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Outcomes in weight loss, fasting blood glucose and glycosylated hemoglobin in a sample of 415 obese patients, included in the database of the European Accreditation Council for Excellence Centers for Bariatric Surgery with Laparoscopic One Anastomosis Gastric Bypass

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Abstract

Background: Obesity is a risk factor for the development of diseases such as type 2 Diabetes Mellitus. Bariatric surgery with laparoscopic single anastomosis gastric bypass is an effective treatment for morbid obesity and diabetes type 2 complete remission, and it has been proven to generate an improvement in glycemic levels and glycosylated hemoglobin (HbA1c) keeping the weight loss for a long time.

Material and methods: In a period of time between June 2002 until May 2012, 2070 patients underwent surgery with LOAGB technique. Between January 2010 an May 2012, 415 patients were included in the European Accreditation Council for Excellence Centers for Bariatric Surgery (EAC-BS) database, from which 79 patients with a glycemic level disturbance in the preoperative blood sample where chosen. Of this group, 47 patients were pre-diabetic (fast plasma glucose ≥ 110 mg/dl ≤ 125 mg/dl) and glycosylated hemoglobin (HbA1c) levels between 5.7-6.4% and 32 were diabetic (fast plasma glucose ≥ 126 mg/dl) and glycosylated hemoglobin (HbA1c) levels ≥ 6.5%. We described the weight evolution, the excess body mass index lost percentage (%EBMIL) the glycemia and the glycosylated hemoglobin levels; and we reported regular laboratory controls during the first year after surgical intervention.

Results: Both patient groups achieved their lowest mean weight loss 12 months after surgery, being average weight in the pre-diabetic group 62.41 ± 10.93 and 68.36 ± 11.16 in the diabetic group. Since 3 months after surgery, pre-diabetic patients achieve a mean BMI < 30, according to the Spanish Society for Obesity Study (SEEDO 2007) this amount is
outside of the definition of obesity. Not being the case of the diabetic patients who don’t achieve this result until 6 months after surgery.

The weight loss was excellent in both study groups, achieving an excess body mass index loss percentage (% EBMI) greater than 65%, since the first three-month postoperative control.

Glycemia levels descend in both groups, achieving the pre-diabetic group a mean glycemia level of < 110 mg/dl in the second day after LOAGB surgery. Pre-diabetic patients maintain more stable glycemia with better controls, and very favorable outcomes 12 months after surgery. The diabetic patients achieve the mean glycemia level of < 110 mg/dl at the first month after surgery and maintained it 12 months after surgery which is the time of this study.

The glycosylated hemoglobin levels descended in both groups, achieving levels of 4% three months after surgery in the prediabetic group and 4.8% at six months in the diabetic group.

Conclusion: LOAGB proved to be an efficient bariatric technique for complete remission of pre-diabetes and diabetes mellitus type 2 and also with the excess weight loss resolution. We showed that the excess weight loss, the glycemia and glycosylated hemoglobin levels continue being normal after one year of follow up after surgery.

The best results are obtained in pre-diabetic patients who underwent LOAGB, this group is integrated with people who are at high risk of suffering a deterioration of their obesity and a rapid advance of the diabetes and the associated comorbidities, that’s why surgery has to be performed as soon as possible when the medical exam continues being favorable.

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Key words: Type 2 diabetes mellitus. Laparoscopic one anastomosis gastric bypass. Surgical glycemia control. Glycosylated hemoglobin HbA1c. Weight loss.

Introduction

The prevalence of obesity is suffering a constant increase all over the world, and is associated with a wide number of diseases that affect a great part of society, such as diabetes mellitus type 2. The World Health Organization (WHO) estimates that approximate 171 million people in 2000 were diagnosed with diabetes mellitus type 2, that number will increase reaching 366 million people in 2030. Type 2 diabetes mellitus and obesity conform two epidemic diseases that are strongly associated one with the other, as the European Decode Study Group prevalence charts confirm.

Bariatric surgery is the most effective treatment for morbid obesity 5, and is currently considered as a metabolic surgery, being an effective treatment to solve a lot of the comorbidities associated with obesity such as diabetes mellitus type 2. The remission of diabetes after bariatric surgery significantly decrease mortality rates in both cases, diabetic and pre-diabetic patients.

The mechanisms that are responsible for the remission of diabetes mellitus type 2 after bariatric surgery intervention are partially known even now. There are mechanisms that depend on the weight loss, and others that are independent of weight loss, showing their effects immediately after surgery, and it depends on the model of surgical procedure. The accepted and safest type of procedures are restrictive, malabsorptive and mixed techniques. Gastric bypass has an effect on insulin levels, improving insulin secretion response...
almost to normal levels\textsuperscript{9,10}, not being the case in the purely restrictive procedures\textsuperscript{11}.

LOAGB is considered a minigastric bypass modification, and it essentially consists of creating a large and narrow gastric pouch 13-15 cm at the long of gastric lesser curvature, with one + 2.5 cm ileum-gastric anastomosis in a side to side position, an anti-reflux mechanism rising up the afferent limb above the anastomosis, and a long bilio-pancreatic excluded malabsorptive segment, in a length of 2 to 3.5 meters depending on the patient conditions (age, sex, BMI, metabolic syndrome, central obesity)\textsuperscript{12}.

The objective of the present study is to describe the evolution in weight loss, glycemia and glycosylated hemoglobin levels in a sample of obese patients who were surgically treated with the LOAGB technique, in which we distinguish two groups of patients: pre-diabetics and diabetics, during one year follow-up after surgery.

Materials and methods

We performed a descriptive retrospective longitudinal study of data prospectively collected from the EAC-BS database who qualified for bariatric surgery under the standards defined by the NIH Consensus Conference.

The study included weight parameters, glycemia and glycosylated hemoglobin levels in one year follow-up after surgery. In a period of time included between June 2002 and May 2012, 2070 patients underwent surgery with LOAGB technique. Between January 2010 and May 2012, 415 patients were included in the European Accreditation Council for Centers of Excellence for Bariatric Surgery (EAC-BS)\textsuperscript{13} registry, which are the ones we chose for the study.

The sample made for the study is conformed of 79 patients with a disturbance in a fasting plasma glucose (glycemia $\geq$ 110 mg/dl) and glycosylated hemoglobin $\geq$ 5.7%, diagnosed in the preoperative blood tests. This sample of 79 patients, were divided into two groups in accordance with the following inclusion criteria\textsuperscript{14,15}:

- Pre diabetic group (n=47): fasting glucose $\geq$ 110 mg/dl y $\leq$ 125 mg/dl and HbA1c between 5.7% and 6.4%.
- Diabetic group (n=32): fasting glucose $\geq$ 126 mg/d and HbA1c $\geq$ 6.5%.

The studied variables were: age, sex, weight, BMI, %EBMIL, glycemia and glycosylated hemoglobin (HbA1c).

On the first medical appointment the age and sex are collected, a nutritional status evaluation is conducted,

### Table I

**Shows the outcomes of Weight, BMI, %EBMIL and glycemic and glycosylated hemoglobin levels evolution in pre-diabetic patients**

<table>
<thead>
<tr>
<th></th>
<th>PreQx</th>
<th>Qx</th>
<th>3 meses postQx</th>
<th>6 meses postQx</th>
<th>12 meses postQx</th>
<th>P Valor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prediabéticos n=47</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peso (Kg)</td>
<td>113,30 ± 22,81</td>
<td>98,54 ± 16,04</td>
<td>78,56 ± 14,63</td>
<td>70,38 ± 13,08</td>
<td>62,41 ± 10,93</td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>IMC</td>
<td>42,73 ± 7,32</td>
<td>37,33 ± 4,95</td>
<td>29,84 ± 5,35</td>
<td>26,66 ± 4,37</td>
<td>23,80 ± 3,05</td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>PEIMCP (%)</td>
<td>29,75 ± 11,14</td>
<td>78,65 ± 19,39</td>
<td>97,57 ± 25,44</td>
<td>109,92 ± 18,58</td>
<td></td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>Glicemia (mg/dl)</td>
<td>114,76 ± 4,09</td>
<td>89,03 ± 8,28</td>
<td>84,63 ± 11,22</td>
<td>85,5 ± 13,04</td>
<td></td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>4,7 ± 1,7</td>
<td>4,5 ± 1,7</td>
<td>4,4 ± 1,7</td>
<td>4,3 ± 1,7</td>
<td>4 ± 1,7</td>
<td>p&lt;0,001</td>
</tr>
</tbody>
</table>

### Table II

**Shows the outcomes and evolution of weight, BMI, %EBMIL, glycemia and glycosylated hemoglobin in diabetic patients**

<table>
<thead>
<tr>
<th></th>
<th>PreQx</th>
<th>Qx</th>
<th>3 meses postQx</th>
<th>6 meses postQx</th>
<th>12 meses postQx</th>
<th>P Valor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diabéticos n=32</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peso (Kg)</td>
<td>115,43 ± 21,95</td>
<td>99,23 ± 16,23</td>
<td>81,59 ± 16,25</td>
<td>75,70 ± 13,77</td>
<td>68,36 ± 11,16</td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>IMC</td>
<td>43,19 ± 6,21</td>
<td>37,23 ± 5,03</td>
<td>30,43 ± 5,03</td>
<td>27,92 ± 3,87</td>
<td>25,59 ± 3,78*</td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>PEIMCP (%)</td>
<td>33,33 ± 10,89</td>
<td>74,97 ± 17,89</td>
<td>88,50 ± 16,48</td>
<td>101,25 ± 19,50</td>
<td></td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>Glicemia (mg/dl)</td>
<td>144,95 ± 23,10</td>
<td>101,19 ± 22,15</td>
<td>98,30 ± 32,11*</td>
<td>96,46 ± 25,55*</td>
<td></td>
<td>p&lt;0,001</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7,9 ± 1,7</td>
<td>7,5 ± 1,7</td>
<td>6,5 ± 1,7</td>
<td>5 ± 1,7</td>
<td>4,8 ± 1,7</td>
<td>p&lt;0,001</td>
</tr>
</tbody>
</table>

\*P<0.05
and we apply a food intake protocol until surgery is done, with the purpose of reducing the perioperative risk.

Weight and BMI were evaluated in the first medical appointment, on the operation day and in the 3rd, 6th and 12th month after surgery. The %EBMIL calculation is made taking by reference the initial BMI in the first visit and the classification criteria formulated by Baltasar et al:

a) Excellent: %EBMIL > 65%.
b) Acceptable or good: %EBMIL between 50-65%.
c) Failure: %EBMIL < 50%.

The glycemia and glycosylated hemoglobin levels are collected prior to the intervention and then in a successive three-month control after surgery. All diabetic patients had oral diabetic medication or preoperative insulin therapy.

The outcomes are expressed as mean ± standard deviation. The statistical analysis includes the ANOVA analysis of the variant with coefficient test of p of Pearson correlation: significant considering a p < 0.05.

Results

The pre-diabetic group is composed of 47 patients, from which the mean age is 46.01 ± 10.78, compose of 12 men with a mean age of 44.06 ± 9.36 and 35 women with a mean age of 46.67 ± 11.27.

The initial average weight in the first medical appointment was 113.30 ± 22.8; at the time of surgery the average decreased 14.76 kg; between surgery and the 3rd month it decreased another 19.98 kg. This is the time where the weight loss is greater; between 3rd and 6th months it decreased an average of 5.89 kg and from 6th to the 12th month decreased 7.36 kg in average. Mean weight loss since preoperative control until 12 month control decreased 47.07 kg with a statistical significance p<0.001.

The BMI follows a proportional tendency to the weight loss evolution in all postoperative controls, since the 1st control until surgery it decrease 5.96%; between surgery and 3 months it drops to 6.8; from the 3rd to 6th month another 2.51; and from 6th to the 12th month BMI decreased another 2.33. From the first appointment to the last 12th month control a 17.6 BMI loss was achieved (p<0.001).

The %EBMIL between 1st consultation and surgery was 33.33%; in the first quarterly control after the surgery a greater %EBMIL of 41.61% was observed; from the 3rd to the 6th month 13.53%, and between the 6th to the 12th month was 12.75 (p<0.001). The mean %EBMIL. From the 1st appointment to the year was 67.92%.

The decrease in mean glycemic levels was gradual in all the study controls. From the preoperative time until the 3rd month control the decreased was 43.76 mg/dl. Between the 3rd and 6th month decreased 2.89 mg/dl, and from 6th to the 12th month decreased another 1.84 mg/dl (p<0.001).

Every control shows a greater weight loss in the pre-diabetic patients group than in the diabetics group, being the average weight loss statistically significant p<0.05 at the 12th month with 50.89 kg in the pre-diabetic group and 47.07 kg in the diabetic group.

BMI decrease is higher in the pre-diabetic group (18.93) than in the diabetic (17.6). At 12th month after surgery the pre-diabetic group achieve a normalization of the BMI 23.80 ± 3.05, on the other hand the diabetic group does not reach normal weight, but they are out of the pre-obesity criteria (p<0.05).

Both groups of patients reach a %EBMIL > 65% since the 3rd postoperative month, and establishing itself as an excellent bariatric surgery quality criteria, as shows in Chart 2. At the moment of surgery control, the pre-diabetic group have a %EBMIL of 29.75 ± 11.14, somewhat less than in the diabetic group (33.33 ± 10.89). This is because the BMI calculated in the first appointment is 0.46 higher in diabetics and in the
preoperative preparation, the weight to lose is higher in the diabetic group to minimize the perioperative risk. We observed a higher mean %EBMIL in pre-diabetic group at 12th month (109.92 ± 18.58) compared with the diabetic group (101.25 ± 19.50) with a statistical significance p<0.05.

As we see in Chart 3, the initial glycemia levels are higher in the diabetic group 144.95 ± 23.10, than in pre-diabetic group 114.76 ± 4.09. In the postoperative controls glycemia levels fall in a gradual way for both groups, nevertheless in the 12 month control the diabetic group rise the mean glycemic levels (96.46 ± 25.55) but always stay under the ranges for diabetes and pre diabetes criteria4,15 (p<0.05).

The HbA1c preoperative levels in diabetic group were >5.7% in all of patients, but already in the first quarter fall below an average of 5.1% and gradually in the next controls until the 12th month. No diabetes medication was necessary after surgery.

Discussion

Remission of diabetes was defined as a HbA1c <6.5% without any treatment for at least one year. Improvements in diabetes, hypertension, dyslipidemia and obstructive sleep apnea syndrome were seen in the first postoperative months in all patients.

The resolution and improvement in diabetes type 2 thanks to bariatric surgery is not only due to the weight loss experimented by these patients but also, and in a more significant way, for the exclusion of a long bilipancreatic limb that originates the exclusion of normal duodenal nutrient pathway and the early arrival of food to distal intestine which improve glucose tolerance18,19, and also make this procedure mainly act as a malabsorptive surgery, with better outcomes immediately after surgery and continues for long term after surgery20.

In our study, both evaluated groups have a mean uniform age average 47.15 ± 10.33, and relatively young, where 30.38% of the 79 patients being under the median ≥ 55 years of age. In both groups exist a predominance in female sex: 74.44 % of pre-diabetics are female, and 81.25% in diabetic group are female also, as it usually happens in recently published series11.

In this study the evolution of BMI compared with those described by Donadelli et al21 in patients that underwent a Roux-en-Y gastric bypass is almost a similar evolution in our patients 12 months after LOAGB. However the most favorable results are obtained with LOAGB achieving a BMI of >30 a year after surgery in diabetic patients, whereas in the Donadelli study did not achieve this results until the second year after the intervention. Moreover, in our center, we developed an dietetic weight loss protocol that begins from the first appointment until the surgery, that it is different in each patient depending on the weight loss required in relation with the obesity grade and comorbidities, with the purpose of diminish the cardiovascular risk23. And unlike other studies where they start from an initial preoperative BMI and afterwards describe their postoperative controls24, we also evaluate the weight loss from the first appointment and that is why the 3th month postoperative control shows more intense weight loss.

To express the weight loss results, is considered valid to use the overweight loss percentage (OWLP) and the changes in the BMI expressed as BMI excess loss or %EBMIL25. We use the %EBMIL to evaluate the success, and the results were excellent in both groups since the 3rd postoperative month. Given that we obtained a %EBMIL of 109.92 ± 18.58 in the pre-diabetic group, and 101.25 ± 19.50 in the diabetic group, we exceed the 100 % of %EBMIL at one year after surgery in comparison with other surgical techniques26.

The outcomes in glycemia levels in LOAGB compared with other study22, we observed that with our technique we achieve similar outcomes in glycemia levels one year after surgery, strengthen the efficacy of LOAGB in the diabetes treatment. In this study only 33% of all patients have a glycemia disturbance before surgery, and in our study 100% had a glycemia disturbance. In a study made by Papapietro K et al27 in obese patients who underwent classic gastric bypass in Y Roux, they report a glycemia evolution, in the immediately postoperative, at 3rd, 6th and 12th months; this study is similar to ours, where we have the same glycemia evolution report, but in the Papapietro K et al27 only 17.3 % were diabetic prior to surgery. We observed a similar tendency in the glycemia levels in both studies in the diabetic group, but in the pre-diabetic group the glycemia levels were lower with the LOAGB. Besides in all patients including in the diabetic group not only the normoglycemia was achieved, also the HbA1c fall to normal levels and their medication disappeared completely.

LOAGB technique is a surgical procedure that in the last years is positioning in many countries as a very good surgical procedure for treating morbid obesity and diabetes mellitus type 228,29,30. This is due to the excellent outcomes in weight loss, metabolic control, and low morbidity-mortality rates, as we have seen in our 2070 patients.

It is important to emphasize that is a priority to keep an strict periodical monitoring of each patient before, during and after surgery, as well as the importance of counting with a central database13 where we could collect all this information, analyze the short, medium and long term outcomes, and also compare the different centers and different surgical techniques results.

Conclusions

LOAGB is an effective surgical technique for weight loss in pre-diabetic patients as well as in diabetic patients after one year control.
Equal to the result variations in the BMI after a year, the pre-diabetic patients reach normalization in weight, and diabetic patients have criteria for grade I overweight. The %EBMIL in both groups reach the excellence criteria by the 3rd month control. Blood glucose normalizes in pre diabetic patients and 100% of them resolve their pre diabetic state in the first month after surgery. In diabetic group by the 3rd month after surgery the diabetes has resolved in all the evaluated patients, with normal levels of glycemia.
glycemia, HbA1c and with total absence of diabetic medication.

The best outcomes are given to people who anticipate to the bigger damage that their obesity and associated comorbidities is causing to them, deciding to have bariatric surgery as soon as possible, whenever the previous medical exam is favorable.

Disclosures

The Authors declare that they do not have any conflict of interest.

References