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Extended Pouch versus Standard Pouch Laparoscopic Roux-en-Y Gastric Bypass for Treatment of Morbid Obese Patients: A Prospective Randomized Study

Mohamed Hussein Elemawy,[1] Mohammad Hamdy Abo-Ryia,[2] Taha Ahmed Ismail,[1] Reda Fawzy Ali[1]

[1]General Surgery Department, Faculty of Medicine, Kafr El Sheikh University, Kafr El Sheikh, Egypt
[2]GI and Laparoscopic Surgery Department, Faculty of Medicine, Tanta University, Tanta, Egypt

Corresponding Author: Mohamed Hussein Elemawy
General Surgery Department, Faculty of Medicine, Kafr El Sheikh University, Kafr El Sheikh, Egypt
Email: amawy2010@gmail.com
Mobile: 01009794941

Mohammad Hamdy Abo-Ryia
Email: mhaboryiah@gmail.com
Mobile: 01001543024

Taha Ahmed Ismail
Email: tahaaesmail@yahoo.com
Mobile: 01004614546

Reda Fawzy Ali
Email: dr_reda2002@yahoo.com
Mobile: 01003626876

Abstract

Background: RYGB is a traditional bariatric operation. It entails the formation of a micro-pouch to which a loop of jejunum is to be anastomosed. This which poses a technical challenge. A long slim pouch (EP) is thought to eliminate this difficulty. We aim to test the efficacy, safety and ease of EP as regard weight reduction, resolution, improvement of co-morbidities and effects on patients' quality of life (QOL).

Methods: This randomized work was conducted on 40 individuals ranging in age from 18 to 60 years old, both genders, patients with severe obesity,individuals with body mass index (BMI) ≥ 40 or > 35 kg/m^2 with obesity related co-morbidities.Participants had been allocated into two equal groups at random: Group 1: submitted to S LRYGB. Group 2: submitted to EP LRYGB.

Results: BMI at 6 and 12 month was significantly lower compared to baseline BMI in group 1 and group 2. HBA1c, participants within the two groups 1 and 2 showed a significant improvement HBA1c at 6 and 12 months when comparing with baseline values. Hypertension (HTN) at 12months remission rate was substantially greater in group 2 contrasted to group 1(P = 0.036).Excess weight loss (EWL %) at 12 months showed a significant increase than EWL % at 6 months in group 1 and group 2. TBWL showed a significant increase at 12 months compared to TBWL % at 6 months.

Conclusions: Both surgical S LRYGB and EP LRYGB are effective and safe techniques as they improve weight loss, resolution and co-morbidities and maintain patients' QOL with minimal complications with no substantial variation among both groups.

Keywords: Laparoscopic, Roux-En-Y, Gastric Bypass, Extended Pouch, Morbidly Obese

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Introduction

Currently, LRYGB is regarded as the standard operation for treating obesity.

However, Multiple variations of this approach are utilized. There are currently no universally accepted worldwide standards or recommendations for anatomical traits that may be significant, like the size of a stoma, the length of a limb, the size of a pouch, or its volume. The increasing recognition of the metabolic, as opposed to the mechanical impacts of bariatric surgery has necessitated a more thorough examination of gastric bypass architecture. This research focused mainly on the morphology of pouches, examining their form and length [1].

Patients and Methods

Eighty-eight individuals were evaluated for eligibility; 34 individuals didn't met the criteria [previous bariatric surgery (n=13), surgically unfit patients with compromised cardiopulmonary function (n=9), chronic decompensated diseases (n=3), major psychological disorders (n=6), secondary obesity (n=3)], and 14 individuals refused to take apart in the work. The other 40 individuals composed the study population. Patients aged 18 to 60 years were indicated for bariatric surgery. The study started in March 2020 and continued until March 2023 after the approval of the Ethics Committee at our institution informed written consent was obtained from the participants or their caregivers.

Patients with history of bariatric surgeries were excluded.

Observational studies have shown that people with a small pouch had a lower chance of developing marginal ulcers. This is because there are fewer parietal cells approximate to the stomach in these patients [2,3].

The metabolic mechanism of the operation seems to be influenced by the length of pouch passage and stomach emptying. This is supported by a study [4]which found that patients with inadequate weight loss following RYGB surgeries had very fast pouch emptying. Based on proven physical ways, a longer pouch may cause a delay in the transit of substances, potentially impacting the functioning of the intestines[5].

The purpose of this study was to evaluate the effectiveness of a newly designed long slim pouch "extended pouch" compared to the regular RYGB small rectangular pouch regardingto loss of weight and resolution of comorbidities.

Participants were assigned at random into two equal groups of 20 patients each by the closed envelope method: **Figure 1**

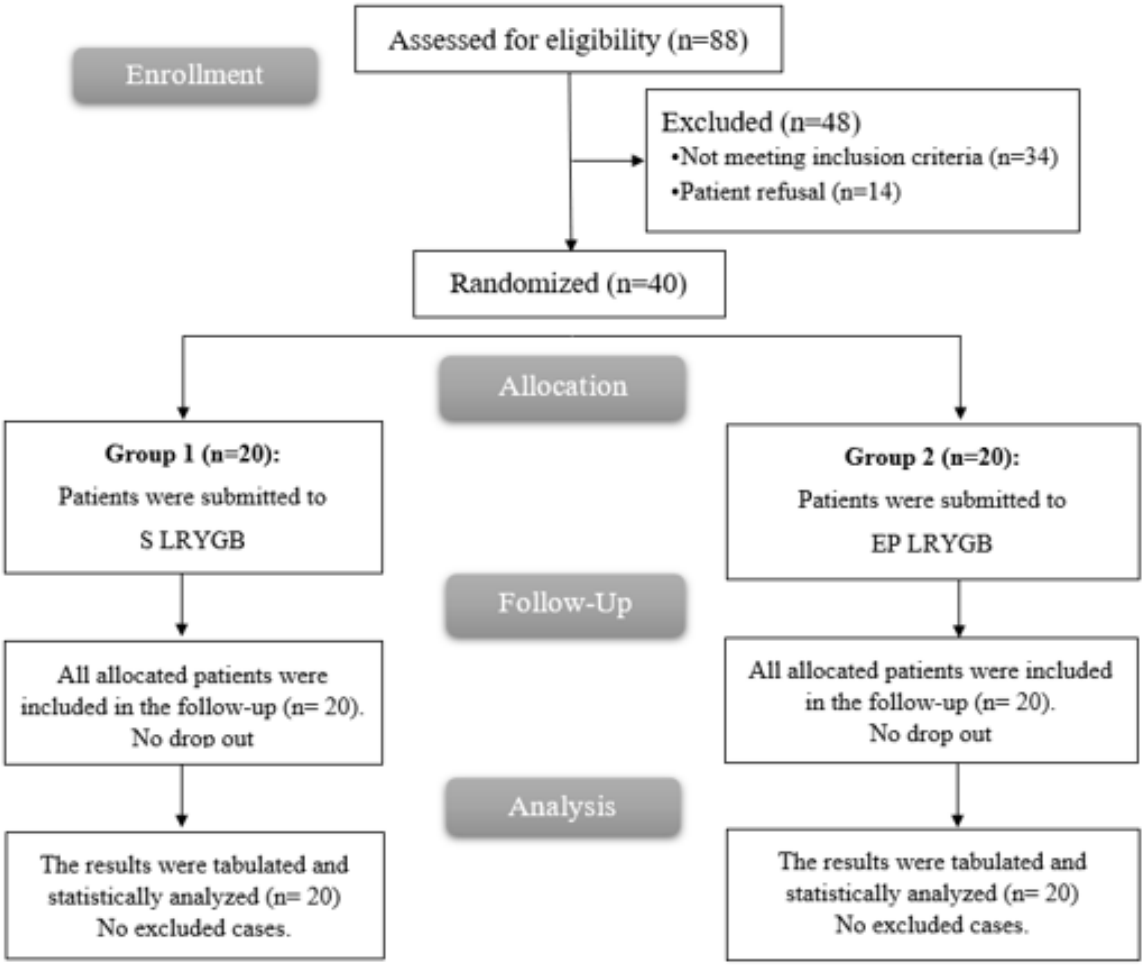

Fig 1: Consort flow chart of the studied groups

Group 1: regular pouch group: S-shaped LRYGB; **Group 2:** extended pouch group: EP-shaped LRYGB.

Surgical Procedures (S-GB and EP-GB):

We utilized antecolic antegastric construction, using an alimentary limb measuring 100 cm and a biliopancreatic limb measuring 100 cm. In order to form the typical gastric pouch, the first blue 60-mm linear stapler was positioned 5 cm beneath the angle of His on the right side of the lesser curvature of the stomach. The tiny proximal pouch was incised utilizing 60-mm blue staplers positioned next to a 40 French stomach tube terminating 1 cm laterally to the angle of His. The expanded pouch was formed by positioning the

The statistical analysis was performed with SPSS v26 (IBM, Inc., Chicago, IL, USA). Quantitative parameters are expressed as the mean and standard deviation (SD) and were contrasted among both groups employing an unpaired Student's t test. Qualitative parameters are expressed as the frequencies and percentages (%) and were analyzed using the chi-square test or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered to indicate statistical significance.

Results

Both groups possess similarities. **Table 1**

Table 1: Demographics, preoperative co-morbidities, laboratory parameters of the studied groups

		Group 1 (n=20)	Group 2 (n=20)	P
Age (years)		42.2 ± 11.85	43.3 ± 7.15	0.712
Sex	Male	7 (35%)	6 (30%)	1.00
	Female	13 (65%)	14 (70%)	
Weight (Kg)		131 ± 18.4	129.3 ± 24.7	0.806
BMI (Kg/m^2)		49.1 ± 7.57	47.9 ± 5.73	0.572
				Co-morbidities
T2DM		13 (65%)	14 (70%)	0.760
HTN		11 (55%)	12 (60%)	0.749
Osteoarthritis		2 (10%)	1 (5%)	0.548
Hyperlipidemia		8 (40%)	7 (35%)	0.744
Respiratory complications		2 (10%)	1 (5%)	0.548
T2DM		13 (65%)	14 (70%)	0.760
				Laboratory parameters
HBA1c (%)		7.5 ± 1.78	7.1 ± 1.65	0.461
Serum ferritin (ng/mL)		27.5 ± 11.03	33 ± 10.07	0.110
Serum albumin (g/dL)		4.3 ± 0.29	4.4 ± 0.39	0.149
Total calcium (mg/dL)		9.6 ± 0.41	9.8 ± 0.43	0.143
Vitamin D (ng/mL)		21.8 ± 8.52	20.9 ± 7.5	0.725
Operation time (min)		140.7 ± 7.34	122.4 ± 8.34	**<0.001***

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, HTN: hypertension, T2DM: Type 2 Diabetes mellitus.

The effect on comorbidities was comparable among both groups (**Table 2).**

Table 2 : Remission of obesity related comorbidities of the studied groups

			Group 1 (n=20)	Group 2 (n=20)	P
T2DM	Baseline		13(65.0%)	14 (70%)	0.760
	12 months	Remission	9(69.2%)	11 (78.6%)	0.678
		Improved	4 (30.8%)	3 (21.4%)	
HTN	Baseline		11 (55%)	12 (60%)	0.749
	12 months	Remission	2 (18.2%)	8 (66.7%)	**0.036***
		Improved	9 (81.8%)	4 (33.3%)	

Data are presented as mean ± SD or frequency (%). * Significant p value <0.05, T2DM: Type 2 Diabetes mellitus, HTN: hypertension.

Loss of weightwas also comparable between the two groups. **Tables 3,4**

Table 3: Weight and BMI change and HBA1c of the studied groups

	Baseline	6 months	12 months	P value within group
				Weight change in Kg
Group 1 (n=20)	131 ± 18.4	102.4 ± 13.9	87.2 ± 9.8	P1**<0.001***, P2**<0.001***
Group 2 (n=20)	129.3 ± 24.7	101.5 ± 16.5	86.8 ± 10.3	P1**<0.001***, P2**<0.001***
P value	0.806	0.845	0.913	
				BMI change Kg/m2
Group 1 (n=20)	49.1 ± 7.57	38.8 ± 5.65	33.1 ± 3.37	P1**<0.001***, P2**<0.001***
Group 2 (n=20)	47.9 ± 5.73	38 ± 4.38	32.6 ± 3.4	P1**<0.001***, P2**<0.001***
P value	0.572	0.633	0.624	
				HBA1c in mg
Group 1 (n=20)	7.5 ± 1.78	6.3 ± 0.72	5.99± 0.36	P1=**0.009***, P2=**0.001***
Group 2 (n=20)	7.1 ± 1.65	6.2 ± 0.97	5.9 ± 0.42	P1<**0.001***, P2=**0.001***
P value	0.461	0.854	0.448	

Data presented as mean ± SD, P1: p value between baseline and6 month, P2: p value between baseline and 12 months. *: statistically significant as P value <0.05, BMI: body mass index.

Table 4: EWL and TBWL % of the studied groups

	6 months	12 months	P value within group
			EWL %
Group 1 (n=20)	41.2 ± 7.09	63.5 ± 4.49	**<0.001***
Group 2 (n=20)	41 ± 8.8	64.5 ± 9.85	**<0.001***
P value	0.950	0.686	
			TBWL %
Group 1 (n=20)	20.5 ± 2.92	31.5 ± 2.95	**<0.001***
Group 2 (n=20)	20.4 ± 4.45	31.6 ± 5.49	**<0.001***
P value	0.891	0.986	

Data presented as mean ± SD, *: significant P value <0.05, EWL: excess weight loss, TBWL: total weight loss.

The effects on vitamin and mineral levels had been also comparable among both groups. **Table 5**

Table 5: Laboratory investigations in both groups

	Baseline	6 months	12 months	P value within group
				Serum ferritin (ng/mL)
Group 1 (n=20)	27.5 ± 11.03	26.3 ± 8.11	25.8 ± 8.91	P1=0.702, P2=0.606
Group 2 (n=20)	33 ± 10.07	31.2 ± 10.98	29.6 ± 10.8	P1=0.573, P2=0.355
P value	0.110	0.117	0.242	
				Serum albumin (g/dL)
Group 1 (n=20)	4.3 ± 0.29	4.1 ± 0.26	4.2 ± 0.26	P1=0.060, P2=0.261
Group 2 (n=20)	4.4 ± 0.39	4.3 ± 0.34	4.3 ± 0.33	P1=0.392, P2=0.386
P value	0.149	0.058	0.144	
				Total calcium (mg/dL)
Group 1 (n=20)	9.6 ± 0.41	9.6 ± 0.45	9.4 ± 0.36	P1=0.691, P2=0.111
Group 2 (n=20)	9.8 ± 0.43	9.7 ± 0.44	9.6 ± 0.4	P1=0.386, P2=0.121
P value	0.143	0.293	0.142	
				Vitamin D (ng/mL)
Group 1 (n=20)	21.8 ± 8.52	21.3 ± 6.88	20.1 ± 6.61	P1=0.874, P2=0.504
Group 2 (n=20)	20.9 ± 7.5	20.6 ± 4.62	20.3 ± 3.63	P1=0.890, P2=0.784
P value	0.725	0.698	0.918	

Data presented as mean ± SD, P1: p value between baseline and 6 months, P2: p value between baseline & 12 month, *: significant P value <0.05.

Long-term, short-term and intraoperative consequences and BAROS at 12 months were comparable among both groups. **Table 6**

Table 6: Incidence of complications and BAROS at 12 months in both groups

		Group 1 (n=20)	Group 2 (n=20)	P
Intraoperative	**Bleeding**	1 (5%)	0 (0%)	1.0
	Misfire (Repaired stitches)	0 (0%)	1 (5%)	
Early postoperative (30 days)	**Readmission**	1 (5%)	1 (5%)	0.598
	Portal vein thrombosis	1 (5%)	0 (0%)	
	Anastomotic leak	0 (0%)	0 (0%)	
	Bleeding	0 (0%)	0 (0%)	
	Mortality	0 (0%)	0 (0%)	
Delayed postoperative	**Gall bladder stones**	1 (5%)	1 (5%)	0.602
	Trocar site hernia	0 (0%)	1 (5%)	
	Readmission	1 (5%)	0 (0%)	
	Mortality	0 (0%)	0 (0%)	
BAROS (12 months)		6.3 ± 1.57	6.4 ± 1.54	0.676

Data are presented as frequency (%). BAROS: Bariatric Analysis and Reporting Outcome System.

omentum, by lowering the extent of gastrojejunostomy. This also protects against mediastinal involvement when leakage from gastrojejunostomy occurs[7].

The newEP LRYGB was found to be quicker (122.4 ± 8.34) than the S LRYGB was (140.7 ± 7.34) (P <0.001).In line with our results, Parmar et al. [8]stated that the operation time of RYGB was

Discussion

Among the different bariatric procedures,LRYGB is widely regarded as the most effective method for attaining sustainable long-term weight reduction and addressing obesity-related health conditions[6]. LEPRYGB is a recent modification of LRYGB that aims at ensuring technical efficacy, especially in the case of short bowel mesentery or heavy

Conflict of interest: None

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129.5 min. On the other hand, Leyba et al. [9]stated that the mean time ofLRYGB operation was 98 min ($p<0.05$).

EP had efficacy comparable to that of regular pouch surgery with regard tolossof weight and enhancementin comorbidities. Boerboom et al. [1] and Parmar et al.[8] also reported similar results.

Abbas et al.[17]reported that for T2DM patients in the LRYGB group,following 12-month period, the remission rate was 62.3%, and the improvement rate was 32.1%. Additionally, remission rates raised throughout follow-up to 36% following 36-month period in the S-GB subgroup and to 61% in the EP-GB subgroup. The remission rate across the groups showed substantial variations following 2 years, and this variation remained substantial following 3 years, favoring the EP-GB group.

At 12 months, the remission rate of HTN was substantiallygreater in the EP-LRYGB group contrasted to in the S-LRYGB group (18.2% vs. 66.7%, P= 0.036).

However, the difference in BAROS at 12 months was not significantamongtheS-LRYGB group and the EP-LRYGB group.

Limitations of this study: The size of the sample was a bit limited. The research was conducted in a solitary facility. Other factors that are not well understood, including as peristalsis, the size of other gastroenterostomies, and stimulation of the vagal nerve, are likely to have a substantial impact. Preoperative ratings for GERD-HRQL weren't evaluated. A 12-month follow-up period is often regarded as an early phase following bariatric surgery, and it doesn't offer sufficient evidence to make definitive judgments on the long-term risk of deficits. The assessment of postoperative pain wasn't conducted using a standardized approach.

Conclusions:

The EP-LRYGB is as effective and safe as the S-RYGB technique. EP LRYGB had a shorter operative time and was technically easier with less tension GJ anastomosis. It is marginally better at controlling HTN

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