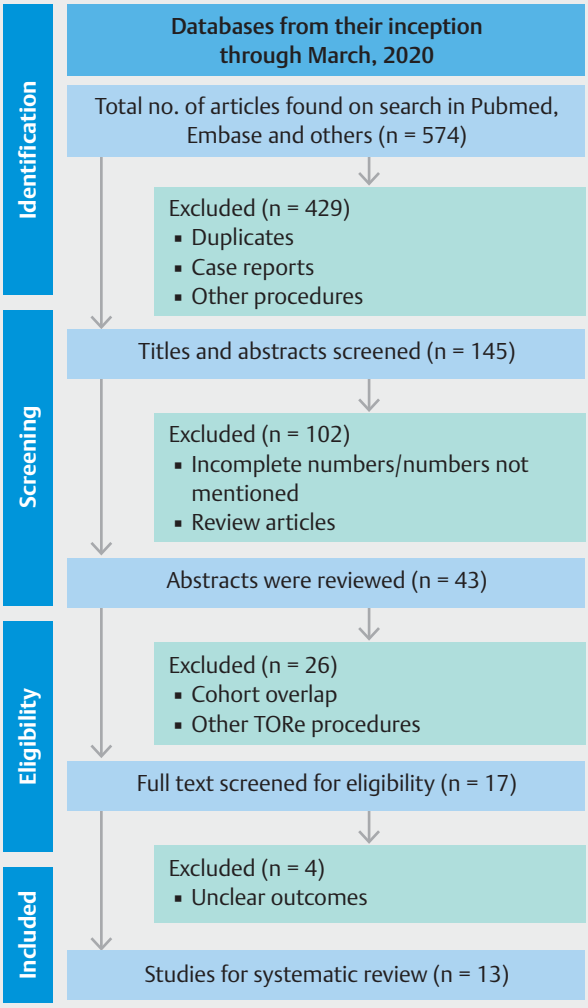
## Introduction

Obesity is a growing global epidemic associated with increased morbidity and mortality [1]. Multiple comorbidities, including diabetes mellitus, cardiovascular disease, and stroke, are associated with obesity [2]. Bariatric surgery is the gold standard of care for effective sustainable weight reduction and has been shown to induce remission of diabetes mellitus and metabolic syndrome [3, 4]. Roux-en-Y gastric bypass surgery (RYGB) is a

common form of effective bariatric surgery that leads to significant long term weight loss compared to sleeve gastrectomy or gastric banding [5].

Despite the efficacy of RYGB, some studies have noted weight regain or insufficient weight loss in a proportion of patients [3, 6]. Factors contributing to weight gain after RYGB include mechanical dehiscence of staples, dilation of the gastrojejunal anastomosis (GJA), and patient-related factors such as dietary noncompliance, physical inactivity, and mental health disorders [7, 8]. Due to the occurrence of weight gain, revision surgery after RYGB has become increasingly popular [9]. The American Society of Metabolic and Bariatric Surgery (ASMBS) estimates that incidence of patients requiring revision of prior bariatric surgeries has more than doubled in United States, increasing from 6% in 2011 to 15.4% in 2018 [10]. Currently, there is no established standard management for revisional surgery after RYGB. Options include gastric banding revision (which involves placement of a prosthetic band distal to the gastro-esophageal junction), conversion to a distal RYGB by taking down the jejunojejunostomy with creation of a reanastomosis to the ileum, biliopancreatic diversion/duodenal switch revision and endoluminal procedures such as transoral outlet reduction (TORe) [3].

TORe is a minimally invasive endoscopic surgery that reduces the size of the GJA to achieve weight loss through mechanical restriction [11, 12]. According to Abu Dayyah et al, the diameter of the GJA is a significant predictor of weight regain [13]. In 2014, TORe was first described as an endoscopic suturing procedure that reduces the size of the GJA [14]. This procedure has been performed using various techniques including plication devices (Stomaphyx; Endogastric Solutions, California, United States), suction based superficial suturing devices (Endocinch; C.R. Bard, Murray Hill, New Jersey, United States) or with the full thickness suturing devices (Overstitch; Apollo Endosurgery, Texas, United States) [15]. TORe initially demonstrated safety and efficacy with the suction-based superficial suturing system (Endocinch; C.R. Bard, Murray Hill, New Jersey, United States) [16]. Further developments with the full-thickness suturing system (Overstitch device) demonstrated superior durability and greater weight loss compared to the suction-based superficial system (Endocinch; C.R. Bard, Murray Hill, New Jersey, United States) [17]. The endoscopic gastric plication device (Stomaphyx; Endogastric Solutions, California, United States) did not demonstrate satisfactory weight loss [18]. TORe has shown promising results in a previous meta-analysis performed for all types of TORe procedures including plication devices, superficial suturing devices, Argon Plasma Coagulation (APC) and over-the-scope-clip (OTSC; Ovesco AG, Tubingen, Germany) [19]. Currently the full-thickness suturing device (Overstitch; Apollo Endosurgery, Texas, United States) with APC is the most commonly used device and this meta-analysis evaluated the efficacy and safety of TORe with this device as a therapeutic option for treating patients with weight regain after a RYGB.




▶ **Fig. 1** Study selection process in accordance with preferred reporting items for systematic reviews and meta-analysis statement.

## Methods

### Search strategy

We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, Google-Scholar, MEDLINE, SCOPUS, and Web of Science databases (earliest inception to March 2020). We followed the Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, by using predefined protocol, to identify studies reporting on TORe in patients with weight regain after RYGB surgery (▶ **Fig. 1**) [20]. MOOSE guidelines checklist and PRISMA checklist can be seen in **Supplementary Fig. 1** and **Supplementary Fig. 2** respectively.

Key words used in the literature search included a combination of 'Transoral, 'outlet', 'reduction', 'Roux-en-Y', 'suture', 'gastric' and 'bypass'. The search was restricted to studies in human subjects in peer-reviewed journals. Two authors (BD, SS) independently reviewed the title and abstract of studies identified in primary search and excluded studies that did not

▶ **Table 1** Quality assessment of the study with Newcastle Ottawa Scale and Jadad scale.

| Study | Year | Type of study | No. of patients | Newcastle-Ottawa Scale | | |
|---|---|---|---|---|---|---|
| | | | | Selection | Comparability | Outcome |
| Jirapinyo [37] | 2019 | Retrospective | 331 | *** | * | *** |
| Callahan [23] | 2019 | Retrospective | 70 | *** | * | *** |
| Kothari [42] | 2018 | retrospective | 10 | ** | * | ** |
| Staudenmann [25] | 2017 | retrospective | 22 | ** | * | ** |
| Tsai [36] | 2018 | retrospective | 81 | *** | * | ** |
| Vargas [12] | 2017 | retrospective | 130 | *** | * | ** |
| Catalano [43] | 2016 | prospective | 29 | ** | * | ** |
| Espinet [26] | 2018 | retrospective | 13 | ** | * | ** |
| Fayad [27] | 2019 | prospective | 44 | *** | * | ** |
| Goyal [24] | 2016 | prospective | 40 | *** | * | ** |
| Hollenbach [28] | 2019 | retrospective | 26 | *** | ** | ** |
| Laterza [44] | 2017 | prospective | 35 | ** | * | * |
| Jadad Scale for RCT | | | | | | |
| Study | Year | Type of study | No. of patients | Randomization | Blinding | Withdrawals |
| Brunaldi | 2020 | RCT | 19 | 2 | 0 | 1 |

address the primary research question, based on pre-specified exclusion and inclusion criteria. The full text of the remaining articles was reviewed to determine whether they contained relevant information. Any discrepancy in article selection was resolved by consensus with a third author (YN).

The bibliographic section of the selected articles, as well as the systematic and narrative articles on the topic were manually searched for additional relevant articles.

## Study selection

In this meta-analysis, we included studies that evaluated performance of a TORe procedure with a full-thickness suturing device (Overstitch; Apollo Endosurgery, Texas, United States) in patients with weight regain after RYGB surgery. Studies irrespective of inpatient/outpatient setting, geography, abstract/manuscript status, were included as long as they provided data needed for the analysis.

The following were our exclusion criteria: (1) alternative methods of TORe like StomaphyX (Endogastric Solutions, San Mateo, California), Bard Endocinch (C.R. Bard, Murray Hill, New Jersey); (2) studies with sample size <10 patients; (3) studies performed in the pediatric population (age <18 years); and (4) studies not in English language.

In cases of multiple publications from the same cohort and/or overlapping cohorts, data from the most recent and/or most appropriate comprehensive report were included.

## Data abstraction and quality assessment

Data on study-related outcomes in the individual studies were abstracted onto a standardized form by at least three authors (BD, SS, AD), and two authors (BD, SS) did the quality scoring independently.

The collected data were treated akin to single group cohort studies, therefore, we used the Newcastle-Ottawa scale for cohort studies to assess the quality of studies [21]. Quality assessment for randomized controlled trials was done with Jadad-Oxford scale [22]. Details of quality assessment are provided in ▶ **Table 1**.

## Outcomes assessed

The primary outcomes assessed were (a) technical success of TORe procedure with full thickness suturing device; (b) absolute weight loss at 3, 6, and 12 months after the procedure; and (c) percent of total weight loss (TWL) at 3, 6, and 12 months after the procedure.

The secondary outcomes assessed were (a) pooled rate of adverse events (AEs) of TORe procedure; (b) pooled rate of AE subtypes: abdominal pain, bleeding, perforation, stenosis; (c) association of size of GJA and percent TWL; and (d) subgroup analysis between prospective and retrospective studies for primary and secondary outcomes.

## Definitions

Definition of outcomes:

Technical success of TORe procedure with full-thickness suturing device was defined in 7 studies. Four studies [12, 23–25]

▶ **Table 2** Description of 13 studies used in the final analysis.

| Study | Year | Country | Single/Multicenter | Manuscript/Abstract | No. of patients | No. of procedures | Tech. Success | Mean age | Males | Females |
|---|---|---|---|---|---|---|---|---|---|---|
| Jirapinyo [37] | 2020 | USA | Single | Manuscript | 331 | 342 | 342 | 50 | 47 | 284 |
| Callahan [23] | 2019 | USA | Single | Manuscript | 70 | 70 | 70 | 51.3 | 7 | 63 |
| Kothari [42] | 2018 | USA | Single | Abstract | 10 | 10 | 10 | 52.6 | 1 | 9 |
| Staudenmann [25] | 2017 | Switzerland | Single | Abstract | 22 | 22 | 22 | – | – | – |
| Tsai [36] | 2018 | Switzerland | Single | Manuscript | 81 | 97 | 97 | 48 | 22 | 59 |
| Vargas [12] | 2017 | USA | Multicenter | Manuscript | 130 | 130 | 130 | 47.12 | 16 | 114 |
| Catalano [43] | 2016 | USA | Single | Abstract | 29 | 29 | 29 | – | 5 | 24 |
| Espinet [26] | 2018 | Spain | Multicenter | Manuscript | 13 | 13 | 13 | 50 | 5 | 8 |
| Fayad [27] | 2019 | USA | Single | Manuscript | 44 | 44 | 43 | – | – | – |
| Goyal [24] | 2016 | USA | Single | Manuscript | 40 | 40 | 40 | 53 | 9 | 31 |
| Hollenbach [28] | 2019 | Germany | Single | Manuscript | 26 | 26 | 26 | – | – | – |
| Laterza [44] | 2017 | Italy | Single | Abstract | 35 | 35 | 35 | – | – | – |
| Brunaldi [29] | 2020 | Brazil | Single | Manuscript | 19 | 19 | 19 | 45.8 | – | – |

considered post procedure GJA size < 10 mm and four studies [26–29] considered post-procedure GJA size < 12 mm to be technically successful.

Absolute weight loss was calculated using the formula TORe weight- follow up weight and TWL was defined as (TORe weight-follow up weight)/TORe weight x 100 %.

AEs were defined as complications that were directly related to the procedure. AE were divided into mild, moderate, severe and fatal as per ASGE guidelines [30].

### Statistical analysis

We used meta-analysis techniques to calculate the pooled estimates for each outcome of interest following the methods suggested by DerSimonian and Laird using the random-effects model where appropriate [31]. In several instances in the data, values of zero occurred. In these instances, we avoided inadvertently adding positive bias to the outcomes by writing syntax to calculate weighted summary statistics. In this way, we preserved the integrity of the actual data values and avoided possible biases in reporting the outcomes. We assessed heterogeneity between study-specific estimates by using Cochran Q statistical test for heterogeneity, 95 % prediction interval (PI), which deals with the dispersion of the effects, and the $I^2$ statistics [32, 33]. In this, values of < 30 %, 30 % to 60 %, 61 % to 75 %, and > 75 % were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively [34]. Publication bias was ascertained, qualitatively, by visual inspection of funnel plot and quantitatively, by the LFK test; further, the extent of potential bias was ascertained utilizing the Doi Plot [35]. Sensitivity analysis was conducted in instances of potential bias by recalculating all statistics after removal of studies leading to LFK asymmetry; if removal of the study impacted estimates, the study was removed from the final analysis. Finally, we investigated potential correlative associations between post TORe GJA size and weight loss at 12 months using a study-based weighted correlation. All meta-analyses were performed using MetaXL software (v. 5.3; Epigear International), and the weighted correlation was calculated using R (v 3.6.1; Vienna, Austria) with the < wtd.cor > script in the "weight" package, with bootstrapped *P* values calculated with n = 10,000 iterations.

## Results

### Search results and population characteristics

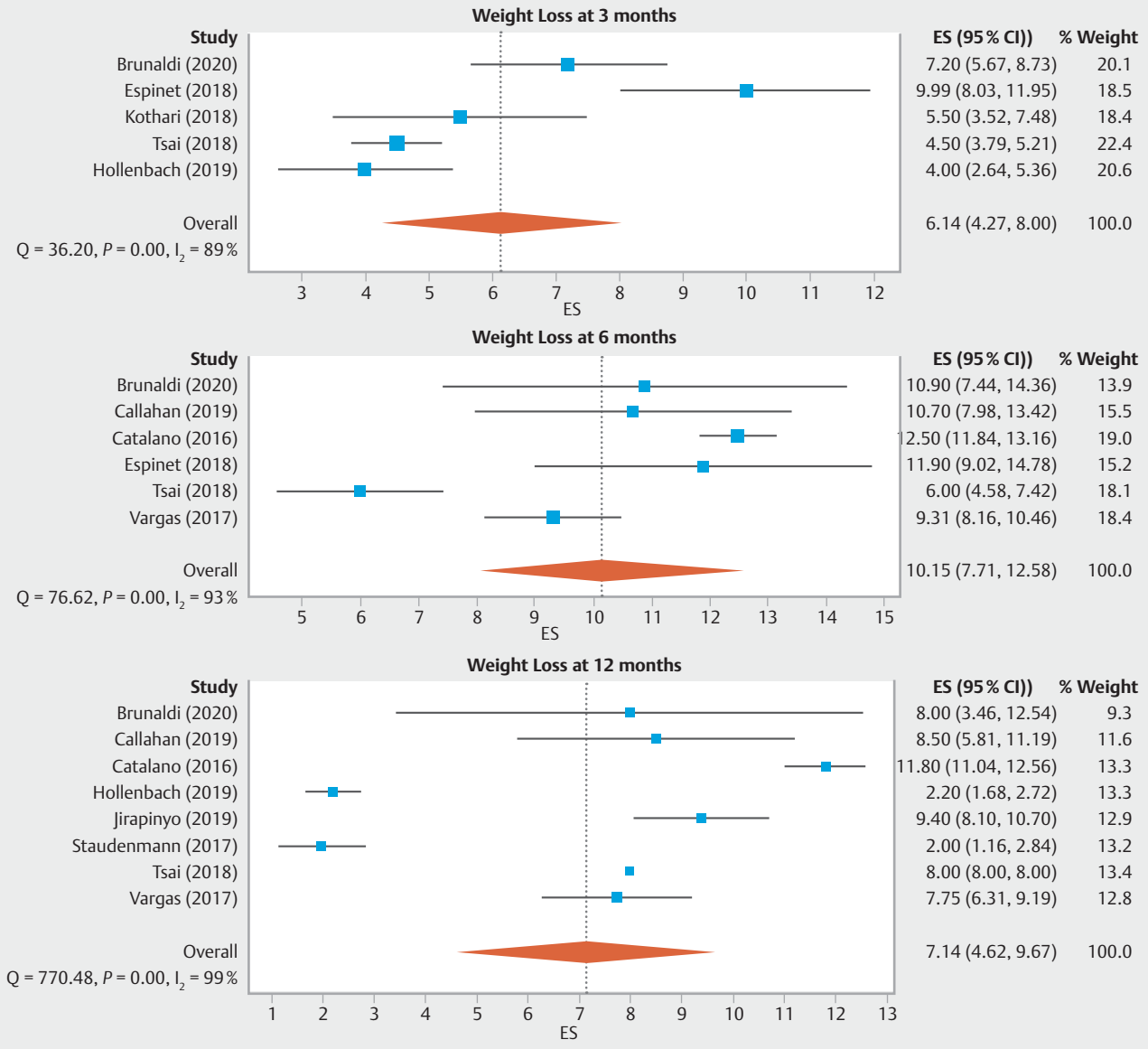
From an initial 574 studies, thirteen studies reported use of TORe with full-thickness suturing device in RYGB patients. In our search process, we encountered multiple studies that had overlapping cohorts. The most comprehensive studies were included in the final analysis. The schematic diagram of study selection is illustrated in ▶ **Fig. 1**.

The majority of patients were females. The indication for TORe procedure was weight gain after RYGB. All studies used the full-thickness suturing device.

### Characteristics and quality of included studies

The meta-analysis included 13 independent cohort studies with total of 850 patients and 877 TORe procedures were performed on these patients.

None of the studies were population-based. Two studies were multicenter, and 11 studies were from a single center. Six studies had more than 40 patients, four studies had more than 20 patients, and three studies had less than 20 patients. All of




▶ **Fig. 2** Forest plots showing absolute weight loss at 3, 6, and 12 months.

the studies included had clear information reporting on the technical success, AE rates, including the sub-category of the AE. Five, six, and eight studies reported on 3-, 6-, and 12-month weight loss outcomes, respectively. Two studies reported 5-year weight loss outcomes. Nine studies were published in manuscript (peer reviewed) form and four studies were in abstract form. Eight studies were retrospective cohort studies, four were prospective cohort studies and one study was a randomized controlled trial.

▶ **Table 1** and ▶ **Table 2** describe the characteristics of the included studies and the study quality assessment, respectively.

## Meta-analysis outcomes

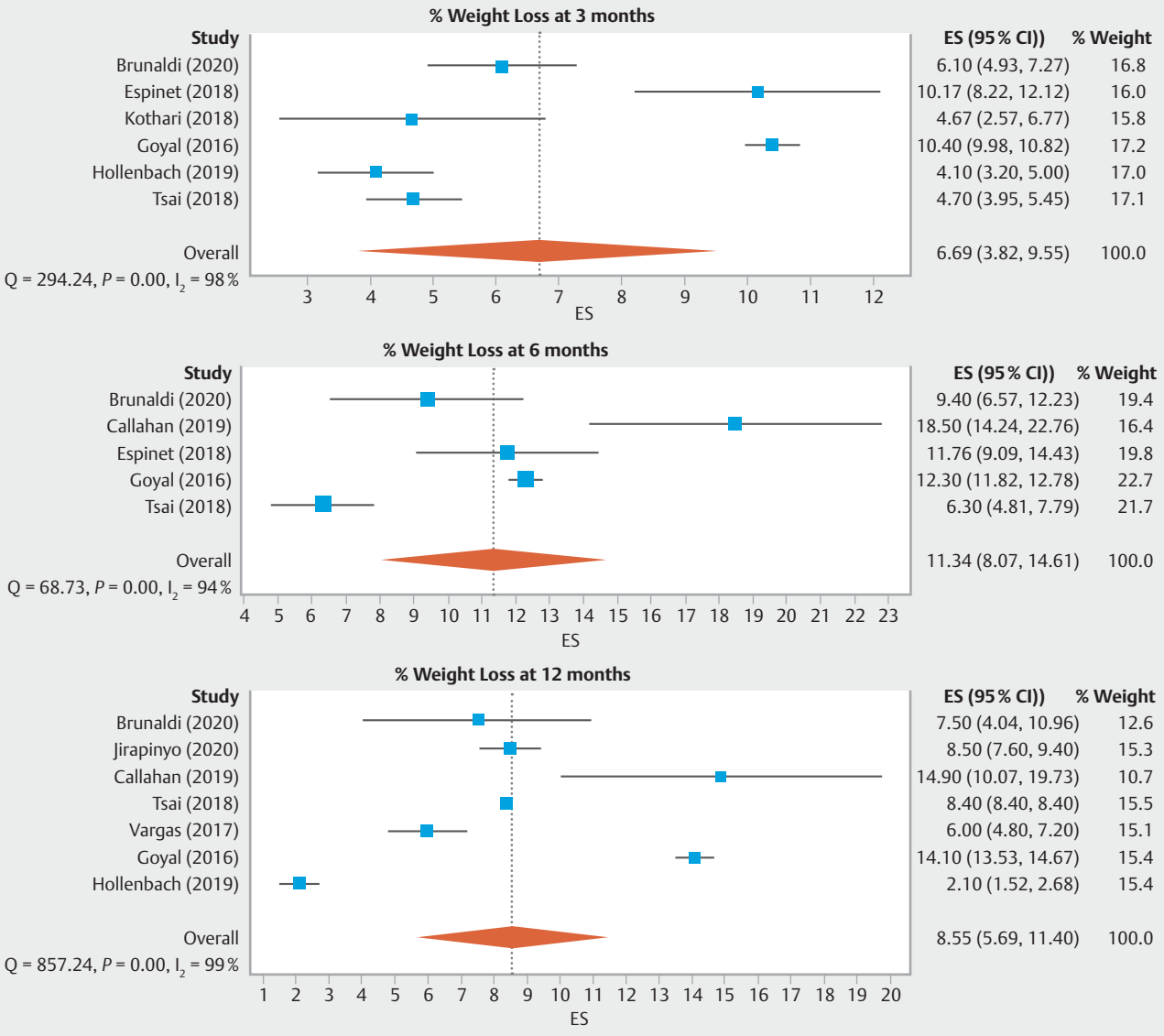
### Primary outcomes

The calculated pooled rate of technical success was 99.89% (± 3.52%).

The absolute weight loss at 3, 6, and 12 months was 6.14 kg (95% CI 4.27–8, $I^2$ = 89%, PI = –0.84 to 13.11), 10.15 kg (95% CI 7.71–12.58, $I^2$ = 93%, PI = 1.54 to 18.74) and 7.14 kg (95% CI 4.62–9.67, $I^2$ = 99%, PI = –2 to 16.29), respectively.

The percednt TWL at 3, 6, and 12 months 6.69% (95% CI 3.82–9.55%, $I^2$ = 98%, PI = –3.87 to 17.2), 11.34% (95% CI 8.07–14.67, $I^2$ = 94%, PI = –0.09 to 23.67) and 8.55% (95% CI 5.69–11.4, $I^2$ = 99%, PI = –1.67 to 18.77) respectively.

▶ **Fig. 2** and ▶ **Fig. 3** show the forest plots for absolute weight loss and percent total weight loss, respectively.




▶ **Fig. 3** Forest plots showing percent total weight loss at 3, 6, and 12 months.

### Secondary outcomes

The calculated pooled rate of AEs was 11.4% (±10.11) with abdominal pain being the most common adverse event at 4.22% (±8). ▶ **Table 3** describes the AEs in different studies. The calculated pooled rate of mild, moderate, and severe AEs was 4.56% (±5.45%), 1.6% (±1.65%) and 0.57% (±1.35%), respectively. Subgroup analysis could be only performed for AEss and showed an overall lower rate of AEs for prospective studies (7.78%±7.46%) compared to retrospective studies (12.25%±10.81%). The correlation coefficient (r) was –0.11 (t=–3.63; $P$ <0.001) between post TORe GJA size and weight loss at 12 months.

## Validation of meta-analysis results

### Sensitivity analysis

To assess whether any one study had a dominant effect on the meta-analysis, we excluded one study at a time and analyzed its effect on the main summary estimate. On this analysis, no single study significantly affected the outcome or the heterogeneity.

## Heterogeneity

We assessed heterogeneity using the $I^2$ percentage values and prediction intervals (PI). Substantial heterogeneity with wide PI was noted in the analysis of absolute weight reduction and percent TWL at 3, 6, and 12 months.

▶ **Table 3** Adverse events in all procedures.

| Study | Year | Total adverse events | Bleeding | Perforation | Abdominal pain | Stenosis | Others |
|---|---|---|---|---|---|---|---|
| Jirapinyo [37] | 2020 | 35 | 6 | 0 | 8 | 2 | 19 |
| Callahan [23] | 2019 | 4 | 2 | 1 | 0 | 0 | 1 |
| Kothari [42] | 2018 | 2 | 0 | 0 | 0 | 0 | 2 |
| Staudenmann [25] | 2017 | 1 | 0 | 1 | 0 | 0 | 0 |
| Tsai [36] | 2018 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vargas [12] | 2017 | 41 | 0 | 0 | 23 | 0 | 18 |
| Catalano [43] | 2016 | 6 | 0 | 0 | 6 | 0 | 0 |
| Espinet [26] | 2018 | 3 | 1 | 0 | 0 | 0 | 2 |
| Fayad [27] | 2019 | 3 | 0 | 0 | 0 | 0 | 3 |
| Goyal [24] | 2016 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hollenbach [28] | 2019 | 1 | 0 | 1 | 0 | 0 | 0 |
| Laterza [44] | 2017 | 3 | 1 | 1 | 0 | 0 | 1 |
| Brunaldi [29] | 2020 | 1 | 0 | 0 | 0 | 1 | 0 |

### Publication bias

Based on visual inspection of the funnel plot and the Doi Plot, as well as quantitative measurement based on the LFK test, there was evidence of asymmetry and hence potential publication bias. Sensitivity analysis by removal of asymmetric studies revealed the impact of the possible publication bias but this did not lead to a statistical change in the calculated estimate or the conclusion of this meta-analysis. However, it should be noted that the ability to detect bias is limited.

## Discussion

Our study demonstrates that TORe is an alternative minimally invasive surgical treatment for patients with weight gain following RYBG. TORe showed a high technical success and a low adverse event rate. To our knowledge, this is the first meta-analysis of the commercially available full thickness suturing device for patients with weight gain after RYGB.

In our meta-analysis, we analyzed % TWL and absolute weight loss at 3, 6, and 12 months. Our pooled percent TWL and AWL at 3 and 6 months showed persistent weight loss. At the 12-month mark there was evidence of weight recidivism from 11.34 % TWL at 6 months to 8.55 %. Two studies [24, 36] showed persistent weight loss and the rest of the studies demonstrated weight recidivism at 12 months. It is hypothesized that the weight loss post TORe was secondary to reduction in GJA size, improved eating habits, quicker gastric emptying times, and induction of satiety by stimulating gastric stretch receptors [11, 24, 27, 28]. Weight recidivism was reported to be due to genetic factors, lack of dietary compliance, or due to suture breakage/migration leading to dilation of the GJA after TORe [26–28, 36].

Long-term outcomes (5 years) were reported in two studies [23, 37]. Callahan et al exhibited weight recidivism in their long-term analysis of TORe. In subgroup analysis of different suture types in this study, the pursestring suture group showed weight loss while the interrupted suture group showed weight recidivism [23]. Jirapinyo et al showed persistent weight loss and the majority of the patients in this study underwent pursestring suturing. Many patients in this study also underwent repeat procedures and received other adjunctive therapies once they attained a weight plateau or had minimal benefit (< 5 % TWL) [37].

In 850 patients, AE rates were 11.4 % (± 10.11) without any mortality. This is comparable to other revisional procedures such as adjustable gastric banding and distal RYGB conversion [38–40]. The most common AE in our study was abdominal pain at 4.22 % (± 8). Rates of perforation and bleeding were low at 0.46 % (± 1.16) and 1.14 % (± 1.38), respectively. This signifies that TORe is a safe procedure if performed by an endoscopist trained in endoscopic suturing.

Post TORe GJA size was weakly related to the percent TWL with r value of –0.1 ($P < 0.001$), which indicates there might be increased weight loss with smaller GJA size. However, according to Jirapinyo et al, there was an increased incidence of nausea and vomiting with GJA < 4 mm [37]. The majority of the studies aimed for a GJA size < 10–12 mm [12, 23–27, 29, 36].

Strengths of this procedure surround the minimally invasive aspect of it and subsequent weight loss observed from doing so. The two studies with over 1-year follow-up show that this procedure may be durable for long-term weight loss. Areas of interest involve the different types of suture styles with the Apollo device and how they affect patients in the long run. Currently, pursestring sutures may provide the best results for sustained weight loss [23, 27, 36, 37].

Two studies have compared TORe with APC to TORe with ESD [28, 41]. One study reported greater weight loss with ESD-TORe as compared to TORe with APC while the other study did not reveal any significant difference between the two groups. This is another novel addition to TORe and more studies are needed to evaluate its safety and efficacy.

Limitations include some of the studies being retrospective in nature, most of the studies had short-term follow-up, and there was loss of follow-up. Our pooled rates were limited by heterogeneity and there was increased risk of confounding bias due to majority of the studies being retrospective. For unexperienced endoscopists, this procedure may be technically challenging and thus affect generalizability. More long-term studies should be done to observe durability as seen in the reports from Callahan and Jirapinyo et al. Future studies should include follow-up endoscopy post TORe to examine the GJA to evaluate its durability and to see if this correlates with weight recidivism after TORe is done.

## Conclusion

In conclusion, TORe is a minimally invasive procedure that may be safe and feasible for post RYGB patients who do not want to undergo a surgical revision due to increased morbidity and mortality. TORe shows promising results in the short term, but more studies are needed to evaluation long-term success of this procedure.

### Competing interests

The authors declare that they have no conflict of interest.

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