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ORIGINAL CONTRIBUTIONS

Development of an Interactive Outcome Estimation Tool for Laparoscopic Roux-en-Y Gastric Bypass in Mexico Based on a Cohort of 1002 Patients

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Abstract

Background Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) is one of the most commonly performed bariatric procedures. Considering significant differences between populations around the world, surgical outcomes may vary widely. The aim of the study was to develop an educational patient-specific interactive application that may estimate the potential outcomes of LRYGB in the Mexican population.

Methods A database with 76 different variables from 1002 patients who underwent LRYGB at two Mexican Institutions between 1992 and 2014 and had a minimum of 6-month follow-up was analyzed. Descriptive and inferential statistics, as well as a multivariate regression analysis, were performed for the primary analysis. Results were based on four statistical models obtained from the cohort outcomes. A tool was designed to provide estimates of absolute weight loss (AWL) and resolution of four major comorbidities: type 2 diabetes (T2D), high blood pressure (HBP), hypercholesterolemia, and the obstructive syndrome of sleep apnea (OSAS).

Results There were 353 males (35.2%) and 649 females (64.8%) with a mean age of 41.9 ± 12.1 years and a mean preoperative BMI of 45.3 ± 7.9 kg/m^2. Mean AWL at 2 years was 39.02 ± 12.7 kg. Mean accumulative percentage of resolution for T2D, HBP, and dyslipidemias at the same time period was 78%, 66.2%, and 84.7%, respectively. Based on these results, the educational tool was developed.

Conclusions We were able to develop an interactive estimation application to provide a population-based guidance for potential outcomes of LRYGB. This might be useful not only for health professionals but also for patients interested in learning potential outcomes in specific circumstances.

Keywords Laparoscopic Roux-en-Y gastric bypass · Mexican · Bariatric surgery · Outcome · Interactive application

Background

Obesity is currently considered a global epidemic disease [1]. It affects almost half of the population, leading to a heterogeneous spectrum of significant comorbidities such as type 2 diabetes mellitus (T2D), metabolic syndrome (MS), dyslipidemia, cardiovascular disease (CVD), high blood pressure (HBP), and sleep obstructive apnea syndrome (SOAS), among many others. Because of this varying range of clinical scenarios, a multidisciplinary approach is necessary for its adequate management. Based on the existing evidence, bariatric surgery currently offers the most effective and durable treatment for morbidly obese patients [2].

Several surgical techniques are currently available for morbid obesity [3]. There is sufficient evidence to substantiate that laparoscopic Roux-en-Y gastric bypass (LRYGB) provides significant and durable weight loss with a relatively low complication rate [4, 5]. There are many different components such as ethnic and genetic

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background, psychological profile, comorbidity rate and lifestyle that affect weight loss [2, 6]. However, it is difficult to ponder all of them and the proportion each one of these contribute to the outcomes of bariatric surgery.

Based on the knowledge that certain stochastic variables could harbor a potential predictive value for weight loss, we decide to scrutinize these by means of a multivariable analysis in our cohort.

The main goal of this study was to develop an educational patient-specific interactive application to estimate potential outcomes (such as AWL and comorbidity resolution) after LRYGB, based on the analysis of a local bariatric patients' database from two different tertiary-care centers in Mexico City: a public institution focused on the care of patients from middle and low socioeconomic status and a private institution dedicated to the care of patients from higher socioeconomic status.

Patients and Methods

A database with 1002 patients who underwent LRYGB at two Mexican Institutions (INCMNSZ and ABC Medical Center, Mexico City) between 1992 and 2014 with a minimum of 6-month follow-up was integrated and analyzed. The protocol was formerly reviewed and approved by the IRB from both institutions.

A total of 30 variables were originally included for the descriptive and inferential statistical analysis of the cohort. However, variables exclusively considered for the multivariable modeling and the development of the estimation tool are listed in Table 1. AWL and control of comorbid conditions such as T2D, HBP, dyslipidemia and SOAS were assessed at 6, 12, 18, and 24 months postoperatively in every patient. AWL is a common metric used for reporting the net effect of bariatric surgery on weight. It was operatively defined as the net weight loss from the preoperative weight at different pre-set times during the clinical follow-up in kilograms. Comorbidity remission was operatively defined as the normalization of biochemical parameters (normal plasma glucose, A1C or lipid profile) in the absence of medication. Descriptive and inferential statistics, as well as data representation, were performed through the use of IBM© SPSS® Statistics version 20.0 and Microsoft® Excel® 2011 for Mac version 14.3.4. For statistical contrasts, any p value below or equal to 0.05 or 5% (type I error) was considered statistically significant for a two-sided hypothesis.

Based on the analyzed clinical and demographic variables (independent variables), four multivariable regression models (calculation at 6, 12, 18, and 24 months of postoperative weight loss) were generated by stepwise selection in order to predict the AWL (as a continuous dependent variable) and other interesting clinical endpoints (T2D resolution). Variables included in the calculating model were among others: initial weight, number of clinical visits, gender, height, age, operative approach (laparoscopic vs. open vs. laparoscopic converted to open), surgical time, hospital stay, T2D, HBP, hyperlipidemia, SOAS, etc.

Estimated percentage of patients with a specific comorbid condition (such as T2D) who experienced its resolution at each of the four follow-up times was generated from comorbidity resolution tables. However, the most important variable considered for this estimation calculator tool was AWL, which provides the best fit for the joint multivariable model, as well as the most informative prediction model. This was generated using a methodology that mirrors MarketScan® and BOLD analysis [7] with the a priori assumption that patients were missing at random in each of these endpoints. New tables were obtained with this information that tabulate the number and percentage of patients with baseline risk factors adjusted by multivariable regression modeling.

Required inputs for the calculator tool fall within different ranges for females and males, as determined by the study data. Weight was divided into five equal groups (by quintile distribution) as a result of their gender. Mean quintile value from this gender-adjusted quintile distribution was utilized in the formula to assess weight changes. Since statistical estimates are only valid for patients that are similar to those used to calculate the estimates, these limits guarantee that inputs are within the range of the study population and thus can be expected to produce reasonable estimates. Values outside the sex-specific study range are programmed to produce an error message on the interactive calculator. The allowable ranges for the female and male patient groups (as seen in the study populations) are the following:

Allowable ranges for females on the calculator:

- Age 16–76 years
- Weight 74–201 kg
- Height 138–182 cm

Allowable ranges for males on the calculator:

- Age 16–71 years
- Weight 91–206 kg
- Height 143–196 cm

Patients outside these allowable ranges can input the closest allowable value in order to obtain a surrogate estimate. In this case, the warning will act as an alert that the estimated value for that patient may be less accurate than for a patient within the study range.

Once an individual patient data is introduced into the tool, it estimates the AWL and the comorbidity remission prediction for that specific patient. Initial weight is then categorized in quintiles for all possible combinations of selected predictive

Table 1 Variables analyzed in the study

Number	Variable name	Mean/ type	SD	Minimum	Maximum
1	Gender	35.2% females		64.8% males	
2	Age (years)	41.9	12	18	78
3	Height* (meters)	1.66	0.09	1.38	1.96
4	Weight* (kg)	124.8	25.9	74	260
5	BMI* (kg/m^2)	45.3	7.9	29.9	91.00
6	T2D* variable type (*n*/%)	Ordinal variable (297/29.6%)			
7	HBP variable type (*n*/%)	Ordinal variable (379/37.8%)			
8	SBP*[§]	126.5	14.2	86	190
9	DBP*[§]	81.3	10.9	50	140
10	SOAS* variable type (*n*/%)	Dichotomous variable (146/14.6%)			
11	Hyperlipidemia* variable type (*n*/%)	Dichotomous variable (203/20.3%)			
12	Operative approach	Laparoscopic, open, or converted to open			
13	Surgical time, minutes	170.9	67.9	75	570
14	Length of stay, days	3.4	3.01	1	44
15	Follow-up date*	Nominal variable			

[§] *SBP*, Systolic blood pressure, *DBP*, Diastolic blood pressure; *These were measured before surgery and at 6, 12, 18, and 24 months postoperatively (repeated tied measures); [¶] Yes or no

variables. Outcomes are then displayed as 80%, 50% and 20% of patients experiencing AWL and percentage of patients experiencing comorbidity remission at considered endpoints. CTI™ Clinical Trial & Consulting Services performed this analysis by using Tableau™ software as well as the creation of the web-based calculator tool.

Results

There were 353 males (35.2%) and 649 females (64.8%) with a mean ± SD age of 41.9 ± 12.1 (range 16–78) years. Five patients (0.5%) were younger than 18 years and 31 (3.1%) were older than 65 years. Mean ± SD preoperative body mass index (BMI) was 45.3 ± 7.9 (range 29.9–91) kg/m^2, which results non-normally distributed, slightly right-biased. Preoperative mean ± SD for height was 1.66 ± 0.1 m for the general group, 1.70 ± 0.1 m for males, and 1.63 ± 0.09 m for females. Preoperative mean ± SD for weight were 124.8 ± 25.9 kg for the total group, 141.4 ± 26.6 for males, and 115.8 ± 20.5 for females. When BMI was contrasted between genres, males presented a higher BMI than females (46.2 ± 8.5 vs. 44.8 ± 7.6 kg/m^2). This observation resulted statistically significant ($p = 0.007$) when contrasted by an independent two-samples *t* test. A total of 297 patients (29.6%) had T2D, 379 HBP (37.8%), 146 (14.6%) hyperlipidemia, and 203 (20.3%) patients had SOAS before surgery.

Most patients (91.4%) underwent laparoscopic bypass (LRYGB), while 66 patients (6.6%) were openly approached and 20 were conversions from laparoscopic to conventional open surgery (2%). Mean ± SD surgical time was 170.9 ± 67.9 min (range 75–570) with a mean length of hospital stay of 3.4 ± 3 days (range 1–44).

These changes are reported as percentile values across the different postoperative follow-up times for their extrapolation to similar patients. Mean weight loss and control of comorbid conditions are shown in Table 2, while weight loss models for each endpoint are displayed in Table 3. Multivariable regression models were generated including these parameter estimates for the calculation formula and stratified by the four different postoperative follow-up times (6, 12, 18, and 24 months) in order to obtain the predicted AWL and percentage of comorbidity improvement. The final regression model included the four most significant variables (initial weight, follow-up time, gender and comorbidities); with this, the following formula was constructed.

$$y = \beta_0 1 + \beta_1 \times_1 + \beta_2 \times_2 + \beta_3 \times_3 + \beta_4 \times_4$$

$$\begin{aligned}\text{Calculated weight loss} = {} & \text{intercept} + (\text{parameter estimate} \times \text{initial weight}) \\ & + (\text{parameter estimate} \times \text{follow-up time in days}) \\ & + (\text{parameter estimate} \times \text{gender}) \\ & + (\text{parameter estimate} \times \text{comorbidity})\end{aligned}$$

Some actual examples applying this information for obtaining the calculated weight loss employed by the tool are displayed in Fig. 1. Parameter estimates for the remission or reduction of different stochastic comorbidities from to the multivariable regression analysis are displayed in Table 4.

Thus, based on these results and a multivariate regression analysis, the educational interactive tool was successfully developed. According to this, an example of a 45-year-old female patient with initial height and weight of

Table 2 Arithmetic mean plus/minus the standard deviation of BMI, weight loss, and control of comorbid conditions at different time periods after surgery

	6 months	12 months	18 months	24 months
BMI, kg/m^2	33.5 ± 7.1	34.0 ± 6.7	31.6 ± 6.7	33.7 ± 6.9
Weight loss, kg	32.79 ± 13.3	40.8 ± 11.7	39.6 ± 12.2	39.02 ± 12.7
T2D remission*, %	56.3	64.4	73.6	78
HBP remission*, %	41.0	54.1	66.2	66.2
Dyslipidemia remission*, %	69.7	82.5	82.5	84.7
SOAS remission*, %	79.3	83.9	86.2	91.6

*Figures represent accumulative remission throughout time on the follow-up

1.60 m and 115 kg, respectively with all four comorbidities (Fig. 2), would have a 50% chance for reaching a net estimated weight of 88 kg at 6 months, 81 kg at 12 months, 79 kg at 18 months, and 79 kg at 24 months after surgery (Fig. 3). The probability for achieving remission of comorbid conditions at 2 years in this hypothetic patient would be 83% for T2D, 66% for HBP, 86% for dyslipidemia, and 91% for SOAS (Fig. 4). From our point of view, this may be very useful for health professionals, physicians, endocrinologists, nurses, surgeons, and patients in order to better plan a bariatric surgery.

Discussion

Statistical tools for assessing and follow-up patients from diverse populations have proven to be highly successful and useful in the actual clinical setting as well as for quick reference. They have been widely used in pediatrics to assess growth and nutritional status for instance. However, they have been used infrequently in bariatric surgery. Most predictive models for weight loss in bariatric surgery are limited to cohort samples or surrogated clinical scores that were not developed specifically for surgical outcomes [8–10]. Moreover,

Table 3 Weight loss (kilograms) models for every follow-up endpoint (6, 12, 18, and 24 months) according to the multivariable analysis for developing the tool

Weight loss (kg) models for four follow-up time periods for calculation of outputs in bariatric weight loss tool					
Weight loss at 6 months			Estimate	Standard error	*p* value
N = 894	6	Intercept	− 20.341	2.416	< 0.0001
	6	Initial weight	0.273	0.013	< 0.0001
	6	Days to visit	0.089	0.009	< 0.0001
	6	Male (reference: female)	1.839	0.682	0.0071
	6	No sleep apnea (reference: on CPAP)	2.836	0.737	0.0001
Weight loss at 12 months					
N = 753	12	Intercept	− 23.058	4.192	< 0.0001
	12	Initial weight	0.396	0.017	< 0.0001
	12	Days to visit	0.035	0.010	0.0004
	12	Male (reference: female)	− 0.568	0.917	0.5362
	12	No sleep apnea (reference: on CPAP)	3.175	0.939	0.0008
Weight loss at 18 months					
N = 439	18	Intercept	− 18.208	7.594	0.0169
	18	Initial weight	0.432	0.022	< 0.0001
	18	Days to visit	0.010	0.013	0.4408
	18	Male (reference: female)	− 2.765	1.332	0.0385
	18	No sleep apnea (reference: on CPAP)	2.439	1.208	0.0441
Weight loss at 24 months					
N = 371	24	Intercept	− 6.645	11.127	0.5507
	24	Initial weight	0.454	0.027	< 0.0001
	24	Days to visit	− 0.012	0.015	0.4317
	24	Male (reference: female)	− 6.598	1.613	< 0.0001
	24	No sleep apnea (reference: on CPAP)	1.263	1.457	0.3867

Case example 1: Female, at six-month follow-up, with no sleep apnea, 100 kg:
Use six-month weight loss equation.
Use 103.1 kg as mean quintile weight since patient is in the second quintile group for females.
Use 182 days to calculate weight loss at six-months.
Use GENDER = 0 (0=female, 1=male).
Use NO SLEEP APNEA = 1 (0=has sleep apnea, 1=no sleep apnea).
LOSS = - 20.341 + (0.273 x MEAN QUINTILE WEIGHT) + (0.089 x DAYS TO VISIT) + (1.839 x GENDER) + (2.836 x NO SLEEP APNEA)
LOSS = - 20.341 + (0.273 x 103.1) + (0.089 x 182) + (1.839 x 0) + (2.836 x 1)
LOSS = - 20.341 + 28.146 + 16.198 + 0.0 + 2.836
LOSS = 26.839 kg
LOSS ≈ 27 kg
ESTIMATED WEIGHT AT SIX-MONTHS = 100 – 27 = 73 kg

Case example 2: Female, at six-month follow-up, with no sleep apnea, 150 kg:
Use six-month weight loss equation.
Use 142.0 kg as mean quintile weight since patient is in the fifth quintile group for females.
Use 182 days to calculate weight loss at six-months.
Use GENDER = 0 (0=female, 1=male).
Use NO SLEEP APNEA = 1 (0=has sleep apnea, 1=no sleep apnea).
LOSS = - 20.341 + (0.273 x MEAN QUINTILE WEIGHT) + (0.089 x DAYS TO VISIT) + (1.839 x GENDER) + (2.836 x NO SLEEP APNEA)
LOSS = - 20.341 + (0.273 x 142.0) + (0.089 x 182) + (1.839 x 0) + (2.836 x 1)
LOSS = - 20.341 + 38.766 + 16.198 + 0.0 + 2.836
LOSS = 37.459 kg
LOSS ≈ 37 kg
ESTIMATED WEIGHT AT SIX-MONTHS = 150 – 37 = 113 kg

Case example 3: Male, at twelve-month follow-up, with sleep apnea (and on CPAP), 150 kg:
Use twelve-month weight loss equation.
Use 152.4 kg as mean quintile weight since patient is in the 4th quintile group for males.
Use 365 days to calculate weight loss at twelve-months
Use GENDER=1 (0=female, 1=male)
Use NO SLEEP APNEA= 0 (0=has sleep apnea, 1=no sleep apnea)
LOSS= -23.058 + (0.396 x MEAN QUINTILE WEIGHT) + (0.035 x DAYS TO VISIT) - (0.568 x GENDER) + (3.175 x NO SLEEP APNEA)
LOSS = -23.058 + (0.396 x 152.4) + (0.035 x 365) - (0.568 x 1) + (3.175 x0)
LOSS = -23.058 + 60.350 + 12.775 - 0.569 + 0
LOSS = 49.499 kg
LOSS = 49 kg
ESTIMATED WEIGHT AT TWELVE-MONTHS = 150 - 49 = 101 kg

Case example 4: Male, at 24-month follow-up, with sleep apnea (and on CPAP), 180 kg:
Use 24-month weight loss equation.
Use 176.0 kg as mean quintile weight since patient is in the fifth quintile group for males.
Use 730 days to calculate weight loss at 24-months.
Use GENDER = 1 (0=female, 1=male).
Use NO SLEEP APNEA = 0 (0=has sleep apnea, 1=no sleep apnea).
LOSS = - 6.645 + (0.454 x MEAN QUINTILE WEIGHT) - (0.012 x DAYS TO VISIT) - (6.598 x GENDER) + (1.263 x NO SLEEP APNEA)
LOSS = - 6.645 + (0.454 x 176.0) - (0.012 x 730) - (6.598 x 1) + (1.263 x 0)
LOSS = - 6.645 + 79.904 - 8.760 - 6.598 + 0.0
LOSS = 57.901 kg
LOSS ≈ 58 kg
ESTIMATED WEIGHT AT 24-MONTHS = 180 – 58 = 122 kg

Fig. 1 Actual examples applying the information resulted from the multivariable regression for obtaining the calculated weight lossafter bariatric surgery

some of these predictive models were generated from multivariate regression. Although they might be very accurate, they are also very difficult to be implemented by a common person or impractical for a clinical application [11, 12].

For the development of these tools, it is important to avoid procedural bias in their development and application. Obesity is strongly influenced by several factors such as gender, age, ethnic group, geographic area and socioeconomic stratum. There is extensive evidence demonstrating differences in weight loss after bariatric surgery among different ethnical groups [13–15]. Other important determinants for surgical outcomes are gender, age, level of education, employment and cultural characteristics. Eating behavior, for example, is even different within Latin American countries [16]. Furthermore, some authors have suggested that the ancestry may have a significant impact on weight loss even when using the same surgical technique [13–17].

Individual variability can also be explained by differences in gut hormone responses. Good responders showing higher circulating anorexigenic hormones such as GLP-1 with lower ghrelin levels have been compared with poor responders [18]. This high variability on the results limits the extrapolation of outcomes to different populations.

Table 4 Parameter estimates for the remission or reduction of different stochastic comorbidities from to the multivariable regression analysis of our data

Comorbidity	Follow-up period (months)	Estimate	95% confidence limits*		Sample size
Comorbidity remission					
Type 2 Diabetes	6	0.76	0.69	0.81	197
	12	0.79	0.71	0.85	155
	18	0.81	0.71	0.88	89
	24	0.83	0.71	0.92	60
High Blood Pressure	6	0.49	0.44	0.55	348
	12	0.63	0.57	0.68	298
	18	0.67	0.60	0.73	198
	24	0.66	0.58	0.73	168
SOAS	6	0.80	0.74	0.86	186
	12	0.85	0.78	0.90	168
	18	0.85	0.78	0.90	146
	24	0.91	0.85	0.95	123
Hyperlipidaemia	6	0.76	0.68	0.83	127
	12	0.89	0.82	0.95	103
	18	0.84	0.74	0.91	87
	24	0.86	0.75	0.93	65
Comorbidity REDUCTION					
Type 2 Diabetes	6	0.79	0.73	0.85	197
	12	0.82	0.75	0.88	155
	18	0.82	0.72	0.89	89
	24	0.85	0.73	0.93	60
High Blood Pressure	6	0.60	0.54	0.65	348
	12	0.68	0.63	0.73	298
	18	0.71	0.64	0.77	198
	24	0.73	0.66	0.80	168

* Clopper-Pearson (exact) confidence limits

Another limiting factor for external comparisons is the lack of standardization of the surgical techniques. If we believe that the anatomic characteristics of the operation are important in the outcomes, we should accept that, for example, the RYGB has experienced significant changes throughout the time with significant changes in the volume of the pouch, the size of the gastrojejunostomy and the limb lengths [19–24]. All these procedural modifications and adjustments should also play an important role in the obtained clinical outcomes. Based on these concepts,

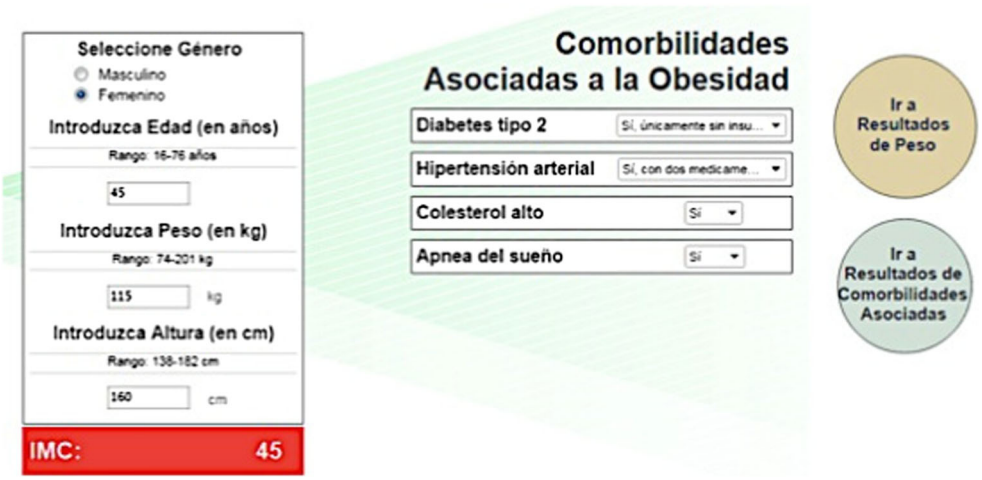

Fig. 2 Case illustration of the use of the interactive educational tool

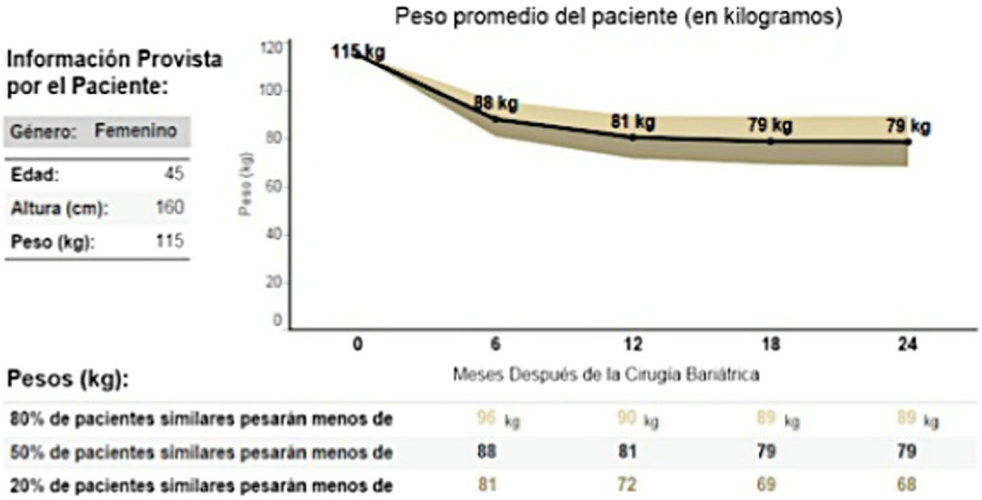

Fig. 3 Case illustration predicting the patient's average weight loss (in kilograms) after LRYGB through the use of the interactive tool. These calculations are based on the patient's gender, age, height, and weight in order to predict the average expected weight loss until 24 months postoperatively

it would be a mistake to apply universally weight loss curves from specific populations. For comparison of results between different groups, the surgical technique should be standardized.

In a study of 1216 patients undergoing RYGB, weight loss during the first month after surgery was found to be predictive for weight loss at 12 months of follow-up. According to these results, patients were stratified in quartiles and results showed that most patients, but especially patients in the first (lowest weight loss) and fourth (highest weight loss) quartiles continue to be in the same weight loss quartile where they were initially classified at 1 month postoperatively. The positive and negative predictive values for first quartile EWL at 1 month resulting in first quartile EWL at 12 months was 39% and 81%, respectively. Multivariate analysis indicated that sex, preoperative body mass index (BMI), EWL at 1 month and EWL velocity were statistically significant predictors of EWL at 12 months [25].

Additionally, results on RYGB in Mexican patients have been scarcely reported. Therefore, our principal aim was to create a weight loss and comorbidity resolution estimation calculator based on actual data obtained from Mexican patients and using a standardized surgical technique with minimal technical variations. Our patient population was obtained from two different institutions, one private and one public, which are representative of the Mexican general overt population.

However, there are some methodological limitations in our study. One is that, based on the limited access for bariatric surgery in our country, the sample size is rather small for demographic-level data extrapolations. Other is that considering its retrospective nature, the follow-up was not homogeneous in the entire cohort and finally, that the tool only predicts the maximum weight loss and remission of comorbidities at certain fixed time set points but does not provide information on the durability of these results. Nevertheless, we think that it can be very useful to estimate expected short-term results based on factual data.

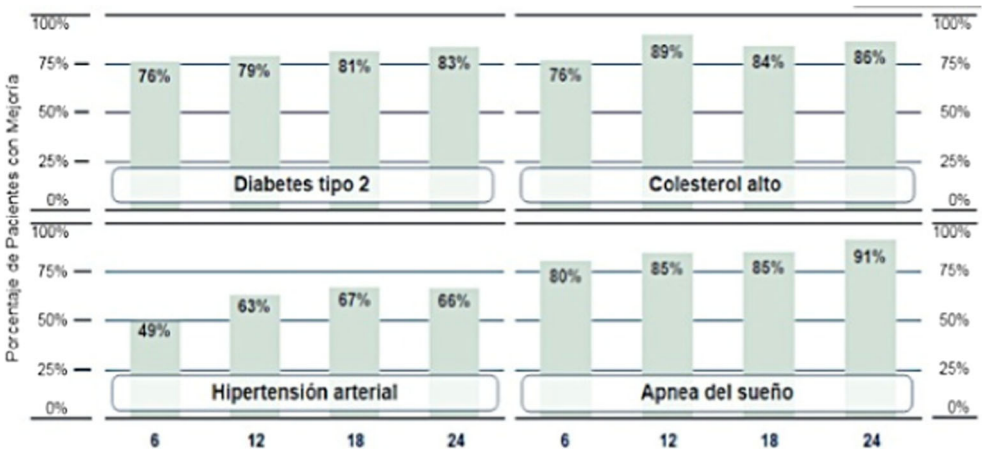

Fig. 4 Case illustration of the use of the interactive tool for predicting the percentage of comorbidities remission after LRYGB

Conclusions

Based on the analysis of this cohort of Mexican individuals, we were able to develop an interactive estimation application to provide a more realistic and population-based guidance about the potential outcomes in terms of AWL and comorbidity resolution for an individual-based approach in bariatric patients. This may serve well to health professionals and patients considering bariatric surgery as an option to come.

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Compliance with Ethical Standards

Conflict of Interest OOZ and HAC are employees of Johnson & Johnson but their participation in the study was independent of their income.

Ethical Approval This study was formerly reviewed and approved by the IRB committee from each enrolled institution.

Consent Statement Primary informed consent statement for bariatric surgery were formerly asked and properly signed from all included patients on this study.

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