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Retrospective Study

Impact of intragastric balloon on blood pressure reduction: A retrospective study in Eastern North Carolina

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Dear Editor,

Please find enclosed the resubmitted revised manuscript titled; Impact of intragastric balloon on blood pressure reduction: A retrospective study in Eastern North Carolina

We have read thoroughly all the reviewer comments, and appreciate the constructive criticism. We have taken all comments into consideration, answered the questions and revised the text accordingly. I have provided point to point replies to the reviewers. I do appreciate your support.

Respectfully Submitted,

Gbeminiyi Samuel MD, MSPH

12-25-2020

RESPONSE TO REVIEWERS

A. Responses to Peer Reviewer

1. **Title:** suitable. The authors studied more than just hypertension. So, why not change the title to "Impact of the intragastric balloon on comorbidities in obesity patients: A retrospective study in Eastern North Carolina."

Response: While we appreciate the comment, it is more relevant in this study to use blood pressure reduction, since we focused our analysis on blood pressure and placed little emphasis on other comorbidities. As such, changing the title to "Impact of intragastric balloon on comorbidities in obese patients" appears to be out of scope of our study.

2. **Abstract:** suitable **Introduction:** It's missing the word "introduction" to mark the beginning of this section. Be more evident in this section about your objectives and the GAP of knowledge of this study.

Response: The abstract (as shown below) has been modified to highlight the study objectives and gap of knowledge of this study. Also, the word "Introduction" has been integrated to mark the beginning of this section.

INTRODUCTION

Obesity has evolved into a global pandemic. The prevalence of obesity and hypertension in Eastern North Carolina (ENC) are comparable, if not higher, than the national prevalence. In the United States, an estimated 34% of adults have hypertension, the most modifiable risk factor for heart disease and stroke. Lifestyle and pharmacological interventions often do not provide sustained weight loss in obese patients. Bariatric surgery offers an effective weight reduction with short- and long-term health improvements; however, a higher body mass index is associated with higher surgical morbidity and mortality, longer hospitalization, and increasing rates of 30-day readmission due to co-morbidities. Intragastric balloon may bridge a critical gap in the treatment of obesity. The objective of this paper is to showcase the impact of Endoscopic bariatric therapy on blood pressure reduction.

3. **Methods:** It's missing the procedure description: how many milliliters to fill the balloon? Complications regarding balloon use? Complications regarding the placement or balloon removal? How was the material used and the technique?

Response: The procedure description and complications regarding placement/removal of the balloon have been added to the Methods as shown below:

A retrospective chart review was conducted from January 1, 2016 to January 31, 2019 of consecutive adults who received IGBT in a gastroenterology private practice in Eastern North Carolina. The balloon was introduced into the stomach under endoscopic guidance, and while in the region of the gastric body, inflation with saline was performed at increments of 50cc until target volume between 500 to 650 cc of saline was attained depending on the patient's gastric capacity. No procedural complications were noted during endoscopic placement and removal of the balloon.

A cohort study design was used for data analysis. A total of 172 patients had the Orbera® intragastric balloon placed. Of the 172 patients who had IGBT at baseline, 11 patients (6.4%) requested early balloon removal due to foreign body sensation (N=1), and/or intolerable gastrointestinal adverse events (N=10). The reported gastrointestinal adverse events were nausea, vomiting, abdominal pain, and diarrhea. Eventually, 6-month follow-up data were available for only 140 patients. As a result, only the 140 available at the 6-month follow-up were included in the analysis. Univariate, bivariate, and multivariate statistical analyses were performed. Specifically, scatterplots were created to show the relationship between weight and blood pressure, and paired two-sample t-test was carried out to determine if there was a significant reduction in weight before and after the IGBT. Multiple regressions were also performed to examine the association between participants' total body weight and blood pressure. The outcome variables for the multiple regression were systolic and diastolic blood pressure measured as continuous variables. This was followed by logistic regression analyses to determine the association between total body weight and hypertension at 6- months post-implantation. The outcome variables for the logistic regression were systolic blood pressure – non-hypertensive (140 mmHg or less) or hypertensive (greater than 140 mmHg), and diastolic blood pressure – non-hypertensive (90 mmHg or less) or hypertensive (greater than 90 mmHg). All authors had access to the study data and reviewed and approved the final manuscript. All statistical analyses were done using STATA 14®.

4. **Results: Use %TBWL to show the balloon results. Add some graphics and images.**

Response: % TBWL has been added to show the balloon results (pls. see highlighted statement in the RESULTS section, as shown below). Also, graphics illustrating the placement of balloon has been included, in addition to the scatterplot showing the relationship between total body weight and systolic and diastolic blood pressure (pls. see attached image file).

RESULTS

*The study included 15% males and 85% females. 50% of the patients were white and just over 22% were non-white, and about 27% declined to give their race. The average baseline patients' weight prior to IGBT was 231.61 Lbs. (SD = 46.53 Lbs.). However, the average patients' weight after IGBT at the 6-month follow-up was 203.88 Lbs. (SD = 41.04 Lbs.). **Hence, on average, the percent total body weight loss (%TBWL) at 6-months is 11.97 after IGBT.** The logistic regression performed revealed that weight ($\beta = 0.0140$, $p < 0.000$) and age ($\beta = 0.0534$, $p < 0.000$) are*

important factors in determining systolic blood pressure after IGBT. None of the other demographic characteristics or indicated comorbidities were found to be significant.

B. Responses to Science Editor

1. Authors are required to provide the signed Conflict-of-Interest Disclosure Form and Copyright License Agreement.

Response: A signed Conflict of Interest Disclosure Form and Copyright License agreement have been attached.

2. Issues raised: (1) I found no “Author contribution” section. Please provide the author contributions;

Response: Author contribution section has been included.

3. (2) I found the authors did not provide the original figures. Please provide the original figure documents. Please prepare and arrange the figures using PowerPoint to ensure that all graphs or arrows or text portions can be reprocessed by the editor

Response: Original figures and tables have been provided in separate power point files(image file and table file respectively).

4. (3) I found the authors did not write the “article highlight” section. Please write the “article highlights” section at the end of the main text;

Response: The “article highlight” section has been integrated at the end of the main text.

5. (4) please don't include any *, #, †, §, ‡, ¥, @....in your manuscript; Please use superscript numbers for illustration; and for statistical significance, please use superscript letters. Statistical significance is expressed as $aP < 0.05$, $bP < 0.01$ ($P > 0.05$ usually does not need to be denoted). If there are other series of P values, $cP < 0.05$ and $dP < 0.01$ are used, and a third series of P values is expressed as $eP < 0.05$ and $fP < 0.01$;

Response: Superscripts have been used to illustrate the results of the statistical analyses. These signs “*, #, †, §, ‡, ¥, @” have been eliminated in the manuscript.

6. (5) I found the authors did not add the PMID and DOI in the reference list. Please provide the PubMed numbers and DOI citation numbers to the reference list and list all authors of the references. Please revise throughout;

Response: With the exception of reference #16 -Ganesh et al, 2007 which has a PMID but no DOI, every other reference has been revised through the auto analyzer and now has a PMID and DOI.

