Obesity Science & Practice

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ORIGINAL ARTICLE OPEN ACCESS

Naltrexone/Bupropion, Liraglutide, or Semaglutide as Adjuvant Therapy After Metabolic and Bariatric Surgery: An Observational Study

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Received: 12 April 2025 | **Revised:** 11 October 2025 | **Accepted:** 2 November 2025

Keywords: ER naltrexone/bupropion | GLP-1 receptor agonist | liraglutide | metabolic and bariatric surgery | obesity management medications | recurrent weight gain | semaglutide

ABSTRACT

Introduction: Obesity is a chronic and relapsing disease and metabolic and bariatric surgery (MBS) provides the greatest weight loss efficacy to improve obesity related complications. However, weight recurrence and suboptimal weight loss occur in some patients leading to a recurrence of disease. Obesity management medications (OMM) to prevent and manage excess weight after MBS are now being recommended. The aim of the study was to determine the efficacy of OMM prescribed for recurrent weight gain (RWG) or suboptimal weight loss (SWL) after primary and conversional bariatric metabolic surgery.

Methods: Patients were prescribed either a fixed-dose extended-release combination of naltrexone and bupropion (NB-ER; 8 mg/90 mg), liraglutide (3.0 mg), or semaglutide (1.0 mg) for RWG and/or SWL following adjustable gastric banding (LAGB), sleeve gastrectomy (LSG), one anastomosis gastric bypass (OAGB), or conversional procedures. Data were reported as categorical values using either parametric or nonparametric statistics.

Results: For the 121 patients analyzed, baseline characteristics were similar at initiation of OMM. Among these patients, 59.7% underwent LSG, 11.8% underwent OAGB, 6.7% underwent LAGB, and 21.8% underwent conversional procedures. Patients regained a median of 9.7 kg (IQR; 5–18.1) or 27.9% (IQR; 15.7–57.8) of total body weight previously lost following MBS. In total, 34 patients (28.1%) were prescribed NB-ER, 23 patients (19.1%) were prescribed liraglutide, and 64 patients (52.8%) were prescribed semaglutide post MBS. Overall, patients prescribed OMM treatment lost 8.8% (IQR; 5.7–14.1; median follow-up, 9 months [IQR; 5–12]) total body weight. Adverse effects were minor and reflected clinical trial nonsurgical cohorts.

Conclusion: Adjuvant OMM conferred additional significant weight loss in patients with RWG or SWL in both primary and conversional surgical procedures and all three OMM studied should be considered as part of MBS aftercare.

1 | Introduction

Currently, metabolic and bariatric surgery (MBS) is the most effective treatment option for people with severe obesity [1, 2]. However, long-term response rates vary between patients, and not all patients maintain their weight loss. Recurrent weight gain (RWG) or suboptimal weight loss (SWL) after MBS is common [3] and can be influenced by changes in eating habits, psychological factors, metabolic adaptation, and/or significant personal life events [4]. An estimated 1/3 of patients after bariatric surgery will regain more than 25% of the initial weight lost [5]. Furthermore, RWG is associated with the recurrence of obesity-related complications [3].

Obesity management medications (OMM) such as phentermine, topimerate, naltrexone/bupropion and the glucagon-like peptide

1 receptor agonists (GLP-1 RA) have evolved as adjuvant therapy post MBS following RWG or SWL [5] as an alternative to reoperative surgery, especially considering that conversional surgery carries a high risk of complications [6]. The fixed-dose extended-release combination of naltrexone and bupropion (NB-ER), liraglutide, and semaglutide are approved obesity management medications (OMM) [7–9] adjunct to lifestyle modification indicated for adult patients with a BMI ≥ 30 kg/m^2 or with a BMI of > 27 kg/m^2 and ≥ 1 obesity complication(s). These OMM have been shown to prevent and manage RWG or SWL following MBS [10–17]. Despite the high incidence of RWG or SWL, OMM are generally underutilized [18].

Only two retrospective studies involving NB-ER reported weight loss data in patients following MBS. A study of 209 patients after Roux-en-Y Gastric Bypass (RNYGB), LSG or LAGB, prescribed either phentermine, phentermine/topiramate, lorcaserin (no longer used), or NB-ER, found a 2.2% TWL over 24 months for all patients without differentiating between OMM [13]. Similarly, weight loss of between 2.2 and 5.7 kg was observed in patients (N = 48) following RNYGB, LSG, or LAGB taking 0 to ≥ 2 medications (metformin, phentermine, phentermine/topiramate, NB-ER, lorcaserin, zonisamide, topiramate, or GLP-1s) [19] without differentiating between medications. Interestingly, the weight-loss effect was halved for patients receiving bariatric surgery and OMM compared with non-bariatric patients. Also, there was no significant difference in weight loss between those taking ≥ 2 medications, regardless of the type of bariatric surgery. Liraglutide has been extensively studied as an adjuvant OMM following MBS [12], including in two randomized controlled clinical trials (RCT). The GRAVITAS trial (N = 71) studied the effect of liraglutide 1.8 mg in patients with T2DM 1 year after RYGB [20]. Treatment with liraglutide versus placebo was associated with a 6.81 kg versus 1.64 kg weight loss difference after 26 weeks. A subsequent RCT study [16] examined the effect of liraglutide (up to 3.0 mg) in nondiabetic patients with SWL (< 20% TWL) ≥ 18 months after either RYGB or LSG. An 8.82% TWL was observed with liraglutide versus placebo at 24 weeks, with 71.9% of patients losing > 5% of body weight. A meta-analysis [12] of 16 studies using liraglutide post MBS including 1 RCT [16] and 15 observational and retrospective studies (N = 881) found an 8-point reduction in BMI and a mean reduction of 16 kg in TWL (follow-up, 3 months–4 years), with 26% of patients losing > 10% of TWL.

Although there are no current RCTs involving semaglutide, four retrospective studies showed significant weight loss in patients with RWG following semaglutide [14, 15, 21, 22] In 55 patients receiving low dose semaglutide (0.5 mg) with RWG/SWL, a TWL of 10.3% ± 55% was observed after 6 months of treatment [14]. Similarly, in 55 patients post MBS following RWG, patients receiving liraglutide versus semaglutide had 7.3% versus 9.8% TWL at 6 months [15]. Another study found that those receiving semaglutide lost more weight than those receiving liraglutide (least squares mean weight loss 12.92% vs. 8.77%) after 12 months [22]. Most recently, tirzepatide, a novel glucose dependent insulinotropic polypeptide and glucagon like peptide-1 receptor agonist (GLP-1 RA), has been shown to be the most effective OMM [23]. Indeed, when used for the treatment of weight recurrence following sleeve gastrectomy, weight loss with tirzepatide was found to be greater than that following semaglutide (15.5% vs. 10.3%) at 6 months follow up [21]. All in all, all index operations studied to date were either gastric band, gastric sleeve resections, or RNGB. No studies as yet have included patients with weight regain or inadequate weight loss following the one anastomosis gastric bypass.

At the time of the study, only naltrexone/bupropion followed by liraglutide was available. Semaglutide had then received approval for patients with type 2 diabetes and its initial use was off label at a maximum dose of 1.0 mg s/c weekly. Tirzepatide had not been approved for use in Australia at the time of the study. The Sydney Bariatric Clinic undertakes a high number of revisional/conversional bariatric procedures and one of the few bariatric centers in Australia to perform the one anastomosis gastric bypass as both a primary and revisional procedure [24]. This environment therefore provided a unique opportunity to study three different obesity medications targeting different appetite regulatory pathways in refractory obesity within a single bariatric clinic as adjuvant therapy following both primary and conversional bariatric metabolic procedures.

2 | Materials and Methods

This was a single-center retrospective analysis of a prospectively collected database at the Sydney Bariatric Clinic, Australia. The center provides interdisciplinary care for the surgical management of patients undergoing MBS. It comprises a single bariatric surgeon, a bariatric medical practitioner, two accredited dieticians, two psychologists, and a bariatric nurse. The database included patients following primary adjustable gastric banding (LAGB), sleeve gastrectomy (LSG), one anastomosis gastric bypass (OAGB), and conversional procedures. Informed consent was obtained from all study participants. As the study was retrospective, ethics approval was not required.

The IFSO reporting standards were used to define RWG (> 30% of the initial surgical weight loss) and SWL (< 20% of body weight loss post bariatric surgery) [25]. However, patients were also considered for OMM if they lacked adequate appetite suppression, inadequate satiety, food cravings, or a desire to lose more weight, reflecting general clinical practice. Patients deemed suitable for conversional surgery decided against further surgery either because they were not covered by private health insurance or because of costly out-of-pocket expenses.

Patients were reviewed by the bariatric medical practitioner and prescribed NB-ER (8/90–32/360 mg oral daily), liraglutide (1.2–3.0 mg subcutaneous daily), or semaglutide (0.5–1.0 mg subcutaneous weekly). None of these medications is reimbursed in Australia and all were self-paid by the patient. Patients' choice of the specific weight-loss medication was based on the initial availability of the medication, efficacy data, mode of delivery, side effect profile, contraindications, cost and individual preference, together with advice from the treating bariatric physician. Patients were excluded from a GLP-1 RA if they had a personal or family history of medullary thyroid cancer or a personal history of pancreatitis and excluded from all 3 OMM if they were pregnant or breast feeding. All patients were

recommended for dietary and psychological counseling based on their needs and medical history.

The extracted data included anthropometric data, type of bariatric metabolic surgical procedure (primary or conversional), weight and BMI (collected pre surgery, lowest weight post surgery [nadir weight], weight at OMM initiation, weight at the latest follow-up time post OMM), time of commencement of OMM, and medication adverse events (AEs).

2.1 | Statistical Analysis

Data were reported as continuous variables as either mean ± 2 standard deviations, interquartile range 50th percentile (25th, 75th percentile) if not normally distributed (Shapiro-Wilk test), or categorical values expressed as either numbers or percentages. Data were analyzed using either parametric or nonparametric statistics (one-way ANOVA with repeated measures; Kruskal–Wallis and Dwass-Steel–Crithlow-Fligner pairwise comparisons) where appropriate. Excel and Janovi (version 2.5, 2024) were used for data analysis. A $p < 0.05$ was considered statistically significant.

3 | Results

3.1 | Baseline Characteristics

There were 121 patients prescribed an OMM: 64 patients (52.8%) receiving semaglutide, 34 patients (28.1%) receiving NB-ER, and 23 patients (19.1%) receiving liraglutide (Table 1). Among these patients, 59.7% underwent LSG, 11.8% OAGB, 6.7% LAGB, and 21.8% conversional procedures (LAGB to LSG in 10.1%, LAGB to OAGB in 6.7%, and LSG to OAGB in 5.0%), which was generally consistent with the clinics clinical practice (73% LSG, 14% OAGB, and 10% revisional/conversional procedures). There was no significant difference in baseline weight, BMI, or types of bariatric procedures, whether primary or conversional, between the three OMM cohorts. OMM was initiated between 4.3 years (IQR; 2.1–5.1) for primary procedures and not significantly different from conversional procedures; 3.6 years (IQR; 2.0–4.1) Across all three OMM, the mean age varied between 46.9 ± 8.6 and 50.1 ± 9.8 years, with most patients being female (88.2%–95.7%).

Eight of 34 patients (23.5%) prescribed NB-ER and 8/22 (36.4%) prescribed liraglutide switched to semaglutide and were not included in the semaglutide cohort. Only 5 (4.1%) patients (NB-ER, 4; liraglutide, 1; semaglutide, 0) underwent conversional surgery within 3 months after the commencement of OMM, otherwise no patient at the time of the study had stopped taking their OMM.

3.2 | Weight-Loss Outcomes Following OMM

There was no significant difference in RWG, commencement of OMM, weight loss following OMM, or duration of OMM usage in patients following either primary or conversional MBS and all outcome data were therefore pooled. Following primary and conversional MBS patients lost 28.4% ± 12.4% body weight or

TABLE 1 | Patient characteristics at baseline surgery, surgery nadir, OMM initiation, and last follow-up of OMM.

	NB-ER	Liraglutide	Semaglutide
Sample size, *n*	34	23	64
Age at OM initiation, year	50.1 ± 9.8	46.9 ± 8.6	47.3 ± 12.3
Female, %	88.20%	95.70%	90.60%
Baseline surgery			
Weight, kg	114.0 (98.7, 128)	116.0 (99.7, 125)	110.5 (98.1, 132.3)
BMI, kg/m^2	40.4 (38.2, 46.1)	32.6 (28.1, 36.0)	42.6 (38.3, 47.7)
Surgery nadir			
Weight, kg	85.1 (70.2, 97.4)	80.9 (71.7, 97.6)	75 (69.9, 91.5)
BMI, kg/m^2	32.6 (26.0, 33.9)	31.2 (27.0, 33.9)	28.8 (26.1, 32.7)
OMM initiation			
Time after MBS, year	3.0 (1.75,4)	3.0 (2, 4.75)	3.0 (1.75, 5)
Weight, kg	92.8 (81.5, 103.9)	94.7 (86.4, 112)	86.3 (79.8, 100.3)
BMI, kg/m^2	35.1 (30.3, 38.6)	34.6 (32.4, 51.1)	33.0 (29.7, 36.5)
OMM last follow-up			
Last follow-up, month	10.0 (5.0, 12.0)	9.1 (7.4, 13.8)	8.7 (4.6,13.6)
Weight, kg	86.7 (72.9, 97.1)[a]	86.1 (74.7, 98.3)[a]	77.5 (69.0, 90.6)[a]
BMI, kg/m^2	32.6 (28.1, 36)[a]	31.8 (29.6, 43.4)[a]	33.0 (29.2, 44.2)[a]

Note: Data are mean ± SD median values or interquartile range in parentheses.
Abbreviations: BMI, body mass index; MBS, metabolic and bariatric surgery; NB-ER, fixed-dose, extended-release combination of naltrexone and bupropion; OMM, obesity management medication; SD, standard deviation.
[a]Significantly different to OMM initiation, $p < 0.0001$.

74.1% ± 36.2% EWL. However, patients regained a mean of 9.7 kg (IQR; 5.0–18.1 kg; maximum 65 kg) or 27.9% (IQR; 15.7%–57.8%) of TWL following MBS (Figure 1). The patient cohort largely consisted of those with RWG, as only 22.1% of patients had SWL.

Overall, patients prescribed OMM lost 8.8% (IQR; 5.7%–14.1%) of TWL ($p < 0.0001$) after a median follow-up of 9.0 months (IQR; 5.0–12.0 months), corresponding to 80.5% (IQR; 38.5%–184.2%) of the weight regained (Figure 1). Specifically, patients prescribed NB-ER (baseline weight, 92.8 kg; IQR 81.5–103.9 kg) lost 6.8% (IQR; 5.3%–9.4%) of TWL ($p < 0.0001$) after a median follow-up of 10.0 months (IQR; 5.0–12.0 months; Figure 2). Patients prescribed liraglutide (baseline weight, 94.7 kg; IQR, 86.4–112 kg) lost 9.1% (IQR; 7.1%–13.8%) of TWL ($p < 0.0001$) after a median follow-up of 9.1 months (IQR; 7.4–13.8 months). Patients prescribed semaglutide (baseline weight, 86.3 kg; IQR, 79.8–100.3 kg) lost 10.9% (IQR; 6.6%–14.7%) of TWL ($p < 0.0001$) after a median follow-up of 8.7 months (IQR; 4.6–13.6 months). While weight loss following semaglutide versus NB-ER was significantly higher ($p < 0.033$), weight loss with semaglutide was only numerically higher than liraglutide. Most patients achieved significant weight loss from baseline following OMM (Figure 1). However, patients treated with semaglutide achieved greater TWL of 5%, 10%, 15%, and 20% than patients prescribed liraglutide or NB-ER (Figure 3).

3.3 | Adverse Effects Following OMM Use

Adverse effects for most patients were minor and reflected those observed during phase 3 regulatory clinical trials of patients with obesity. Patients in the present study prescribed NB-ER were the most likely to stop treatment due to AEs. Of the 44 patients originally prescribed NB-ER, 10 patients (22.7%) stopped taking the drug within 6 weeks due to AEs (e.g., headaches, blurred vision, slurred speech, anxiety, palpitations, and vivid dreams) and were not included in the efficacy data base. No patient prescribed either liraglutide or semaglutide stopped taking the medication due to AEs.

4 | Discussion

In this study, patients prescribed OMM after MBS had 8.8% TWL, corresponding to 80.5% of the weight regained following MBS. Adjuvant OMM resulted in patients almost returning to their nadir surgical weight. Regardless of the OMM used, more than 75% of patients achieved a weight loss > 5% of body weight, and > 20% of patients achieved a weight loss > 10% of body weight. Moreover, the study showed that < 5% of patients decided to undergo further conversional surgery. Together, these results support the adjuvant use of NB-ER, liraglutide, or semaglutide for weight loss in patients following RWG/SWL post MBS. Furthermore our study supports the safety and efficacy of OMM regardless of the type of MBS procedure, including the one anastomoses gastric bypass and in both primary and conversional surgeries.

This study is the first retrospective observational study to specifically examine the role of NB-ER in a large cohort of patients following RWG/SWL post MBS. Substantial weight loss (6.8%) was observed, with over 75% of patients achieving > 5% weight loss. These results are consistent with the COR-BMOD trial, which showed weight loss of 7.8% ± 0.4% using NB-ER for 56 weeks in nonsurgical patients [7]. In the COR-BMOD trial, 67% of patients who completed 56 weeks of treatment had lost ≥ 5% of their weight loss. These results showed greater weight loss than the two previous retrospective studies involving NB-ER in post bariatric cohorts [13, 19]. Therefore, the current study adds to the

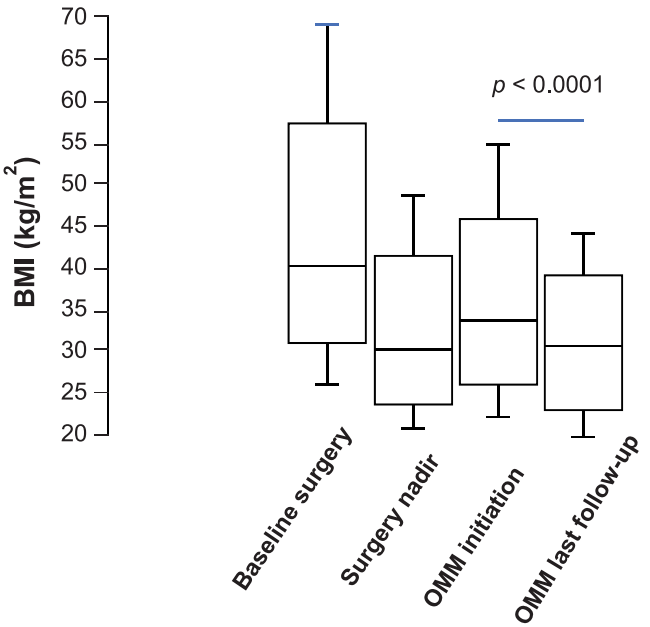

FIGURE 1 | Box plot showing BMI (kg/m^2) at baseline surgery, surgery nadir, at OMM initiation, and at OMM last follow-up visit. BMI, body mass index, OMM, obesity management medications.

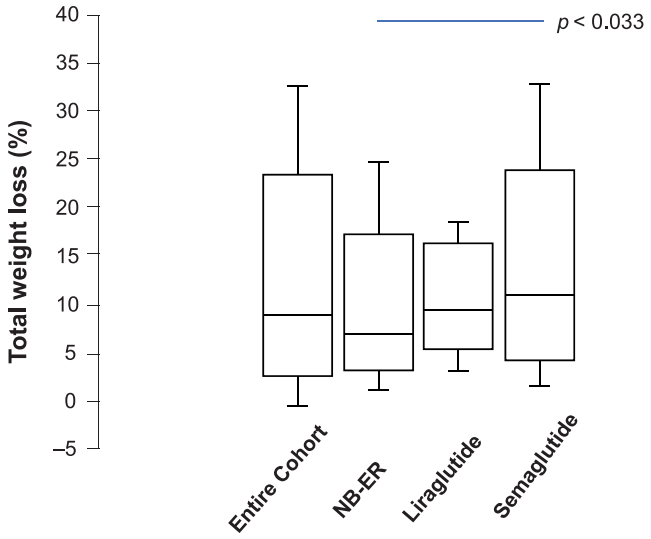

FIGURE 2 | Box plot showing total weight loss (%) following commencement of OMM for the entire cohort, and following treatment with NB-ER, liraglutide, and semaglutide. NB-ER, fixed-dose, extended-release combination of naltrexone and bupropion; OMM, obesity management medications.

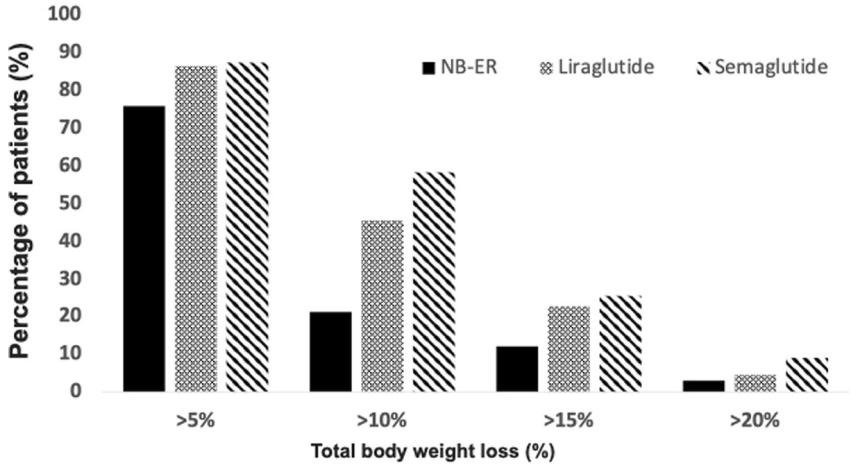

FIGURE 3 | Histogram of the proportion of patients with > 5%, > 10%, > 15%, and > 20% of total body weight loss following OMM treatment. NB-ER, fixed-dose, extended-release combination of naltrexone and bupropion; OMM, obesity management medications.

body of evidence of a clinically meaningful weight-loss benefit in using NB-ER in patients with RWG/SWL following bariatric surgery. Further evaluation of NB-ER following bariatric surgery is ongoing in an RCT (NCT04902625).

Liraglutide has been extensively studied as an adjuvant OMM for RWG/SWL following MBS [6]. Consistent with the meta-analysis [12], patients in the current study also lost significant weight, with a median weight loss of 9.1%, but more than double the number of patients (45.5%) loosing > 10% of TWL. This study is consistent with the range of weight-loss efficacy previously published, confirming the effectiveness of liraglutide in patients with RWG/SWL after MBS.

More recently, semaglutide has been studied in patients after MBS [6, 14, 15, 21, 22]. Although there are no current RCTs, four retrospective studies showed significant weight loss in patients with RWR following MBS. Lautenback et al. [14] observed a TWL of 10.3% ± 55% after 6 months of treatment. Similarly, Jensen et al. [15] observed that patients receiving liraglutide lost only 7.3% of TWL, whereas those receiving semaglutide lost 9.8% TWL at 6 months. Furthermore, for those patients receiving liraglutide versus semaglutide, > 15% TWL was observed in only 3.5% versus 23.5% of patients. In another study of patients post MBS with weight recurrence, those receiving semaglutide (1.0 mg) versus liraglutide (3.0 mg) lost more weight (least squares mean weight loss 12.9% vs. 8.8%) after 12 months [22]. This study showed similar significant weight loss with GLP-1 medications following MBS, including a trend for greater weight loss and greater proportion of patients reaching 5%, 10%, 15%, or 20% weight loss with low dose of 1.0 mg semaglutide compared with liraglutide.

Conversional bariatric procedures are efficacious in the treatment of RWG/SWL following primary procedures (LAGB, SG, and RNYGB) but carry a burden of increased morbidity and mortality compared with primary procedures [25]. Indeed, in a previous study on conversional OAGB or LSG following weight recurrence in patients with an LAGB, twice the frequency of complications was observed in the OAGB group compared with the LSG group (15.1% and 6.7%, respectively; 24). Hence, the current study supports the growing body of evidence that pharmacotherapy is a safe and effective alternative to further bariatric surgery. However, in cases where there is substantial weight regain, poor response to OMM in both weight and persisting obesity related complications, and a trial of pharmacotherapy is deemed insufficient, then conversional surgery will need to be considered.

In Australia, the OAGB has now out passed the RNYGB as a primary bariatric procedure [26]. However, insufficient weight loss response does occur following OAGB, with approximately 7%–34% of patients requiring further surgical revision for insufficient weight loss response [27, 28]. There are indeed limited alternatives for weight recurrence following the OAGB with surgical complication rates of between 10% and 16% [28]. This study is the first to show the safe and efficacious use of all three OMM in patients with RWG/SWL following the OAGB.

Indeed, all OMM were generally well-tolerated and AEs were largely minor. For NB-ER, 22.7% of patients discontinued medication due to AEs. This is consistent with a discontinuation rate due to AEs of 23.5% in the four COR randomized, double-blind, placebo-controlled trials with over 4500 patients [7, 29–31]. The 1/3 of the cohort who discontinued NB-ER or liraglutide and switched to semaglutide primarily did so due to the costs of the medication. Thus far, there are no post-bariatric studies which have reported data on the higher 2.4 mg semaglutide dose. The current study is consistent with previous studies reporting transient and mild gastrointestinal side effects following GLP-1 agonists post MBS [14, 15, 20, 22]. This study provides further evidence of the safe use of liraglutide, semaglutide, and NB-ER in post-MBS patients. However, more long-term data are needed.

Although semaglutide showed the greatest weight loss, consistent with published literature, all three medications resulted in a clinically meaningful 5% reduction in weight (Figure 3). Hence, in some circumstances patients may just require appetite suppression, improved craving control with minimal weight loss, and preferring an oral medication over an injectable. Greater weight loss may be required in circumstances where patients have regained a lot of weight and/or have recurrence of obesity related complications. This study supports personalization of

pharmacotherapy and familiarization of all three OMMs within all bariatric clinics. Thus, selection of the appropriate OMM needs to be made on a case-by-case basis. The 12-month real-world study by Acosta et al. [32] assessed phenotype-guided versus non-phenotype-guided treatment. They constructed four obesity phenotypes: the hungry brain (abnormal satiation), emotional hunger (hedonic eating), hungry gut (abnormal satiety) and slow burn (decreased metabolic rate). They found a 1.75-fold greater weight loss with phenotype-guided treatment after 12 months. NB-ER was prescribed to patients with a history of emotional hunger and food cravings, whereas the GLP-1 RA's were prescribed to patients with abnormal satiety. This was reflected in the current study's clinical approach in that many of the patients who had issues primarily due to lack of craving control and unhealthy snacking self-selected NB-ER.

The current study had a number of strengths and limitations. The strengths of the study included a large sample size, use of several different OMM, and inclusion of patients who had undergone three common bariatric surgical procedures including conversional procedures. This study also represented real-world clinical practice, generalizable to a typical population of post-surgical bariatric patients. However, it was a retrospective analysis of a prospectively collected database and lacked a placebo control group, allowing for selection bias and confounding. However, all procedures were conducted by a single surgeon using the same technique, thereby reducing the variability in the data set. Comparisons between the different OMM were purely exploratory, as patient cohorts were not intentionally matched for demographic or baseline weight data. Sensitivity analyses were not performed to look at efficacy differences between those patients with RWG or SWL, as only 22.1% of our patient cohort had SWL. Furthermore, sensitivity analyses were not performed to compare efficacy between the OMM and the type of bariatric surgical procedure, as the majority of primary MBS cases were LSG (59.7%) with 21.8% conversional procedures, including patients with weight recurrence following the OAGB.

Similar to previous reports [12], large heterogeneity, defined by wide IQR, was observed in response to treatment in this study. This is expected, as the cohorts consisted of patients with RWG/SWL, insufficient response to medication, and medication prescribed specifically for appetite suppression and food cravings. Additionally, there are no specific treatment guidelines for OMM use post MBS, and current guidelines on the use of OMM in non-metabolic and bariatric surgery patients recommend discontinuation of treatment for those with < 5% TWL [11]. This may not be ideal post-MBS and was not applied to the current study patients. All these factors may have impacted on the overall variability of weight loss.

5 | Conclusions

This study adds to the body of evidence demonstrating that the use of OMM confers additional significant weight loss in patients with RWG or SWL following both primary and conversional MBS. Therefore, all bariatric centers need to consider OMM as part of comprehensive bariatric after care. Additional rigorous and long-term studies are required to elucidate the timing, duration, dose and safety of OMM post MBS.

Acknowledgments

Editorial support was provided by Chuck Blajszczak, PhD, CMPP, of Red Nucleus and funded by Currax Pharmaceuticals.

Funding

The authors have nothing to report.

Ethics Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national health research committee and with the 1964 Helsinki declaration and its later amendments of comparable ethical standards.

Consent

Informed consent was obtained from all individuals included in the study.

Conflicts of Interest

A.B. received speaker honoraria from both iNova and Novo Nordisk, and financial support for the preparation of the manuscript from Currax Pharmaceuticals. B.R. did not declare any conflicts of interest.

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