

EDGE in Roux-en-Y gastric bypass: How does it compare to laparoscopy-assisted and balloon enteroscopy ERCP: a systematic review and meta-analysis




Authors

Banreet Singh Dhindsa¹, Amaninder Dhaliwal², Babu P. Mohan³, Harmeet Singh Mashiana², Mohit Girotra⁴, Shailender Singh², Gordon Ohning⁵, Ishfaq Bhat², Douglas G. Adler⁶

Institutions

- 1 University of Nevada Las Vegas School of Medicine, Las Vegas, Nevada, United States
- 2 Division of Gastroenterology and Hepatology, University of Nebraska Medical Center, Omaha, Nebraska, United States
- 3 Banner University Medical Center, University of Arizona, Tucson, Arizona, United States
- 4 Division of Gastroenterology and Hepatology, University of Miami Miller School of Medicine, Miami, Florida, United States
- 5 Division of Gastroenterology, University of Nevada Las Vegas School of Medicine, Las Vegas, Nevada, United States
- 6 Department of Gastroenterology and Hepatology, University of Utah School of Medicine, Salt Lake City, Utah

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Corresponding author

Douglas G. Adler, MD, FACC, AGAF, FASGE, Professor of Medicine, Director of Therapeutic endoscopy, Director, GI fellowship program, Gastroenterology and Hepatology, University of Utah School of Medicine, Huntsman Cancer Center, 30 N 1900 E, Room 4R118, Salt Lake City, Utah 84132
 Fax: +1-801-581-8007
douglas.adler@hsc.utah.edu

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ABSTRACT

Background and study aims Endoscopic ultrasound-directed transgastric ERCP (EDGE) is a new endoscopic procedure to perform ERCP in Roux-en-y gastric bypass (RYGB) patients. The aim of this study was to conduct a systematic review and meta-analysis to evaluate technical success, clinical success and adverse effects of EDGE and compare it to laparoscopic ERCP (LA-ERCP) and balloon ERCP (BE-ERCP).

Patients and methods We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, Google-Scholar, LILACS, SCOPUS, and Web of Science databases to identify studies reporting on EDGE, LA-ERCP, and BE-ERCP. The primary outcome was to evaluate technical and clinical success of all three procedures and the secondary analysis focused on calculating the pooled rate of all adverse events (AEs), along with the commonly reported AE subtypes.

Results Twenty-four studies on 1268 patients were included in our analysis with the majority of the population being males with mean age 53.72 years. Pooled rates of technical and clinical success with EDGE were 95.5% and 95.9%, with LA-ERCP were 95.3% and 92.9% and with BE-ERCP were 71.4% and 58.7%, respectively. Pooled rates of all AEs with EDGE were 21.9%, with LA-ERCP 17.4% and with BE-ERCP 8.4%. Stent migration was the most common AE with EDGE with 13.3% followed by bleeding with 6.6%.

Conclusion Our meta-analysis demonstrated that the technical and clinical success of EDGE procedure is better than BE-ERCP and comparable to that of LA-ERCP in RYGB patients. EDGE also has a similar safety profile as compared to LA-ERCP but has higher AE rate as compared to BE-ERCP.

Introduction

Obesity is an epidemic in United States, with 35% of adults having body mass index (BMI) >30 kg/m² [1]. Indications for bariatric surgery are BMI >40 or BMI >30 with comorbid conditions [2]. Roux-en-Y gastric bypass (RYGB) is the most commonly performed bariatric procedure in the world, consisting of 47% of the bariatric surgeries with around 200,000 surgeries performed worldwide every year [3, 4].

Rapid weight loss post-bariatric surgery is a risk factor for development of gallstones, choledocholithiasis, and pancreatitis with up to 32% to 42% of patients developing gallstones [5, 6]. Obesity can also lead to increased incidence of pancreaticobiliary cancers [7]. This reflects the sheer number of patients who would potentially require biliary intervention. Endoscopic retrograde cholangiopancreatography (ERCP) in patients with RYGB is challenging for three reasons: (1) The small bowel limb to be traversed is very long and standard endoscopes and duodenoscopes are typically inadequate to reach the ampulla; (2) acute angles and stenosis at the jejunostomy site decrease the success of reaching papilla; and (3) tortuosity of the scope trajectory [8, 9]. Various specialized procedures to perform biliary interventions in Roux-en-Y procedures include balloon enteroscopy-assisted ERCP (BE-ERCP) (single and double), spiral enteroscopy, laparoscopic-assisted ERCP (LA-ERCP) and gastrostomy tube-assisted ERCP.

BE-ERCP is commonly employed in this situation, however, due to inferior technical success it is not ideal for all patients. The reasons for the lower technical success of BE-ERCP are: (a) length of limb to be traversed; (b) absence of elevator; (c) forward viewing endoscopic view, making it difficult to cannulate; and (d) narrow diameter and long length of scopes making it hard to use the proper accessory instruments [8].

LA-ERCP has high technical success rates (papilla identification and cannulation) even though it has higher complication rates [10]. However, LA-ERCP is associated with longer hospital stays, higher hospital costs, increased complications, and requirement of multiple teams to do the procedure, all of which are disincentives to performing biliary access via this route [11, 12].

Endoscopic ultrasound-directed transgastric ERCP (EDGE) was first described by Kedia et al in 2014 [13]. EDGE uses a lumen-apposing metal stent (LAMS) to create a transluminal gateway from the gastric pouch or the proximal jejunal efferent limb to the remnant stomach to perform ERCP using a standard duodenoscope. In studies of EDGE, it has shown to have a high technical success rate with low risk of complications and lower hospitals costs [14–17].

The aim of this study was to evaluate technical success, clinical success, and adverse events (AEs) associated with EDGE and compare it to LA-ERCP and BE-ERCP.

Patients and methods

Search strategy

We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, Google-Scholar, LILACS, SCOPUS, and Web of Science databases (earliest inception to February 2019). We followed the Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and Meta-analyses of Observational Studies in Epidemiology (MOOSE) protocol, to identify studies reporting on EDGE procedure, LA-ERCP, and BE-ERCP [18, 19]. An experienced medical librarian using inputs from the study authors helped with the literature search.

Keywords used in the literature search included a combination of 'EDGE', 'endoscopic', 'ERCP', 'GATE', 'balloon', 'enteroscopy' and 'laparoscopic'. The search was restricted to studies in human subjects and published in English language in peer-reviewed journals. Two authors (BD, AD) independently reviewed the title and abstract of studies identified in primary search and excluded studies that did not address the research question, based on pre-specified exclusion and inclusion criteria. Full text of remaining articles was reviewed to determine whether it contained relevant information. Any discrepancy in article selection was resolved by consensus, and in discussion with a co-author.

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 EDGE, LA-ERCP, and BE-ERCP in patients with RYGB. 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 gastric bypass procedures other than RYGB; (2) studies with sample size <10 patients; (3) studies done in pediatric population (age <18 years); and (4) studies not published in the 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, AD, HM), and two authors (BD, BPM) did the quality scoring independently.

In the situation of randomized controlled trials and case-control studies, data collection was done as number of reported events (n) out of total number of patients (N) from each study. 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 [20]. This quality score consisted of eight questions, the details of which are provided in **Supplementary Table 1**.

Outcomes assessed

Primary outcomes

1. Pooled rate of technical success: EDGE vs LA-ERCP vs BE-ERCP.
2. Pooled rate of clinical success: EDGE vs LA-ERCP vs BE-ERCP.

Secondary outcomes

1. Pooled rate of AEs: EDGE vs LA-ERCP vs BE-ERCP.
2. Pooled rate of AE subtypes: post-ERCP pancreatitis (PEP), bleeding, perforation, stent migration, and infection.

Assessment methodology and definitions

Collected data were matched between the groups (EDGE, LA-ERCP, BE-ERCP) before statistical analysis. Although, this model of comparison is indirect, and the approach is comparable to a retrospective case-control study with matched groups.

Definition of outcomes

Technical success in EDGE studies was defined as successful cannulation and deployment placement of LAMS across the fistula and successful cannulation of the desired duct in LA-ERCP and BE-ERCP studies.

Clinical success was defined as resolution of symptoms, laboratory investigations and imaging via desired therapeutic maneuvers.

AEs and their severity were reported according to the American Society of Gastrointest Endosc (ASGE) Lexicon [21].

Statistical analysis

We used meta-analysis techniques to calculate pooled estimates in each case following the methods suggested by DerSimonian and Laird using the random-effects model [22]. When incidence of an outcome was zero in a study, a continuity correction of 0.5 was added to the number of incident cases before statistical analysis [23]. 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 I² statistics [24,25]. In this, values of <30%, 30% to 60%, 61% to 75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively [26]. Publication bias was ascertained, qualitatively, by visual inspection of funnel plot and quantitatively, by the Egger test [27]. When publication bias was present, further statistics using the fail-Safe N test and Duval and Tweedie's "Trim and Fill" test was used to ascertain the impact of the bias [28]. Three levels of impact were reported based on concordance between the reported results and the actual estimate if there were no bias. The impact was reported as minimal if both versions were estimated to be same, modest if effect size changed substantially but the final finding would still remain the same, and severe if basic final conclusion of the analysis is threatened by the bias [29].

All analyses were performed using Comprehensive Meta-Analysis (CMA) software, version 3 (BioStat, Englewood, New Jersey, United States).

Results

Search results and population characteristics

From an initial 605 studies, 24 studies reported use of EDGE, BE-ERCP and LA-ERCP in RYGB patients.

In our search process, we encountered studies by Irani et al [30], Kedia 2015 et al [31], Tyberg et al [32], Kedia 2019 et al [33], and Ngamruengphong et al [34] that had overlapping cohorts. The most comprehensive studies (Chiang et al [15] and Bukhari et al [35]) were included in the final analysis.

Overall, four studies [15–17, 35] provided data on EDGE, 18 studies [11, 33, 36–51] provided data on LA-ERCP, and five studies [35, 44, 49, 52, 53] provided information on BE-ERCP for our analysis.

The schematic diagram of study selection as per PRISMA guidelines and MOOSE protocol are illustrated in **Supplementary Fig. 1** and **Supplementary Table 1**, respectively.

Baseline population characteristics were comparable between the EDGE, LA-ERCP, and BE-ERCP groups. Mean age was 53.72 years with a predominantly male population. Patient demographic characteristics are described in ► **Table 1** and reported AEs are summarized in ► **Table 2**.

Characteristics and quality of included studies

Three studies were prospective, and the rest were retrospective. Seven studies were multicenter and the rest were single-center. None were population-based. All studies reported adequately on clinical outcomes, and assessment and factors were comparable between the study groups. Overall, 21 studies were considered of high quality, three were of medium quality. There were no low-quality studies. The detailed assessment of study quality is given in ► **Table 3**.

Meta-analysis outcomes

A total of 1268 patients were included in the analysis. One hundred twenty-four patients from four studies underwent EDGE, 939 patients from 18 studies underwent LA-ERCP, and 205 patients from five studies underwent BE-ERCP.

Primary outcomes

1. Technical success

The calculated pooled rate of technical success (► **Table 4**) with EDGE was 95.5% (95% CI 84.2–98.8, 95% PI 52 to 99.7, I²=0), with LA-ERCP was 95.3% (95% CI 91.3–97.5, 95% PI 75.7 to 99, I²=46.3), and with BE-ERCP was 71.4% (95% CI 51–85.7, 95% PI 6.3 to 98.9, I²=87). Statistical p-value was significant for EDGE vs BE-ERCP, *P*=0.01 and LA-ERCP vs BE-ERCP, *P*=0.001 but was not significant for EDGE vs LA-ERCP, *P*=0.98.

2. Clinical success

The calculated pooled rate of clinical success (► **Table 4**) with EDGE was 95.9% (95% CI 81.2–99.2, 95% PI 37.5 to 99, I²=0), with LA-ERCP was 92.9% (95% CI 83.9–97.1, 95% PI 14 to 99, I²=84.2), and with BE-ERCP was 58.7% (95% CI 27.6–84.1, 95% PI 7.4 to 96, I²=0). Statistical p-value for the difference was significant for EDGE vs BE-ERCP, *P*=0.001

► **Table 1** Description of 24 studies used in the final analysis.

Author	Type of study	center	Case-control/cohort/RCT	Mean age	Total no. patients	Male	Female
LA-ERCP							
Abbas 2018 [11]	retrospective	multi	Cohort	51	579	488	91
Habenicht Yancey 2018 [43]	retrospective	single	Cohort	55.8	16	np	np
Kedia 2018 [33]	retrospective	multi	Case-control	55	43	7	36
Frederiksen 2017 [41]	retrospective	single	Cohort	46	29	4	25
May D 2017 [38]	retrospective	single	Cohort	np	51	np	np
Bowman 2016 [37]	retrospective	multi	Cohort	48.8	11	3	8
Farukhi 2016 [40]	retrospective	single	Cohort	np	7	np	np
Kumar 2016 [44]	retrospective	single	Case-control	51.5	19	2	17
Mejia 2016 [46]	retrospective	single	Cohort	51	4	2	2
Paranandi 2016 [47]	retrospective	single	Cohort	50.2	7	0	7
Grimes 2015 [42]	retrospective	single	Case-control	47.8	38	2	36
Snauwaert 2015 [50]	retrospective	multi	Cohort	54	21	5	18
Lin 2014 [45]	prospective	single	Cohort	np	8	np	np
Sun 2014 [51]	retrospective	single	Cohort	np	22	np	np
Falcão 2012 [39]	prospective	multi	Cohort	35.3	23	4	19
Schreiner 2012 [49]	retrospective	single	Case-control	52	24	5	19
Bertin 2011 [36]	retrospective	single	Cohort	np	22	np	np
Saleem 2010 [48]	retrospective	single	Cohort	50.8	15	3	12
BE-ERCP							
Kashani 2018 [53]	retrospective	single	Cohort	50	103	13	90
Bukhari 2018 [35]	retrospective	multi	Case-control	61.8	30	12	18
Kumar 2016 [44]	retrospective	single	Case-control	52.1	12	1	11
Choi 2013 [52]	retrospective	single	Case-control	44.8	28	2	26
Schreiner 2012 [49]	retrospective	single	Case-control	53	32	1	31
Edge							
Wang-2019 [17]	prospective	single	Cohort	60	9	np	np
Chiang 2018 [15]	retrospective	multi	Cohort	58.3	66	20	46
James 2018 [16]	retrospective	single	Cohort	55.5	19	4	15
Bukhari 2018 [35]	retrospective	multi	Case control	61.8	30	12	18
NP, not provided							

and La-ERCP vs be-ERCP, $P=0.009$. but was not significant for EDGE vs LA-ERCP, $P=0.65$.

Secondary outcomes

The pooled rates of all AEs and AE subtypes with EDGE, LA-ERCP, and BE-ERCP are summarized in ► **Table 2** (Forest plots: **Supplementary Fig. 2, 3, 4, 5, 6, 7, 8, 9**). Pooled rates of PEP and perforation were comparable between the groups,

whereas the pooled rate of bleeding with BE-ERCP was 1.5% (95% CI 0.4–5, $I^2=0$), which was significantly lower when compared to EDGE and LA-ERCP, $P=0.04$.

► **Table 2** Adverse events in all procedures

Author	Total no. AE	Infection	Perforation	Bleeding	PEP	Stent dislodgement	Other
LA-ERCP							
Abbas 2018 [11]	106	30	5	13	43	0	15
Habenicht Yancey 2018 [43]	1	0	0	0	1	0	0
Kedia 2018 [33]	8	3	2	1	0	0	2
Frederiksen 2017 [41]	11	3	0	5	2	0	2
May D 2017 [38]	9	5	0	1	0	0	4
Bowman 2016 [37]	3	1	0	0	0	0	2
Farukhi 2016 [40]	2	0	0	0	0	0	2
Kumar 2016 [44]	3	0	0	1	2	0	0
Mejia 2016 [46]	0	0	0	0	0	0	0
Paranandi 2016 [47]	2	1	0	0	1	0	0
Grimes 2015 [42]	5	np	np	np	np	0	np
Snauwaert 2015 [50]	0	0	0	0	0	0	0
Lin 2014 [45]	0	0	0	0	0	0	0
Sun 2014 [51]	1	1	0	0	0	0	0
Falcão 2012 [39]	1	0	0	0	1	0	
Schreiner 2012 [49]	2	0	0	0	1	0	1
Bertin 2011 [36]	3	0	1	1	0	0	1
Saleem 2010 [48]	0	0	0	0	0	0	0
BE-ERCP							
Kashani 2018 [53]	13	1	2	0	10	0	0
Bukhari 2018 [35]	3	1	1	0	1	0	0
Kumar 2016 [44]	0	0	0	0	0	0	0
Choi 2013 [52]	1	0	0	0	1	0	0
Schreiner 2012 [49]	1	0	0	0	1	0	0
EDGE							
Wang-2019 [17]	2	0	0	1	0	1	0
Chiang 2018 [15]	13	0	1	5	1	6	0
James 2018 [16]	7	0	0	0	0	6	1
Bukhari 2018 [35]	4	0	0	1	0	2	1

AE, adverse event; LA-ERCP, laparoscopic endoscopic retrograde cholangiopancreatography; BE-ERCP, balloon endoscopic retrograde cholangiopancreatography; EDGE, endoscopic ultrasound-directed transgastric retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis; NP, not provided

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. Therefore, including or excluding either one of the studies

by Chiang et al [15] and/or Bukhari et al [35] would give us essentially the same pooled results.

Heterogeneity

We assessed dispersion of the calculated rates using the prediction interval (PI) and I² percentage values. The PI gives an idea of the range of the dispersion and I² tell us what proportion of the dispersion is true vs chance [54]. The pooled rate of technical success with LA-ERCP had a narrow PI, whereas EDGE and

► **Table 3** Quality assessment of the study with Newcastle Ottawa Scale.

Author	Study type	Cohort/case-control	No. patients	Newcastle-Ottawa Scale		
				Selection	Comparability	Outcome
LA-ERCP						
Abbas 2018 [11]	Retrospective	Cohort	579	***	*	***
Habenicht Yancey 2018 [41]	Retrospective	Cohort	16	***	*	***
Kedia 2018 [31]	Retrospective	Case-control	43	***	**	***
Frederiksen 2017 [39]	Retrospective	Cohort	29	***	*	***
May D 2017 [36]	Retrospective	Cohort	51	***	*	***
Bowman 2016 [35]	Retrospective	Cohort	11	***	*	**
Farukhi 2016 [38]	Retrospective	Cohort	7	**	*	*
Kumar 2016 [42]	Retrospective	Case-control	19	***	**	***
Mejia 2016 [44]	Retrospective	Cohort	4	**	*	**
Paranandi 2016 [45]	Retrospective	Cohort	7	***	*	***
Grimes 2015 [40]	Retrospective	Case-control	38	***	*	***
Snauwaert 2015 [48]	Retrospective	Cohort	21	***	*	**
Lin 2014 [43]	Prospective	Cohort	8	**	*	**
Sun 2014 [49]	Retrospective	Cohort	22	**	*	*
Falcão 2012 [37]	Prospective	Cohort	23	**	*	**
Schreiner 2012 [47]	Retrospective	Case-control	24	****	*	***
Bertin 2011 [34]	Retrospective	Cohort	22	***	*	***
Saleem 2010 [46]	Retrospective	Cohort	15	***	*	**
BE-ERCP						
Kashani 2018 [51]	Retrospective	Cohort	103	***	*	***
Bukhari 2018 [33]	Retrospective	Case-control	30	***	**	***
Kumar 2016 [42]	Retrospective	Case-control	12	***	**	***
Choi 2013 [50]	Retrospective	Case-control	28	***	*	**
Schreiner 2012 [47]	Retrospective	Case-control	32	****	**	***
EDGE						
Wang-2019 [17]	Prospective	Cohort	9	***	*	***
Chiang 2018 [15]	Retrospective	Cohort	66	***	*	*
James 2018 [16]	Retrospective	Cohort	19	***	*	***
Bukhari 2018 [33]	Retrospective	Case control	30	***	**	***

LA-ERCP, laparoscopic endoscopic retrograde cholangiopancreatography; BE-ERCP, balloon endoscopic retrograde cholangiopancreatography; EDGE, endoscopic ultrasound-directed transgastric retrograde cholangiopancreatography

be-ERCP had wide PI with heterogeneity. The PI for clinical success was wide with all the modalities, suggesting heterogeneity.

Publication bias

Based on visual inspection of the funnel plot (**Supplementary Fig. 10**), there seemed to be possible publication bias, but quantitative measurement that used the Egger regression test,

the statistical 2-tailed *P* value was not significant for publication bias (*P*=0.15).

Discussion

Our study demonstrated that, in patients with RYGB, EDGE procedure has comparable technical and clinical success rates to LA-ERCP and has a statistically superior technical and clinical

► **Table 4** Pooled rates of technical success, clinical success and adverse events of EDGE, LA-ERCP and BE-ERCP.

(95% CI, I2%, P value in comparison to EDGE)	EDGE	LA-ERCP	BE-ERCP
Technical success	95.5% (84.2–98.8, 0)	95.3% (91.3–97.5, 46.3, $P=0.98$)	71.4% (51–85.7, 87, $P=0.01$)
Clinical success	95.9% (81.2–99.2, 0)	92.9% (83.9–97.1, 84.2, $P=0.65$)	58.7% (27.6–84.1, 0, $P=0.001$)
All adverse events	21.9% (14.6–31.4, 21.2)	17.4% (14–21.5, 18.1, $P=0.32$)	8.4% (5–13.6, 0, $P=0.001$)
PEP	2.2% (0.6–7.4, 0)	6.8% (5.3–8.8, 0, $P=0.07$)	6.3% (3.7–10.4, 0, $P=0.12$)
Bleeding	6.6% (3.3–13, 0)	3.7% (2.6–5.4, 5.8, $P=0.15$)	1.5% (0.4–5, 0, $P=0.04$)
Perforation	2.2% (0.6–7.4, 0)	2.2% (1.3–3.7, 0, $P=0.99$)	1.8% (0.7–4.7, 0, $P=0.79$)
Stent migration	13.3% (5.7–28.1, 57.6)	NP	NP
Infection	NP	5.8% (4.4–7.6, 0)	1.9% (0.7–5.2, 0, $P=0.04$ as compared to la-ERCP)

LA-ERCP, laparoscopic endoscopic retrograde cholangiopancreatography; BE-ERCP, balloon endoscopic retrograde cholangiopancreatography; EDGE, endoscopic ultrasound-directed transgastric retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis; NP, not provided

success rates when compared to BE-ERCP. To our knowledge, this is the first meta-analysis comparing the outcomes of EDGE, LA-ERCP, and BE-ERCP in patients with RYGB.

Based on our analysis, the pooled rate of technical success of EDGE in RYGB patients was comparable to LA-ERCP (96.5 vs 95%, $P=0.98$) but was statistically superior to BE-ERCP (96% vs 71%, $P=0.01$). Similarly, the pooled clinical success rate with EDGE was comparable to LA-ERCP (96% vs 93%, $P=0.65$) and markedly superior to BE-ERCP (96% vs 59%, $P=0.001$).

The core reason for the technical success of EDGE is the advent and commercial availability of LAMS which creates a tract for passage of the endoscope (easily bringing the papilla within reach).

Clinical success of EDGE in most the studies was also 100% [16, 17, 35] except for one study where it was 92% [15]. The clinical success of the procedure was directly related to the technical success of the procedure, indicating the importance of a successful transluminal access procedure and operator expertise.

All AEs and subtypes of AEs (PEP, bleeding, perforation) were comparable between EDGE and LA-ERCP. However, when compared to BE-ERCP, EDGE had higher incidence of AEs. It is, however, interesting to note that rates of PEP were comparable between all the three groups. The absolute rate of PEP was the lowest with EDGE procedure and showed a trend towards statistical significance when compared to LA-ERCP.

LAMS migration was the most common AE encountered with a pooled event rate of 13.3%. The main causes of stent migration are immaturity of the fistula and the manipulation of the LAMS via the duodenoscope resulting in LAMS dislodgement. This risk can potentially be reduced via performing a two-stage procedure so as to allow the fistula to mature before it is traversed. Study with a higher percentage of two-stage procedure had a lower rate of stent migration [35]. Also, lubricating the scope generously showed decreased migration in one study [33].

Weight gain is an AE that was a concern due to presence of a persistent fistula following EDGE. Only one study reported

weight gain in our literature search [35]. All the other studies reported an overall average weight loss [32–35]. The reason for weight loss is unclear, but it has been hypothesized that majority of the food flows through the Roux tract and not through the fistula resulting in weight loss [33].

Failure of the fistula to close is another concerning AE for EDGE. Various techniques have been described to prevent this including exchange of LAMS with plastic stents, endoscopic suturing and OTSC (over-the scope-clips) or a combination thereof. Limited data is available on the mechanism of plastic stents and its role in closure of fistula. It works likely by irritation of mucosa resulting in granulation tissue formation resulting in closure of fistula [17]. More data are needed on this aspect to find out the best way to facilitate closure of the fistula.

The strengths of this review are as follows: systematic literature search with well-defined inclusion criteria, careful exclusion of redundant studies, inclusion of good quality studies with detailed meticulous extraction of data, rigorous evaluation of study quality, and statistics to establish and/or refute the validity of the results of our meta-analysis. Heterogeneity was minimal to zero with the pooled outcomes of EDGE. We report the prediction intervals for the primary outcomes, thereby enabling our results to be applicable to the real population. With 1268 patients and 27 studies, this is the largest, most comprehensive, and up-to-date meta-analysis evaluating and comparing EDGE, LA-ERCP, and BE-ERCP in RYGB anatomy patients.

There were limitations to this study, most of which are inherent in any meta-analysis. The included studies were not entirely representative of the general population and community practice, with most studies being performed in tertiary-care referral centers. Also, the procedure is a novel procedure and does not reflect the skill of an average endoscopist. Our analysis had studies that were retrospective in nature contributing to selection bias. Our analysis has the element of indirect comparison. Nevertheless, this study is the best available in literature thus far with respect to EDGE. More studies are warranted to better evaluate the clinical performance of EDGE procedure, especially with respect to its adverse events.

Conclusion

In conclusion, our meta-analysis demonstrates that the technical and clinical success of EDGE procedure is better than BE-ERCP and comparable to that of LA-ERCP in RYGB patients. EDGE is not as expensive as LA-ERCP, minimally invasive, and can be performed by one endoscopist in one session if needed, although it is usually performed in a two-stage manner. EDGE also has a similar safety profile as compared to LA-ERCP but has higher adverse event rate as compared to BE-ERCP.

Competing interests

None

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