

Baseline BMI, Gender, & Age as Predictive Factors for Intra-gastric Balloon Weight Loss Outcomes

Miranda Myers-Burton, PA-S & Nirali Shah, PA-S

James Madison University Physician Assistant Masters Program



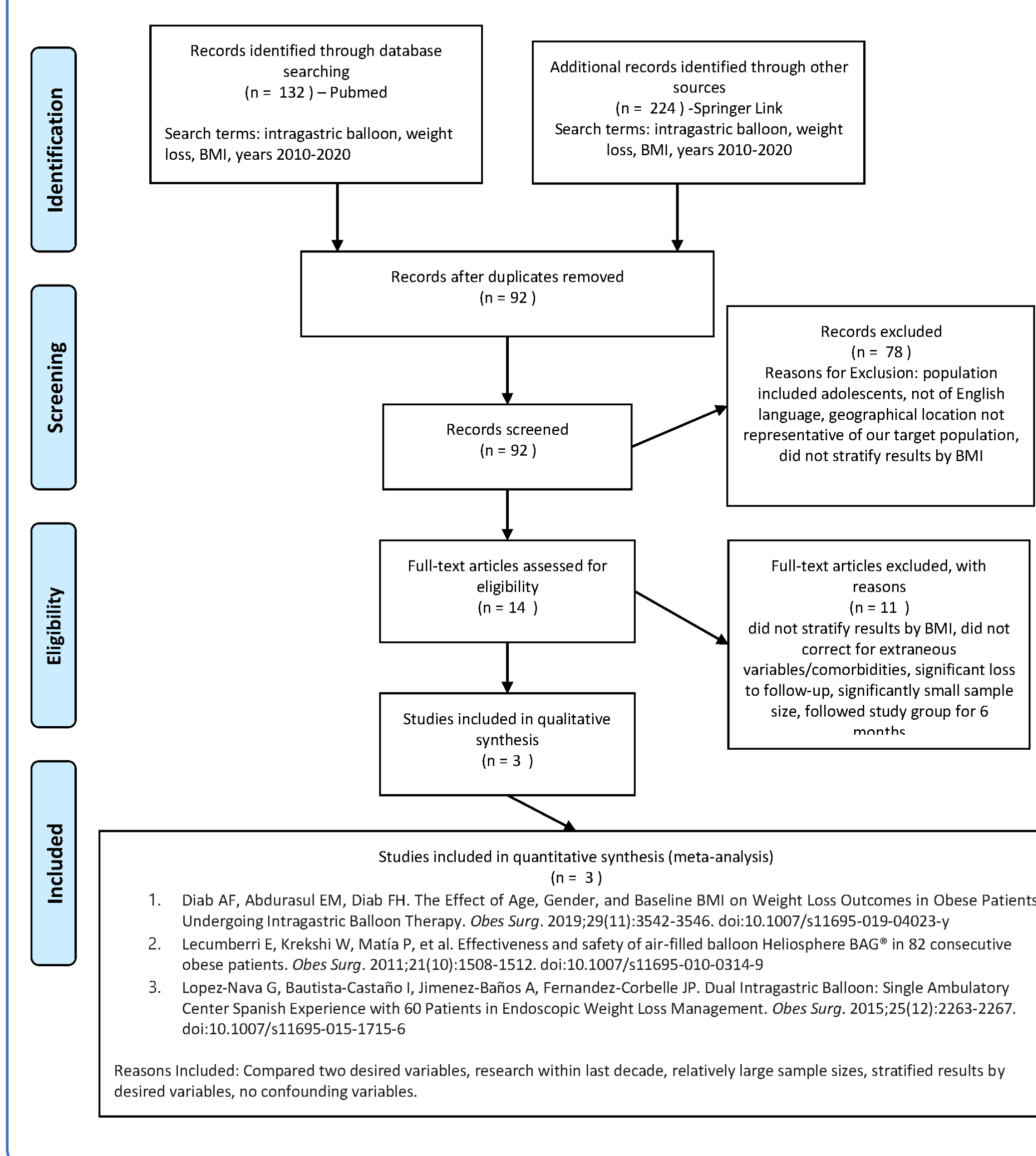
INTRODUCTION

- Obesity is defined as a body mass index (BMI) of over 30.0 kg/m² and morbid obesity over 40.0.¹
- By 2030, nearly 1 in 4 Americans will be morbidly obese.^{2,3}
- Obesity is a risk factor for seven out of the top ten leading causes of death in the U.S.⁴
- Current management of obesity includes lifestyle and dietary changes, pharmaceutical therapy, and in more severe cases bariatric procedures.^{5,6}
- Bariatric surgeries are considered the most successful long-term interventions for weight loss but come with significant complications and limitations.
- Intra-gastric balloon (IGB) systems are a minimally invasive weight loss treatment option for obese patients that induce early satiety. Balloons are orally or endoscopically placed in the stomach and filled with nitrogen, air, or saline.^{7,8}
- Defining predictive factors of successful weight loss with IGBs will guide eligible patient selection and reduce healthcare risks and costs associated with complications.

OBJECTIVE

To determine whether among obese and morbidly obese patients aged 18-75 who received an intra-gastric balloon do individuals with a lower baseline BMI (BMI 30-39.9 kg/m²) have a higher percentage of total body weight loss (%TBWL) and percentage of excess weight loss (%EWL) compared to those with a higher baseline BMI (BMI > 40 kg/m²). Secondary objective was to ascertain whether gender and age are also predictors of weight loss outcomes following an IGB procedure.

METHODS



RESULTS

Table 1.	Study #1: Diab et al. ⁹	Study #2: Lopez-Nava et al. ¹⁰	Study #3: Lecumberri et al. ¹¹
Study type	Prospective Cohort	Case Control	Prospective Cohort
Sample Size	184	60	84
Population	Aged ≤ 30 years old and ≥ 50 years old with baseline BMI ≤ 35 kg/m ² and ≥ 40 kg/m ²	Aged 18 or older with BMI ≥ 30 kg/m ²	Aged 18-70 Overweight with significant comorbidity and obese patients.
Location	Khaldi Medical Center in Amman, Jordan	Madrid Bariatric Endoscopic Unit of the Sanchinarro University Hospital in Madrid, Spain	Endocrinology and nutrition department of San Carlos University Hospital and endocrinology department of Santa Elena Clinic in Madrid, Spain
Balloon Type	Orbera; 600-650 cc saline and 10cc methylene blue solution	Dual Intra-gastric Balloon; each filled with 450cc saline/methylene blue solution	700cc Air filled Heliosphere bag
Loss to Follow-Up	-	-	2 patients were excluded due to weight or height data missing. 1 patient was found to have a psychiatric disorder affecting their weight and was removed from the study.
Complications	-	1 early removal due to patient intolerance. 1 early deflation without migration or surgical removal. 1 gastric perforation. 14 gastric ulcers or erosions at time of removal, however clinically insignificant.	1 surgical removed due to technical problems with endoscopic extraction. 2 spontaneous deflations without migrations. 1 patient who gained weight was suspected to have psychiatric disorder after balloon insertion

Study 1 – Diab et al. *The Effect of Age, Gender, and Baseline BMI on Weight Loss Outcomes in Obese Patients Undergoing Intra-gastric Balloon Therapy.*

Results: Significant effect of age on weight loss in females. No significant difference in %EWL was found between age groups in male patients (p value=0.836). %TBWL was not significantly different between age groups or genders, however TBWL was higher amongst males and those with a higher baseline in both sexes. Lower baseline BMI was found to have a significant impact on %EWL in both genders. Neither TBWL or %TBWL were significantly different between baseline BMI groups among either gender group.

Critique: Strengths include strict inclusion criteria, and adherence to post procedure protocols and follow-up visits. Limitations include exclusions of patients aged 40-49 and BMI 35-40, and small sample size.

Study 2 – Lopez-Nava et al. *Dual Intra-gastric Balloon: Single Ambulatory Center Spanish Experience with 60 Patients in Endoscopic Weight Loss Management.*

Results: Morbidly obese patients had greater TBWL than non-morbidly obese patients. No significant difference in TBWL between age, gender groups, and no statistically significant difference in %TBWL regarding gender, age, or obesity grade. Women had a higher %EWL than men. Nonmorbidly obese patients had a higher %EWL than morbidly obese patients.

Critique: Strengths include frequent visits with multidisciplinary teams for physical, nutritional, and counseling support for increased follow-up and monitoring. The dual balloon design also decreases the risk of migration and associated adverse effects. Limitations included unspecified inclusion and exclusion criteria, and a lower percentage of male participants, making it difficult to extrapolate results for a broader patient population, comparison to other studies, and reproducibility.

Study 3 – Lecumberri et al. *Effectiveness and Safety of Air-Filled Balloon Heliosphere BAG[®] in 82 Consecutive Obese Patients*

Results: With adjustment for age and sex, patients with higher baseline BMI saw greater BMI and absolute weight loss. However, a higher baseline BMI was associated with a lower %EWL. The % body weight loss (BWL) was not associated with baseline BMI. Age was inversely related with weight loss, and greater treatment length was associated with greater average absolute weight loss.

Critique: Strengths include a reasonable exclusion criteria, as well as involvement of pharmacological therapy and dietitians to maximize tolerability, safety and benefits of the treatment. Limitations include a small number of male participants and lack of transparency regarding exclusion of participants.

Table 2.	Study #1: Diab et al.		Study #2: Lopez-Nava et al.		Study #3: Lecumberri et al.			
	%EWL	%TBWL	%EWL	%TBWL	%EWL	%TBWL		
Male, BMI <40	50.1±12.3	11.8±2.8	All participants	41.7± 26.72	15.4±7.95	All participants	33.2 (32.4)*	13.4 (12.8)*
Male, BMI ≥40	32.1±17.1	12.9±7.2	BMI <40, Total	52.27± 28.72	14.90±7.71	Male, BMI <40	30.7	11
Female, BMI <40	53.72± 22.3	12.63±5.5	BMI ≥40, Total	37.48± 19.72	16.46±8.47	Male, BMI ≥40	29	14.4
Female, BMI ≥ 40	32.5±16.7	13.2±6.4	Males, Total	30.92± 21.03	12.09±7.63	Female, BMI <40	35.8 (36.7)*	10.7 (12.8)*
Male, Age <40 years old	50.2±39	14.2± 4.7	Females, Total	50.73± 26.68	16.2± .89	Female, BMI ≥ 40	30.3	14.8
Male, Age > 40 years old	47±10	13.9±2.7	Age ≤40 years old	48.49± 26.72	15.56±8.01			
Female, Age < 40 years old	47.3±28	12.9±5.2	Age >40 years old	45.28± 27.13	15.31±8.02			
Female, Age >40 years old	38±22.5	11.9± 6.9						*see discussion

DISCUSSION

- All three studies found that the IGB was a safe procedure, with minor side effects (nausea, gastric erosion, etc.) and infrequent events of balloon migration or need for early removal.
- Lower baseline BMI was found to have higher %EWL after six months post-treatment in all three studies.
- Gender and IGB weight loss outcomes showed no association in two out of the three studies. One study found that women had higher %EWL, however this result may have been influenced by a significantly lower number of male participants in their sample size.
- Results based on age were variable. Lecumberri et al. found age to be inversely proportional with weight loss outcomes, Diab et al. found age only effected female participants' weight loss, and Lopez et al. found no statistical difference in weight loss across age groups.
- * Data provided by Lecumberri et al. includes patients with a BMI of 25-29.9, which does not fit the inclusion criteria of this literature review. Results excluding this data have been calculated and provided in parentheses in table 2. %EWL and %TBWL in all participants overall differ minimally.

CONCLUSION

- Baseline BMI is a **useful predictive factor** for weight loss outcomes following IGB placement.
- Lower baseline BMI associated with **greater %EWL** following IGB placement
- No significant difference in %TBWL**
- Limiting factors** of weight loss associated with gastric bypass **not similarly associated** with intra-gastric balloon treatment
- More studies** are needed to determine the usefulness of gender and age as IGB weight loss outcome predictive factors.

REFERENCES

- Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, 2020. Defining Adult Overweight and Obesity | Overweight & Obesity | CDC. [online] Cdc.gov.
- Finkelstein EA, Khayrjou OA, Thompson H, et al. Obesity and severe obesity forecasts through 2030. *Am J Prev Med.* 2012;42(6):563-570. doi:10.1016/j.amepre.2011.10.026
- Ward ZJ, Bleich SN, Craddock AL, et al. Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity. *N Engl J Med.* 2019;381(25):2440-2450. doi:10.1056/NEJMsa1909301
- CDC National Center for Health Statistics, 2020. Faststats. [online] Cdc.gov. Available at: <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm> [Accessed 1 December 2020].
- Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *N Engl J Med.* 2012;366(17):1567-76.
- O'Brien PE, Brennan L, Laurie C, Brown W. Intensive medical weight loss or laparoscopic adjustable gastric banding in the treatment of mild to moderate obesity: long-term follow-up of a prospective randomised trial. *Obes Surg.* 2013;23(9):1345-1353. doi:10.1007/s11695-013-0990-3
- Kim SH, Chun HJ, Choi HS, Kim ES, Keum B, Jeon YJ. Current status of intra-gastric balloon for obesity treatment. *World J Gastroenterol.* 2016;22(24):5495-5504. doi:10.3748/wjg.v22.i24.5495
- Choi SJ, Choi HS. Various Intra-gastric Balloons Under Clinical Investigation. *Clin Endosc.* 2018;51(5):407-415. doi:10.5946/ce.2018.140
- Diab AF, Abdurusul EM, Diab FH. The Effect of Age, Gender, and Baseline BMI on Weight Loss Outcomes in Obese Patients Undergoing Intra-gastric Balloon Therapy. *Obes Surg.* 2019;29(11):3542-3546. doi:10.1007/s11695-019-04023-y
- Lopez-Nava G, Bautista-Castaño I, Jimenez-Baños A, Fernandez-Corbelle JP. Dual Intra-gastric Balloon: Single Ambulatory Center Spanish Experience with 60 Patients in Endoscopic Weight Loss Management. *Obes Surg.* 2015;25(12):2263-2267. doi:10.1007/s11695-015-1715-6
- Lecumberri E, Krekhi W, Matia P, Hermida, C, García de La Torre N, Cabrerizo L, Rubio MÁ. Effectiveness and Safety of Air-Filled Balloon Heliosphere BAG[®] in 82 Consecutive Obese Patients. *Obes Surg.* 2011; 21(10):1508-1512 (2011). doi:10.1007/s11695-010-0314-9

ACKNOWLEDGEMENTS

We would like to thank Dr. Abby Massey, Carolyn Shubert, the JMU Communication Center, and the JMU Writing Center for their assistance with this project.