Duodenal-Jejunal Bypass Liners are Superior to Optimal Medical Management in Ameliorating Metabolic Dysfunction: A Systematic Review and Meta-Analysis

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INTRODUCTION

Despite substantial advances, rising incidence of obesity and its associated metabolic complications, including type 2 diabetes (T2D), continue to present a substantial burden on patient morbidity, mortality, and healthcare resources.[1-3] Duodenal-jejunal bypass liners (DJBLs) are innovative reversible endoscopically implanted devices that have demonstrated great potential as either a primary or adjunct therapy for patients with obesity and metabolic disease.[4, 5] Due to promising preliminary observational studies[4], numerous prospective, multi-centre, and randomized controlled studies have since been recently published evaluating DJBL outcomes.[6-8] Despite the growing interest in this novel therapy, few contemporary studies have systematically reviewed current literature including comparative studies, posing a barrier to our modern understanding of optimal DJBL adoption and delivery.

DJBL involves endoscopic placement of a plastic liner distal to the pylorus and proximal to the ampulla of Vater, whereby chyme is excluded from the proximal gastrointestinal tract (**Figure 1).** In effect, the DJBL is thought to induce anatomic, physiologic, and gut microbial changes similar to that observed with the current gold-standard metabolic procedure- Roux-en-Y Gastric Bypass (RYGB).[9-11] The first paper describing human use of DJBLs in 2008 described the need for non-surgical, preoperative weight loss option to bridge patients to definitive bariatric surgery .[12] More recent literature, however, has explored the use of DJBLs beyond that of a bridging therapy and evaluates its promise as a standalone treatment for obesity and T2D.[6, 13, 14] The current lack of comprehensive evaluation of DJBL indications and its outcomes has led to growing debate regarding its use. An updated review and analysis of this important data is thus required to better inform device safety, efficacy, and to more clearly delineate DJBL indications.

The aim of the present study was to conduct a comprehensive systematic review and meta-analysis to characterize DJBL patient selection, metabolic and anthropometric outcomes with comparison to best medical therapy (BMT) in improving obesity and metabolic outcomes.

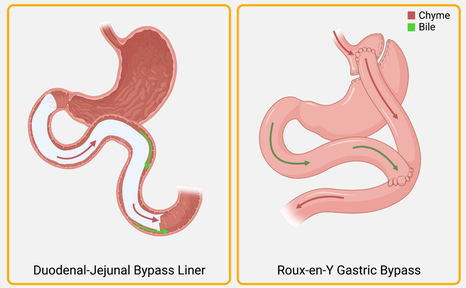


Figure 1. Illustration of duodenal-jejunal bypass liners compared to Roux-en-Y gastric bypass final anatomy with arrives to indicate pathway of chyme (red) and bile (green). This figure was made using BioRender.com

METHODOLOGY

POPULATION	INTERVENTION / COMPARISON	OUTCOMES
Adult (≥ 18 years) patients undergoing DJBL treatment	DJBL treatment vs. Best Medical Therapy	HbA1c, Fasting Plasma Glucose, BMI and weight change

All observational and comparative studies enrolling >5 adult patients were eligible, while case reports, abstracts, letters, narrative, or systematic reviews were excluded.

Search terms:
duodenal-jejunal bypass liner, duodenal-jejunal bypass sleeve, duodeno-jejunal bypass liner, duodeno-jejunal bypass sleeve, EndoBarrier, duodenal sleeve, jejunal sleeve, gastrointestinal liner, bypass liner

Data Sources:
Scopus, MEDLINE (via Ovid), Web of Science Core Collection, EMBASE (Ovid), and Cochrane Library (Wiley). Gray literature was evaluated using the first 200 results from Google Scholar in addition to subscription databases.

Search Date: April 1, 2022

Statistical Analysis:
Weighted means or percentages were used to summarize patient characteristics and follow-up data.
Meta-analysis was used to evaluate post-explant changes in weight, BMI, HbA1c and FPG for included comparative studies. RevMan 5.4 software provided by the Cochrane website was used to apply the Mantel-Haenszel random-effects method in our analysis assuming the true effect estimates varied among studies.

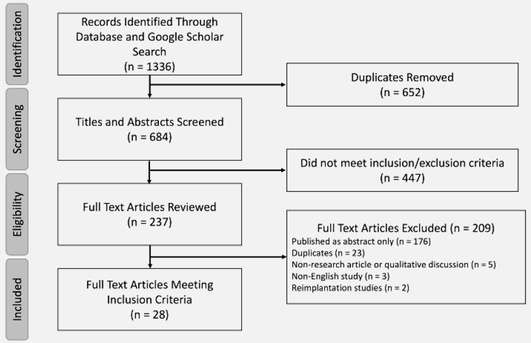


Figure 2. PRISMA summary of systematic review study search and inclusion criteria.

RESULTS

Metabolic and Anthropometric Outcomes at DJBL Explant:

DJBL Implant Duration	HbA1c % (SD)	FPG mmol/L (SD)	BMI kg/m² (SD)	Weight kg (SD)
≤6-months (n = 170)	Baseline: 8.1 (2.3) Explant: 7.0 (2.3)	Baseline: 10.7 (2.7) Explant: 8.7 (2.4)	Baseline: 40.2 (4.1) Explant: 36.1 (3.3)	Baseline: 115.4 (17.4) Explant: 105.4 (6.3)
>6-months (n = 1093)	Baseline: 7.9 (1.8) Explant: 6.7 (1.8)	Baseline: 9.9 (2.5) Explant: 7.8 (1.7)	Baseline: 40.3 (5.7) Explant: 35.1 (6.0)	Baseline: 112.4 (18.4) Explant: 98.7 (17.4)

Post-explant data demonstrated a gradual return to baseline of these characteristics

Meta-Analysis of Comparative Studies:

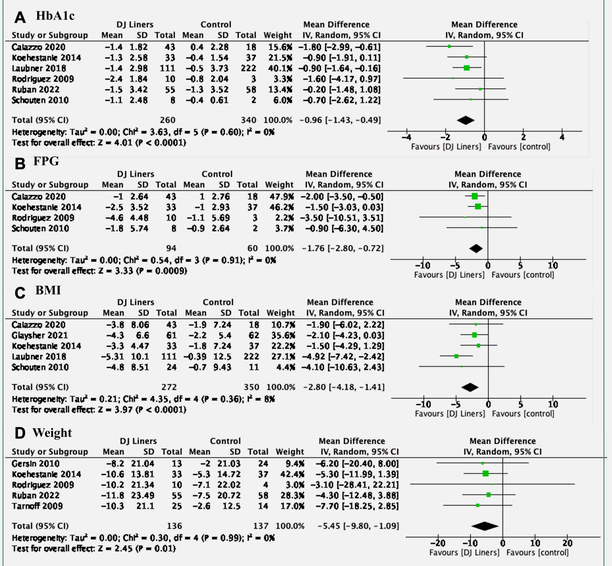
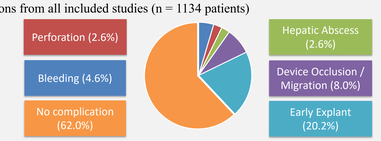


Figure 3. Meta-analyses comparing duodenal-jejunal bypass liners at explant and medical therapy for (A) HbA1c (%), (B) fasting plasma glucose (mmol/L), (C) BMI (kg/m²), and (D) Weight (kg), outcomes at DJBL explant.

RESULTS

Summary of Complications:
Overall complication rate of Clavien-Dindo Grade III or higher - 17.7% (n = 201)

Total complications from all included studies (n = 1134 patients)



CONCLUSIONS

DJBL implantation provides short-term weight loss and glycemic control for patients with obesity and impaired glucose homeostasis

Early device explant is a common complication

Additional studies evaluating long-term outcomes are needed

Overall, we caution against the use of DJBL as a definitive treatment for obesity and its metabolic complications until more data is available.

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