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Research article

The role of duodenal jejunal bypass liner in obesity treatment

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Abstract: Endoscopic bariatric procedures including Duedenal Jejunal Bypass Liner (DJBL) have become widespread in obesity treatment in recent years. The aim of this systematic review was to assess the role of DJBL in obesity treatment. A comprehensive search of several databases, including Cochrane Library, PubMed, and Web of Science was conducted to December 2020. Twenty-four clinical studies were assessed. According to the results, it is clear that DJBL provides effective weight reduction at 6–12 months and significant improvements in parameters associated with metabolic syndrome and cardiovascular disease. This technique also has potential to reduce comedications in patients with obesity and type 2 diabetes. Although these positive effects of DJBL are clear, its effect on liver, pancreatic functions, and inflammation markers are not clear yet. In addition, the overall and serious complication (gastrointestinal bleeds, pancreatitis, hepatic abscess, obstruction of the sleeve, biliary colic without cholecystitis and cholangitis) rate causing from the DJBL is very high. DJBL has not been approved by the Food and Drug Administration due to the frequency and severity of complications it causes. While it is certain that DJBL has significant effects on obesity and obesity related comorbidities, the safety aspect needs to be improved.

Keywords: duodenal jejunal bypass liner; duodenal jejunal bypass sleeve; EndoBarrier; obesity

1. Introduction

Obesity and overweight are major risk factors for several chronic diseases (cardiovascular diseases, diabetes, cancer etc.) and have increased enormously over the last 20 years [1]. The global obesity epidemic has underscored the need for reliable, simple and effective weight reduction strategies [2]. In recent years, developments in endoscopic bariatric techniques have created different alternatives for patients and physicians.

Duodenal-jejunal bypass liner (DJBL) is an endoscopically implantable fluoropolymer device and has been widely used in the treatment of obesity in recent years (Figure 1). DJBL is the first endoscopic device that excludes proximal gut from nutrient absorption by covering it and this device mimics the duodenal/jejunal exclusion component of the Roux en Y gastric bypass [3]. The efficacy of the DJBL in obesity treatment has now been studied for more than 10 years. The safety aspect of DJBL is still controversial due to the high and serious complications it causes. It is obvious that DJBL will be used more frequently in the future. In order for this technique to become more effective and safe in the future, it is important to determine the effectiveness of, and the complications that arise from, this procedure. For this purpose, it was aimed to investigate the effect of DJBL on weight loss and obesity related parameters in this systematic review. In addition, adverse events that occurred due to the DJBL were also investigated.

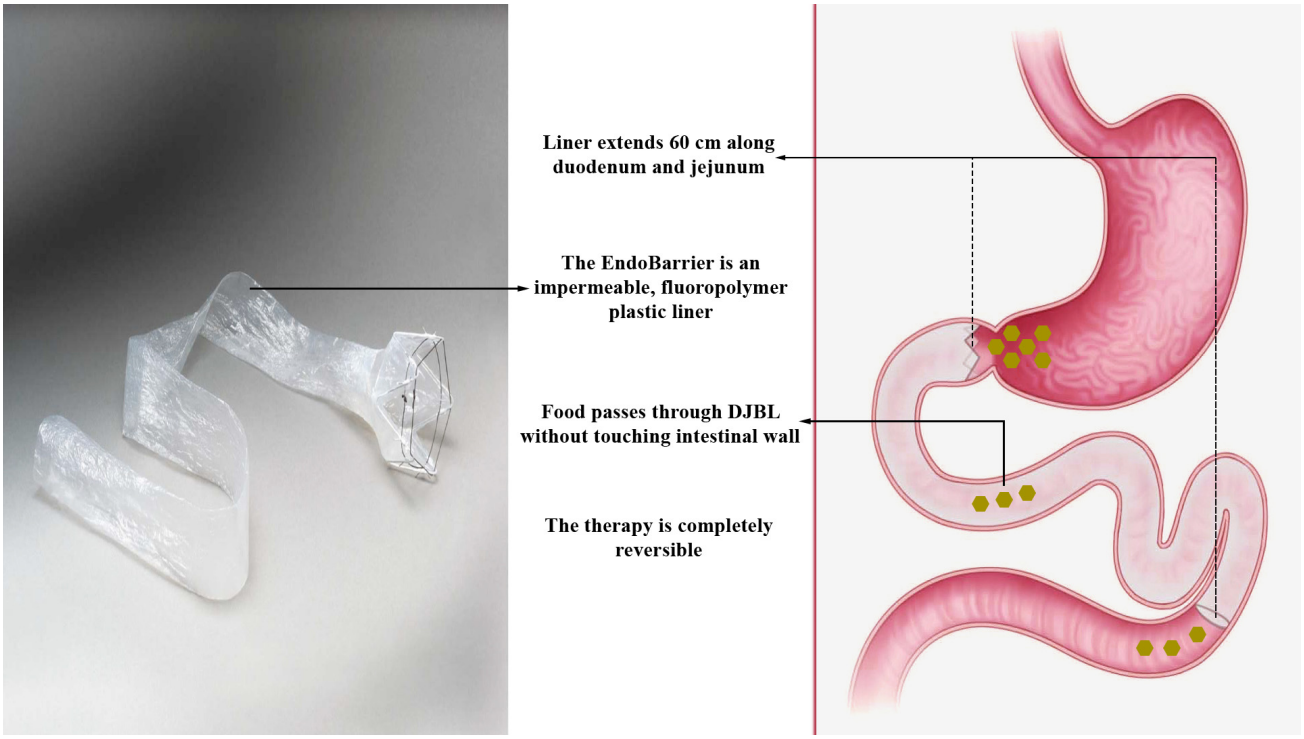

Figure 1. A Duodenal Jejunal Bypass Liner (EndoBarrier).

2. Materials and methods

2.1. Data Sources and searches

A comprehensive search was conducted to identify available studies evaluating the outcomes of DJBL in the treatment of obesity by adhering to preferred reporting items for systematic reviews and meta-analyses (PRISMA) statements (Figure 2). We searched three databases including Cochrane Library, Web of Science, and PubMed from inception to 25 December 2020 without study design or language restriction. A systematic search was conducted using the search terms as ‘‘Endobarrier’’, “Duodenal Jejunal Bypass Liner” and ‘‘Duodenal Jejunal Bypass Sleeve’’ by four authors (T.G.Ü, M.T, F.P.Ç and Ç.Ö). We attempted to identify additional eligible researches by reviewing the reference list of all included studies, and manual search to retrieve other articles that may have been missed by the initial search strategy. Four authors (T.G.Ü, M.T, F.P.Ç and Ç.Ö) also screened all titles and abstracts for relevance to the study and reviewed the full text of the relevant studies.

2.2. Eligibility criteria

Clinical trials and observational prospective cohort studies that were published and peer reviewed were included. Retrospective studies, reviews, case reports, editorials, studies using nonhuman subjects and conference abstracts were excluded as were articles without English translation or full text availability. Studies were also excluded for the following reasons: (1) if there were subjects under the age of 18; (2) if a study was designed to evaluate endoscopic intervention’s efficacy for a specific disease (non-alcoholic fatty liver disease, renal diseases etc.) other than obesity, type 2 DM and metabolic syndrome; (3) if a study’s outcomes were not reported as total weight loss, percentage of excess weight loss, or absolute weight loss; (4) if a study was designed primarily to evaluate the effectiveness of medication, aftercare programs, or a special diet application (ketogenic diet, low carbohydrate diet, etc.) rather than endoscopic intervention; (5) if the number of patients underwent endoscopic intervention is 20 or less at the beginning or at the end of the study.

2.3. Data extraction and outcomes

Twenty-four studies on DJBL were examined. Data for study characteristics, procedure technique, patient baseline characteristics, weight loss outcomes at follow-up, adverse events, and the changes in all parameters associated with obesity were collected for each study and organized in the form of tables. All results and adverse events determined in included studies stated without any classification because of to help guide clinical decision making and procure better treatment of obesity.

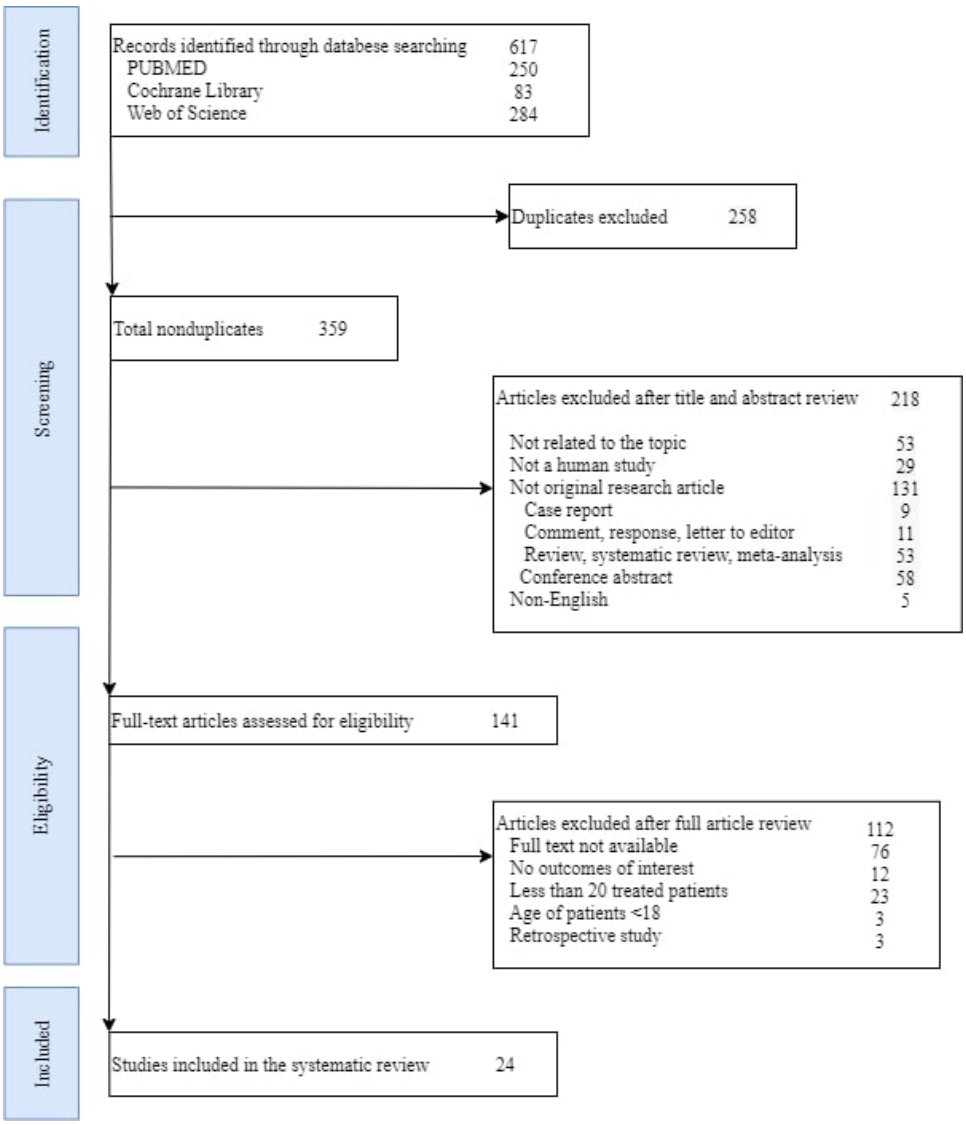

Figure 2. PRISMA flow diagram detailing the process of study selection.

3. Results and discussion

The effect of DJBL application on weight reduction has been evaluated in many clinical studies so far and it is obvious that the technique has positive effect on weight loss (Table 1). In addition to providing significant improvements in parameters associated with diabetes [4–9], cardiovascular diseases [10–12], and metabolic syndrome [13–16], DJBL also has potential to reduce comedications in patients with obesity and type 2 DM [17–21].

Gastrointestinal bleeds [3,8–10,21–23], pancreatitis [3,9,18,24], hepatic abscess [3,8,10,17,18,21,24], obstruction of the sleeve [18,19], biliary colic/pain without cholecystitis [2,6,7,9,13,14,18,19,22,23,25], cholangitis [3,18] etc. are the most common serious adverse events due to the method (Table 1). In another systematic review [26], it was reported that the overall complication rate caused by DJBL (85%) is higher than other endoscopic techniques and the rate of serious complications such as hepatic abscess, pancreatitis and esophageal perforation is 3.7%. DJBL application longer than 1 year increase the severity and frequency of adverse events. In cases of serious adverse events, it is important to

remove the device early. For example, in acute pancreatitis caused by DJBL, early removal of the device results in rapid and complete recovery, while delayed diagnosis and delayed remove may lead to necrotizing acute pancreatitis [27]. On the other hand, it was also stated that DJBL should not be implanted in individuals with duodenal bulbs less than 25 mm in length because of size limitations [22].

Although the positive effect of DJBL on weight loss is clear, its effects on liver, pancreatic functions and inflammation markers are not clear yet. According to De Jonge et al. [28], DJBL application has no positive effect on systemic inflammation in patients with morbid obesity and type 2 DM. Contrary to this, it has been stated that DJBL administration improves insulin tolerance and lipid metabolism reducing fat accumulation and inflammation in hepatocytes, resulting in positive changes in liver function tests (aminotransferase, aspartate transaminase, and gamma-glutamyl transpeptidase) associated with non-alcoholic fatty liver [29]. Besides these parameters, DJBL causes an increase in alkaline phosphatase level and a decrease in bone mineral density, which is thought to be the result of increased osteoclast activity. These changes in bone metabolism are among the complications associated with laparoscopic bariatric techniques also [29]. Another change caused by DJBL application in liver functions is that DJBL procedure increases postprandial unconjugated bile acid responses and disrupts the bile acid-farnesoid X receptor-fibroblast growth factor 19 axis in humans. This change is the main reason for the high risk of liver abscess due to the method. In addition, the increase in bile acids seen after DJBL operation is more exaggerated compared to changes seen after RYGB surgery [30].

Although the physiological effects of the DJBL technique are similar to the RYGB technique, both techniques have different effects on hormones related to appetite metabolism. It was determined that DJBL administration decreased cholecystokinin and leptin concentrations, and increased postprandial peptide YY and ghrelin concentrations. RYGB is associated with a decrease in ghrelin concentrations unlike DJBL. It means is that implantation of the DJBL preserve normal physiological responses of gut hormones linked to dietary restriction and nutrient deprivation compared with RYGB [31]. On the other hand, although the effects of DJBL on gut microbiota composition have not been studied much, De Jonge et al. [32] stated that DJBL administration resulted in an increased abundance of typical small intestinal bacteria such as Proteobacteria, *Lactobacillus spp.* and *Veillonella* in feces, but fecal microbiota composition was similar to that observed at baseline after removal of the DJBL. Despite different hormonal responses and different effects on microbiota composition, both techniques (DJBL and RYGB) have an improving effect on glycemic control and insulin resistance. However, after explantation of DJBL, weight improvements and glycemic control may be impaired.

The effect of DJBL on gastric emptying rate is not clear yet but Escalona et al. [33] stated that the DJBL implanted patients exhibited delayed gastric emptying that was reversed after device removal. De Moura et al. [25] also reached the same result that the method delays gastric emptying, but stated that prolonged gastric emptying resulting from DJBL has no relationship to type 2 DM control and weight loss.

Finally, the most curious thing about DJBL is whether it causes vitamin/mineral deficiencies. Although there are many studies in the literature evaluating the effects of DJBL on weight loss and different parameters, the number of studies investigating whether DJBL causes nutrient deficiencies is quite limited. In one of these studies, it was stated that ferritin, albumin, vitamin B12, folic acid, 25-hydroxy vitamin D3 (25 OH-Vit-D3), calcium, essential fatty acids and their longer chain derivatives levels decreased with DJBL application [17]. Based on these findings, intravenous vitamin and mineral supplementation may be required during the DJBL application.

Table 1. Summary of reported outcome data following Duodenal Jejunal Bypass Liner.

Ref.	DJBL Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application **(IV)** Treatment period	Control Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application	**(I)** Weight loss **(II)** Excess weight loss	Results other than weight loss	Adverse events (n/%)
Kaválková et al. [2]	**(I)** 30 **(II)** 42.7 **(III)** Diabetic diet+NC **(IV)** 10 months	**(I)** - **(II)** - **(III)** -	**(I)** 12.4 kg	Fasting plasma glucose, HbA1c, total cholesterol, LDL cholesterol, triglycerides, CRP, leptin, ferritin, iron, zinc, vitamin B12, albumin, prealbumin, red blood cell count, waist circumference, hip circumference (↓) Bile acids, fibroblast growth factor 19, white blood cell count (↑)	Mild abdominal pain and nausea (NA)
Quezada et al. [3]	**(I)** 80 **(II)** 42 **(III)**1200–1500 kcal/day diet+PA **(IV)** 1,2, and 3 years	**(I)** - **(II)** - **(III)** -	**(II)** 44%, 40%, and 39% (at 1, 2 and 3 years, respectively)	Fasting plasma glucose, insulin, HbA1c, total cholesterol, LDL cholesterol, triglycerides, iron, systolic/diastolic blood pressure (↓)	Total serious adverse events (72). Upper GI bleeding (4), liver abscess (3), acute pancreatitis (1), cholangitis (1) and esophageal perforation (during explantation) (2). Early device removal (23).
De Moura et al. [4]	**(I)** 54 **(II)** 43.8 **(III)** NA **(IV)** 6 months	**(I)** - **(II)** - **(III)** -	**(I)** 12.6%	HbA_1c, TG/HDL ratio (↓)	NA
Muñoz et al. [5]	**(I)** 79 **(II)** 35.4 **(III)**1200–1500 kcal/d diet+PA **(IV)** 12 months	**(I)** - **(II)** - **(III)** -	**(II)** 46%	NA	Device migration (8), device obstruction (5), abdominal pain (2), liver abscess (1), upper gastrointestinal bleeding (1), cholangitis (1), ulcerative colitis (1), acute cholecystitis (1). Total early device removal (21).
Koehestanie et al. [6]	**(I)** 38 **(II)** 35.7 **(III)** NC **(IV)** 6 months	**(I)** 39 **(II)** 37.1 **(III)** NC	**(II)** 32% (DJBL), 16.4% (control)	HbA_1c, postprandial glucose level, daily insulin dosage, usage of sulphonylurea derivatives (↓)	Melena (NA), abdominal discomfort (NA), pain in the epigastric region (NA), DJBL blockage resulting in early removal of the liner (NA), symptomatic gallstones subsequent dehydration etc.) requiring hospitalization (NA).

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Ref.	DJBL Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application **(IV)** Treatment period	Control Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application	**(I)** Weight loss **(II)** Excess weight loss	Results other than weight loss	Adverse events (n/%)
Vilarrasa et al. [7]	**(I)** 21 **(II)** 33.4 **(III)** 1200–1500 kcal/d diet **(IV)** 48 weeks	**(I)** - **(II)** - **(III)** -	**(I)** 14.9%	HbA_1c, fasting plasma glucagon, total cholesterol, LDL cholesterol, usage of antihypertensive drugs and cholesterol-lowering treatment (↓) Fasting peptide YY, fasting plasma ghrelin, HDL/LDL ratio (↑)	Severe abdominal pain, acute cholecystitis and duodenal fistula (2) and mild abdominal pain (40%). Early removal of device (1).
Deutsch et al. [8]	**(I)** 51 **(II)** 37.3 **(III)**Diabetic diet+NC **(IV)** 12 months	**(I)** - **(II)** - **(III)** -	**(I)** 15%	HbA_1c (↓)	Major bleedings (2) and hepatic abscesses (2).
Caiazzo et al. [9]	**(I)** 49 **(II)** 38.4 **(III)**1200–1800 kcal/d diet+NC+PA **(IV)** 12 months	**(I)** 31 **(II)** 37.9 **(III)**1200–1800 kcal/d diet+ NC+PA	**(I)** 9.7% (DJBL), 2.1% (control)	HbA_1c, usage of hypoglycemic drug (↓)	Total serious adverse events (39%). Abdominal pain (13), gastrointestinal bleeding (3), acute pancreatitis (1), gastritis (1), device occlusion, bezoar (4), device migration (1).
Ryder et al. [10]	**(I)** 62 **(II)** 41.9 **(III)** NA **(IV)** 12 months	**(I)** - **(II)** - **(III)** -	**(I)** 15.9 kg	HbA_1c, systolic blood pressure, total cholesterol, alanine aminotransferase, daily insulin dosage (↓)	Gastrointestinal haemorrhage (4), liver abscess (2), another intra-abdominal abscess (1) and other gastrointestinal symptoms (3). Early removal of device (10).
Ruban et al. [11]	**(I)** 85 **(II)** 36.8 **(III)** IMT **(IV)** 12 months	**(I)** 85 **(II)** 35.8 **(III)** IMT	**(I)** 11.4 kg (DJBL), 5.6 kg (control)	HbA_1c, blood pressure (↓) peripheral insulin sensitivity (↑)	Total adverse events (89%), total serious adverse events (24%).

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Ref.	DJBL Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application **(IV)** Treatment period	Control Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application	**(I)** Weight loss **(II)** Excess weight loss	Results other than weight loss	Adverse events (n/%)
Glaysher et al. [12]	**(I)** 70 **(II)** 37 **(III)**1200–1800 kcal/d diet+PA **(IV)** 12 months	**(I)** 70 **(II)** 35.4 **(III)** 1200–1800 kcal/d diet	**(I)** 11.3% (DJBL), 6% (control)	Total serum cholesterol, LDL cholesterol, HDL cholesterol, absolute concentrations of linoleic acid and a-linolenic acid, and their bioactive derivatives, arachidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid (↓)	NA
Escalona et al. [13]	**(I)** 42 **(II)** 43.7 **(III)**1200–1500 kcal/d diet **(IV)** 52 weeks	**(I)** - **(II)** - **(III)** -	**(I)** 22.1 kg **(II)** 47%	Waist circumference, blood pressure, total cholesterol, LDL cholesterol triglycerides, fasting plasma glucose, fasting plasma insulin (↓)	Upper abdominal pain (81%), device migration (8), vomiting (33%), nausea (41%), and gastroenteritis (4.8%).
Van Rijn et al. [14]	**(I)** 38 **(II)** 34.8 **(III)**1200–1500 kcal/d diet **(IV)** 6 months	**(I)** 39 **(II)** 35.2 **(III)**1200–1500 kcal/d diet	**(I)** 9.5 kg (DJBL), 3 kg (control) **(II)** 32.8% (DJBL)	HbA_1c, fasting plasma glucose, fasting plasma insulin, total cholesterol, LDL cholesterol, HDL cholesterol (↓)	Upper abdominal pain due to an eversion of the liner (NA), vomiting due to pylorospasm (NA), nausea and abdominal pain caused by a food bolus blocking (NA) and migration of the liner (NA).
Patel et al. [15]	**(I)** 45 **(II)** 40 **(III)** NC **(IV)** 12 months	**(I)** - **(II)** - **(III)** -	**(I)** 15 kg	HbA_1c, fasting plasma glucose, fasting plasma insulin, usage of metformin and sulphonylureas (↓)	Total adverse events (88.9%), total serious adverse events (14).
Colás et al. [16]	**(I)** 30 **(II)** 42.3 **(III)** NA **(IV)** 10 months	**(I)** - **(II)** - **(III)** -	(BMI) 4.2 kg/m^2	HbA_1c, waist circumference, fasting plasma glucose (↓)	NA
Riedel et al. [17]	**(I)** 66 **(II)** 43.4 **(III)** NA **(IV)** 12 months	**(I)** - **(II)** - **(III)** -	**(I)** 15.9 kg **(II)** 33.8%	HbA_1c, total cholesterol, LDL cholesterol, usage of comedications/insulin, systolic and diastolic blood pressure, serum concentrations of ferritin, albumin, vitamin B12, folic acid, 25-hydroxyvitamin D3 (25 OH-Vit-D3), and calcium (↓)	Liver abscess (1.7%), dislocation (1.7%) and intestinal obstruction (1.7%).

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Ref.	DJBL Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application **(IV)** Treatment period	Control Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application	**(I)** Weight loss **(II)** Excess weight loss	Results other than weight loss	Adverse events (n/%)
Roehlen et al. [18]	**(I)** 71 **(II)** 45.2 **(III)** NC **(IV)** 9–12 months	**(I)** - **(II)** - **(III)** -	(BMI) 5.4 kg/m^2	HbA1c, waist circumference, body fat proportion, systolic and diastolic blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, VLDL, fasting plasma glucose, high-sensitive CRP, lipoprotein-associated phospholipase A2 and small dense lipoprotein fraction LDL-4 (↓)	Flatulence (28.2%), nausea (23.9%), mild-to-moderate abdominal pain (16.9%), diarrhoea (15.5%), vomiting (14.1%), severe abdominal pain (9.9%), constipation (8.5%), migration/dislocation (5.6%), liver abscess (4.2%), hypoglycaemia (4.2%), biliary pancreatitis (2.8%), duodenal ulcer with perforation (1.4%), sleeve obstruction (1.4%) and cholangitis (1.4%).
Schouten et al. [19]	**(I)** 30 **(II)** 48.9 **(III)** LCD **(IV)** 12 weeks	**(I)** 11 **(II)** 49.2 **(III)** LCD	**(II)** 19% (DJBL), 6.9% (control)	Insulin dosage, usage of oral antidiabetic medication (↓)	Device migration (1), sleeve obstruction (1), dislocation of the anchor (1), continuous epigastric pain (1), abdominal pain (NA) and nausea (NA).
Betzel et al. [20]	**(I)** 59 **(II)** 34.4 **(III)** NC **(IV)** 6 months	**(I)** - **(II)** - **(III)** -	**(I)** 13.6 kg **(II)** 48.8%	HbA1c, fasting blood glucose (↓)	NA
Betzel et al. [21]	**(I)** 198 **(II)** 35.1 **(III)** NC **(IV)** 12 months	**(I)** - **(II)** - **(III)** -	**(I)** 12.8 kg	HbA1c, usage of antidiabetic medication, blood pressure, total cholesterol, HDL cholesterol, triglycerides (↓)	Arterial bleeding and an affixed anchor in the duodenal bulb (2), esophageal lesion during implantation (1), esophageal perforation during explanation (1), severe acute pancreatitis (1) and hepatic abscesses (4). Early removal of device (20).
Gersin et al. [22]	**(I)** 21 **(II)** 46 **(III)** LCD **(IV)** 12 weeks	**(I)** 26 (SE) **(II)** 46 **(III)** LCD	**(I)** 8.2 kg (DJBL), 2.1 kg (control) **(II)** 11.9% (DJBL), 2.7% (control)	None	Gastrointestinal bleeding (3), abdominal pain (2), nausea and vomiting (2).
Tarnoff et al. [23]	**(I)** 25 **(II)** 42 **(III)** NC+LFD **(IV)** 12 weeks	**(I)**14 **(II)** 40 **(III)**NC+ LFD	**(I)** 10.3 kg (DJBL), 2.6 kg (control) **(II)** 22.1% (DJBL), 5.3% (control)	Usage of antidiabetic medication/insulin, fasting plasma glucose and HbA1c (in diabetic patients) (↓)	Gastrointestinal hemorrhage (4), abdominal pain (16), abdominal distension (11), nausea (7), vomiting (8), constipation (1) and epigastric discomfort (1).

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Ref.	DJBL Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application **(IV)** Treatment period	Control Group **(I)** n **(II)** Initial BMI (kg/m^2) **(III)** Extra application	**(I)** Weight loss **(II)** Excess weight loss	Results other than weight loss	Adverse events (n/%)
Betzel et al. [24]	**(I)** 44 **(II)** 35.1 **(III)** NA **(IV)** 12–24 months	**(I)** - **(II)** - **(III)** -	**(I)** 15.9 kg	HbA1c, insulin dosage (↓)	Total adverse events (68%), hepatic abscess (2). Early removal of device (12).
De Moura et al. [25]	**(I)** 25 **(II)** 46.8 **(III)** NA **(IV)** 16 weeks	**(I)** - **(II)** - **(III)** -	**(I)** 14 kg	Gastric emptying time (↑), usage of antidiabetic medication and HbA1c (in diabetic patients)	Abdominal pain (96%), nausea (40%), vomiting (48%), hypoglycemia (20%), weakness (8%) and back pain (16%).

Note: **BMI:** Body mass index; **CRP:** C-Reactive protein; **DJBL:** Duodenal jejunal bypass liner; **HDL:** High density lipoprotein; **IMT:** Intensive medical therapy; **LCD:** Low calorie diet; **LDL:** Low density lipoprotein; **LFD:** Low fat diet; **NA:** Data not available; **NC:** Nutritional counseling; **PA:** Physical activity; **SE:** Sham endoscopy; **TG:** Triglyceride; **VLDL:** Very low density lipoprotein.

4. Conclusions

Consequently, the positive effects of DJBL on weight loss in short term is obvious and this device provides significant improvement in parameters associated with cardiovascular diseases and metabolic syndrome. This technique has also potential to reduce comedications in patients with obesity and type 2 diabetes. The rate of general and serious complications (hepatic abscess, pancreatitis, and esophageal perforation, etc.) caused by DJBL is higher than other endoscopic techniques. DJBL has not been approved by the FDA due to the frequency and severity of complications it causes. Supportive care, expert use of the device at placement and removal and patient selection are key for effective and safe use of the DJBL. Since the benefits seen with DJBL are temporary, and the positive changes observed after removal of the device disappear, it is thought that its routine use for weight reduction and glucose control is not suitable in patients with obesity. In addition, DJBL prevents nutrient contact with the duodenal and proximal jejunal mucosa, which may result in nutrient malabsorption. Therefore, intravenous vitamin and mineral supplementation may be required during DJBL application. On the other hand, DJBL should not be implanted in individuals with duodenal bulbs less than 25 mm in length because of size limitations.

Conflict of interest

All authors declare no conflicts of interest in this paper.

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