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ORIGINAL CONTRIBUTIONS

Efficacy and Safety of the Over-the-Scope Clip (OTSC) System in the Management of Leak and Fistula After Laparoscopic Sleeve Gastrectomy: a Systematic Review

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Abstract
Background Endoscopic management of leaks/fistulas after laparoscopic sleeve gastrectomy (LSG) is gaining popularity in the bariatric surgery.
Objectives This study aimed to review the efficacy and safety of over-the-scope-clip (OTSC) system in endoscopic closure of post-LSG leak/fistula.
Methods PubMed/Medline and major journals of the field were systematically reviewed for studies on endoscopic closure of post-LSG leaks/fistula by means of the OTSC system.
Results A total of ten eligible studies including 195 patients with post-LSG leaks/fistula were identified. The time between LSG and leak/fistula ranged from 1 day to 803 days. Most of the leaks/fistula were located at the proximal staple line, and they sized from 3 to 20 mm. Time between leak diagnosis and OTSC clipping ranged from 0 to 271 days. Thirty-three out of 53 patients (63.5%) required one clip for closure of the lesion. Regarding the OTSC-related complications, a leak occurred in five patients (9.3%) and OTSC migration, stenosis, and tear each in one patient (1.8%). Of the 73 patients with post-LSG leak treated with OTSC, 63 patients had an overall successful closure (86.3%).
Conclusion OTSC system is a promising endoscopic approach for management of post-LSG leaks in appropriately selected patients. Unfortunately, most studies are series with a small sample size, short-term follow-up, and mixed data of concomitant procedures with OTSC. Further studies should distinguish the net efficacy of the OTSC system from other concomitant procedures in treatment of post-LSG leak.

Keywords Laparoscopic sleeve gastrectomy · Leak · Fistula · Endoscopic clipping · Over the scope clip · OTSC

Introduction

Laparoscopic sleeve gastrectomy (LSG) is currently the most commonly performed bariatric procedure for treatment of morbid obesity [1–3]. The procedure is technically less challenging and bears a lower complication rate compared to that of the gastric bypass. Nevertheless, LSG carries a burden of early- and late-onset complications which still occur despite adequate modification in its technique [4–6].

As a major postoperative complication, leaks have been reported in 1.09–3.3% of patients after LSG [7]. Despite its high mortality rate in the acute stage [8, 9], post-LSG leak can lead to the development of gastric fistula over time [10, 11]. Surgical repair for leaks has been very effective in the past [12–14]. Recently, endoscopic management of gastrointestinal (GI) leaks is increasingly utilized as the means of management [11, 15–17]. Therapeutic endoscopy might use fibrin glue, metallic stents, plugs, or clips for full-thickness GI wall closure [18–20].

Over-the-scope-clips (OTSC) system has shown potential in the successful management of gastric leaks and fistulas

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[21–30]. However, evidence on the efficacy of OTSC in management of postbariatric leaks and fistulas are sparse. This systematic review aimed to abstract the existing literature on the utility of the OTSC system in endoscopic management of leaks and fistulas after LSG. The main focus will be on the technical characteristics and successful rate of OTSC in the treatment of post-LSG leak.

Methods and Materials

Study Design

In adherence to the checklist of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [31], a systematic review was conducted in July 2016 to summarize the available data on the management of post-LSG leak/fistula with the OTSC system. Two independent reviewers screened the retrieved citations, selected the eligible studies, and extracted the data for analysis. Any conflict was resolved by a third investigator.

Search Strategy

A literature review was conducted in MEDLINE/PubMed database to identify studies regarding the endoscopic management of leaks/fistula after LSG by the OTSC system. A combination of the following search terms was used: "Leak" AND "over the scope clip OR OTSC" AND "sleeve gastrectomy OR SG OR LSG." The bibliography list of the included studies were manually searched for the relevant references. Similarly, the major journals in the field of bariatric and metabolic surgery including *Surgery for Obesity and Related Disease* and *Obesity Surgery* journals were screened.

Eligibility

English studies reporting the endoscopic management of LSG-related leak/fistula in humans using the OTSC system were eligible. Review articles, commentaries, and studies concerning management of leaks/fistula without the use of OTSC system and after other bariatric procedures were excluded.

Endpoint Definition and Data Analysis

Extracted data comprised characteristics of the included studies (author name, publication year, type of study, sample size, age, gender, preoperative BMI, and number of treated leaks); clinical and anatomical features of leaks/fistulas (BMI at the time of diagnosis, time interval between LSG and leak, size and location of the leak, fistula development, and clinical presentation); timing for the patients outcome (leak diagnosis to endoscopic management, OTSC to starting the oral feeding, oral feeding to the hospital discharge, and discharge to the follow-up control imaging); and technical characteristics of endoscopic management (type, size, and number of the clips including the OTSC, size of the stent, clip-related complications, success rate, and additional techniques [glue, plug, or other types of clip]). The primary endpoint was the efficacy of OTSC in the management of post-LSG leak/fistula defined by the success rate. The secondary outcome was OTSC safety determined as the incidence of clip-related complications.

Results

Included Studies (10 Studies, 215 Patients)

A total of 12 papers were identified by our initial search protocol (Fig.1). No other relevant papers were found by an additional search of the *Obesity Surgery* and *Surgery for Obesity and Related Disease* journals or manual screening of the reference lists of the eligible articles. Of these, ten studies encompassing 215 patients corresponding to 195 leaks/fistulas were eligible (Table 1) [21, 22, 24–26, 28–30, 32, 34].

Of 182 patients with post-LSG leak whose gender was reported, 41 were male (22.5%) and 141 were female (77.5%). There were five case reports (six patients) [21, 22, 24, 25, 33] and five retrospective review studies (209 patients) [26, 28, 30, 32]. Patient age varied between 18 and 67 years old [32]. Preoperative BMI was reported by one study (110 patients) which varied between 27.3–83.5 kg/m^2 [32]. Number of post-LSG leaks/fistula ranged from 1 [22, 24, 25] to 110 [32]. Postclosure follow-up ranged from 14 days (1 patient, 0.5%) [25] to 1070 days (30 patients, 13.9%) [29].

Clinical and Anatomical Characteristics of Post-LSG Leaks/Fistula (10 Studies, 195 Leaks/Fistulas)

BMI at the time of leak/fistula were reported by three studies (29 patients, 14.9%) [21, 24, 28], ranging from 42.9 [28] to 49 kg/m^2 [24]. Time interval from LSG to leak/fistula was available in seven studies (162 patients, 83.5%) [21, 22, 24–26, 28, 32] ranging from 1 day to 803 days [32]. Size of leak/fistula was reported by five studies (131 patients, 67.5%) [22, 24, 25, 29, 32] between 3 and 20 mm [29]. Of these, 69 leaks/fistulas (52.7%) sized less than 10 mm [22, 24, 25] and 44 leaks/fistulas (33.9%) greater than 10 mm [32]. Seven studies reported fistula formation after leak (178 patients, 91.7%). The location of fistula/leak could be retrieved from nine studies (84 patients, 43.3%) [21, 22, 24–26, 28–30, 33]. Of these, proximal staple line was the most common site (71 patients, 84.5%) [21, 22, 24–26, 28–30, 33], followed by the middle part (five patients, 5.9%) [26, 30], and the distal part (four patients, 4.7%) [28]. Additionally, there were three

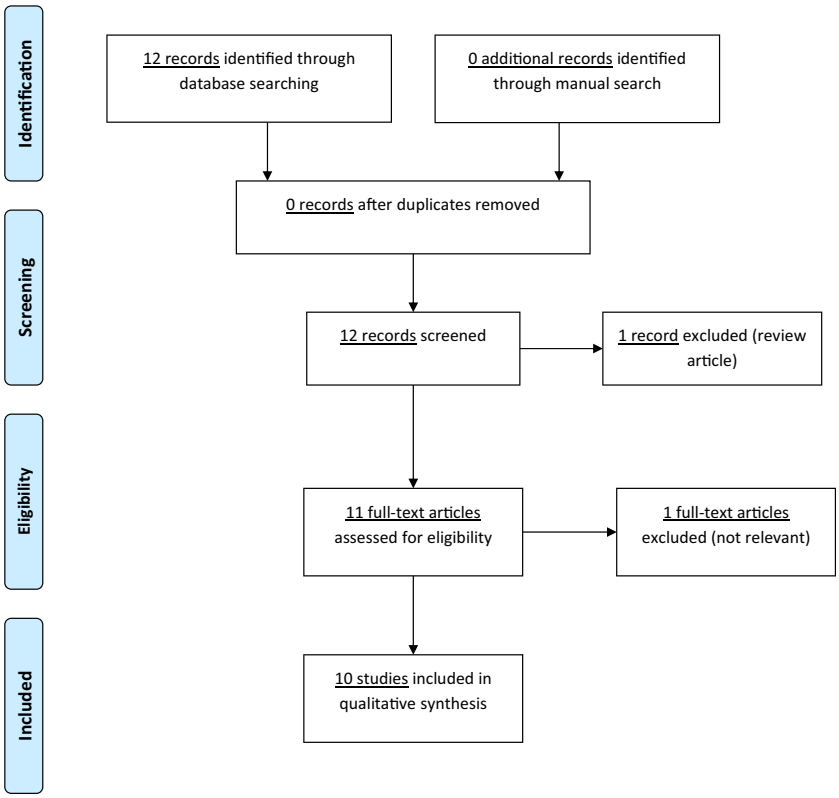

Fig. 1 PRISMA flowchart for search strategy and selection of eligible studies

gastrocutaneous fistulas (3.5%) and one gastrobronchial fistula (0.1%) reported [29]. Six studies reported the manifestations of leak/fistula (52 patients, 26.8%) [21, 22, 24, 26, 28, 33]. Of these, fever and peritonitis (18 patients, 34.6%) and abdominal pain (11 patients, 21.1%) were the most common presentation of post-LSG leak/fistula (Table 2).

Technical Considerations for Endoscopic Management of Post-LSG Leak (9 Studies, 73 Patients)

Details for endoscopic management of post-LSG leak/fistula by OTSC system were available for nine studies (73 patients) [21, 22, 24–26, 28, 29, 32, 33]. Number of the deployed

Table 1 Characteristics of studies and included patients

	Study	Type of study	Sample size	Age (yrs)	Gender (M:F)	Number of post-LSG leak	Preoperative BMI (kg/m^2)	Maximum follow-up
1	Caballero/2016 [24]	Case report	1	29	1:0	1	49	12 months
2	Shehab/2016 [30]	Retrospective	22	39 ± 10.7	NA	13	NA	355.3 days (30–723)
3	Christophorou/2015 [32]	Retrospective	110	39.7 ± 11.8 (18–67)	18:92	110	44.4 ± 8 (27.3–83.5)	>12 months
4	Aranez/2015 [22]	Case report	1	40	0:1	1	NA	1 month
5	Keren/2015 [28]	Retrospective	26	26–60 (M: 39)	12:14	26	NA	NA
6	Donatelli/2014 [26]	Retrospective	21	23–65 (M: 41)	3:18	21	NA	150.3 days (20–276)
7	Mercky/2014 [29]	Retrospective	30	38.7 (23–59)	7:12	19	NA	312 days (30–1070)
8	Gomez/2013 [33]	Case report	1	45	0:1	1	NA	NA
9	Aly/2013 [21]	Case report	2	58 and 44	0:2	2	NA	8 months
10	Conio/2010 [25]	Case report	1	43	0:1	1	NA	2 weeks
	Total	–	*215*	*18–67 years*	*41:141*	*195*	*27.3–83.5 kg/m^2*	*14–1070 (days)*

yrs years, *M:F* male to female, *LSG* laparoscopic sleeve gastrectomy, *BMI* body mass index, *NA* not available

Table 2 Clinical and anatomical features of post-LSG leaks

Author	BMI at Leak (kg/m^2)	Time from LSG (days)	Size	Location	Fistula	Presentation					
						AP	F	T	C	N/V	P
Caballero/2016 [24]	49	8	5 mm	Proximal staple line: 1	Yes	1	–	–	–	–	–
Shehab/2016 [30]	NA	NA	NA	GEJ: 10 Mid-sleeve: 3	NA	NA	NA	NA	NA	NA	NA
Christophorou/2015 [32]	NA	40.6 ± 116 (1–803)	≤1 cm: 66 patients >1 cm: 44 patients	Staple line: 110	Yes	–	–	–	–	–	–
Aranez/2015 [22]	NA	21	8 mm	Proximal staple line: 1	NA	1	–	–	–	–	-
Keren/2015 [28]	42.9	16.9 (2–240)	NA	GEJ: 22 Lower antral: 4	Yes	6	9	3	6	–	2
Donatelli/2014 [26]	NA	14.6 (3–97)	NA	Cardia: 19 Mid-staple line: 2	Yes	–	6	–	6	–	15
Mercky/2014 [29]	NA	NA	4.6 mm (3–20)	GEJ: 14 Gastrocutaneous: 3 Gastrobronchial: 1	Yes	–	–	–	–	–	–
Gomez/2013 [33]	NA	NA	Medium size	Cardia: 1	Yes	1	1	–	1	–	–
Aly/2013 [21]	45	8	NA	GEJ: 1	NA	1	1	–	–	–	–
	44	30	NA	GEJ: 1	NA	1	1	–	–	–	–
Conio/2010 [25]	NA	7	7 mm	GEJ: 1	Yes	NA	NA	NA	NA	NA	NA
Total	*42.9–49*	*1–803*	*5 mm–>10 mm*	*Proximal: 71* *Middle: 5* *Distal: 4*	*178*	*11*	*18*	*3*	*14*	*1*	*18*

BMI body mass index, *LSG* laparoscopic sleeve gastrectomy, *NA* not available, *GEJ* gastroesophageal junction, *N/V* nausea/vomiting, *AP* abdominal pain, *F* fever, *T* tachycardia, *C* collection, *P* peritonitis

OTSC was reported by six studies (52 patients, 72.3%) [22, 24, 26, 28, 32, 33]. Of these, 33 patients (63.5%) required one clip for closure of the lesion, 14 patients (26.9%) required one or more clips, and five patients (9.6%) required only two clips. Size of OTSC was specified by four studies for five patients (6.8%) [21, 24, 26, 30]. Of these, OTSC size was 11/6t-9 mm in two patients (40%), 12/6t-10 mm in two patients (40%), and 14/6t-11 mm in one patient (20%). OTSC was the employed clip by all the included studies. Only one study reported the use of other clips in 31 patients including Quick Clip and EZ Clip (Olympus, Tokyo, Japan), resolution (Boston Scientific), and triclip (Cook Medical, Winston-Salem, NC, USA) [32]. Nevertheless, data of patients receiving clips other than OTSC was not included in our analysis (Table 3).

Endoscopic procedures in addition to OTSC were reported in eight studies (70 patients, 95%) [22, 24–26, 28, 29, 32, 33]. Of these, nine stents were applied prior to the treatment by OTSC (12.8%) while simultaneous endoscopic procedures in addition to the OTSC were performed in 34 patients (48.6%). Of these, a stent was used in 24 patients (70.6%), biologic glue in eight patients (23.5%), and other procedures in two patients (5.8%). Three studies (10 patients, 13.7%) demonstrated the complications of postendoscopic treatment [26, 28, 29]. Of these, leak was the most common complication (40%) followed by stent migration (one patients, 10%) and OTSC-related stenosis, migration, and tear (each in one patient, 10%).

Timeline for Leak/Fistula Management by OTSC after Diagnosis (9 Studies, 73 Patients)

Time between leak diagnosis and clipping by OTSC system was available in eight studies (72 patients, 98.6%), which ranged from 0 to 271 days [21, 22, 24–26, 28, 29, 32]. Time between clipping and initiation of oral feeding was retrieved in four studies (29 patients, 39.7%) [22, 24, 25, 28] ranging from 1 day [22, 25] to 70 days [28]. Only two studies (two patients, 2.7%) specified the discharge day to be the same as the day of oral feeding initiation [24, 25]. Length of hospital stay could be calculated for two studies (two patients, 2.7%) [24, 25].

The follow-up imaging to control for the OTSC stability was performed between 1 week [25] and over a year [32] after endoscopic management. Data for the type or time of control modality was reported by eight studies (58 patients (79.4%) and 28 patients (38.3%), respectively) [21, 22, 24–26, 28, 29, 33]. Of these, endoscopy was the most common control procedure (33 patients, 56.9%). Additionally, control imaging were performed at 1 week (one patient, 3.6%), 2 weeks (two patients, 7.2%), 4 weeks (one patient, 3.6%), 6 months (two patients, 7.2%), and ≥12 months (15 patients, 53.6%) after OTSC treatment (Table 4).

Table 3 Technical characteristics of endoscopic management of post-LSG leak by OTSC

Author	OTSC				Additional procedures		Complications of Endoscopic treatment
	Patients	Size	Number	Type	Prior to OTSC	Concomitant with OTSC	
Caballero/2016 [24]	1	12/6t-10 mm (1)	1 clip	OTSC	NA	NA	NA
Shehab/2016 [30]	N/A	12 mm?	NA	OTSC	Mega stent (N/A)	Mega stent (N/A)	Stent migration (N/A) Intolerance (N/A) Bleeding (N/A) Esophageal stricture (N/A) Perforation (N/A)
Christophorou/2015 [32]	14	NA	≥1	OTSC (14), Quick2, EZ, and Resolution Clips (31)	NA	FCSEMS (9) Biologic glue (2)	Stent migration (N/A) Incarceration (N/A) Ulcer (N/A)
Aranez/2015 [22]	1	NA	1 clip	OTSC	NA	FCSEMS (1)	NA
Keren/2015 [28]	26	NA	1 clip: 21 2 clips: 5	OTSC	NA	Stents (6) Biologic glue (1) Argon cautery (1) Plastic prosthesis (1)	Antral leaks (2) Staple line leaks (3)
Donatelli/2014 [26]	9	11/6t-9 mm (2) 14/6t-11 mm (1)	1 clip	OTSC	Plastic stent (7) Internal and pigtail drainage (NA)	None	Stent migration (1)
Mercky/2014 [29]	18	NA	NA	OTSC	NA	Stent (8) Biologic glue (1) Standard glue (4)	Stenosis (1), migration (2), and tear (1)
Gomez/2013 [33]	1	NA	1 clip	OTSC	FCES (1)	NA	NA
Aly/2013 [21]	2	12/6t −10 mm (1)	NA	OTSC	NA	NA	NA
Conio/2010 [25]	1	NA	NA	OTSC	LCECS (1)	None	NA
Total	*73*	*14/6t-11 mm: 1* *12/6t-10 mm: 2* *11/6t-9 mm: 2*	*≥ 1*	*OTSC*	*Stent: 9* *Drainage: N/A*	*Stent: 24* *Glue: 8* *Others: 2*	*Leak: 5* *Stent migration: 1* *Clip migration: 2* *Stenosis: 1* *Tear: 1*

NA not available, *OTSC* over-the-scope-clip, *FCSEMS* fully covered self-expanding metal stents, *SEMS* self-expandable metal stent, FCES fully covered esophageal stent, LCECS large colorectal expandable covered stent

Table 4 Outcome of endoscopic treatment of post-LSG leaks using OTSC system

	Timeline after admission for leak				Control imaging	Timing of control imaging	WL	OTSC-related Complications	Success rate		Total success
	Clipping	Oral feeding	Discharge	Total LOS					W/	W/O	
Caballero/2016 [24]	28 days	4 days	0	32 days	Endoscopy	6 months (E) 12 months (Ph/E)	78 kg	NA	NA	1/1	1/1
Shehab/2016 [30]	NA	NA	NA	NA	NA	NA	NA	Stent migration Intolerance Bleeding Esophageal stricture Perforation	NA	NA	NA
Christophorou/2015 [32]	17.8 ± 30.9 (0–200)	NA	NA	NA	NA	> 12 months (NA)	NA	N/A	11/11	NA	11/11
Aranez/2015 [22]	21	1	NA	NA	Endoscopy	4 weeks (E)	NA	None	1/1	NA	1/1
Keren/2015 [28]	56.3 days (16–271)	33.3 days (14–70)	NA	NA	Endoscopy	NA (E)	NA	2 antral leaks after OTSC 3 staple line leaks after OTSC	9/21	12/21	21/26
Donatelli/2014 [26]	11 (0–70)	NA	NA	NA	Endoscopy	150.3 days (20–276) (E)	NA	None	NA	9/9	9/9
Mercky/2014 [29]	141.4 (7–760)	NA	NA	NA	CT scan and laboratory	NA	NA	3 (stenosis, migration, and tear) after OTSC	13/16	3/16	16/18
Gomez/2013 [33]	NA	NA	NA	NA	Barium study	NA	NA	NA	NA	1/1	1/1
Aly/2013 [21]	43	NA	NA	NA	Endoscopy	2 weeks (E)	82% EWL	NA	NA	2/2	2/2
	30	NA	NA	NA	Laboratory	6 months (Lab)	NA				
Conio/2010 [25]	28 days	1 day	0	29	Endoscopy and imaging	1 week (E, RI); 2 weeks (E, RI)	NA	NA	NA	1/1	1/1
Total	*0–271 days*	*1–70 days*	*0*	*29–32*	*Lab: 1* *Endoscopy: 33* *Imaging: 1*		*NA*	*Leak: 5* *Clip migration: 2* *Others: 2*	*34/49 (69.4%)*	*29/51 (56.8%)*	*63/73 (86.3%)*

LOS length of hospital stay, *WL* weight loss, *OTSC* over-the-scope clip, *E* endoscopy, *Ph/E* physical examination, *NA* not available, *CT* computerized tomography, *EWL* excess weight loss, *Lab* laboratory testing, *RI* radiographic imaging, *W/* with additional procedure, *W/O* without additional procedure

Outcome of OTSC System in Management of Post-LSG Leak/Fistula (9 Studies, 73 Patients) (Table 4)

Data of OTSC-related complication was available in four studies (54 patients, 74%) [22, 26, 28, 29]. Of these, OTSC migration, stenosis, and tear each occurred in one patient (1.8%). There was also a continued leak in five patients (9.3%). Weight loss after OTSC treatment was reported by two studies (two patients, 2.7%) as greater than 80% excess weight loss [24, 32]. Of 73 patients with post-LSG leak who were finally treated by OTSC, 63 patients had an overall successful closure, (86.3%) of which 34 had an additional procedure (69.4%) while 29 had solo OTSC procedure (56.8%).

Discussion

Leak is a rare but serious complication after LSG [6, 11, 14], with potential morbidity and mortality [5, 8, 9, 35–37]. Due to the increasing number of bariatric procedures performed in response to the booming obesity prevalence and with the changing trend toward LSG as a feasible and effective weight loss surgery, post-LSG leaks are increasingly reported [1, 2, 35, 37]. A systematic review on the risk of leak after LSG revealed that leak in 89% of cases is found in the proximal third of the gastric staple line [37]. However, the study estimated a successful rate of 11% for endoscopic management of post-LSG leaks, which seems relatively low. This low success rate is expected as many of the citations in this review article were performed prior to the availability of the OTSC system or alternative methods of full thickness endoscopic closure, and the majority of leaks was treated using an endoscopic stenting alone.

Management of post-LSG leak requires a multidisciplinary attempt comprising medical, surgical, and endoscopic approaches [1, 11, 12, 14, 17, 18, 30]. Although surgical revision has been the only curative option for post-LSG leaks over the last decade [13, 14, 37, 38], endoscopy has shown promise in successful treatment of postoperative complications of gastrointestinal surgeries [16, 22, 30, 32]. Nevertheless, proper management of acute GI leak is still one of the major challenges in endoscopy.

OTSC is a novel clipping system for endoscopic closure of GI leak after surgical or endoscopic procedures. The system provides unique features in flexible endoscopy by securing larger tissue volume, higher stability at the site of injury, and decreasing the strain on the surrounding tissue [39]. The system is gaining popularity as a reliable option for treatment of leaks/fistula after bariatric surgery [21, 23, 26, 28–30, 34].

Efficacy of OTSC in the Treatment of Post-LSG Leak

Although the number of post-LSG leaks being treated by an endoscopic procedure is on the rise, only 73 cases have been treated by the OTSC system [21, 22, 24–26, 28, 32]. Even with this small pool of patients, the overall success rate surpasses 85%. A systematic review evaluating the performance of the OTSC system in the endoscopic closure of iatrogenic gastrointestinal perforations revealed a procedural success rate of 80–100% and a clinical success rate of 57–100% [40]. The review, however, has included all the experimental and clinical studies regardless of the location of perforation or the indication for GI defect closure. Moreover, their evaluation is based on the abstracts providing very limited technical information.

In our systematic review, three studies reported OTSC failure in the management of post-LSG leak [26, 29, 32]. Christophorou et al. demonstrated that 11 out of 14 leaks treated by OTSC healed [32]. Although the authors did not comment on the reason for OTSC failure and how they managed it, their multivariate analysis revealed that no history of gastric banding, small fistula, and a shorter time between LSG and fistula formation or between fistula diagnosis and first endoscopy are associated with faster healing. Keren et al. reported five cases of OTSC failure among the 26 treated patients [28]. There was no difference between patients with OTSC failure and those with successful healing in terms of age (23–46 years), gender, (three at GEJ and two at the antrum), comorbidity, and previous gastric banding (one patient). Three patients had previous endoscopic treatments prior to clipping by OTSC. Most patients (four out of five) had an interval of greater than 21 days between leak/fistula development and first endoscopy. Moreover, one patient underwent OTSC 210 days after leak/fistula diagnosis and had argon cautery prior to the OTSC. In the third study reporting OTSC failure, Mercky et al. showed a success rate of 88.9% (16 out of 18) for post-LSG fistula [29]. Both of these patients had simultaneous endoscopic procedure and delayed endoscopy after diagnosis of leak while one patient had a gastrocutaneous fistula. Additionally, although the author noticed impossibility of OTSC placement in one patient due to major fibrosis, the fistula was rectovesical and hence was not included in our analysis. Overall, 14 out of 59 leaks treated with OTSC in our review led to failure of which five leaks, two clip migrations, one stenosis, and one tear were reported.

Determinants of OTSC Success Rate

The included studies in this systematic review did not elucidate the underlying reason for OTSC failure. Rather, they briefly pointed out the type and number of postclipping complications and reported an average value for the interval between LSG, leak diagnosis, and endoscopic closure. In a multivariate analysis of factors associated with shortened duration of healing after endoscopic closure of post-LSG leak, Christophorou et al. showed that no previous gastric banding, small leak/fistula (≤1 cm), a short interval between LSG and

fistula (≤3 days), and an interval of ≤21 days between fistula diagnosis and the first endoscopy are associated with better outcome [32]. This might bear an important message to the bariatric surgeons in terms of early performance of endoscopy in suspicious patients for postoperative leak/fistula formation. Moreover, studies with a longer duration of follow-up were those reporting more complications in relation to the OTSC system and subsequently a success rate <100% [28, 29, 32]. Nonviable tissue around the defect margin or hardened fibrosis that is difficult to grasp is attributed to the clip deployment failure [40–42]. Moreover, depending on the location of the leak/fistula inside the GI tract, aligning the tip of the endoscope with the lesion becomes challenging in some cases [43, 44]. Although it might be inevitable to deploy more than one clip in patients with large leak/fistula, obstruction of the GI lumen may pursue [45, 46]. Our study found that a success rate of 100% correlate with those endoscopies performed no later than 70 days after leak/fistula diagnosis with most of them having the patients undergoing the endoscopic closure within 30 days.

Safety

Data regarding the safety and durability of endoscopic closure of leaks/fistulas using the OTSC system is scarce. Although there is no report of fatal complication in relation to OTSC, the majority of studies fail to provide an adequate follow-up and control imaging after leak/fistula closure. Although our study identified ten OTSC-related complications with no reported mortality, the included studies did not comment on the rescue alternatives to manage the OTSC failures. Regardless, all these studies as well as the only published systematic review conclude that OTSC is a safe endoscopic closing device [21, 22, 24–26, 28, 29, 32, 40].

Limitation

Because there is no prospectively collected database for OTSC system in postbariatric surgery leaks/fistulas, our systematic review pooled the existing evidence on this topic from all available studies and case reports. Although this increased the pooled number of leaks treated by OTSC, missing data still exist for our study variables of interest such as the appropriate time point and indication/contraindications for OTSC application. Another limitation of our study is the short-term follow-up of patients undergoing OTSC closure of leak. With the increasing acceptance of OTSC system in endoscopic closure of the GI perforations, future studies should attempt to include larger population of patients undergoing post-LSG leak using the OTSC system and provide longer follow-up. Moreover, these studies should properly distinguish the efficacy of the solo OTSC system from concomitant OTSC and endoscopic procedures in the treatment of post-LSG leak/fistula. Finally, leaks should be more concisely distinguished from fistulas, as the latter represents a chronic condition following sleeve gastrectomy.

Conclusion

The OTSC system is a promising endoscopic system for the closure of post-LSG leaks/fistulas in appropriately selected patients. Although the system currently holds an overall success rate of 86% in the management of LSG-related leaks/fistulas, further studies should distinguish the sole efficacy of the OTSC from other concomitant procedures. Early closure of the leak/fistula seems to increase the success rate. Further, well-designed studies are required to warrant the long-term durability and safety of the OTSC system compared to that of the available endoscopic options.

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Compliance with Ethical Standards

Conflict of Interest Statement The authors declare that they have no conflict of interest.

Statement of Informed Consent Not applicable.

Statement of Human and Animal Rights Not applicable.

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