

ROUX-EN-Y GASTRIC BYPASS WITH SILICONE RING FOR THE OBESITY TREATMENT: STUDY OF THE COMPLICATIONS RELATED TO THE RING

Derivações gástricas em Y-de-Roux com anel de silicone para o tratamento da obesidade: estudo das complicações relacionadas com o anel

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ABSTRACT – Background - The silicone ring is used as containment factor of the Roux-en-Y gastric bypass to induce greater ponderal loss. However, it may have some inconveniences from this stressed restriction. **Aim** – To analyze the complications related to silicone ring in patients who underwent Roux-en-Y gastric bypass surgery with silicon ring. **Methods** - From 1994 to 2005, 7 000 patients were submitted to Roux-in-Y gastric bypass with silicone ring in order to treat morbid obesity. Only 50% were followed from two to 11 years. The mean excess weight loss was around 85%. But ring complications were registered in 160 patients (2,28% of the total and 4,56% of the followed patients). Therefore, this series consist of 38 male patients (23,8%) and 122 female patients (76,2%) with average age of 44 years old and BMI of 54.4 kg/m². **Results** - Five types of ring complications were found. The most frequent was displacement (61%) causing obstructive symptoms. The second most frequent complication was ring erosion to the lumen (22%) causing epigastric pain and nausea. **Conclusions** - The ring complications occur in low frequency. Ring removal, either surgical or endoscopically done, is the most usual treatment, but tends to cause partial regain of the weight lost.

HEADINGS - Anastomosis, Roux-en-Y, Morbid obesity, Postoperative complications.

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Financial source: none
Conflicts of interest: none

Received for publication: 02/05/2011
Accepted for publication: 04/08/2011

DESCRITORES - Anastomose em-Y de Roux, Obesidade mórbida, Complicações pós-operatórias

RESUMO – Racional - O anel de silicone é utilizado como fator de contenção do bypass gástrico em Y-de-Roux para induzir maior perda ponderal. No entanto, ele pode ter alguns inconvenientes nesta restrição forçada. **Objetivo** - Analisar as complicações relacionadas ao anel em pacientes submetidos à operação de bypass gástrico em Y-de-Roux. **Métodos** - De 1994 a 2005, 7 000 pacientes foram submetidos à bypass gástrico em Y-de-Roux com anel de silicone para o tratamento da obesidade mórbida. Apenas 50% foram acompanhados de dois a 11 anos. A perda média de peso em excesso foi de cerca de 85%. Mas complicações do anel foram registrados em 160 pacientes (2,28% do total e 4,56% dos pacientes seguidos). Assim, esta série é composta de 38 pacientes do sexo masculino (23,8%) e 122 pacientes do feminino (76,2%) com idade média de 44 anos e IMC de 54,4 kg/m². **Resultados** - Cinco tipos de complicações do anel foram encontradas. A mais frequente foi o de deslocamento (61%) causando sintomas de obstrução. A segunda, foi a erosão do anel de luz (22%), causando dor epigástrica e náuseas. A presença de anel estreito, anel aberto e a inadequação do mesmo são outras complicações que ocorreram, porém em menor percentual. **Conclusões** - As complicações do anel ocorrem em baixa frequência. Sua remoção, cirúrgica ou endoscópica, é o tratamento mais usual, mas com sua realização o paciente tende a recuperar o peso perdido.

INTRODUCTION

Obesity causes major damage globally. About 300 000 people die each year worldwide due to it²¹. It is the second cause of preventable death in the world, only surpassed by smoking⁷. In the United States obesity is associated with five of the 10 leading causes of death¹⁷.

The class III obese patients are unlikely to lose weight with medical treatment; 98% of those who loose have recurrence in less than one year, and 100% in five¹⁶. For this reason morbid obesity became surgical

problem.

In the consensus conference of the National Institutes of Health of the United States of America parameters were established for the selection of candidates for surgery¹⁴. These standards were adopted internationally and accredited in our country in 2000.

Obesity surgery aims to provide lasting weight loss and resolution or improvement of comorbidities such as type 2 diabetes, hypertension, cardiovascular disorders and risk of early death⁷.

The rates of surgical complications and mortality are acceptable, provided that operations are conducted by knowledgeable staff, in proper hospital and suitable materials. It is just part of a long multi-professional work that must be followed for life by the patient. Before the operation is very important to inform about the surgical technique to be employed, possible complications and negative implications in the short and long term, it is also important to dialogue with the patient and their family members for deliberation of the best alternative therapy in each case. Among the methods used today, gastric bypass has earned the preference of many experts, representing 65% of bariatric operations performed in the emerging countries³.

Fobi and Lee¹⁰ in California and Capella et al.⁶ in New Jersey, associated a ring to Roux-en-Y gastric bypass, restricting the output of the functioning small gastric chamber, in order to enhance efficiency in weight loss long-term. Carried out the vertical gastric pouch along the lesser curvature of the stomach, where the muscles thickness difficult dilatation. Also, brought a segment of the Y jejunal loop between the two severed parts of the stomach in order to prevent contact between them and possible gastrogastric fistulas.

Berti et al.², in 1996, studying the emptying of the gastric pouch using radioisotope-labeled solid food, noted that the emptying rate is higher when there is no ring, than when it is associated with gastric bypass. Also found that weight reduction is more pronounced when the ring is present².

The intestinal Roux-en-Y gastric bypass (DGYR) arrived in Brazil through the teachings of Rafael Capella, New Jersey, in 1994 and was initially performed at the Hospital of the Faculty of Medicine, University of São Paulo and then at the Institute Garrido, also in São Paulo. This procedure was initially performed without drainage of the abdominal cavity and without gastrostomy, according to the standards of Capella⁶. From the year 2000, these authors adopted the proposals of Mathias AL Fobi adding upper abdominal cavity drainage and gastrostomy in the excluded stomach¹⁰.

Practical experience of the authors of the service for over 10 years indicates that the silicone ring used as a factor in restraining this procedure

demonstrates advantages, providing, as a rule, truly effective and persistent weight loss¹². On the other hand, there are also disadvantages for the presence of the ring, which can cause complications from persistent vomiting to increase intake capacity and recovery of lost weight.

This study aims to analyze the complications related to silicone ring in patients who underwent surgery on Roux-en-Y gastric bypass with silicone ring analyzing the types of complications, the time of its occurrence and to assess the evolution of patient's weight in the pre and post removal of the ring.

METHODS

From March 1994 to December 2005, 7,000 patients underwent Roux-en-Y gastric bypass with silicone ring for treatment of morbid obesity, at the Institute Garrido in São Paulo, SP, Brazil. Of these, 2380 were male (34%) and 4620 females (66%). The average age was 36 years and BMI of 44kg/m².

Of the operated patients, the follow-up ranged from two to 11 years in 3500 cases. There were complications with the ring in 160 patients, or 2.28% of the total series. From them, 38 were male (27.8%) and 122 females (76.2%) with a mean age of 44 years and mean BMI of 54.4 kg/m².

The results were statistically analysed by Chi-square test, variance analysis by Kruskal-Wallis and Mann-Whitney tests.

RESULTS

The preoperatively average BMI of the patients in kg/m² who suffered complications after the operation, according to gender, were women in 45.6 and 50.1 in men, which was statistically significant (p < 0.05).

The percentage weight loss of patients who suffered complications after the operation according to gender in women was 94.7 and 84.6 in men, demonstrating that proportionally women lost more weight than men (mean ± 10%), with no statistically significant difference.

Complications experienced by patients according to time of appearance in months are detailed in Table 1.

Complications related to displacement and erosion, appear more frequently in 12 to 24 months, and narrow ring, open and inadequacy, within six months. This difference is statistically significant.

The mean appearance time in months of complications was variable and may be from the first month until the late postoperative period, with no statistically significant difference in this group of patients (Table 2).

TABLE 1 – Complications of silicone ring in time periods ranging up to more than 60 months (m)

Time	Complications										Total	
	Displacement		Erosion		Narrow ring		Inadequacy		Ring-opened		N	%
	N	%	N	%	N	%	N	%	N	%		
0 a 6m	15	18.5	8	26.7	1	12.5	1	12.5	1	20	26	19.7
6,1 a 12m	15	18.5	4	13.3	0	0	4	50	2	40	24	18.2
12,1 a 24m	28	34.6	10	33.3	0	0	0	0	0	0	36	27.3
24,1 a 36m	10	12.3	6	20	4	50	1	12.5	1	20	21	15.9
36,1 a 48m	6	7.4	1	3.3	2	25	2	25	0	0	11	8.3
48,1 a 60m	5	6.2	0	0	0	0	0	0	0	0	5	3.8
> 60 m	2	2.5	1	3.3	1	12.5	0	0	1	20	5	3.8
Total	81	100	30	100	8	100	8	100	5	100	132*	100

The changes in weight after removal or not of the ring, showed that weight gain was higher in the displacement than it was in the erosion and ring-opened cases (p <0.05). Among other complications there was no statistically significant difference (Table 2).

TABLE 2 – Complications according to the average time of onset* and weight gain after removal of the ring**

	Displacement	Erosion	Narrow ring	Open ring	Inadequacy
Mean time of appearance	N= 81 Mean= 19,2	N= 30 Mean= 16,7	N= 8 Mean= 35	N= 5 Mean= 19,4	N= 8 Mean= 24,2
Weight gain after removal of the band	N= 84 Mean =-4,97	N= 30 Mean=-0,10	N= 9 Mean =2,73	N= 4 Mean=-11,2	N= 8 Mean =4,2

* Analysis of variance by Kruskal-Wallis - Hcalculado = 6.49 (ns)
 ** H calculated = 19.14 * p <0.05

Second surgical approach taken to treat the complications varied and are detailed in Table 3.

TABLE 3 – Techniques applied in the correction of complications of the ring*

Approach	Complications										Total	
	Displacement		Erosion		Narrow ring		Inadequacy		Ring-opened		N	%
	N	%	N	%	N	%	N	%	N	%		
Laparotomy	83	95.3	1	2.3	9	100	8	100	5	100	106	69.7
Endoscopy	1	1.2	41	95.4	0	0	0	0	0	0	42	27.7
Laparoscopy	2	2.3	0	0	0	0	0	0	0	0	2	1.3
Without treatment	1	1.2	1	2.3	0	0	0	0	0	0	2	1.3
Total	87	100	43	100	9	100	8	100	5	100	152*	100

* Six did not have data and two were not allocated among the complications. - Chi-squared - computed X² = 136.9 * - p>0.001.

Laparotomy was used for treatment of complications of displacement, the narrow ring, the open and the inadequacy. Endoscopy was used for erosion. There was a statistic significant difference in this group of patients treated with erosion of the ring by endoscopy.

In the evolution of weight by the time after the removal of the band, the average difference in weight gain was found between zero to six months and 12.1

to 24 months - statistically significant -, generally ± 10 kg between 0 to 36 months. The longer the withdrawal of the ring, the greater the weight regain (Table 4).

TABLE 4 – Evolution of the weight by the time after the removal of the band

3-6m	6,1-12m	12,1-24m	24,1-36m	36,1- 48m	>48m
N =28 A = 3,96	N = 25 A = 4,98	N = 39 A = 9,85	N = 24 A = 6,14	N = 12 A = 9,98	N = 9 A = 10,4

Analysis of variance by Kruskal-Wallis - H calculated = 13.74 * p <0.05; A = Average

Evolution of the weight of patients who suffered complications after surgery, with or without removal of the second ring, showed that those who had removed the ring had weight gain (96.9%) compared to those that did not remove. In this group of patients was found statistic significant difference (Table 5).

In the evolution of weight by removing the ring or not, patients who had it removed gained more

TABLE 5 – Evolution of the weight of patients who suffered complications after surgery

Removal	Evolution of the weight						Total	
	Gain		Maintenance		Loss		N	%
	N	%	N	%	N	%		
Yes	96	96,9	4	80	22	78,6	122*	92,5
Not	3	3,1	1	20	6	21,4	10**	7,5
Total	99	100	5	100	28	100	132	100

Calculated X² = 11.69 * p> 0.02

weight (6.1 kg) compared to ones that did not; this difference was statistically significant.

In the evolution of the weight of those who continued with the ring, second ring repositioned or open, those who have relocated or closed the ring, had an average weight loss with no statistic difference (-0.35 and open repositioned average -3.6).

In the evolution of BMI before the withdrawal of the ring and those patients who had complications of obstructive type, showed a significant decline of BMI and a slight increase after treatment. Patients with complications, like loss of restriction, had less pronounced reduction in BMI, and after their treatment maintained this reduction (Table 6).

TABLE 6 – Evolution of BMI before the withdrawal of the ring, at diagnosis and after treatment of the ring when the ring was repositioned

Complications	BMI			Total	
	Before	Withdrawal	After	N	%
Displacement	52.2	31.4	34.5	65	52
Erosion	56.7	41.1	35.8	45	36
Narrow ring	51.5	28.4	26.5	7	5.6
Inadequacy	45.7	27.1	28	8	6.4
Total	-	-	-	125	100
Repositioned	47.1	28.2	31.1	7	58.3
Ring-opened	56	39.6	36.7	5	41.7
Total	-	-	-	12	100

In the evolution of BMI before, at diagnosis and after treatment of the ring who had complications - whose ring was repositioned -, showed significant reduction in the time of diagnosis and after treatment slight tendency to increase. Since the BMI of patients with open ring at the time of diagnosis had a less marked reduction, after treatment tended to maintain this reduction (Table 6).

DISCUSSION

Based on the results, it is evident that the complications of the ring tend to occur late. Only after three years from the beginning of the use of Roux-en-Y gastric bypass ring (DGYRA), began to be diagnosed the first cases of complications related to it. With greater number of operations, higher incidence was found.

Fobi et al.¹¹ and Capella and Capella² in similar work, showed 2.5% of complications related to the ring, as long-term erosion and 1% of inadequacy. Maremma and Perez¹⁸ needed to remove 0.3% of the rings and S. White 6.7%. These authors had after five years only 50% of patients in follow-up and only 28% ten⁹, reporting 0.5% of obstructions in 652 patients⁵.

The suspected diagnosis of complications

was made from symptoms that occurred in most cases, but not all. The most common were related to the displacement of the distal ring, causing sub-occlusion on gastrojejunal anastomosis. Rocha, et al.²¹ reported incidence of less than 1% of slip ring. The main symptom was vomiting after eating solid food and liquids in some cases. Similar symptoms have been reported in patients with rings in the correct position, but whose lumen was very narrow since the operation. In these cases unlike the sliding, the symptoms of sub-occlusion started early, since solid foods were introduced into the diet, about a month after the operation. Even with the ring correct diameter and correct position, there were also symptoms of the same type, also starting early, not because there was narrowing, but because patients were not able to adapt to new eating habits with more persistent chewing of solid foods, smaller amounts and longer intervals. Similar symptoms are also seen in the cases of Fobi et al.¹¹.

The age factor may be a requirement for greater or lesser weight loss, due to the metabolism. The older has less weight loss. But there are publications in the literature^{1,19}, saying that younger than 18 years and greater than 65 years old could benefit from the results that surgical treatment provides, when targeted and aware of the commitment with follow-up and with the team multiprofessional recommendations⁴. This series had patients with this profile in relation to age and there was a great benefit in many clinical and psychosocial approaches.

It can be seen in this study, that there was no age difference between genders with no statistic significant difference. It was found that, in regard to weight reduction, proportionally women lost more weight than men ($\pm 10\%$), with no statistic significant.

In regard to BMI was found that men (mean BMI = 50.1) had higher number than women (mean BMI 45.6); this difference was statistically significant.

When the results were analyzed in relation to weight loss, it must be considered the percentage loss of excess weight; the average percentage of excess weight loss in patients undergoing Roux-en-Y gastric bypass with ring is about 70% to 80%, with slight variation of 5% to 10% up or down.

This loss^{5,9}, intensified by the presence of small ring around the gastric chamber, differs from gastric bypasses with no ring, which has faster gastric emptying and therefore less weight loss, an average of 60% to 70% of excess weight. Anyway, it is believed that it is necessary to perform a prepyloric calibration to work as a ring in an attempt to delay gastric emptying and, consequently, lead to feel full longer.

In complications such as narrow ring (eight patients) and inadequate (eight patients), they had signs and symptoms such as difficult feeding from solid to viscous vomiting, since the introduction of

solid foods. Patients with open ring (five patients) were well in relation to weight loss and food intake but they were concerned with food intake of greater volume than before, stopping or reducing the weight loss.

Fobi, et al.¹¹ reported the occurrence of ring erosion in 1.6%, ranging from 0.9 to 7%. Patients with erosion of the ring (30 patients) could have epigastric pain associated with difficulty in swallowing food. Sometimes, it was suspected the disappearance of the obstacle with the increased of food intake. In the latter case the greater ease of ingestion, as a rule, was preceded a few weeks or months of epigastric pain, and sometimes by vomiting. Occasionally the occurrence of erosion of the gastric ring lumen was asymptomatic and without changes in weight loss and was only detected by endoscopic control. Huang¹³ in 2005 indicated upper gastrointestinal endoscopy in patients postoperatively with frequent symptoms of abdominal pain, upper gastrointestinal bleeding and weight change.

Jewel-Neto, Jacob and Lopes¹⁵, showed that the diameter of the ring had no association with significant weight reduction and no significant nutritional changes. In this study was found that most patients had complications related to obstructive ring by displacement. With weight loss initially satisfactory from one point, began to have more difficulty eating solid foods. As a result, greater weight loss than usual happens, with more marked restriction, tending to evolve into protein-calorie malnutrition, sometimes with important clinical implications; surgery becomes necessary to remove the ring and have nutritional compensation.

It is understood that the fact of having a foreign body represented by the silicone ring around the small chamber attached and fixed on its walls, can lead to chronic local inflammation and the formation of hypertrophic scarring around the ring, providing the complications previously reported.

Another factor to consider are the repeated attempts to intake greater amount than the capacity of the small chamber, followed by frequent vomiting; this can trigger the onset of erosion, displacement of the ring or removal from the original position gradually.

The therapeutic approach in patients who had complications related to the ring varied according to the nature and whenever possible is indicated to remove it.

The expected evolution after removal or replacement is the recovery of the weight. However this does not always happen, although is true for most of patients. Some patients continued to lose weight or maintain, possibly by a greater adherence to dietary and nutritional new status.

Weight gain in dislocation, narrow ring and

inadequacy was higher than in the erosion and the open ring.

When is analyzed the BMI (kg/m²) before the withdrawal of the ring and after it is concluded that the BMI in patients who had obstructive complications presented significant drop and then slightly increased after treatment. Patients with complications like loss of restriction had less pronounced reduction in BMI after treatment and maintained this reduction.

Analyzing the BMI before the withdrawal of the ring and after, patients who had repositioned the ring showed significant tendency to a small increase.

With the onset of complications related to the ring, raises questions and doubts about the real need to offer patients important constraint represented by the ring in order to enhance weight loss. It is unclear what is best for the patient. Theoretically to cause fewer problems the ring must have: 1) a flat shape, not cylindrical, to have greater adherence to the gastric wall; 2) without the need to be fixed; 3) ring with silicone material which offers less tissue reaction and adjustment holes at their ends.

Another possibility would be to use a ring of marlex or polypropylene mesh, which can also be adjusted. It is known that there may be more likely to erosion over time as it is incorporated into the gastric wall. On the other hand would have fewer complications like displacement.

Therefore, more scientific studies are needed to be able to document and determine the best treatment option.

CONCLUSIONS

Complications related to silicone ring in Roux-en-Y gastric bypass were displacement, erosion and narrow ring, and occurred at low frequency. Symptoms such as vomiting and epigastric pain were variable according to the time of postoperative obstruction and symptoms. Treatment was almost always a procedure to remove the ring by laparotomy or endoscopic approach. Upon removal of the ring, the patients tended to recover some of the lost weight.

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