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Review

Methodological appraisal of the evidence about efficacy of metabolic surgery in adults with non-morbid obesity and hypertension: An overview of systematic reviews

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ABSTRACT

Background: Nowadays, the high morbimortality of obesity is mainly related to diabetes, cancer, and hypertension. It is reported that obesity in patients with hypertension can lead to resistance to pressure reduction through pharmacological therapy and lifestyle changes, so bariatric surgery emerges as a proposed treatment for obesity.
Methods: We performed an umbrella review that included systematic reviews of clinical trials that evaluated patients with hypertension and non-morbid obesity. The quality and certainty of the evidence was evaluated with the AMSTAR-II and GRADE tools.
Results: 677 systematic reviews were identified, of which only three were included for analysis. We considered the outcomes addressed by the reviews on hypertension, identifying that 5 RCTs evaluated pressure reduction at 1 year of follow-up and 5 RCTs at more than 1 year, 5 RCTs evaluated hypertension rate, 6 RCTs analyzed changes in systolic pressure and 5 RCTs changes in diastolic pressure. Likewise, when assessing the methodological quality, it was concluded that the three reviews have critically low quality.
Conclusions: We found only three systematic reviews that evaluated the topic with critically low methodological quality. They reported results in favor of metabolic surgery, but with very low certainty of evidence.

1. Introduction

Obesity is considered a worldwide pandemic with a trend that is increasing over time [1] and currently affects 13% of the world's adult population [1]. The impact of obesity lies in the reduction of life expectancy, which can vary between 2 and 10 years depending on the stages and severity of the disease [2], mainly as a result of metabolic complications [3] related to diabetes and hypertension [4].

It has been reported that the presence of obesity in hypertensive patients can lead to resistance to the usual pharmacological treatment [5,6], an increased risk of cardiac complications, and death (60–70% more) [7] compared to non-obese patients [8]. However, several studies have shown that lifestyle interventions and pharmacotherapy for weight reduction are often insufficient, mainly due to lack of patient adherence to treatment and lack of strict supervision [9], leading to the inclusion of surgical procedures as a treatment approach [10].

Bariatric surgery has been proposed for the treatment of obesity, having been widely explored in patients with morbid obesity, and showing beneficial results in mortality and weight reduction [11]. In recent years, the indication for bariatric surgery has been expanded to patients with a body mass index (BMI) greater than 30 kg/m2 and important comorbidity, such as arterial hypertension, due to its potential benefits [12–14], defining it as metabolic surgery.

At present, there is a large number of publications on the effect of bariatric/metabolic surgery; however, the quality of these publications has not been evaluated, and this may affect the relevance of their results [15,16], especially in the subgroup of patients with non-morbid obesity where the uncertainty of benefits and harms its controversial [12]. For this reason, the present study was carried out to evaluate the certainty and quality of the available evidence on the efficacy of metabolic surgery in adult patients with hypertension and non-morbid obesity.

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2. Methodology

We performed a systematic review of systematic reviews (umbrella review) of studies that evaluate the efficacy of metabolic surgery as a treatment in hypertensive patients with non-morbid obesity (obesity type I and II). The present study followed the guidelines for systematic reviews of systematic reviews stipulated in the "Preferred Reporting Items for Overviews of Reviews" (PRIOR) guideline [17] *(Supplementary material 1)*, the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) [18], and AMSTAR (Assessing the methodological quality of systematic reviews) guideline. The study protocol is available in the Figshare scientific repository [19] (https://doi.org/10.6084/m9.figshare.12824918).

2.1. Search strategy

A search for studies up to June 2020 was conducted using PubMed (Medline), Scopus, Web of Science, and Cochrane Library databases. The search strategy of each database was structured to include words related to "bariatric/metabolic surgery" and "hypertension" *(Supplementary material 2)*.

2.2. Inclusion and exclusion criteria

We included systematic reviews of clinical trials evaluating a population of patients with a diagnosis of arterial hypertension (regardless of type) and a BMI of 30–39.9 kg/cm2 (type I or II obesity). If the reviews did not describe the BMI defined above as an inclusion criterion for the primary studies, the study was considered for inclusion if the mean weight of the population evaluated in the primary studies with the largest sample size was within the range. There was no restriction of language or date of publication.

2.3. Study selection

Study selection was performed independently and double-blinded by two authors and was divided into two stages, first by reviewing titles and abstracts and then by full text. Disagreements were resolved by discussion between the two authors, and if no consensus was reached, a third author made the final decision. In addition, the bibliographic references of the studies included were reviewed to identify potential studies that met the inclusion criteria. *Flowchart 1 shows a flowchart of the study selection.*

2.4. Assessment of study quality

The quality of the systematic reviews was assessed independently by two authors using A Measurement Tool to Assess Systematic Reviews version 2 (AMSTAR-II) [20]. The AMSTAR-II tool evaluates the quality of the studies using a total of 16 domains (seven critical and nine non-critical), giving rise to four levels of confidence: 1) high (no critical weaknesses and up to one non-critical weakness); 2) moderate (no critical weaknesses and more than one non-critical weakness); 3) low (up to one critical weakness, with or without non-critical weaknesses); and 4) critically low (more than one critical weakness, with or without non-critical weaknesses) [20].

Likewise, the certainty of the evidence was evaluated for each outcome addressed by the systematic reviews using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. This system classifies the certainty of the evidence into four levels: 1) high (certainty that the real effect of the intervention is close to the estimate; 2) moderate (moderate certainty that the effect of the intervention is close to the estimate, due to the possibility that it may be different); 3) low (limited certainty given that the effect may be different from the estimate); and 4) very low (very little certainty due to the probability that the effect is different from the estimate) [21].

2.5. Data extraction and analysis

Data extraction was carried out utilizing a double-independent data entry. The variables of the author, year of publication, number of studies included, type of studies included, overall risk of bias, type of surgical procedure, mean weight, mean blood pressure, outcomes, and main results were extracted.

The results of the systematic reviews included were synthesized using a summary of findings table, including relative and absolute results and the certainty of the evidence for each outcome.

3. Results

3.1. Selection and characteristics of the included studies

A total of 677 studies were identified, 61 of which were eliminated because they were duplicates, resulting in a total of 314 studies for selection. Of these, 33 studies were identified as potentially eligible to evaluate a full text, and finally only three were included for the systematic review (Fig. 1).

We found the systematic reviews by Cohen 2017 [22], Müller 2015 [23], and Yan 2016 [24], which addressed an adult population with a diagnosis of non-morbid obesity (BMI range 30–39.9 kg/m2) and other comorbidities such as hypertension, diabetes, among others, that underwent metabolic surgery. In terms of the interventions addressed, all systematic reviews analyzed Roux-en-Y gastric bypass and only one evaluated more than one type of surgery (Müller 2015). In all cases, these interventions were compared with medical treatment and evaluated outcomes of benefit rather than safety for more than 12 months. None of the studies described specific data for the population presenting with hypertension, reporting, mean pressure values greater than 120 mmHg, in systolic pressure and 80 mmHg in diastolic pressure (Table 1).

The systematic review by Müller included 5 randomized clinical trials (RCTs), while Yan included 6 RCTs, and Cohen included 10 studies. Among the studies included, one primary study (1/14; 7.2%) was found in all three reviews, and five (5/14; 35.7%) were evaluated in two reviews (Table 2).

3.2. Quality and certainty of the evidence

According to the AMSTAR-2 tool, the three systematic reviews assessed had critically low overall confidence, obtaining scores of 7, 11, and 10 by the systematic reviews by Müller, Cohen, and Yan, respectively *(Supplementary material 4)*.

When evaluating the certainty of the evidence for each outcome, we

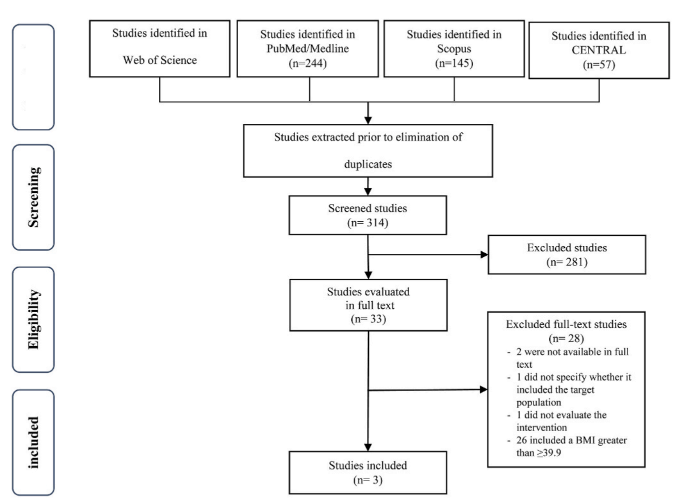

Fig. 1. PRISM flowchart for the selection of the studies.

Table 1
Studies included in the systematic review.

Author year	Types of studies included	Population	Type of surgery	Comparator	Preoperative BMI	Blood pressure	Follow-up time	Outcome	Results
Müller 2015	5 RCT	463 persons over 18 years of age with hypertension and other comorbidities (diabetes mellitus, dyslipidemia, etc.).	RYGB, AGB, SG	Medical treatment	IMC <37.2 kg/m2[a]	Medical treatment: systolic: 131.9 mmHg Diastolic: 80.95 mmHg. Surgery: systolic: 131.9 mmHg Diastolic: 81.68 mmHg	Range from 12 to 36 months	Change in BMI	−5.4 (−6.6; −4.2)
								Arterial hypertension rate	0.26 (0.12; 0.56)
Yan 2016	6 RCT	376 persons over 18 years of age with diabetes and other comorbidities (hypertension, etc.)	Gastric bypass Roux-en-Y	Medical treatment	Medical treatment: 36.5 kg/cm2 Cases with RYGB: 36.45 kg/cm2[a]	Medical treatment:: • Systolic: 139.84 mmHg • Diastolic: 82.94 mmHg. Cases undergoing RYGB • Systolic: 139.74 mmHg • Diastolic: 83.19 mmHg	Range from 12 to 60 months	Change in BMI	−6.54 (−9.28; −3.80)
								Change in systolic pressure	−2.83 (-4.88, −0.78)
								Change in diastolic pressure	0.28 (−1.89, 2.45)
Cohen 2017	5 RCT	322 people over 18 years of age with hypertension and other comorbidities (diabetes, dyslipidemias, etc.).	Gastric bypass RYGB	Medical treatment	BMI less than or equal to 35 kg/cm2	130.58 mmHg (Mean systolic pressure)	Range from 12 to 60 months	Reduction in blood pressure at 1 year of follow-up	6.0 (11.7; 0.2)
								Blood pressure reduction at more than 1 year of follow-up	−6.84 (−13.61; −0.08)

RCT: randomized clinical trial; RYGB: Roux-en-Y Gastric Bypass; AGB: Adjustable Gastric Band; SG: Sleeve gastrectomy.
[a] This study included not only patients with arterial hypertension but also with other comorbidities, since it was not possible to see disaggregated data.

Table 2
Primary studies included in the systematic reviews analyzed.

Studies	Systematic reviews		
	Müller 2015	Yan 2016	Cohen 2017
Dixon 2008	X	–	–
Schauer 2012	–	–	X
Ikramuddin 2013	X	–	X
Liang 2013	–	X	–
Courcoulas 2014	X	–	X
Schauer 2014	X	X	X
Wentworth 2014	X	–	–
Halperin 2014	–	X	X
Courcoulas 2015	–	X	X
Ikramuddin 2015	–	X	X
Mingrone 2015	–	X	–
Singh 2015	–	–	X
Cummings 2016	–	–	X
Schauer 2017	–	–	X
Total	5	6	10

observed very low certainty in all cases, mainly due to inconsistency across studies and imprecision in the results (Table 3).

3.3. Evidence synthesis

We assessed important but non-critical outcomes such as reduction of blood pressure, rate of hypertension, and changes in systolic and diastolic blood pressure. The Cohen systematic review evaluated the reduction in blood pressure measured in patient follow-up at 1 year and more than 1 year, while Müller evaluated the rate of hypertension and Yan changes in systolic and diastolic blood pressure. All the systematic reviews showed a statistically significant effect for the outcomes assessed, except for changes in diastolic pressure. In hypertensive patients, metabolic surgery was found to lead to a reduction in blood pressure of 6.0 mmHg (95% confidence interval [CI] 11.7 to 0.2) and 6.85 mmHg (95%CI 13.65 to 0. 1, at 1 and more than 1 year of follow-up, respectively; a reduction in the rate of arterial hypertension (297 less per 1000; 95% CI 398 less to 142 less); and a reduction in systolic pressure of 2.83 mmHg (95%CI 4.88 to 0.78).

4. Discussion

Hypertension is one of the most frequent chronic diseases in the world population. The presence of hypertension is closely related to obesity [25], and this association potentiates changes in blood pressure, making a difficult management of the disease [26–29]. Metabolic surgery is a surgical intervention for the treatment of obesity and aggregate hypertension [30–32] with potential successful results described in weight reduction and resolution of hypertension [33–35].

Our study identified three systematic reviews that evaluated a population of hypertensive patients with type I and II obesity. However, in all cases, the evaluation of this population was part of a secondary objective of the reviews, the primary objective being to evaluate the efficacy of metabolic surgery in diabetes. This was to be expected, however, considering that metabolic surgery emerged as a strategy for the treatment of diabetes [36], and most studies are performed in diabetic populations [37,38]. Although, diabetes is closely related to hypertension, the extrapolation of the results would ideally have been to hypertensive patients with multi-comorbidity and the search strategies executed may not have captured studies including hypertensive patients but not diabetics.

On the other hand, when identifying the studies included by each systematic review, there was a difference between the number of RCTs included among the 3 reviews. Although the Cohen systematic review included more studies than the others, this was the most current systematic review among the three and therefore a more up-to-date search would have been expected. However, three, six, and four studies were not included in Müller, Yan, and Cohen reviews, respectively, even though they corresponded to their search times. This can be explained in multiple ways; first, because the main objective of the systematic review was based on the evaluation of bariatric surgery in diabetic patients, some inclusion criteria for this population led to the exclusion of some studies. Second, this may be the result of an incomplete search leading to incomplete reporting, and may even lead to bias [39]. This last problem is quite common in published systematic reviews and has even been

Table 3
SOF table of results addressed to hypertension by the systematic reviews included.

Nº of studies	Nº of patients		Effect		Certainty	Importance
	Bariatric surgery	No surgery	Relative (95%CI	Absolute (95%CI)		
Blood pressure reduction at one year of follow-up						
5 RCT	165	157	–	**MD:** 6.0 mmHg (11.7 a 0.2)	Very low[a,b,c,d] (⊕⊖⊖⊖)	IMPORTANT
Blood pressure reduction at more than 1 year of follow-up						
5 RCT	165	157	–	**MD:** 6.85 mmHg (13.65 a 0.1)	Very low[a,b,c,d] (⊕⊖⊖⊖)	IMPORTANT
High blood pressure rate						
5 RCT	248	163	**OR:** 0.26 (0.12–0.56)	297 less per 1000 (398 less to 142 less)	Very low[a,e,f] (⊕⊕⊖⊖)	IMPORTANT
Changes in systolic pressure						
6 RCT	195	181	–	**MD:** - 2.83 mmHg (−4.88 a −0.78)	Very low[d,f,g] (⊕⊖⊖⊖)	IMPORTANT
Changes in diastolic pressure						
5 RCT	164	147	–	**MD:** 0.28 mmHg (−1.89 a 2.45)	Very low[d,h] (⊕⊕⊖⊖)	IMPORTANT

RCT: randomized clinical trial; CI: confidence interval; MD: mean difference; OR: Odds ratio.
Explanations.
[a] One point was lowered for inconsistency due to high heterogeneity, I^2 greater than or equal to 60%.
[b] A point was lowered for inconsistency because three studies reported positive results and two showed no effect.
[c] It was lowered two points for imprecision because the confidence interval crossed imprecision points and approached the null value.
[d] One point was reduced for indirect evidence because it included only one type of metabolic surgery intervention.
[e] One point was lowered for imprecision because the confidence interval crossed an imprecision point.
[f] It was reduced two points for imprecision because the confidence interval crossed the imprecision points and the null value.
[g] One point was lowered for imprecision as the sample size of the included studies was considered small.
[h] One point was reduced for inconsistency because one study, with greater weight within the meta-analysis, reported positive results and five showed no effect.

reported in previous studies [40,41] showing a probable source of important bias from the conception and initiation of the systematic review.

When assessing the quality of the studies included, we observed a critically low overall confidence in all the systematic reviews, due to the absence of some basic specifications that could lead to a lack of rigor in the systematic review procedure. This situation is not new, as the validity of many systematic reviews has been questioned in the past [42], making us question whether the decisions we make based on evidence from systematic reviews are correct. This finding does not invalidate the results evidenced in the systematic reviews. Considering the principle of evidence-based medicine, the objective is to use the best available evidence [43,44]; however, it should encourage the development of new systematic reviews, based on the main limitations of those already published.

All of the systematic reviews available on the efficacy of bariatric surgery included only important outcomes, such as changes in blood pressure, BMI, and weight, but not critical outcomes that are important for decision-making processes.

However, the results reported by the systematic reviews analyzed showed a beneficial effect of bariatric surgery in hypertensive patients with type I or II obesity. In the first instance, we identified a greater decrease in the BMI of patients who received bariatric surgery; however, this outcome is addressed by two studies, Müller and Yan. Some studies have reported that in obese patients, a 3–5% reduction in weight leads to a beneficial impact on their health [45], but in obese patients with comorbidities, significant changes start with weight losses of 10–15% [46]. Thus, despite the differences in weight reductions observed in the studies, a clinically important reduction for the patient was identified in both cases.

There are different bariatric surgery techniques [47]. However, gastric sleeve and Roux-en-Y gastric bypass are the two most used techniques [48]. Similar results have been described in the resolution of comorbidities as well as in weight reduction with both approaches [48]. However, in this review, there was evidence of a greater loss with Roux-en-Y bypass, suggesting that this result could be due to its high malabsorptive component [48]. On the other hand, success in weight loss depends not only on the technique but also on the multidisciplinary team as well as good patient selection and follow-up [49]. These conditions, however, were not evaluated.

In relation to the effect of bariatric surgery on blood pressure, we found a reduction in arterial and systolic blood pressure. Some studies have postulated that the decrease in blood pressure could be associated with weight loss [50–52]and this reduction may be even greater in certain procedures such as Roux-en-Y bypass [52–56]. Although the American Heart Association specifies that for every 1 kg of weight lost, a reduction in blood pressure of around 1 mmHg is expected [57], it has been shown that the higher the pressure is, the more significantly it is reduced after surgery [58–60]. Likewise, it has been reported that to prevent an important outcome the minimum pressure reduction is 2 mmHg [61,62].

Likewise, we found that the rate of arterial hypertension decreased (297 less per 1000 patients; 95% CI 398 less to 142 less) in individuals undergoing bariatric surgery. This is clinically relevant considering that in many cases these patients present resistance to the usual pharmacological treatment and poor adherence to medication [63]. However, it is important to note that the definition of the rate of arterial hypertension was not defined in the systematic reviews, generating uncertainty about the considerations used to define remission of the disease.

Finally, when evaluating the certainty of the evidence of the results for each outcome, we observed that in all cases it was very low, indicating that it is likely that the real effect of bariatric surgery in hypertensive patients is substantially different from the estimates [64]. While this could suggest that future studies will change the direction of the effect of bariatric surgery on hypertension, it is also likely that new studies will lead to the same direction of benefit, but with even larger effects. It is necessary to encourage the performance of new RCTs, as has been done in the last three years [65], in order to perform good quality systematic reviews with the main objective of evaluating the effect of bariatric surgery in hypertensive patients with type I and II obesity. In this way, the physician is able to have the certainty of offering a beneficial intervention for patients.

5. Conclusions

We found only three systematic reviews evaluating the efficacy of metabolic surgery in patients with non-morbid obesity and arterial hypertension, showing a reduction in weight and blood pressure after metabolic surgery. However, the low methodological quality of the reviews and the low certainty of the evidence lead to low confidence in the results observed, and may even underestimate the effect of metabolic surgery in this group of patients. New systematic reviews are needed to evaluate the efficacy of metabolic surgery in hypertension, considering the new clinical trials published and using a rigorous methodology.

Provenance and peer review

Not commissioned, externally peer-reviewed.

International journal of surgery author disclosure form

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories, then this should be stated.

Conflicts of interest

None.

Sources of funding

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Ethical approval

Not applicable for systematic reviews.

Research Registration Unique Identifying Number (UIN)

1. Name of the registry: Figshare scientific repository
2. Unique Identifying number or registration ID: https://doi.org/10.6084/m9.figshare.12824918
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://doi.org/10.6084/m9.figshare.12824918

Author contribution

MCT, CES, and WNG performed the design, study protocol, and data extraction. WNG performed the evaluation of the methodological quality and certainty of the evidence of the included studies. All authors participated in the writing and approval of the final manuscript.

Guarantor

All authors are the guarantors of this study.

Data statement

Source Data.

The data for this study were extracted from three systematic reviews (Cohen 2017 [1], Muller 2015 [2] and Yan 2016 [3]) and can be obtained from the following links respectively: https://link.springer.com/article/10.1007%2Fs11695-017-2869-1, https://journals.lww.com/annalsofsurgery/Abstract/2015/03000/Surgical_Versus_Medical_Treatment_of_Type_2.1.aspx, https://journals.lww.com/md-journal/Fulltext/2016/04260/Roux_en_Y_Gastric_Bypass_Versus_Medical_Treatment.29.aspx.

The electronic data are available from PubMed® and other journals under their terms of use. Before downloading the full text, users must subscribe as a user of the journal and purchase the article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2022.106716.

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