

RING INFLUENCE ON PONDERAL EVOLUTION AFTER FOUR YEARS OF LAPAROSCOPIC ROUX-EN-Y GASTRIC BYPASS

A influência do anel na evolução ponderal após quatro anos da derivação gástrica em y-de-roux laparoscópica

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HEADINGS – Gastric bypass. Gastroplasty. Bariatric surgery. Weight loss.

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Financial source: none
Conflicts of interest: none

Received for publication: 02/04/2012
Accepted for publication: 03/08/2012

DESCRITORES - Derivação gástrica. Gastroplastia. Cirurgia bariátrica. Perda de peso.

ABSTRACT - Background - Use of ring in Roux-en-Y gastric bypass is still a matter of controversy among bariatric surgeons. There is no consensus on its impact in relation to weight loss and weight maintenance in the long term. **Aim** - To evaluate the influence of the ring on the evolution of body weight over four years after bariatric surgery. **Methods** – Retrospective analysis of 143 women who underwent laparoscopic Roux-en-Y gastric bypass paired on the use or not use of Silastic® ring. Follow-up time was 48 months. Inclusion criteria were age over 18 years, primary bariatric operation and regular attendance at the clinic during the period of interest for research. The technique kept small gastric reservoir estimated in a volume of 30 ml. The food limb had in average 150 cm and the bile one 40 cm from the duodenojejunal angle. The group “ring” used Silastic® device with length of 6.5 cm, placed 2 cm from gastrojejunal anastomosis. The ring was closed for five polypropylene surgical thread sutures. In the morning after surgery the patients received isotonic fluids; on the second day salty liquid diet and were discharged on the third day. Semisolid diet started from the 20th day and solid on the 30th, with daily tablet of polivitamins. **Results** - The weight loss was larger on the ring than without ring groups in all periods, respectively 10% and only 5% in the third postoperative year. The proportion of not having reached the 50% excess weight loss expectative was significantly higher in the group without ring than in the group with the ring (31% and 8% respectively in the fourth year). There was no difference between groups in delayed recovery of weight lost with the operation. **Conclusions** - The results were favorable to use the ring exclusively when it is analyzed only the weight loss.

RESUMO - Racional - A utilização de anel nas derivações gástricas em Y-de-Roux ainda é motivo de polêmica entre os cirurgiões bariátricos. Não há consenso quanto às suas repercussões em relação à perda ponderal e à manutenção do peso em longo prazo. **Objetivo** - Avaliar a influência do anel sobre a evolução do peso corporal no decorrer de quatro anos após operação bariátrica. **Método** - Foram analisadas retrospectivamente 143 mulheres submetidas à derivação gástrica em Y-de-Roux videolaparoscópica pareadas pela utilização ou não do anel de Silastic®. O tempo de seguimento foi de até 48 meses. Os critérios de inclusão foram idade superior a 18 anos, operação bariátrica primária e frequência regular à clínica no período de interesse para a pesquisa. A técnica manteve reservatório gástrico de pequena curvatura, volume estimado em 30 ml. A alça alimentar media 150 cm e a biliar 40 cm a partir do ângulo duodenojejunal. O grupo “com anel” utilizou anel tubular de Silastic® com comprimento de 6,5 cm, colocado à 2 cm da anastomose gastrojejunal. O anel era fechado por cinco nós com fio de polipropileno em seu interior. Na manhã seguinte ao procedimento cirúrgico as pacientes recebiam líquidos isotônicos; no segundo dia dieta líquida salgada sem resíduos e alta hospitalar no terceiro dia. Dieta pastosa iniciava a partir do 20o dia e sólida no 30o, juntamente com uma drágea diária de polivitamínico. **Resultados** - O emagrecimento do grupo com anel foi maior que o sem anel em todos os períodos analisados a nível de 10% e de 5% apenas no 3o ano pós-operatório. A proporção das operadas que não atingiram perda do excesso de peso de 50% foi significativamente maior no grupo sem anel que no grupo com anel (31% entre as sem anel e 8% das com anel no 4o ano). Não houve diferença entre os grupos na recuperação tardia do peso perdido na operação. **Conclusões** - Os resultados foram favoráveis à utilização do anel ao se analisar exclusivamente a perda de peso.

INTRODUCTION

The ring use in Roux-en-Y gastric bypass (DGYR) is still a matter of controversy among bariatric surgeons. Considered the “gold standard” of operations to control body weight⁵ in morbidly obese, DGYR includes the optional use of a prosthesis in the terminal portion of the gastric remnant - the containment ring or gastric banding. However, there is still no consensus about the impact caused by this increase in gastric restriction in relation to weight loss and weight maintenance in the long term.

The use of constricting the gastric pouch began with Linner & Drew in 1985^{9,17}, who employed an element of restraint to prevent possible expansion of gastroenterostomy. Subsequently, Fobi¹¹ and Capella⁶ proposed changes in DGYR including synthetic materials in the distal end of the gastric pouch to restrict emptying.

Placing the ring upstream of the gastrojejunal anastomosis is considered effective and sustainable alternative to enhance weight loss in morbidly obese patients, although intermediate and late results are still relatively scarce in the literature^{21,22}.

After bariatric operations weight reduction is clearly visible, with consequent improvement of comorbidities and quality of life. However, the individual may recover partially or even totally the lost of weight if changes his lifestyle and dietary practices regarding physical activity do not occur¹². Some studies have indicated an uncomfortable weight gain in the late postoperative period^{7,18}, especially between the 3rd and 5th postoperative year. Failure to use the containment ring may be related to a larger later increase in weight compared to patients who do not have this prosthesis¹³. Weight gain after surgery should be targeted for study and monitoring, with the aim of preserving the benefits obtained.

Whereas there are few studies evaluating the limiting factor of the ring or if it significantly interferes with the maintenance of weigh loss, this study is justified. The objective was to evaluate the influence of the ring on the evolution of body weight over four years after bariatric surgery.

METHOD

The study involved 143 women attended in Bariatric Clinic® - Hospital Fornecedor de Cana, Piracicaba, SP, Brazil, accredited by Surgical Review Corporation TM. These women were classified as to have the presence (ring: n = 75) or absence (no ring: n = 68) of the restriction ring, with the follow-up time of 12, 24, 36 and 48 months. It is one retrospective study of the medical records from 1999 to 2005. For inclusion in the study were used the following criteria: age over 18 years, primary bariatric surgery and regular attendance at the clinic during the period of interest for research, women who agreed to participate in the study after signing the informed consent. The study was approved by the Research Ethics Committee of the Paulista State University, School of Pharmaceutical Sciences of Araraquara under number 16/2006. In Table 1 it can be seen that the weight and age of the study participants were similar in both groups.

The technique used was laparoscopic DGYR, gastric reservoir with small curvature and estimated volume of 30ml and manual gastrojejunal anastomosis in two planes with dimensions between 1.5 and 2.0 cm. The food limb had 150 cm and bile limb 40 cm from the Treitz angle. The average time of surgery was 130 minutes, ranging from 250 to 90 minutes of the first in relation to the latest. The drainage of cavity was done with tubulolaminar vacuum drain routinely. The group “ring” used annulus of Silastic®, length of 6.5 cm, placed at a distance of two inches from gastrojejunal anastomosis. The ring was

TABLE 1 -Age and weight preoperatively according to the type of operation and follow-up time

		No ring				With ring				p*	
		n	P25	P50	P75	n	P25	P50	P75		
Age (Years)	12 m	68	29	34	42	12 m	75	30	38	43	0,167
	24 m	61	29	34	42	24 m	75	30	38	43	0,122
	36 m	56	29	34	42	36 m	75	30	38	44	0,081
	48 m	52	29	34	41	48 m	49	29	40	45	0,141
Overweight (%)	12 m	68	74	88	101	12 m	75	76	84	102	0,891
	24 m	61	76	90	101	24 m	75	76	84	102	0,577
	36 m	56	77	89	101	36 m	75	75	83	104	0,638
	48 m	52	76	88	100	48 m	49	76	81	105	0,968
Weight (kg)	12 m	68	103	113	125	12 m	75	104	112	125	0,932
	24 m	61	105	114	125	24 m	75	104	112	125	0,619
	36 m	56	105	113	125	36 m	75	104	112	124	0,800
	48 m	52	104	113	125	48 m	49	105	113	127	0,750

* Mann-Whitney test for independent samples, P = percentile in the distribution curve in the population, where: P25 = first quartile (25%), P50 = median, P75 = third quartile(75%). m = months after surgery. Excess weight was calculated from the Metropolitan Height and Weight tables, 1983

closed by polypropylene five sutures. The morning after surgery the patients received water, coconut water and isotonic solutions and, on the second day, liquid diet without salt; discharge was on the third postoperative day. Soft diet was started from the 20th day after surgery and solid on the 30th day, along with daily single tablet of multivitamin.

Data were obtained from electronic medical records in the computerized system of the surgery center, collecting data related to body weight preoperatively and at 12 months after surgery.

With women grouped according to the type of surgery and the time of follow-up, were analyzed loss of excess weight and the recovery of excess weight relative to the lowest weight attained after surgery. The amount of weight excess was obtained from the weight difference between the preoperative and the ideal weight, according to international standards(19). Women who remained in the study until 48 months were evaluated in paired manner.

Data analysis

Data were tabulated, with absolute weight and transformed into relative values expressed as median percentages. Comparisons between the medians were performed using the Mann-Whitney, after finding the characteristics nonparametric data. Comparisons between more than two groups of data were made by Friedman test. The proportions between dichotomous categorical variables were tested by Fisher's exact test. The level of significance was set at 5%. Analyses were performed using the computer program BioEstat 3 ®.

RESULTS

The slimming on "ring" group could be considered higher than in the group "no ring" for all periods (12 m = 74% x 72%; 24 m = 79% x 76%; 36 m = 76% x 72% and 48 m = 76% x 71%) if adopted significance level of 10%; was significant in the third postoperative year at 5% (Table 2).

When assessing the number of patients whose loss of overweight was less than 50%, it was found that the proportion of not reaching this weight loss per period was significantly higher in the group "no ring" than in the group "ring" to 48 months (12 m = 25,9% x 2,7%; 24 m = 23,4% x 2,7%; 36 m = 28,8% x 5,3% and 48 m = 30,9% x 8,2%) (Table 3).

TABLE 2 - Excess weight loss without and with ring

	Without ring					With ring					p*
	n	P25	P50	P75		n	P25	P50	P75		
Excess weight loss	12 m	68	55%	72%	82%	12 m	75	65%	74%	86%	0,102
	24 m	61	55%	76%	88%	24 m	75	68%	79%	92%	0,062
	36 m	56	51%	72%	82%	36 m	75	65%	76%	88%	0,026
	48 m	52	49%	71%	80%	48 m	49	62%	76%	86%	0,060

Mann - Whitney test for independent samples. m = Months after surgery. P = percentile in the distribution curve in the population, where: P25 = first quartile (25%), P50 = median, P75 = third quartile (75%).

TABLE 3 - Loss of excess weight frequency less than 50% in the groups "no ring" and "ring"

	Without ring Weight loss < 50% from excess		With ring Weight loss < 50% from excess		p*
	n	%	n	%	
12 months	14	25,9	2	2,7	0,001
24 months	15	23,4	2	2,7	0,001
36 months	17	28,8	4	5,3	0,001
48 months	17	30,9	4	8,2	0,006

* Fisher's exact test

Figure 1 shows the paired analysis of women's groups "ring" and "no ring" followed by four years. It was found that both groups showed excess weight loss > 50% maintained until the fourth year after surgery. The curve of loss of excess weight in both surgical procedures shown marked on the first postoperative year, with stabilization after the second year. The curves remain constant distance between them. Even excluding the women followed for less than 48 months, the differences in the percentage of excess weight loss between the groups "ring" and "no ring" in the second and third year postoperatively were maintained.

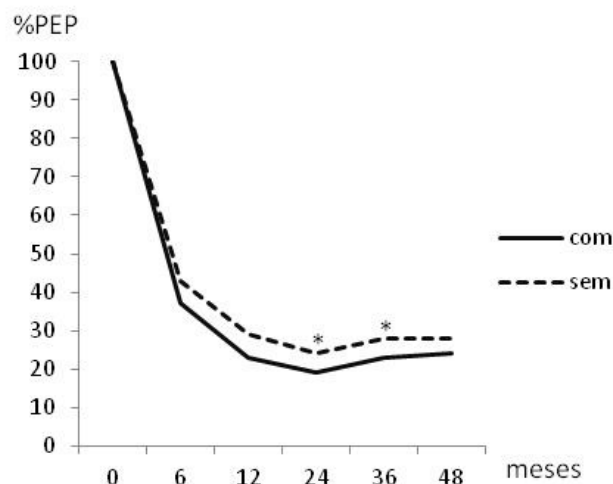


FIGURE 1 - Evolution of median loss of excess weight depending on the type of operation, with ring (n = 49) and without ring (n = 38). Excess weight was calculated from the Metropolitan Height and Weight tables, 1983. $p < 0.05$ in the Friedman test, which confirmed the difference of the times 0 and 6 m in relationship to for subsequent ones. * = $p < 0.05$ by Mann-Whitney test comparing with and without ring

TABLE 4 - Excess amount of weight regained in groups "ring" and "no ring"

	Without ring					With ring					p*
	n	P25	P50	P75	n	P25	P50	P75			
Recovery of weight excess (in relation to the lowest one)	12 m	68	0,0%	0,0%	0,0%	12 m	75	0,0%	0,0%	0,0%	1,000
	24 m	61	0,0%	0,0%	0,4%	24 m	75	0,0%	0,0%	0,0%	0,341
	36 m	56	0,0%	3,1%	7,9%	36 m	75	0,0%	0,8%	7,6%	0,543
	48 m	52	0,3%	8,4%	11,9%	48 m	49	0,0%	6,5%	11,0%	0,541

* Mann-Whitney test for independent samples. m = months after surgery. Excess weight was calculated from the Metropolitan Height and Weight tables, 1983. P = percentile in the distribution curve in the population, where: P25 = first quartile (25%), P50 = median, P75 = third quartile (75%).

The delayed weight recovery began after 24 months postoperatively in both groups and progressively increased (Table 4). There was no difference between groups "ring" and "no ring" in the amount of excess weight that was recovered at the different times. The median recovery were 6.5% and 8.4% overweight, respectively to the groups "ring" and "no ring" after four years from surgery. There was no difference between groups in the proportion of women who recover weight over time.

After the 4th year of DGYR in both groups, over 30% of patients had weight regain above 10% of weight excess. Around 10% of them, the recovery was greater than 20% of weight excess presented before surgery and lost up to 24 months (Table 5).

TABLE 5 - Frequency and ratio of weight recovered in groups "ring" and "no ring"

	Without ring - Weight recovery > 10%		With ring - Weight recovery > 10%		p*
	n	%	n	%	
24 months	01	01,6	04	05,3	0,379
36 months	11	19,6	12	16,0	0,341
48 months	23	44,2	15	30,6	0,217
	Weight recovery > 20%		Weight recovery > 20%		
36 months	02	03,6	04	05,3	0,700
48 months	05	09,6	05	10,2	1,000

* Fisher's exact test. At 24 months, one woman without ring group recovered more than 20% of body weight.

73,3 x 57,7). Likewise, the percentage of excess weight loss was always higher in the group with the ring, although significant at the 5% level after only in three years. Awad et al.², after studying 244 patients undergoing DGYR, found loss of the excess weight of 81% and 80.5% after 24 and 36 months respectively, both statistically significant compared with the group without ring with loss of 69.6% and 63.9%. Arceo-Olaiz et al.¹ in a controlled study with 60 patients, found no differences by 24 months.

Some limitations of this study, such as the fact that it is retrospective, nonrandomized, and with a convenience sample of moderate size, limits its conclusions. It must be also considered that losing weight is not the only criterion for measuring success or outcome in bariatric surgery. The authors chose not to include in this study the impact of comorbidities on the evolution, nor on the quality of life or intolerance in each food group, nor about the complications related to the use of the ring. These aspects will be the objective of future randomized trial. The focus of this paper was to verify the isolated action on body mass, which still sets itself up as a point of doubt in the current literature and may be a guide for the sample size calculation in prospective studies.

Very striking are the findings of the failures on group without ring, by considering as criteria of success a percentage loss of excess weight greater than 50%, acceptable among many investigators^{4,15}. Nearly a third of the group without ring can be classified as failure according to this criterion. In the ring group only 8.2% did not reach the minimum for success after four years.

In relation to weight regain, there was no difference between the groups with and without ring. This recovery begins in the second year of surgery and progresses in terms of recovered weight ratio (Table 4) and prevalence (Table 5).

Among the techniques of DGYR variations exist, including the length and format of the new gastric pouch, and various sizes of gastrojejunal anastomoses with or without ring or not adjustable containment band. All these variations may influence the final results, which leads us to the hypothesis that the restrictive component is significantly influential. Virtually all patients have weight regain after lowering the restriction caused by the removal of the ring due to complications¹⁰. Gastric bypasses whose

DISCUSSION

The results of this retrospective study suggest that the placement of the containment ring in gastric DGYR shows superiority in weight loss, but did not differ from the technique without ring in the stability of the weight lost during the time. The curves of changes in the percentage loss of excess weight (Figure 1) are clear by showing the upper positioning of ring group, although not statistically significant at the 5% level at all times. This is not a definitive conclusion about the advantages of using the ring, but provides evidence that, solely for the purpose of "weight loss" the higher restriction may be the most effective way.

Bessler³ in a randomized double-blind study with 90 superobese undergoing DGYR, with or without polypropylene band of 5.5 cm, obtained results of excess weight loss similar to this study in 12, 24 and 36 months with and without ring (12 m = 64% x 57,7%; 24 m = 64,2 x 57,7% e 36 m =

reservoirs are large, with little restriction, weight loss can lead to a modest capacity and high intake of solid food²⁰, although it occurs decreased expression of ghrelin in the stomach. Likewise, gastrojejunal anastomoses too large may not generate satiety, although theoretically promote a greater release of glucagon-like peptide-1 (GLP-1) by the arrival of fast food into the small intestine.

The proof of the almost immediate and significant reduction of serum ghrelin after DGYR¹⁴ stimulated further questioning about the real need to use containment rings, since the mere fact of excluding most of the gastric fundus was enough to reduce hunger and provide weight loss. The DGYR promotes hormonal condition most favorable providing an environment for the intrinsic loss and maintenance of weight. But this mechanism appears to be outweighed by the power of mechanical restriction. If the restriction is small, can increase the chance of surgical failure, even in the presence of hormonal changes. If the restriction is excessive, it can cause complications. The DGYR even without ring presents significant degree of restriction of food intake. This retrospective study suggests that a bit more restricted, if it is medically acceptable without causing complications in high rates, may be beneficial to achieve greater than 50% loss of excess weight.

Several studies have shown that the use of ring in DGYR presents complications such as stenoses, erosions and intolerances within limits considered acceptable. Although the size of the ring is not consensus, the length between 6.0 to 7.0 cm is associated with a lower incidence of these complications while maintaining its restrictor function⁸. The evolution up to this measure followed shorter lengths attempts since 5.0 cm with prohibitive incidence of vomiting. Capella and others used polypropylene or Marlex[®] not adjustable band instead of Silastic[®] ring, with reports of good results^{3,6}.

The weight recovery can occur for physiological adaptation processes that happen in the gastrointestinal tract over time. Adoption of healthy lifestyle instead old habits that contributed to the condition of obesity must be considered by patients. This new behavior is crucial for long-term maintenance of weight, since obesity is a chronic, progressive disease that has no cure and requires specialized treatment even after surgery.

The doctor-patient relationship is an important element when discussing the use of the ring. Nowadays, the authors consider reasonable to suggest that the team's experience and cultural factors are considered when deciding on the placement of the prosthesis or not, until more scientific evidence exist to define this issue.

CONCLUSIONS

Patients undergoing DGYR with the containment ring had gastric weight loss greater, statistically significant only at 36 months after surgery, and a higher proportion of surgical success (excess weight loss > 50%) in this period. The weight regain was not different between groups. Given the limitations of the study, the findings should be interpreted as calling for the use of the ring when considering only weight loss, but also as initial evidence for randomized trials with larger numbers of patients and variables, including assessments to quality of life.

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