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### 1. Introduction

- Obesity is a major global health problem associated with comorbidities such as diabetes, cardiovascular disease and cancer.
- Bariatric surgery is recognized to be the most effective weight loss intervention, but it is highly invasive, costly and can have serious side effects.
- Intragastric balloon placement by endoscopy has been shown to be comparatively well tolerated and effective in patients with obesity.
- In this study, we compared the efficacy, safety and cost-effectiveness of the hypocaloric OPTIFAST program (OPT) with endoscopic intragastric balloon (IGB) placement for weight loss.

### 2. Methods

- This was a retrospective comparative study and 586 patients aged between 18-65 years, with obesity (Body mass index [BMI] > 30 kg/m<sup>2</sup>) were screened.
- Results were expressed as change in BMI ( $\Delta$ BMI), weight loss in kilograms, percentage of excess weight loss (%EBWL), and percentage of total weight loss (%TBWL). Weight loss parameters were calculated according to the international bariatric indication.
- IGB procedure; All BIB devices were placed and removed under unconscious sedation. Placement of the device was preceded by a diagnostic endoscopy to exclude possible lesions. All patients received the same post-operative care
- Optifast program; a 52-week hypocaloric diet program called Optifast52® (franchise holder Nestlé Inc., Vervey, CH).
- Propensity score matching methodology was used to reduce potential bias and to adjust potential confounding effects. Propensity scores (PS) were estimated using IBM SPSS version 25.0 and Python 3.0 according to the following 3 factors: age, gender, and BMI.

### 3. Results

- The medical records of 586 patients were screened and eligibility of 275 (144 IGB, 131 Optifast) patients were confirmed.
- Propensity Score Matching (according to gender, age and BMI) was applied to 122 patients of IGB and 87 patients of Optifast groups and 74 patients randomized to each group (Figure 1).
- These patients were demographically similar, typically middle-aged (44.1 ± 10.4 years years), predominately female (77%). The baseline characteristics of the groups is presented in Table 1.
- The change in weight loss parameters are presented in Figure 2. Optifast program had better weight loss outcomes.
- IGB was found to incur significantly higher costs per kg and per BMI unit lost in comparison to OPT after both 6 and 12 months.

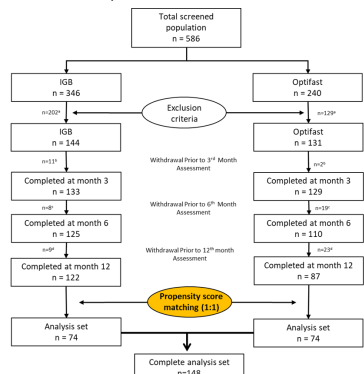


Figure 1. Consort diagram

IGB: \*BMI<30 kg/m<sup>2</sup> (13), age <18 or >65 years (4), incomplete documentation (185).  
 Adverse events: Nausea (4), Recurrent vomiting (4), Spontaneous rupture (3). Adverse events: Migration (3), Hyperinflation (2), Spontaneous rupture (1), Gastric ulcers (1), Mechanic pancreatitis (1). Adverse events: Insufficient weight loss (6), Therapy resistant dysphagia (1), Gastric ulcers (1), Mechanic pancreatitis (1) Optifast: \*BMI<30 kg/m<sup>2</sup> (57), age <18 or >65 years (5), incomplete documentation (47). Adverse events: Hunger (2), Adverse events: Hunger (1), Dizziness (3); Lost to follow up (15). Adverse events: Heartburn (2), Dizziness (1); Lost to follow up (17)

Table 1. Baseline characteristics

Baseline characteristics	IGB (n=74)	Optifast(n=74)
Gender		
Female, n (%)	57 (77)	57 (77)
Male, n (%)	17 (23)	17 (23)
Age (years), mean ± sd	44.1 ± 10.4	44.3 ± 10.8
BMI (kg/m <sup>2</sup> ), mean ± sd	38.0 ± 8.2	39.5 ± 5.3
Weight (kg), mean ± sd	109.6 ± 23.2	114.8 ± 20.5
Height (m), mean ± sd	1.7 ± 0.1	1.7 ± 0.1
Classification of BMI (kg/m <sup>2</sup> ), n (%)		
30 – 34.9 (obese class I)	23 (31.1)	15 (20.3)
34.9 – 39.9 (obese class II)	30 (40.6)	31 (41.9)
≥ 40.0 (obese class III)	21 (28.4)	28 (37.8)
Excess weight (kg), mean ± sd	45.8 ± 22.7	50.8 ± 16.6

BMI, body mass index; IGB, intragastric balloon. No statistical significance between groups.

### 4. Conclusion

- This propensity score matched analysis demonstrated that a medically supervised high-intensity program comprising meal replacements, behavioral education and a supervised physical exercise program led to clinically significantly greater weight loss at 26 and 52 weeks compared with IGB placement.
- Moreover, despite incurring higher costs as a result of its more intensive need for personnel and time resources, OPT was found to be more economical in relation to actual weight and BMI reduction and has additional clinical and economic advantages due to its very low complication and adverse event rates.

### 5. References

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### 6. Declaration of conflicts of interest

- Aysegül Aksan has received consultancy and lecturing fees from Vifor Pharma and Immunodiagnostik AG
- Miriam Oster, Nathalena Hein, Heiner Krammer, Sophia Theodoridou have no conflicts of interest.
- Jürgen Stein has received consultancy fees from Abbvie, Fresenius-Kabi, Immunodiagnostik, MSD, Pharmacosmos, Takada, GI Dynamics and Vifor. Dr. Stein has also received payment for lectures from Abbvie, Falk Foundation, Ferring, Immunodiagnostik, MSD, Pharmacosmos, Takada, Thermofischer, GI Dynamics and Vifor, and payment for manuscript preparation from Abbvie, Falk Foundation and MSD.

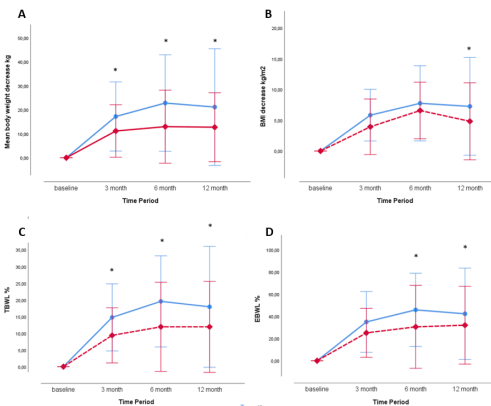


Figure 2. Change in weight loss parameters during follow up. BMI, body mass index; IGB, intragastric balloon; %EBWL, percentage of excess body weight loss; %TBWL, percentage of total body weight loss. \*p<0.005; student-t test

