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A Case-Controlled Matched-Pair Cohort Study of Laparoscopic Roux-en-Y Gastric Bypass and Lap-Band® Patients in a Single US Center with Three-Year Follow-up

Daniel R. Cottam, MD; James Atkinson, MD; Aaron Anderson; Brian Grace, PAC; Barry Fisher, MD

Surgical Weight Control Center, Las Vegas, NV, USA

Background: Open or laparoscopic Roux-en-Y gastric bypass (RYGBP) is the most common operation for treatment of morbid obesity in USA. The laparoscopic adjustable gastric band (LAGB) has been the most common bariatric operation performed worldwide. The Lap-Band® was approved for use in USA in July 2001. Since then, several US surgeons have adopted one procedure preferentially over the other, and several have reported patient outcomes. We added the option of the LAGB to the RYGBP in our practice in July 2001. We hypothesized that both procedures will provide similar weight loss and co-morbidity reduction if followed for a sufficient length of time. To enhance weight loss, we adopted a patient behavioral program that is easy to remember, in an attempt to ensure a reduction in caloric intake and reduce hunger regardless of the operation performed.

Methods: A case-controlled matched-pair cohort study was conducted. All patients who presented to the Surgical Weight Control Center of Las Vegas between Aug 2001 and Aug 2004 for LAGB were placed into one group, and a matched-pair RYGBP cohort group was created. Patients in the RYGBP cohort were matched for age, sex, date of surgery, and BMI. All patients were evaluated on an intention to treat basis. Data were collected prospectively and analyzed retrospectively. All patients were subjected to the same preoperative education regarding calorie reduction behaviors and diet change, and received the same postoperative counseling regarding long-term eating behavior and food choices.

Results: During this period, 208 patients underwent LAGB and 600 underwent RYGBP. Of the 208 LAGB patients, 181 had suitable open or laparoscopic RYGBP matches. The two groups were similar in terms of age, sex, BMI, and co-morbidities. There were no deaths in either group. Resolution of co-morbidities statistically favored RYGBP as did the weight loss, over the study period.

Conclusion: When patients are matched with 3-year follow-up according to time of surgery, age, sex and BMI, LRYGBP provides superior weight and co-morbidity reduction and can be done without severe complications. However, the LAGB is an effective weight loss tool and not every patient wishes to have the LRYGBP.

Key words: Morbid obesity, gastric banding, gastric bypass, laparoscopy

Reprint requests to: Daniel R. Cottam MD, 3802 Meadows Lane, Las Vegas, NV 89102, USA. Fax: 702-221-8446; e-mail: danamycottam@yahoo.com

Introduction

The increase of bariatric surgery around the world has led to a debate regarding which bariatric procedure is more advantageous and safer for patients.[1] Proponents of each operation vigorously defend their respective positions. To date, there have been no randomized studies which have attempted to compare different operations being performed concurrently in the same practice. Most surgeons who compare one procedure to another have performed different procedures sequentially rather than concurrently. This debate results from deeply held convictions of surgeons as well as patients' deeply held convictions. These convictions have essentially eliminated the opportunity to perform truly randomized non-biased studies.

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An increasing number of centers in the USA are beginning to offer patients a choice between several operative procedures, provide patients impartial information regarding the different methods of achieving weight loss, and allow patients to decide which option is right for them.[2] One recent retrospective paper from a highly academic private practice has highlighted this practice; that paper reported that dedicated American bariatric centers can achieve excellent outcomes using any operation that they choose to perform.[3] The paper reported significant differences in weight loss between laparoscopic adjustable gastric banding (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGBP). Yet, questions remain, because reports have made no effort to compare populations receiving different operations who had similar weight and co-morbidities and what effects, if any, those differences in starting weight and co-morbidities might have on eventual weight loss. Additionally, few reports have stressed the nature and importance of the patient teaching program on outcomes of surgery.

In order to answer some of these questions, we matched 181 LAGB patients with 181 LRYGBP patients in terms of weight and time since surgery. Whenever possible, we matched patients according to age, sex and co-morbid conditions as well. These patients were followed prospectively, and their results over the subsequent 3-year period were analyzed in order to ascertain changes in co-morbid conditions and weight.

Methods

All data were retrospectively drawn from our prospectively kept database (Remedy MD, Salt Lake City, UT) and patient charts. Our first 208 LAGB (Lap-Band®, Inamed, Santa Barbara, CA), all using the pars flaccida technique, were entered into the study. Each LAGB patient was matched to an open RYGBP (ORYGBP) or a laparoscopic (LRYGBP) patient according to time of surgery ± 2 weeks and BMI ± 2. ORYGBP and LRYGBP procedures varied only by the incision employed. If there was more than one possible match for a LAGB patient then patients were matched (in order of importance) according to age, sex, and co-morbid conditions. If there were no possible matches for a LAGB patient, that patient was removed from the study.

All patients entered into the study had their weight and co-morbid conditions followed over a 3-year period from Oct 2001 to Apr 2005. Follow-up was scheduled in our office at 3, 6, 9, 12, 18, 24 and 36 month intervals. Laboratory analysis was performed at 3, 6, 12, 18, 24, and 36 months. Weight was recorded at each time-point, and EWL and BMI were calculated and recorded based on the Metropolitan Life insurance tables with the midpoint of the medium frame being used as ideal body weight.[4]

We chose to follow several co-morbid conditions through time that were easily identifiable and whose resolution was easily verifiable: type 2 diabetes, insulin resistance, hypertension, elevated cholesterol, and elevated triglycerides. Each of these co-morbidities was graded as improved, resolved, worse, unchanged or unknown. All laboratory results which normalized were graded as *resolved*. A 20% improvement in a pathologic laboratory value was graded as *improved* if the resultant value was not within the normal range. If the change in values was <20%, it was listed as *unresolved*. A few patients were completely lost to follow-up and were listed as *unknown*. Since hypertension can vary greatly, we did not have an improved category; all patients were either resolved, unresolved or unknown.

Both LAGB and RYGBP patients were exposed to the same preoperative education regarding calorie reduction behaviors and diet change, and received the same postoperative counseling regarding long-term eating behaviors, food choices, and exercise (Table 1). For postoperative reoperation rate, we chose to include both diagnostic gastroscopy (EGD) as well as EGD-with-dilation, because both these procedures require a return to the operating or endoscopic suite and an anesthetic. Additionally, we chose to include port-site breakage and well as port revisions, because these also include a return to the operating-room. We did not include EGDs or port problems in the category of major operations.

Statistical analysis was performed with Sigma Stat Software. Mann-Whitney Rank Sum test was used to compare the preoperative groups wherever the groups were not normally distributed, and *t*-tests were used to compare data between normally distributed groups. Z-tests were used to compare percentages between groups. ANOVA was used to compare

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Table 1. Educational guidelines for both gastric band and gastric bypass

1. **Three meals per day**
   a. Neither two nor five, no snacking
2. **Four ounces of solids by weight per meal**
   a. Always weigh every meal
3. **Solid Foods are better choices than Soft foods**
   a. Natural foods are better than prepared foods
   b. Start every meal with protein
   c. Avoid white carbohydrates
   d. High protein, low fat, very low carbohydrate meals
4. **No carbonated beverages**
5. **Take at least 30 minutes to eat**
   a. Chew very well to avoid food getting stuck
6. **Do not do anything else while eating**
   a. Avoid distractions
   b. Make every bite a conscious choice
7. **Do not drink and eat at the same time; do not drink for 30 minutes before eating or 45 minutes after eating**
   a. Drink at least 32 ounces of calorie-free liquid every day between meals
8. **You are in control of your weight**
   a. Choose wisely, the space is limited
9. **Renew your commitment every day**

weight change over time within the matched cohorts.

The patient training program began with an introductory seminar in which the importance of a fundamental and permanent change in diet was stressed. Patients were then given a set of diet behavior instructions (Table 1) before surgery, made up of 9 sentences, and viewed an explanatory video regarding these instructions following surgery. These behavioral rules were frequently reviewed in support groups and at office visits. Exercise along with a change in diet was also stressed.

Results

Of the first 208 LAGB patients entered into the study, 181 found suitable LRYGBP or ORYGBP matches. Of these patients, 41 pairs had 3-year or greater follow-up. There were no significant differences in weight, age and co-morbid conditions (Table 2 and 3) in the two patient cohorts studied. At 3 years, 85% of the 41 LAGB patients were available for follow-up while 65% of the 41 ORYGBP and LRYGBP patients were available for follow-up. Follow-up at all other time-points conformed to the ASBS standards for reporting results.[5]

Table 2. Characteristics of the matched-pair cohort groups

	LAGB		LRYGBP		
	Mean	Median	Mean	Median	***P*-value**
BMI (kg/m^2)	47.2±	46	47.2±	46	0.8
Weight (kg)	292±47	279	286±49	284	0.17
Age (years)	42±13	44	43±10	41	0.4
Males	20%		11%		0.026

Table 3. Co-morbidity characteristics of the matched-pair groups

	LAGB	LRYGBP	*P*-value
Type 2 diabetes	44	48	NS
Hypertension	66	71	NS
Insulin resistance	50	51	NS
Hypercholesterolemia	88	87	NS
Hypertriglyceridemia	71	66	NS

Weight loss at all but the first time-point showed significant differences between LRYGBP and LAGB patients (Table 4 and Figure 1). There was a significant difference observed in resolution of co-morbidities (Table 5). There were no deaths in either group. There were no statistically significant differences in the rate of major or minor reoperations in either group ($P>0.05$, Table 6).

During the first year of our experience with LAGB, we performed 41 Lap-Band® procedures, and 22 of these were returned to the operating-room (53%) to

Table 4. Mean excess weight loss outcomes in the matched-pair cohort

	LAGB		LRYGBP		
Months	Mean	Median	Mean	Median	***P*-value**
1	16.6 ± 5	17	17.7 ± 7	17	0.587
3	26.2 ± 8	27	33.8 ± 9	35	<0.001
6	36.8 ± 15	35	56.9 ± 13	59	<0.001
9	44 ± 22	43	68 ± 13	70	<0.001
12	48 ± 19	47	76 ± 16	77	<0.001
18	51 ± 21	51	83 ± 16	84	<0.001
24	55 ± 23	59	80 ± 21	80	<0.001
36	51 ± 23	49	74 ± 25	80	<0.001

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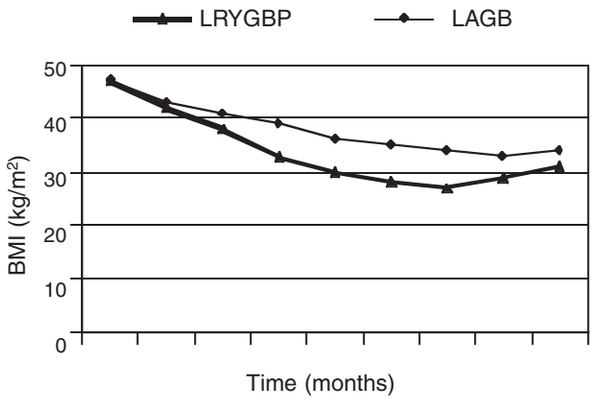

Figure 1. Changes in body mass index through time in the matched-pair cohort.

treat some problem during their 3-year follow-up. Only 19 of the 103 patients operated upon during our second year (18%) needed to return to the operating-room. The reoperation rate dropped to zero for the remaining 37 patients who underwent LAGB in the third year of this study and who have 1-year follow-up.

In the LRYGBP group, there were 7 reoperations in the first year for a rate of 17%. There were 20 reoperations in the second year for a rate of 19%, and 9 reoperation in the third year for a rate of 24%.

The major and minor reoperation rate between the two groups was not statistically different ($P>0.4$). There was no statistical difference between the first, second or third year reoperation rate for the LRYGBP group either ($P>0.5$). However, the observed reduction in the rate of reoperations in the LAGB group over time was statistically significant ($P<0.001$, Table 7).

Discussion

The observed mortality rate of zero in this cohort is consistent with the balance of our practice, because there have been no deaths within 30 days of surgery in our over 750 LRYGB and 280 LAGB patients and only two in our 800 ORYGBP cases (0.25%). Likewise, the absence of observed leaks following LRYGBP is in line with other authors who employ the circular stapler method, and has been achieved without fibrin glue or staple-line reinforcement.[6] There has been only one leak in our 750 primary LRYGBP patients, but that patient was not matched in this cohort. Our rate of stenosis requiring EGD dilatation (7%) compares favorably with other recent series reporting occurrence rates up to 15% using the circular stapler, and is similar to that reported in series

Table 5. Co-morbidity resolution between matched-pair cohort groups

		LAGB	LRYGBP	*P*-value	Power
Type 2 diabetes	Resolved	50%	78%	0.010	0.742
Total LRYGBP 48	Improved	34%	20%	NS	0.208
LAGB 44	No change	6.8%	0		
	Unknown	9%	2%		
Insulin resistance	Resolved	56%	94%	<0.001	0.993
Total LRYGBP 51	Improved	24%	0		
LAGB 50	No change	6%	0		
	Unknown	14%	6%		
Hypercholesterolemia	Resolved	40%	61%	0.009	0.752
Total LRYGBP 87	Improved	23%	15%	NS	NS
LAGB 88	No change	34%	10%	<0.001	.363
	Unknown	3%	14%		
Hypertryglyceridemia	Resolved	46%	81%	<0.001	.998
Total LRYGBP 66	Improved	25%	13%	NS	.251
LAGB 71	No change	25%	7%	0.008	.761
	Unknown	4%	0		
Hypertension	Resolved	56%	81%	0.003	.852
Total LRYGBP 71	Current	27%	18%	NS	
LAGB 66	Unknown	17%	1%		

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Table 6. Reasons for reoperation between the two groups

LAGB		
Minor Surgery		
EGD	11	6%
Port revision	6	3%
Port Replacement	11	6%
Total	**28**	**15%**
Major Surgery		
Band Removal	2	1%
Prolapse	11	6%
Hiatal Hernia Repair	2	1%
Total	**15**	**8%**
LRYGBP		
Minor Surgery		
EGD	11	6%
EGD with Dilation	14	7%
Total	**25**	**13%**
Major Surgery		
Obstruction	2	1%
Internal Hernia	1	.6%
Revision of JJ anastomosis	2	1%
Ventral Hernia	5	2.7%
Total	**10**	**5.3%**

using both the linear stapler, and hand-sewn anastomotic techniques.[2,3,7,8] We perform our own EGDs, and are unlikely to miss stenosis in our practice.

Although our weight loss data differs from that reported by most US authors, our LAGB weight loss results do not approach worldwide reports of >60% EWL at 3 to 5 years. We suspect that this observed difference in %EWL results from the difference in baseline preoperative eating habits and diet composition found in many European countries compared to that encountered in the USA. There is a greater dependence on fast foods, high fat, high carbohydrate foods and substantially larger portion size per serving in the US diet, compared with that commonly found in most European countries. Yet, weight loss resulting from both the LAGB and the RYGBP in our practice meets or exceeds other published US reports. The observed weight loss of our RYGBP cohort is similar to that reported by proponents of the duodenal switch,[9] biliopancreatic diversion, and Fobi pouch operations.[10] This weight loss was achieved without employing long Roux limbs, silastic rings, or malabsorption procedures (we construct Roux limbs of 100 cm for BMI <50 and 150 cm for BMI >50).

Table 7. Annual rate of reoperations

Year	LAGB	LRYGBP
1	53%	17%
2	19%	19%
3	0	18%
P-value	<0.001	NS

Historically, throughout the 1970s and 1980s, bariatric surgical research was aimed at finding the operation that would provide the best weight loss for the most people with the fewest complications, failures, and reoperations. In the 1990s, it became apparent that each operation had limitations, but the weight loss results could best be improved by means of an organized program of patient education, support and behavior modification.

We believe that the difference in observed weight loss compared to that reported by others is the result of our pre- and postoperative patient education program, whose goals are simplicity, free food choice, and patient empowerment. By making the program easy to remember (9 sentences) and combining this with clear education to guide patient food choices, patients becomes more responsible for their choices and resultant weight loss. The three principles of permanent diet change to reduce caloric intake include taking advantage of the *three hunger spikes* per day invoked by increased ghrelin.[11] By eating only when ghrelin spikes occur, we attempt to reduce hunger and snacking between meals. *Portion control*, the second principle, addresses one of the main causes of obesity in the USA. The final principle is *improved food choices*, including beginning each meal with a protein source, and avoiding insulin stimulation and the concomitant hunger provoked by elevated insulin levels by avoiding starches and simple sugars. Patients exposed to this program before surgery to achieve preoperative weight loss often report no hunger despite successful weight loss.

To avoid intake of non-nutritious calories, only calorie-free liquids are advocated. This total program is taught as a change in diet rather than "dieting". Actual recipes, and meal plans are avoided to allow patients free choices to control their weight. Office visits, on-line email lists, and support groups

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continue to reiterate the role of these principles in achieving and maintaining weight loss.

The final element that may have a significant psychological influence on our patients is the fact that they select their surgical procedure. By allowing patients to choose both their procedure of choice, and their menu as well, they are encouraged to take full credit for the eventual outcome, and thereby become empowered where they had previously felt powerless and controlled by others who established the "correct" diet plan, controlling their weight. The nutritional and psychological construct of our program appears to have been more successful than most others, and is equally successful independent of the bariatric operation performed.

Our initial LAGB reoperation experience matches the data of many published authors.[12] The high reoperative rate in the first year of our LAGB series is not unlike that of other authors where reoperative rates in the first 100 patients approached 25 to 30%. In contrast to other series, which did not include EGDs when reporting reoperations, we included EGD because it involves an anesthetic (Deep IV Sedation), and adds cost and risk. This is important information for insurers and surgeon when obtaining informed consent and when trying to calculate the cost of an operation to the patient or the insurer. However, we do not consider EGDs or port complications to be life-threatening; therefore, they were all classified as minor reoperations. Currently, the major reoperation rate for LAGB procedures in our practice approaches that reported by other surgeons worldwide (2 to 4%). The annual rate of reoperations reached zero in the last year of this study. (Table 7). This contrasts with our annual reoperation rate after RYGBP, which remained statistically unchanged from year to year. This is primarily due to the endoscopies performed in the RYGBP group. The dramatic decline in reoperations following LAGB likely resulted from the redesigned LAGB access-port introduced in 2002 by the manufacturer, our increasing experience securing the access-port to the fascia, and our ability to eliminate endoscopy in LAGB patients except when symptoms suggest erosion or gastroesophageal reflux.

None of the LAGB reoperative procedures were performed to treat urgent life-threatening conditions, and all were managed on a semi-elective laparoscopic basis. This contrasted with major reoperations in our LRYGBP patients, in whom reoperation occurred to treat jejuno-jejunostomy obstruction, staple-line and marginal ulcer bleeding, internal hernia with bowel infarction, staple-line leak with gastrocutaneous fistula, and an incarcerated port-site hernia. Two of these patients required ICU admission after surgery, because they were in extremis caused by their primary problem despite emergent surgical intervention. Two required conversion from laparoscopy to laparotomy to successfully correct the observed condition. Another observation concerning reoperation rate in our RYGBP group was that four of the five ventral hernia repairs performed were from the small cohort of 30 ORYGBP patients. The fifth was the result of another abdominal surgery unrelated to the gastric bypass. This 13% ventral hernia rate after ORYGBP is consistent with the literature. Without these hernia repairs, the major reoperative rate for LRYGBP in our series is 2.7%. This is in line with our current practice rates and compares favorably with that of LAGB. Currently, the major reoperative rate in our hands between the LRYGBP and the LAGB does not differ. There were two band removals during the study. One patient had an erosion, and since her band removal she has maintained her weight loss for 8 months, and has undergone several plastic procedures to remove redundant skin. Another patient never followed-up with our office after having the band placed and presumably also never had band adjustments. She then had the band removed 2 years later by another surgeon and was converted to a LRYGBP. We classified this patient as a failure despite the fact that the band never had the opportunity to fail.

One of the striking findings and one of the purposes of this study was to observe the difference in co-morbidity resolution between the two groups. We have never been comfortable with the assertion that co-morbidity resolution resulting from 50% EWL is equal to that from 75% EWL. Indeed, there are many patients whose co-morbid conditions are exquisitely weight sensitive to changes of 5 kg. This may explain the differences in reductions in co-morbidities that we observed when comparing RYGBP to LAGB cohorts. However, these differences may change as band patients lose more weight over time.

Major criticisms of this paper would include the fact that there were more males in the LAGB group. This was unfortunate but we were unable to match the sex of the patient in every instance. Another criticism

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would be our inclusion of what could be classified as minor surgical procedures in our analysis. However, we believe that an honest discussion of both LAGB and LRYGBP includes all returns for invasive medical care. We are confident that both patients and insurers regard these as significant events.

Conclusion

Both LAGB and LRYGBP operations have positive impact on weight loss and patient co-morbidities. However, LRYGBP is significantly better than LAGB at 3 years when looking at only weight loss and co-morbidity reduction. There is no difference in major surgery reoperation rates between these two procedures. However, the minor reoperation rates for LRYGBP remained steady from year to year while they fell annually for LAGB. It would appear that we can expect minor reoperation rates in later years to be less for LAGB than for LRYGBP, while major reoperation should remain similar between the two groups.

A program that encourages patient responsibility and free choice, one that encourages diet change instead of dieting and endows patient empowerment, may result in better weight loss than other techniques of patient support and education. The same general preoperative and postoperative behavioral directions can be successfully employed regardless of the operation performed.

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