Review article

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SURGICAL ENDOSCOPY
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Evidence-based medicine: open and laparoscopic bariatric surgery

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Abstract
Background: The aim of this study was to perform an evidence-based analysis of the literature on open and laparoscopic surgery for morbid obesity.
Methods: Human studies on surgery for morbid obesity were conducted. Multiple publications of the same studies, abstracts, and case reports were reviewed. Current Contents, MEDLINE, EMBASE, and Cochrane Library databases were investigated.
Results: Open Roux-en-Y gastric by pass (RYGB) for morbidly obese patients and long-limb RYGB for superobese patients are highly effective procedures. Randomized controlled trials comparing malabsorptive procedures with other bariatric operations are needed. The long-term efficacy of adjustable silicone gastric banding (ASGB) still is undetermined because of poor evidence. Laparoscopic RYGB is as safe as its open counterpart, although its long-term results are lacking. Laparoscopic ASGB is less invasive than open ASGB, although its efficacy cannot be determined because of poor evidence. Laparoscopic vertical banded gastroplasty (VBG) is becoming unpopular since the decreasing trend of open VBG. Laparoscopic biliopancreatic diversion with duodenal switch is feasible, but needs further studies.
Conclusions: Randomized controlled trials comparing the various laparoscopic operations are strongly needed.

Key words: Evidence-based medicine — Morbid obesity — Bariatric surgery — Laparoscopy

Three facts emphasize the need for better integration of the results from medical research and clinical practice: (a) the percentage of medical decisions based on scientific evidence is estimated at 15% to 40% [40]; (b) the time lag between ensured scientific knowledge and the introduction into medical routine is 8 to 10 years [7] and; (c) medical knowledge is rapidly becoming outdated, with a currently decreasing half-life of approximately 5 to 45 years [58].

As defined by Sackett et al. [107], evidence-based medicine [71] "is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. The target of evidence-based medicine is improved patient care achieved by bridging the gap between research and clinical practice, thus allowing medical decisions to be based on the best available scientific evidence [107].

Morbid obesity is present when body mass index (BMI), determined by dividing body weight expressed in kilograms by height expressed in square meters, is greater than 40 kg/m^2 or greater than 35 kg/m^2 with concomitant obesity-related morbidity.

The relationship between BMI and mortality was described recently by the American Cancer Society [23]. In their large, prospective study, the lowest rates of death from all causes were found at a BMI between 22.0 and 23.4 kg/m^2 in women and 23.5 and 24.9 kg/m^2 in men. Among healthy patients who had never smoked, the relative risk for all causes of mortality increased with BMI levels of approximately 30 kg/m^2 or more.

Nonsurgical methods fail to maintain clinically significant weight loss more than 5 years in patients who are morbidly obese [94]. Findings show that surgery is the only effective treatment for morbid obesity over the long term [103]. A recent meta-analysis focused on the amount of weight reduction after bariatric surgery [83]. The study confirmed that bariatric surgery is an appropriate therapy for patients who are morbidly obese in whom nonsurgical treatment options have failed.

By systematically reviewing the literature on open and laparoscopic surgery for morbid obesity, this study aimed to evaluate the published evidence relating to the efficacy and safety of each bariatric operation.

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Materials and methods

To identify available evidence, electronic databases have to be used [6]. MEDLINE is the most commonly used database. However, even a good MEDLINE search may not produce the best existing evidence [39]. To reach this goal, the current literature review also included EMBASE (Elsevier), which contains journals not covered by MEDLINE. Another database, that contains systematic reviews and protocols of reviews, the Cochrane Library (Update Software, Oxford, England), was fully searched. No date limit was set for the literature search, which was performed up to May 2001. Multiple search terms were used, as either single terms or matched terms: obesity, morbid obesity, bariatric surgery, surgery, laparoscopy, laparoscopic surgery, gastric banding, vertical banded gastroplasty, gastroplasty, bypass, gastric bypass, isolated gastric bypass, Roux-en-Y gastric bypass, diversion, biliopancreatic diversion, biliopancreatic diversion and duodenal switch, outcomes, randomized controlled trials, and controlled clinical trials. Additionally, we evaluated the references of each report included in the database as a result of the first search to find any other report not covered by the electronic search. We also hand-searched the following journals from 1991 to 2001: *Obesity Surgery, Obesity Research and International Journal of Obesity*.

Three questions guided the evaluation and critique of each article: Are the results valid? What are the results? Are the results applicable to my patients? A number of parameters were evaluated in answering these three main questions (Table 1) [121]. To complete a correct evaluation of an article comparing different treatment groups, absolute risk, absolute risk reduction, relative risk, and relative risk reduction were calculated.

Various hierarchies have been proposed for classifying study design [111]. Table 2 shows the classification used in the current review. It identifies case studies, case–control studies, cohort studies, and randomized controlled trials. The case study is the weakest and the randomized controlled trial the strongest for determining the effectiveness of treatment. In fact, the risk of bias is minimized in a randomized controlled trial. Bias is defined as any factor or process that tends to cause the results or conclusions of a trial to deviate systematically (not randomly) from the truth [80].

Several grading systems are available for assessing the level of evidence. In the current analysis, we used a system from the Oxford Center for Evidence-Based Medicine (UK) (Table 3) [116].

The most commonly performed bariatric procedures, by either laparotomy or laparoscopy, such as adjustable silicon gastric banding, vertical banded gastroplasty, Roux-en-Y gastric bypass, and biliopancreatic diversion with duodenal switch are shown in Figs. 1, 2, 3, and 4, respectively. The results from surgical therapy were evaluated according to Reinhold classification [105] (Table 4). Articles were selected on the basis of the following criteria.

Participants

Human studies were included, specifically, studies on patients who were morbidly obese (BMI > 35 kg/m^2). Studies on new and comparative interventions were considered, as well as articles containing information on the following outcomes: weight loss (kg/pounds lost or gained, change in BMI, change in excess weight), complications, mortality, and revision rates.

Exclusion

Multiple publications of the same study, abstracts alone, and case reports were excluded. Studies with at least 20 patients were considered.

Types of studies

Randomized controlled trials, cohort studies, case–control studies, and case series (excluding abstracts alone) were included.

Language

Articles in all languages were considered in the literature search.

Table 1. How to critique an article evaluating surgical interventions

Question	Critique
Are the results valid?	Was patient assignment randomized and randomization process "concealed"? Were all patients who entered the trial accounted for? Was follow-up adequate? Were patients analyzed according to the "intention-to-treat" principle? Were study personnel "blinded" to treatment? Were the patient groups similar before treatment? Apart from the experimental intervention, were the groups treated equally?
What are the results?	How large was the treatment effect? How precise was the estimate of the treatment effect?
Are the results applicable to my patients?	Were the study patients similar to my patients? Were the measured outcomes clinically relevant? Are my surgical skills similar to those of the study surgeons?

Table 2. Hierarchy of study designs

	Control group	Prospective follow-up	Random allocation of subjects
Case study	No	No/Yes	No
Case–control study	Yes	No/Yes	No
Cohort study	Yes	Yes	No
Randomized controlled trial	Yes	Yes	Yes

Table 3.

Grade of recommendation	Level of evidence	Study
A	1A	SR/MA of RCTs based on individual patient data
	1B	SR/MA of RCTs based on summary effect measures
	1C	Individual RCT
	1D	Non-RCT with dramatic treatment effect
B	2A	SR of cohort studies
	2B	Individual cohort study
	3A	SR of case–control studies
	3B	Individual case–control study
C	4	Case study
D	5	Expert opinion

SR, Systematic review; MA, meta-analysis; RCT, randomized controlled trial

Databases

Current Contents, MEDLINE, EMBASE, and Cochrane Library were searched up to May 2001.

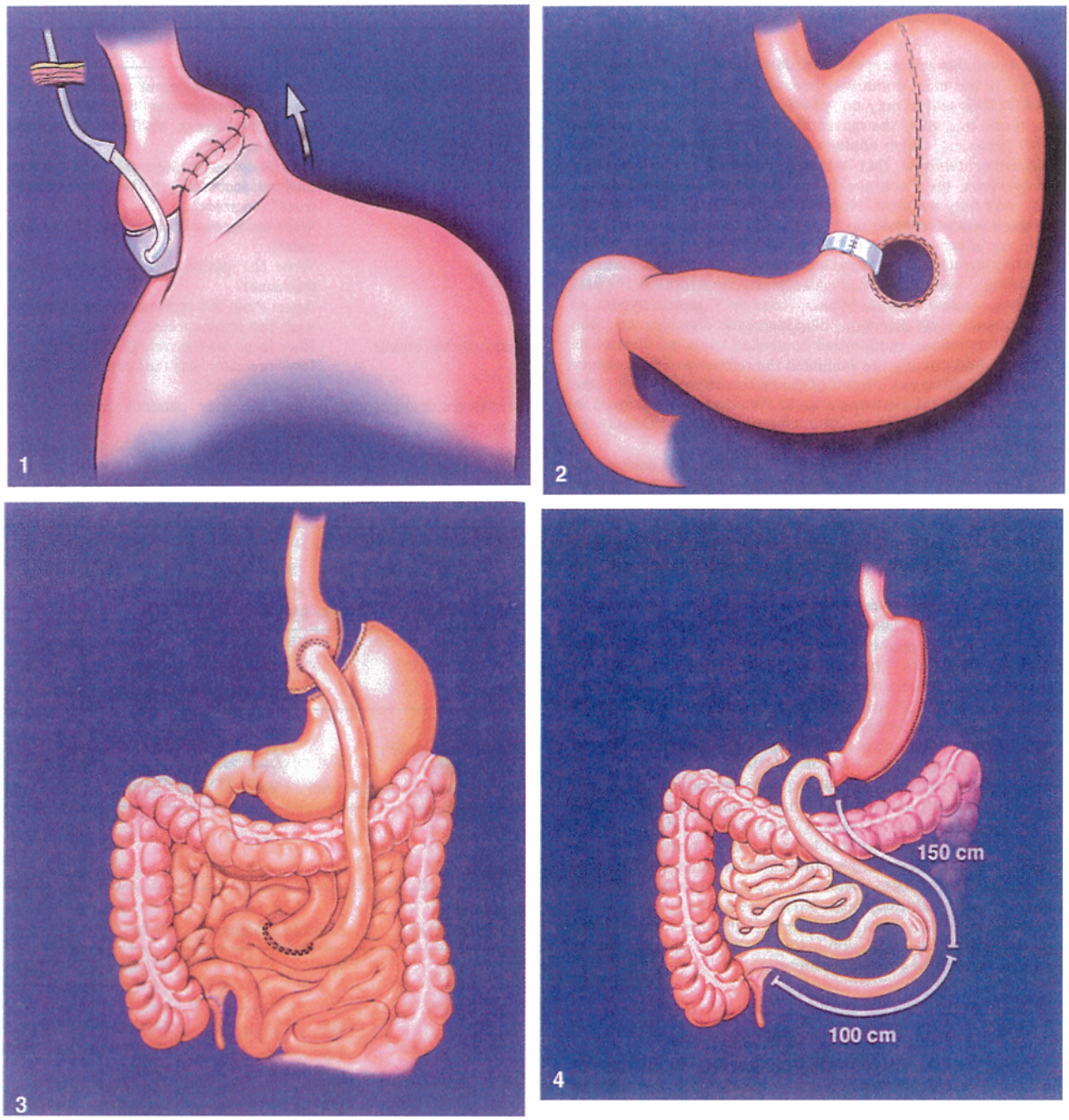

Fig. 1. Adjustable silicon banding
Fig. 2. Vertical banded gastroplasty
Fig. 3. Roux-en-Y gastric bypass
Fig. 4. Biliopancreatic diversion with duodenal switch

Results

Open bariatric surgery

Table 5 illustrates the results from the literature review of randomized controlled trials comparing different open bariatric operations [3, 18, 51, 57, 59, 66, 69, 70, 77, 88, 102, 113]. Besides historical studies evaluating procedures that have been abandoned, such as jejunoileal bypass, horizontal gastroplasty, and gastrogastrostomy, the most important outcomes refer to the comparison of vertical banded gastroplasty (VBG) versus Roux-en-Y gastric bypass (RYGB) and RYGB versus long-limb RYGB (LL-RYGB).

All the randomized controlled trials comparing VBG and RYGB showed a significant greater long-term weight loss after RYGB (level of evidence, IB; grade A) [51, 66, 69, 70, 77, 88, 102, 113]. One randomized controlled trial comparing LL-RYGB and RYGB in the superobese (>200 pounds overweight) showed a significant greater weight loss after LL-RYGB (level of evidence, 1C; grade A) [18].

Table 4. Basis for evaluation of results[a]

Result	Body mass index (kg/m^2)	Excess body weight (%)
Excellent	< 30	0–25
Good	30–35	26–50
Failure	> 35	> 50

[a] Modification of Reinhold classification

Table 5. Randomized controlled trials comparing various open obesity operations

Procedures	Reference
JI vs RYGB	Griffen WO, et al. [57]
HG vs VBG	Andersen T, et al. [3]
GG vs VBG vs RYGB	Hall JC
VBG vs RYGB	Sugerman, Freeman, Laws, Pories, MacLean, Howard, Nasfund, Lechner
LL-RYGB vs RYGB	Brolin

JI, jejunoileal bypass; RYGB, Roux-en-Y gastric bypass; HG, horizontal gastroplasty; VBG, vertical banded gastroplasty; GG, gastrogastrostomy; LL-RYGB, long-limb Roux-en-Y gastric bypass

No randomized controlled trial compared either biliopancreatic diversion (BPD) or biliopancreatic diversion with duodenal switch (BPD/DS) and other bariatric operations. Four cohort studies [2, 15, 24, 85]. Two case–control studies [11, 19], and 10 case studies [10, 29, 30, 45, 49, 76, 81, 86, 110, 120] showed excellent weight loss after BPD (level of evidence, 2A; grade B). One case–control study [104] and three case studies [13, 61, 78] showed excellent weight loss after BPD/DS (level of evidence, 3B; grade B). One randomized controlled trial (38) comparing open and laparoscopic adjustable silicon gastric banding (ASGB) showed good weight loss after open ASGB, but with only 1 year of follow-up evaluation.

In conclusion, the only procedures proved to be highly effective on a long-term basis are open RYGB for patients who are morbidly obese patients and open LL-RYGB for patients who are superobese patients (levels of evidence 1B and 1C, respectively). Randomized controlled trials comparing malabsorptive procedures (BPD, BPD/DS) with other bariatric operations are needed. The long-term efficacy of ASGB cannot be determined currently because of incomplete and poor evidence (levels 3 and 4).

Laparoscopic bariatric surgery

Laparoscopic ASGB

At this writing, 61 laparoscopic ASGB studies have been reported [1, 4, 5, 8, 12, 14, 16, 20–22, 26–28, 31, 33, 35–38, 42–44, 46–48, 52–55, 60, 62, 65, 67, 68, 72, 82, 84, 89, 90, 95–101, 109, 112, 114, 115, 118, 122–127, 129, 132–134]. Table 6 shows the number of studies for each level of evidence. Three randomized controlled trials involving laparoscopic ASGB have been reported. In the first, Ashy and Merdad [8] compared open VBG (30 patients) with laparoscopic ASGB (30 patients). At 6 months, VBG patients had experienced a significantly greater weight loss than ASGB patients (87% vs 50%).

Table 6. Laparoscopic adjustable silicon gastric banding

Level of evidence	No. of studies
1 Randomized controlled trials	3
2 Cohort studies	4
3 Case–control studies	10
4 Case studies	44
Total	61

De Wit et al. [38] compared open ASGB (25 patients) with laparoscopic ASGB (25 patients) and found no difference in postoperative morbidity (8 in the open group vs 6 in the laparoscopic group, with a relative risk reduction of 25%). The investigators found a significant longer operative time for laparoscopic ASGB (76 vs 150 min), a significant shorter hospital stay for laparoscopic ASGB (7.2 vs 5.9 days), and a significantly lower rate of readmission (15 vs 6) and overall hospital stay (11.8 vs 7.8 days) for laparoscopic ASGB. No difference in weight loss results was found (34.4 vs 35 kg at 1 year).

Weiner et al. [123] compared two different surgical techniques of laparoscopic ASGB. In the first 50 patients, the band was placed around the stomach through an esophagogastric route (EGP), whereas in the next 51 patients, a retrogastric placement (RGP) of the band was performed. The authors observed a similar operative time (54.5 vs 58 min) and no difference in weight loss results (34 vs 37 kg at 1 year). Whereas the EGP group had no complications, two patients in the RGP group had slippage of the band and one patient had a pouch dilation. Therefore, the laparoscopic EGP of the band was found to be safer than the RGP.

Overall morbidity rate for laparoscopic ASGB was 11.5% (687/5,937 patients; range, 0–60%). The overall mortality was 0.05% (3/5,165 patients). The most frequent complications were band slippage (3.80%) and pouch dilation (3.25%). The reintervention rate ranged from 1.7% to 66.7%. The mean estimated weight loss ranged from 18% to 72%. The evidence with regard to long-term weight loss was rather thin. Only two studies [37, 98] provided precise data up to 4 years postoperatively. They showed a mean estimated weight loss of 68% ± 21% [98] and of 44% ± 24% [37] at 4 years. It must be noted that in the first study [98], only 12 of 302 patients reached the 4-year follow-up evaluation, and, as compared with only 4 of 37 patients in the second study (37).

Laparoscopic RYGB

After excluding multiple reports of the same study, case reports, and studies with fewer than 20 patients we were able to identify the following studies on laparoscopic RYGB: two randomized controlled trials, one with two different studies investigating different parameters: one case–control study, and seven case studies [34, 50, 63, 73, 79, 91–93, 108, 117, 128, 130] Table 7.

Table 7. Evidence-based medicine and laparoscopic Roux-en-Y bypass

2 Randomized controlled trials (one with two different studies)
1 Case–control study
7 Case studies

The first randomized controlled trial was performed by Nguyen et al. [93]. They evaluated pulmonary function, postoperative pain, and intraabdominal pressure in two groups of patients. The first group received laparoscopic RYGB (36 patients), whereas the second group underwent open RYGB (34 patients). The laparoscopic patients had less impairment of pulmonary function on the first three postoperative days (p RRR, 25%). On the first postoperative day, laparoscopic RYGB patients used less morphine ($p < 0.001$). Visual analog pain scores were lower after laparoscopic RYGB ($p < 0.05$). After laparoscopic RYGB fewer patients experienced hypoxemia ($p < 0.001$) and segmental atelectasis ($p < 0.005$). Laparoscopic RYGB also resulted in significantly lower intraabdominal pressure, less postoperative fluid required, and greater postoperative urine output than open RYGB [92]. There was no difference in postoperative morbidity.

The second randomized trial was, recently reported [128], 51 patients were allocated randomly to either laparoscopic ($n = 30$) or open RYGB ($n = 21$). In the laparoscopy group, seven patients (23%) were converted to open surgery. Six patients in the laparoscopy group needed reoperation because of Roux-limb obstruction in the mesocolic tunnel. Morphine doses used postoperatively were significantly lower ($p < 0.005$) in the laparoscopic group. Hospital stay also was significantly shorter in the laparoscopic group ($p < 0.025$). Weight loss was similar at 1 year. The authors concluded that laparoscopic RYGB, although associated with reduced pain and hospitalization, must still be considered an investigational procedure because of a higher incidence of complications than with open RYGB. On the other hand, it is also true that this study referred to an initial experience with laparoscopic RYGB, still in the learning curve period. Roux-limb obstruction in the mesocolic tunnel, for example, also was observed by other authors [64], but only in the first patients.

Overall morbidity for laparoscopic RYGB was 16% (332/2,073 patients). Overall mortality was 0.2% (6/2,073 patients). The overall conversion rate was 2.4% (50/2,073 patients). Only two studies reported estimated weight loss at 3 years (77% in both studies).

Laparoscopic VBG

After excluding multiple reports of the same study, case reports, and studies with fewer than 20 patients, we were able to identify the following studies on laparoscopic VBG: one randomized controlled trial, one cohort study, four case–control studies, and five case studies [9, 17, 25, 32, 41, 56, 71, 74, 75, 87, 119] (Table 8). All the studies compared laparoscopic and open VBG.

Azagra et al. [9] reported the only randomized controlled trial comparing laparoscopic (34 patients) and open VBG (34 patients). They found a significantly longer operative time for laparoscopic VBG ($p = 0.001$), but a significantly higher incidence of wound infections (RRR 69.4%) and incisional hernias after open VBG ($p = 0.04$). Although the follow-up period was short, no difference in weight loss results was reported. Laparoscopic VBG therefore was found time-consuming, but with a statistically significant decrease in the incidence of wound infections and incisional hernias.

Table 8. Evidence-based medicine and laparoscopic vertical banded gastroplasty

1 Randomized controlled trial (LVBG vs OVBG)
1 Cohort study (LVBG vs OVBG)
3 Case–control studies (LVBG vs OVBG)
5 Case-studies

LVBG, laparoscopic vertical banded gastroplasty; OVBG, open vertical banded gastroplasty

Laparoscopic BPD/DS

Only one case study on laparoscopic BPD/DS was reported [106]. In this study, 40 consecutive patients underwent laparoscopic BPD/DS as a primary bariatric procedure. Median BMI was 60 kg/m^2 (range, 42–85 kg/m^2). One patient was converted to laparotomy (2.5%). The median length of hospital stay was 4 days (range, 3–210 days). There was one 30-day mortality (2.5%). Major morbidities occurred in six patients (15%). The estimated weight loss was 58% ± 3% at 9 months.

Discussion

Obesity surgery was extensively evaluated by a consensus panel assembled by the National Institutes of Health in 1990. The consensus statement published in 1991 [94] stands as the major document defining the standard of care for obesity surgery. Four main outcomes were highlighted: (a) Obesity surgery was defined to be appropriate for patients with a BMI greater than 40 kg/m^2 or a BMI greater than 35 kg/m^2 accompanied by significant and life-threatening comorbidities; (b) scientific evidence was insufficient to support any of the malabsorptive procedures; (c) only VBG and RYGB could be recommended; (d) RYGB was found to be a superior operation over VBG.

Since the introduction and development of laparoscopic techniques, many abdominal procedures have been performed laparoscopically. Proven benefits of laparoscopic surgery include shorter hospital stay, quicker return to normal activity, less pain, and better cosmesis. The incidence of incisional hernia clearly is diminished. Other advantages include less systemic and immunologic stress, reduced adhesion formation, and reduced incidence of ileus.

Morbidly obese patients have multiple comorbidities, and they are at high risk for cardiopulmonary and wound-related complications. The idea of a laparoscopic approach to bariatric surgery came from the

need to offer morbidly obese patients important benefits deriving from a less invasive approach.

Adjustable silicon gastric banding through a laparoscopic approach was first performed in 1993. At this writing, 61 laparoscopic ASGB studies have been reported [1, 4, 5, 8, 12, 14, 16, 20–22, 26–28, 31, 33, 35–38, 42–44, 46–48, 52–55, 60, 62, 65, 67, 68, 72, 82, 84, 89, 90, 95–101, 109, 112, 114, 115, 118, 122–127, 129, 132–134]. Despite this amount of data, the evidence with regard to long-term weight loss after laparoscopic ASGB is rather sparse. Only two studies [38, 98] have provided precise data up to 4 years postoperatively.

In conclusion, laparoscopic ASGB is a relatively safe procedure. However the long-term efficacy of laparoscopic ASGB cannot be determined currently because of incomplete and poor evidence (levels 3 and 4). Level 1C evidence is provided regarding the shorter hospital stay and the lower readmission rate of laparoscopic ASGB, as compared with open ASGB as well as the greater safety of the band placed via EGP as compared with RGP. By randomized controlled trial, open VBG has proved to be associated with a greater weight loss than laparoscopic ASGB (Level of evidence 1C).

Grade A evidence concerning the greater weight loss after RYGB than after VBG is provided by open surgery. Therefore, vertical banded gastroplasty is becoming unpopular among bariatric surgeons. At this writing, laparoscopic VBG is performed only in selected centers.

In a prospective randomized trial comparing laparoscopic and open VBG, laparoscopic VBG was found to be time-consuming, but associated with a statistically significant decrease in the incidence of wound infections and incisional hernias [9]. These data allow for level 1C evidence that laparoscopic VBG is associated with fewer complications and a shorter hospital stay than its open counterpart. However, the effectiveness of laparoscopic VBG is not yet well determined, and not comparable with open VBG because of poor evidence (levels 3 and 4).

Wittgrove et al. [131] first described a laparoscopic approach to RYGB. Currently laparoscopic RYGB is performed by various surgeons from many institutions using different techniques. Briefly, the main differences are in the creation of the gastrojejunostomy (hand-sewn, mechanical side-to-side, and mechanical end-to-side), in the position of the gastrojejunostomy (antecolic or retrocolic), and in the length of the Roux limbs. Overall morbidity and mortality rates (16% and 0.2%, respectively) compare fevorably with those for open RYGB [66, 77, 102].

Laparoscopic RYGB is as safe as open RYGB. It is associated with less impairment of pulmonary function and postoperative pain than open RYGB (level of evidence, 1C). However, it is not yet proved (levels of evidence, 3 and 4) that laparoscopic RYGB is as effective as open RYGB.

Only one case study has investigated the feasibility and safety of laparoscopic BPD/DS for morbid obesity [106]. The evaluation of laparoscopic BPD/DS is therefore still an "expert opinion."

Conclusion

Currently, laparoscopic RYGB has proved to be as safe as its open counterpart, although its long-term weight loss results are still lacking. Laparoscopic ASGB is less invasive and preferable to open ASGB. The efficacy of both procedures cannot be determined currently because of poor evidence. Laparoscopic VBG is following the decreasing trend of open VBG as a result of randomized controlled trials comparing VBG and RYGB. As for laparoscopic BPD/DS, its feasibility has been proved, but very poor evidence is provided currently regarding its effectiveness.

The feasibility and safety of a laparoscopic approach to patients who are morbidly obese have been demonstrated for all bariatric procedures. Further research is needed to examine the long-term efficacy of the various laparoscopic procedures for morbid obesity. In this area, high priority should be given to randomized controlled trials comparing the various laparoscopic operations.

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