Laparoscopic Adjustable Gastric Banding: 1,014 Consecutive Cases

Jaime Ponce, MD, FACS, Steven Paynter, MD, FACS, Richard Fromm, MD, FACS

BACKGROUND: The purpose of this study was to examine 1,014 consecutive laparoscopic adjustable gastric banding (LAGB) procedures with up to 48 months of followup, including evolution and changes in surgical technique, learning curve issues, weight loss outcomes, and complications.

STUDY DESIGN: Between October 2000 and December 2004, 1,014 consecutive patients (81.8% women, mean age 42.3 years, mean body mass index 47.7 ± 8.6 kg/m^2) underwent LAGB operation at our center. Perigastric dissection was used in the first 44 patients; pars flaccida technique was used for the latter 970 patients. Fluoroscopy-guided adjustments were performed and patients received intensive followup.

RESULTS: Excess weight loss at 12, 24, 36, and 48 months was 40.5 ± 17%, 52.9 ± 19.5%, 62 ± 20.9%, and 64.3 ± 19%, respectively, with data available in > 85% of patients who had reached each of the time intervals. Patients with lower preoperative body mass index had higher excess weight loss initially, but this difference was not apparent at 3 and 4 years' followup. At 36 and 48 months, respectively, 73.5% and 75% of patients had > 50% excess weight loss. Perigastric dissection led to 9 of 44 (20.5%) slippages, compared with 14 of 970 (1.4%) with pars flaccida technique. Other complications included 2 erosions (0.2%), 5 tubing breaks (0.5%), 7 access port problems (0.7%), and 14 acute stoma obstructions (1.4%). Eight (0.8%) bands were explanted. No deaths occurred.

CONCLUSIONS: LAGB can achieve effective and safe weight loss. Change from perigastric to pars flaccida technique reduced slippage rate. Preoperative body mass index alone was not found to be a predictor of effective weight loss in the longterm. (J Am Coll Surg 2005;201:529–535. © 2005 by the American College of Surgeons)

Laparoscopic adjustable gastric banding (LAGB) has proved to be a safe and effective bariatric procedure.[1–13] Advantages of LAGB over other bariatric procedures include the ability to adjust the stoma, safe laparoscopic placement, and reversibility. Important changes in the placement technique have improved outcomes and reduced late complications, such as band slippage.[14]

Since its approval by the FDA in June 2001, reports have been published from a number of centers throughout the United States demonstrating successful weight loss with LAGB and an evolving understanding of the importance of appropriate patient management.[8,10,11,15-18]

Competing Interests Declared: Dr Ponce is a consultant for Inamed Health and Ethicon Endo-Surgery.

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From Dalton Surgical Group, PC, and Hamilton Medical Center, Dalton, GA. Correspondence address: Jaime Ponce, MD, FACS, 1504 Broadrick Dr, Dalton, GA 30720.

METHODS

This study includes the first 1,014 consecutive patients who underwent LAGB (LAP-BAND System, Inamed Health) from October 2000 to December 2004 at our institution, with a maximum followup of 48 months. Data are available on 91.8% (812 of 885) of patients with 6 months of followup, 89.9% (668 of 743) of patients at 1 year, 88.5% (240 of 271) of patients at 2 years, 88.3% (68 of 77) of patients at 3 years, and 85.7% (12 of 14) patients at 4 years.

All patients met minimal eligibility criteria for bariatric surgery according to the NIH Consensus Development Panel report of 1991.[19] The first 28 patients were part of a continued access study leading to FDA approval of the LAGB in the United States. Surgical procedures were performed initially by one attending surgeon (JP), with the addition of a second and third attending surgeon (RF and SP) after approximately 100 patients. Data were collected prospectively and reviewed retrospectively.

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Abbreviations and Acronyms

BMI = body mass index
%EWL = percentage of excess weight loss
LAGB = laparoscopic adjustable gastric band
RYGB = Roux-en-Y gastric bypass

Demographics

Mean age of patients at time of operation was 42.3 ± 10.3 years (range 18 to 69 years), 81.8% (n = 829) were women, and 98.5% (n = 999) were Caucasian. Mean preoperative body mass index (BMI) was 47.7 ± 8.6 kg/m^2 (range 35 to 84.4); 32.5% (n = 330) were superobese (BMI ≥ 50 kg/m^2). Complete demographic data are listed in Table 1.

Preoperative patient evaluation and preparation

A "clinical management pathway," which included preoperative assessments by the anesthesiologist, nutritionist, and clinical nurse coordinator, was used at our institution. All patients participated in an extensive preoperative evaluation including history and physical examination, nutritional and psychological evaluation, indicated specialty consultations, and multistage educational and informational programs.

Preparation for operation included providing patients with a detailed explanation of the LAGB procedure, elucidating functional and technical aspects, alternatives, benefits, risks (possible short- and longterm complications), and important behavioral modifications needed to decrease risk of slippage and erosions. Patients were repeatedly reminded of the importance of complying with intensive followup for the procedure to succeed.

Preoperative laboratory tests, including blood chemistry panels, complete blood counts, and upper gastrointestinal series (to detect presence of hiatal hernias for concomitant repair) were obtained.

Table 1. Demographics

N	1,014
Mean age ± SD (y), range	42.3 ± 10.3, 18−69
Gender, female/male (% female)	829/185 (81.8)
Race, Caucasian/African American/ Asian/Hispanic (% Caucasian)	999/13/1/1 (98.5)
Mean preoperative BMI ± SD (kg/m^2), range	47.7 ± 8.6, 35−84.4
Superobese,* n (%)	330 (32.5)

*BMI ≥ 50 kg/m^2.
BMI, body mass index.

Patients were admitted to the hospital on the day of operation and given 40 mg enoxaprin (Lovenox; Aventis Pharmaceuticals, Inc) subcutaneous 2 hours before operation and 2 g cefazolin IV in the operating room before an incision was made.

To prevent vomiting in the immediate postoperative period, all patients received 4 mg ondansetron (Zofran; GlaxoSmithKline) IV before the end of anesthesia, and transcutaneous acupoint electrical stimulation (Relief Band; Abbott Laboratories) was started after completion of cauterization. Within 4 to 6 hours after operation, all patients were ambulatory and given clear liquids. The nutritionist reinstructed all patients to remain on a nonsolid diet for 1 month. Initially, patients were discharged from the hospital the morning after operation, after a contrast swallow study to document the position of the band and ensure stoma patency. After the first 100 patients without any action indicated from the swallow studies, we decided to discontinue them and, in most instances, discharged patients the same day once they were able to tolerate clear liquids and ambulate.

Surgical technique

Perigastric dissection of the lesser curvature was used in the first 44 patients; thereafter, pars flaccida method was performed. The complete laparoscopic technique has been described previously.[15] Figure 1 summarizes our pars flaccida technique:

A. Minimal blunt dissection creating a small opening at the Angle of His, preserving most of the gastrophrenic attachments to preserve stomach stability.
B. Passage of articulating blunt dissector (Karl Storz) behind the esophagus, just anterior to the most posterior aspect of the right crus using virtually no force. Dissector tip is articulated to emerge in the small opening created at the Angle of His.
C. LABG introduced using a trocarless Ponce Gastric Band Introducer (Richard Wolf Medical Instruments).
D. End plug is inserted in the aperture of the retrogastric dissector tip.
E. Band is locked anteriorly; and
F. Gastro-gastric sutures are placed anterior-lateral to create a small virtual pouch. Access port is placed high in the epigastrium fixed to the anterior rectus muscle fascia.

Followup and adjustments

Patients were followed every 2 to 3 months for the first 2 years, then yearly. Adjustments were done with a barium swallow under fluoroscopy, looking for maximal restric-

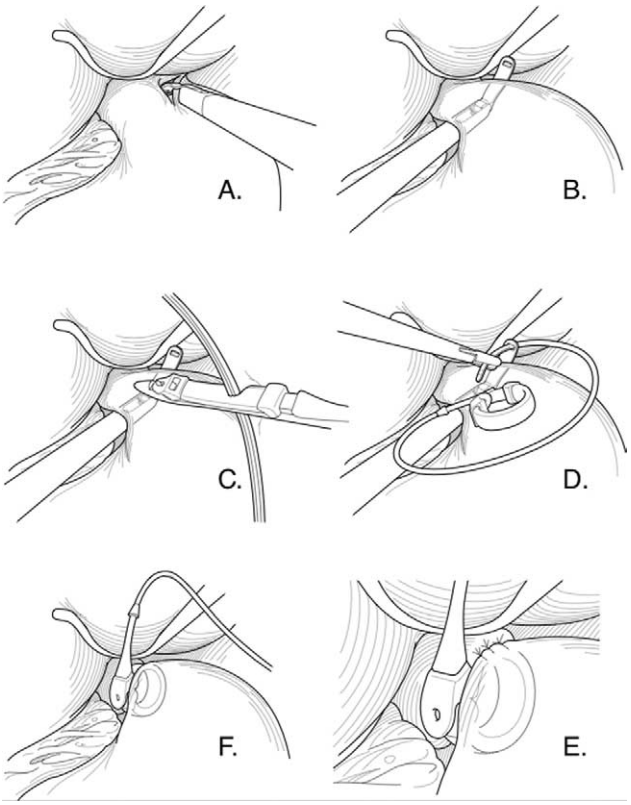

Figure 1. Laparoscopic adjustable gastric banding placement technique.

tion without obstruction and for the patient's ability to swallow without clinical discomfort or regurgitation. Patients were encouraged to attend recommended activities, which included monthly support group meetings with eating workshops and supervised exercise programs.

Weight loss

Followup weights were obtained from postoperative visits to our clinic or, in the few instances of patient unavailability for followup, from physicians' office scales, telephone interviews, or email questionnaires. This method was used with the intention of achieving better followup rate. Weight loss was expressed in terms of change in BMI (kg/m^2) or percentage of excess weight loss (%EWL). Ideal body weight was determined according to the Metropolitan Life Insurance Co. 1983 height/weight tables.[20]

Statistical analysis

Summary statistics, including mean, standard deviation, median, and range, were calculated for all numeric variables. Analyses of categorical variables were performed by chi-square statistic or by Fisher's exact test. In the case of classification variables with two levels, comparison of continuous end points was performed with independent group *t*-tests; in the case of classification variables with more than two levels, comparison of continuous end points was performed by ANOVA.

RESULTS

Surgical outcomes and complications

All bands were placed laparoscopically, with the exception of one patient who had a large fatty hepatomegaly. There were no perioperative deaths. Median hospital stay after operation was 0.3 days (range 0.2 to 5). Overall mean operating time for cases not involving a concomitant procedure was 47.1 $\pm$ 20 minutes (range 26 to 128). Associated procedures included hiatal hernia crural repair in 34 patients and cholecystectomy in 12 patients.

Intraoperative complications included one conversion to open technique (0.1%) and one iatrogenic gastrostomy during insufflation/trocar insertion, which was repaired laparoscopically (0.1%). In both patients, recovery was uncomplicated.

Early complications included 1 intraabdominal hemorrhage from a trocar site that required laparoscopic reintervention (0.1%); 3 gastric microperforations from suture pull-through after postoperative stoma obstruction (0.3%); 6 access port infections (0.6%), 4 of which were treated with access reservoir removal, local wound care, antibiotics, and access port replacement, the other 2 required band explantation for intractable foreign body infection; and early acute stoma obstructions developed in 14 patients (1.4%) and were treated conservatively with IV hydration and resolved spontaneously in 3 $\pm$ 2 days (3 of these patients presented 7 to 10 days later with microperforation described previously).

Late complications included 5 episodes of access port displacement or tubing breaks in 4 patients (0.4%), all of which were corrected surgically in an outpatient setting. One of these patients experienced two consecutive tubing breaks, likely related to excessive upper extremity and abdominal exertion from pulling herself up in bed while lying on her abdomen. This patient had severe lower extremity arthropathy, which compromised ambulation. She underwent three surgical procedures, the last of which was band explantation requested by the patient, who anticipated recurrent tubing problems. Band erosions developed in 2 patients (0.2%): one pre-

Table 2. Adverse Events

	n	%
Intraoperative		
Conversion to open	1	0.1
Iatrogenic gastrostomy	1	0.1
Early		
Intraabdominal hemorrhage	1	0.1
Access port infection	6	0.6
Acute stoma obstruction	14	1.4
Stomach pouch microperforation	3	0.3
Late		
Tubing break/port displacement	5 in 4 patients	0.4
Erosion	2	0.2
Slippages	23	2.3

sented early at 5 months postoperative with a delayed access-port infection, and the second patient presented at 1 year postoperative with lack of stoma restriction, but was otherwise asymptomatic. Both had elective laparoscopic band explantations and their recoveries were uneventful.

From the initial 44 patients who received perigastric dissection, gastric prolapse developed in 9 (20.5%), an average of 13 months (range 9 to 22 months) postoperatively. These were mainly posterior prolapses and two were concentric stomach pouch dilatations. Among the group of patients who received the pars flaccida technique, 14 (1.4%) patients experienced anterior gastric prolapses an average of 12 months (range 6 to 17 months) after the operation. Intractable gastroesophageal reflux symptoms developed in 5 patients (0.5%), and fluoroscopy suggested the presence of a hiatal hernia with the band in the normal orientation. In each of the five patients, laparoscopic reintervention in an outpatient setting was required to perform a crural repair, and each experienced uneventful recovery. One patient presented with a recurrent prolapse and a reoperation was performed to reposition the band.

Adverse events requiring reoperation occurred in 49 patients (4.8%), 13 of 44 were in the perigastric group (29.5%) and 36 of 970 (3.7%) in the pars flaccida group (Table 2). The majority of these reinterventions (n = 46, 93.9%) were performed in either an outpatient setting or with an overnight hospital stay. In all patients, recuperation was uneventful.

Asymptomatic and incidental findings during fluoroscopy-guided adjustments: 12 patients experienced transitory esophageal dilatation that disappeared after band deflation. Overall, 8 bands have been explanted (0.8%), associated with erosion (n = 2), infection (n = 2), obstruction (n = 3), and recurrent tubing break (n = 1) (Table 3).

Table 3. Band Explantations

Reason for band explantation	n	%
Erosion	2	0.2
Recurrent tubing break	1	0.1
Infection	2	0.2
Gastric microperforation (stitch pull-through)	3	0.3
All	8	0.8

Weight loss

Mean BMI decreased from 47.7 ± 8.6 kg/m^2 preoperative to 41 ± 7.9 kg/m^2 at 6 months, 37.2 ± 7.7 kg/m^2 at 12 months, 33.9 ± 7.6 kg/m^2 at 24 months, 31.6 ± 7.6 kg/m^2 at 36 months, and 31.7 ± 6.5 kg/m^2 at 48 months postoperative (Fig. 2).

Mean %EWL was 26.1 ± 13.1% at 6 months, 40.5 ± 17% at 12 months, 52.9 ± 19.5% at 24 months, 62 ± 20.9% at 36 months, and 64.3 ± 19% at 48 months postoperative (Fig. 3).

Table 4 shows the %EWL according to preoperative BMI category. Patients with higher preoperative BMI lost more weight (as measured by actual kilograms and reduction in BMI), although their %EWL was lower.

Table 5 shows the distribution of %EWL over time. After 24 months' followup, 57.5% of patients had lost > 50% of their excess weight, and at 36 and 48 months, 73% and 75% of patients had lost > 50% EWL, respectively ($p < 0.05$). Only 5.9% of patients had a %EWL < 25% at 36 months and no patients had a %EWL of < 25% at 48 months.

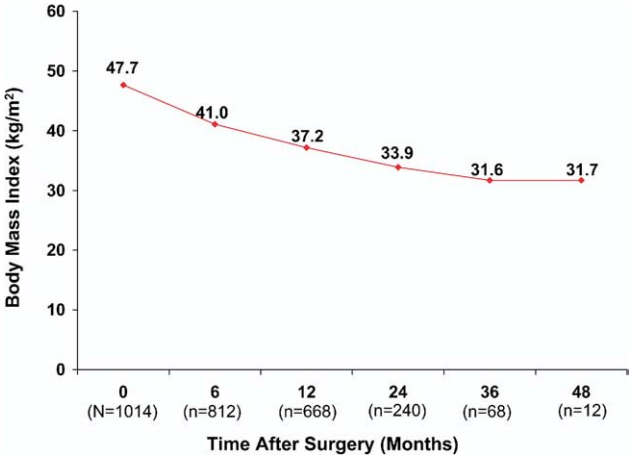

Figure 2. Change in body mass index.

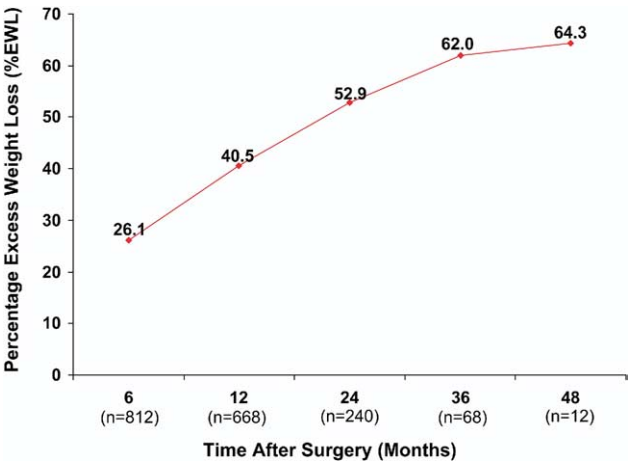

Figure 3. Excess weight loss.

When %EWL was examined by preoperative BMI category, after 36 months of followup a significant percentage (66% to 91% of patients) of each of the groups had lost > 50% excess weight (Table 6).

DISCUSSION

The LAGB has unique features that offer advantages over other bariatric procedures. One of the most important is the ability to adjust the stoma size without reoperation. The LAGB can be placed laparoscopically in almost all morbidly obese patients and the procedure is reversible, an advantage that could allow patients access to future treatments and procedures if necessary.

Evolution of the surgical technique and patient management methods have decreased complications.[14] The perigastric technique was used in the early experience[21,22] and, along with steep learning curves on the part of the surgeons and early deficiencies in postoperative management protocols, probably contributed to poor results in some centers.[11] O'Brien and colleagues[14] documented a significant decrease in gastric prolapse when the surgical technique was modified to pars flaccida. In our experience, during the initial 44 perigastric cases, we found a significantly higher incidence of gastric prolapse compared with that seen in the pars flaccida group of patients (20.5% versus 1.4%) that followed. Also, no cases of posterior prolapse occurred in the pars flaccida group. Using the pars flaccida technique, erosions occur less frequently, possibly a result of less perigastric tissue dissection, less tension during suturing, and change in practice to more gradual adjustment protocols.

The LAGB has proved to be very safe. The Australian

Table 4. Percent Excess Weight Loss by Preoperative Body Mass Index Category over Time

Preoperative BMI category (kg/m^2)	% Excess weight loss				
	6 months (n = 812)	12 months (n = 668)	24 months (n = 240)	36 months (n = 68)	48 months (n = 12)
< 40	30 ± 14.6 (n = 142)	46.7 ± 20.5 (n = 117)	61.6 ± 23 (n = 41)	76.2 ± 17.8 (n = 11)	NA (n = 0)
40–49.9	27.3 ± 13.2 (n = 403)	41.9 ± 16.1 (n = 336)	53.3 ± 17.2 (n = 125)	60.1 ± 21 (n = 37)	69.3 ± 21.5 (n = 7)
50–59.9	22.8 ± 11.5 (n = 195)	35.3 ± 15.4 (n = 160)	49.8 ± 20 (n = 53)	61.1 ± 17.9 (n = 14)	50.1 ± 11.4 (n = 3)
≥ 60	21.2 ± 10.1 (n = 72)	34.3 ± 11.9 (n = 55)	42 ± 17.6 (n = 21)	49.7 ± 23.4 (n = 6)	68.4 ± 10.7 (n = 2)
All	26.1 ± 13.1	40.5 ± 17	52.9 ± 19.5	62 ± 20.9	64.3 ± 19

BMI, body mass index; NA, not applicable.

Table 5. Distribution by Percent of Excess Weight Loss over Time

	% Excess weight loss group					
	<25		25–49		>50	
Months	n	%	n	%	n	%
12 (n = 668)	114	17.1	365	54.6	189	28.3
24 (n = 240)	19	7.9	83	34.6	138	57.5
36 (n = 68)	4	5.9	14	20.6	50	73.5
48 (n = 12)	0		3	25	9	75

Safety and Efficacy Register of New Interventional Procedures-Surgical systematic review of the worldwide literature found a significant difference in mortality between the Roux-en-Y gastric bypass (RYGB), vertical banded gastroplasty, and LAGB. The LAGB had 1 death in 2,000 (0.05%), which is one-tenth the mortality seen with RYGB and one-sixth the mortality with vertical banded gastroplasty.[1] We have had no perioperative mortality in our series of over 1,000 patients. In a study from a New York University program, the LAGB had significantly fewer complications compared with RYGB and biliopancreatic diversion with duodenal switch (10% versus 29.2% versus 27.6%).[23]

Weight loss associated with the LAGB is slower compared with that seen with RYGB; progression is gradual over a 2-, 3-, or 4-year period and then %EWL usually stabilizes at approximately 50% to 60%, corresponding with that of RYGB in the same time frame.[1]

Data from recently published US studies demonstrate weight loss outcomes as good as those achieved by some international groups.[8,10,11,15–18] One unanswered question remains: how much weight loss is necessary to improve or resolve comorbidities in morbidly obese patients? Many studies have shown significant improvement in comorbidities with LAGB-associated weight loss.[24] In one of the author's previous reports, resolution of type 2 diabetes and hypertension was documented in 80% and 74% of patients, respectively, at 2 years after LAGB placement, with an associated decrease in glycosylated hemoglobin from 7.2% preoperatively to 5.6% postoperatively.[15]

There has been some suggestion in the literature that LAGB works better in certain BMI categories. After analysis of selected literature and specific criteria and suppositions, Buchwald[25] suggested an algorithm showing the LAGB to be more favorable in lower BMI categories. In more recent studies, others have shown that LAGB can be equally effective in all BMI categories in the longterm. Fielding[26] documented a %EWL of 61% at 5-year followup in patients with massive superobesity (BMI $\geq$ 60 kg/m^2) using the LAGB. In another study, Angrisani and colleagues[27] reviewed the experience of a group of patients who received LAGB in Italy. Again, there was no difference between different BMI categories, ranging from 54.6% EWL in the lower group (BMI 30 to 39.9 kg/m^2) to 59.1% EWL in the higher group (BMI 60 kg/m^2). Our results showed that superobese patients lost more weight (as measured by actual kilograms and reduction in BMI) than the morbidly obese group, although their %EWL was lower.

Acute stoma obstruction was one problem we encountered postoperatively in our first cases using the pars flaccida technique. This was most likely a mechanical problem associated with encircling the fat pad around the lesser curvature.[28] After passing the learning curve and using perigastric fat pad dissection (and on some occasions, the two-step technique described by Weiner and colleagues[4]), our rate of obstructions decreased. Now, with the new larger band size available (VG Vanguard LAP-BAND; Inamed Health), this problem should not be an issue. In our practice, we have used this band recently in 35 patients with significant perigastric fat thickness without having a single episode of obstruction.

The LAGB procedure has proved to be effective and

Table 6. Distribution by Percent of Excess Weight Loss in Different Preoperative Body Mass Index Categories over Time

	% Excess weight loss group					
	<25		25–49		>50	
Preoperative BMI category (kg/m^2)	n	%	n	%	n	%
< 40						
24 mo (n = 41)	4	9.7	8	19.5	29	70.7
36 mo (n = 11)	0		1	9	10	91
48 mo (n = 0)	NA		NA		NA	
40–49.9						
24 mo (n = 125)	4	3.2	46	36.8	75	60
36 mo (n = 37)	2	5.4	9	24.3	26	70.3
48 mo (n = 7)	0		1	14.3	6	85.7
50–59.9						
24 mo (n = 53)	5	9.4	23	43.4	25	47.2
36 mo (n = 14)	0		4	28.6	10	71.4
48 mo (n = 3)	0		2	66.7	1	33.3
≥ 60						
24 mo (n = 21)	6	28.6	6	28.6	9	42.8
36 mo (n = 6)	2	33.3	0		4	66.7
48 mo (n = 2)	0		0		2	100

BMI, body mass index; NA, not applicable.

safe, but to reproduce good results and outcomes, a commitment must be made by surgeons and their practices to use the adjustable component of the band and incorporate intensive, comprehensive followup into their programs. Similarly, patients must be compliant, motivated, and have good understanding of the followup process. With appropriate followup, LAGB can become the primary intervention for bariatric patients because of its safety and efficacy.

Author Contributions

Study conception and design: Ponce
Acquisition of data: Fromm, Paynter, Ponce
Analysis and interpretation of data: Ponce
Drafting of manuscript: Ponce
Critical revision: Ponce
Statistical expertise: Ponce

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