

# Safety of Laparoscopic vs Open Bariatric Surgery

## A Systematic Review and Meta-analysis

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**Objective:** To perform a systematic review and meta-analysis evaluating the risk of reoperation, wound infection, incisional hernia, anastomotic leak, and all-cause mortality associated with laparoscopic vs open bariatric surgery at a minimum of 12 months' follow-up.

**Data Sources:** We systematically searched the Cochrane Library, EMBASE, and MEDLINE databases through June 1, 2010, for randomized controlled trials comparing laparoscopic with open bariatric surgery.

**Study Selection:** We included all randomized controlled trials that reported weight loss outcomes and complications at a minimum of 12 months' follow-up and had a minimum of 50 patients. We identified 6 randomized controlled trials, which randomized 510 patients.

**Data Extraction:** Data were extracted by 2 reviewers on study design, baseline characteristics, and surgical procedure. The outcome data extracted included change in

weight and body mass index and the incidence of reoperation, wound infection, incisional hernia, anastomotic leak, and all-cause mortality.

**Data Synthesis:** We used random-effects models, which accounted for within-study and between-study variability, to estimate pooled risk ratios (95% CIs). Compared with open surgery, laparoscopic surgery was associated with lower risk of wound infection (relative risk [RR], 0.21; 95% CI, 0.07-0.65) and incisional hernia (RR, 0.11; 95% CI, 0.03-0.35). The risk of reoperation (RR, 1.06; 95% CI, 0.70-1.61), anastomotic leak (RR, 0.64; 95% CI, 0.14-2.95), and all-cause mortality (RR, 0.86; 95% CI, 0.22-3.28) may be similar for laparoscopic and open bariatric surgery.

**Conclusion:** Laparoscopic surgery may be a safer treatment than open surgery for patients requiring bariatric surgery.

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**M**ORBID OBESITY IS A SERIOUS problem in North America. Increasing by 52.0% from 2000 to 2005, the prevalence of morbid obesity (defined as body mass index, calculated as weight in kilograms divided by height in meters squared,  $\geq 40$ ) in the United States is estimated at 5.7%.<sup>1,2</sup> Morbid obesity is associated with increased risk of mortality and morbidity, including arthritis, back pain, cardiovascular disease, diabetes mellitus, and hypertension.<sup>3-5</sup>

### See Invited Critique at end of article

Bariatric surgery is an efficacious treatment of morbid obesity and has been shown to promote considerable weight loss and to reduce the risk of cardiovascular disease, certain cancers, and all-cause mortality.<sup>6-10</sup> Bariatric surgery can be performed laparoscopically (via a small incision in the abdomen) or using an open procedure (ie, laparotomy). Laparo-

scopic bariatric surgery has been performed since 1993 and has quickly surpassed open surgery in popularity.<sup>11</sup> Between 2004 and 2006, more than 16 000 laparoscopic gastric bypass procedures were performed compared with approximately 6000 open gastric bypass procedures in academic medical centers across the United States.<sup>12</sup> Based on results of observational studies and small randomized controlled trials (RCTs), laparoscopic technique is thought to reduce length of hospital stay and risk of complications; however, this has not been substantiated. Because of the increasing popularity of bariatric surgery for the treatment of morbid obesity, it is important to identify the safest method.

Our objective was to pool the results of previous RCTs comparing the risk of complications associated with laparoscopic vs open bariatric surgery. Specifically, we compared the risk of reoperation, wound infection, incisional hernia, anastomotic leak, and all-cause mortality associated with laparoscopic vs open bariatric surgery.

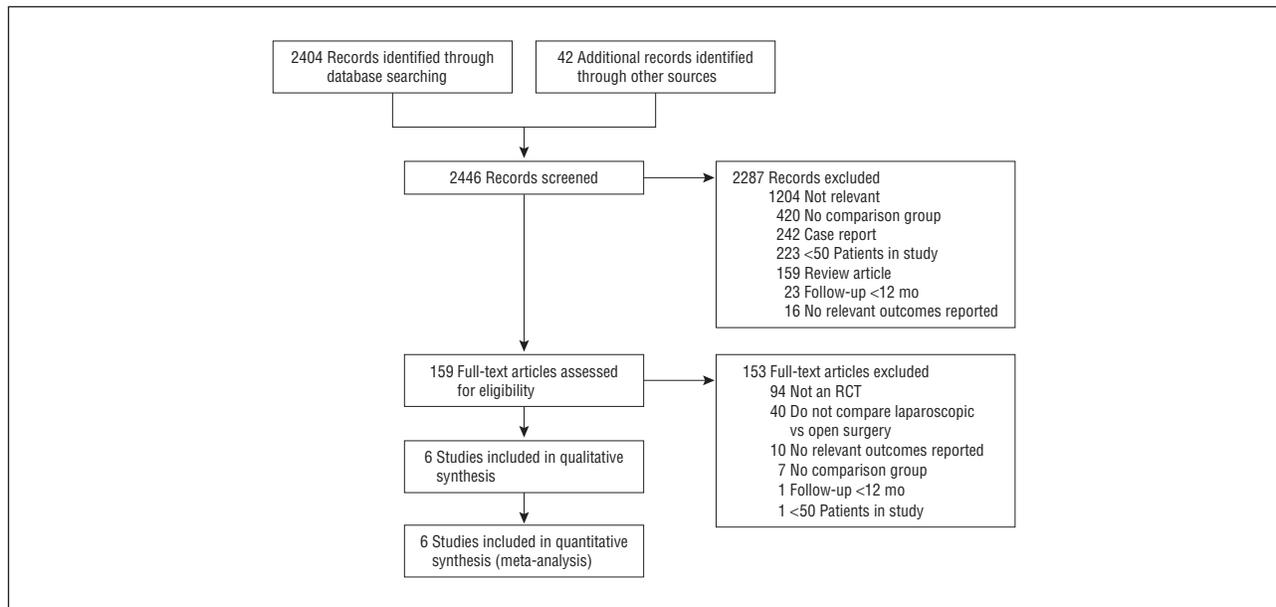


Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) flow diagram of randomized controlled trials (RCTs).<sup>13</sup>

## METHODS

### DATA SOURCES AND SEARCHES

We systematically searched the Cochrane Library, EMBASE, and MEDLINE databases through June 1, 2010, using the following terms: *adjustable gastric banding, bariatric, bariatric surgery, biliopancreatic diversion with duodenal switch, bypass, gastric bypass, gastric pacing, gastric stimulation, gastroplasty, implantable gastric stimulation, jejunoileal bypass, ligation, obesity, Roux-en-Y, sleeve gastrectomy, vertical banded gastroplasty, and weight loss*. We limited our search to RCTs involving adults and published in English. References from previous RCTs and reviews were examined for potentially relevant publications not identified in the database search.

### STUDY SELECTION

Studies eligible for inclusion met the following criteria: (1) they randomized patients to laparoscopic vs open bariatric surgery, (2) they reported weight loss outcomes and complications (reoperation, wound infection, incisional hernia, anastomotic leak, and all-cause mortality), (3) they had a follow-up period of at least 12 months, and (4) they had 50 or more patients. The sample size criterion was included to minimize the effects of publication bias. All studies that did not meet these criteria were excluded.

### DATA EXTRACTION

Our study was performed according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) statement for reporting systematic reviews and meta-analyses (Figure 1).<sup>13</sup> Two reviewers (J.R. and S.M.) independently extracted data using a standardized extraction form. The rate of disagreement for extracted data was less than 5% between the 2 reviewers. Disagreements were resolved by consensus or, when necessary, by a third reviewer (M.J.E.). Data extracted included the following: patient population, type of procedure, duration of procedure, length of hospital stay, baseline characteristics (age, sex, weight, and body mass index), study design

characteristics (eg, setting, number of patients per treatment arm, and length of follow-up period), and outcome data (change in weight and body mass index and the incidence of reoperation, wound infection, incisional hernia, anastomotic leak, and all-cause mortality).

### QUALITY ASSESSMENT

We used the Cochrane Collaboration's tool for assessing the risk of bias,<sup>14</sup> focusing on the following 6 criteria: (1) sequence generation; (2) allocation concealment; (3) blinding of participants, personnel, and outcome assessors; (4) incomplete outcome data; (5) selective outcome reporting; and (6) other sources of bias. Each RCT was classified as "high quality," "low quality," or "unclear quality" for each criterion.

### DATA SYNTHESIS AND META-ANALYSIS

We used random-effects models by DerSimonian and Laird,<sup>15</sup> which accounted for within-study and between-study variability, to estimate pooled risk ratios (95% CIs). Forest plots were created for each outcome. We used a 0.5 continuity correction for trials with no events in one or both treatment groups. We calculated  $I^2$  statistics to estimate the proportion of overall variation that was attributable to between-trial heterogeneity. We assessed for publication bias using the modified test for small-study effects by Harbord et al.<sup>16</sup> For data handling and statistical analyses, we used commercially available software (Excel 2007<sup>17</sup> [Microsoft Corporation, Redmond, Washington] and STATA 9.0<sup>18</sup> [StataCorp LP, College Station, Texas]).

## RESULTS

### SEARCH FINDINGS AND STUDY INCLUSION

Our literature search identified 2446 potentially relevant studies (Figure 1); 159 were retrieved for full-text assessment, and 6 met our inclusion criteria. The remaining 153 studies were excluded for the following rea-

sons: (1) they were not an RCT (n=94), (2) they did not compare laparoscopic with open bariatric surgery (n=40), (3) they did not include outcomes relevant to our study (n=10), (4) they did not include a comparison group (n=7), (5) the total sample size was fewer than 50 patients (n=1), or (6) the follow-up period was less than 12 months (n=1). The RCT<sup>19</sup> excluded for having fewer than 50 patients did not report enough relevant outcomes to warrant inclusion.

### RISK OF BIAS

The risk of bias was unknown for many included RCTs (**Figure 2**). Specifically, 3 RCTs<sup>20-22</sup> did not report sequence generation, and 4 RCTs<sup>20-23</sup> did not report allocation concealment. Only 1 RCT<sup>21</sup> blinded the participants to their treatment group, and none mentioned whether outcome assessors were blinded.<sup>20-25</sup> Two RCTs<sup>21,25</sup> did not provide the number of patients at follow-up periods, and 1 RCT<sup>25</sup> reported weight loss outcomes in a figure; therefore, the risk of incomplete outcome data was unknown. Finally, 2 RCTs<sup>20,21</sup> used blocked randomization with fixed block sizes in an unblinded trial, and 1 study<sup>22</sup> had an unbalanced prevalence of comorbidity between the treatment groups; these RCTs were classified as having a high risk of other sources of bias. Using the modified test for small-study effects by Harbord et al,<sup>16</sup> our results suggest that there

was no publication bias among the RCTs in our meta-analysis for reoperation (P=.18), wound infection (P=.95), incisional hernia (P=.22), or anastomotic leak (P=.99).

### BASELINE CHARACTERISTICS

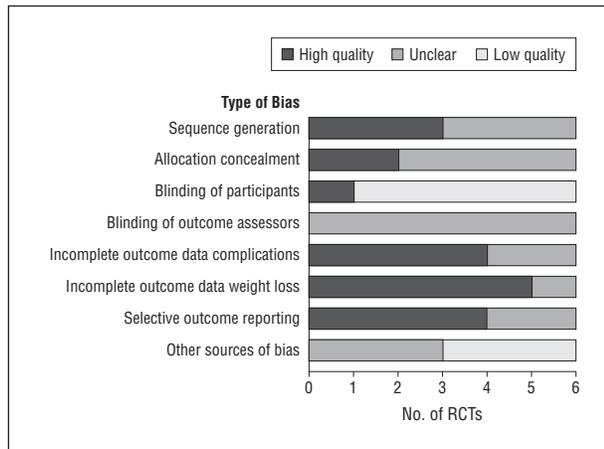
Reported baseline data were similar across laparoscopic and open bariatric surgery groups (**Table 1**). The mean age ranged from 37 to 42 years, and the percentage of female patients ranged from 68% to 92%. All patients were considered to have morbid obesity. The mean weight at baseline, reported in 3 RCTs, ranged from 130.7 to 152.2 kg. The mean body mass index at baseline ranged from 41 to 52.

### STUDY DESIGN AND OPERATIVE CHARACTERISTICS

The 6 included RCTs randomized a total of 262 patients to laparoscopic bariatric surgery and 248 patients to open bariatric surgery (**Table 2**). Follow-up periods ranged from 12 to 24 months. Four RCTs reported the prevalence of loss to follow-up, which ranged from 0.0% to 2.0%. Operative time ranged from 150 to 245 minutes in the laparoscopic group and from 76 to 202 minutes in the open group. The mean length of hospital stay ranged from 3 to 6 days in the laparoscopic group and from 4 to 8 days in the open group, suggesting that laparoscopic surgery was associated with, on average, a reduction of 1 to 3 days in the hospital. We were unable to pool the data on length of hospital stay because only 2 studies reported standard deviations.

### COMPLICATIONS

Complications reported for each RCT include reoperation, wound infection, incisional hernia, anastomotic leak, and all-cause mortality (**Table 3**). The number of patients who required reoperation ranged from 1 to 20 patients in the laparoscopic group and from 0 to 21 patients in the open group. The risk of reoperation was similar in the 2 groups (relative risk [RR] of laparoscopic vs open surgery, 1.06; 95% CI, 0.70-1.61), albeit with a wide 95% CI (**Figure 3**). Most RCTs included in our meta-analysis reported anastomotic leak (4 studies) and intestinal obstruction (3 studies) as reasons for re-



**Figure 2.** Quality assessment of 6 included randomized controlled trials (RCTs) using the *Cochrane Handbook for Systematic Reviews of Interventions*.<sup>14</sup>

**Table 1. Baseline Characteristics Reported in Included Randomized Controlled Trials**

Source	Sample Size		Age, Mean (SD), y		Female Sex, %		Weight, Mean (SD), kg		BMI, Mean (SD)		No. (%)			
	LAP	Open	LAP	Open	LAP	Open	LAP	Open	LAP	Open	Diabetes Mellitus		Hypertension	
											LAP	Open	LAP	Open
Nguyen et al, <sup>20</sup> 2001	79	76	40	42	91	88	131.1 (17.2)	134.2 (20.0)	48 (5)	48 (5)	8 (10.1)	14 (18.4)	26 (32.9)	31 (40.8)
Luján et al, <sup>25</sup> 2004	53	51	37	38	81	75	130.7	137.6	49	52	...	...	...	...
van Dielen et al, <sup>23</sup> 2005	50	50	37 (10)	39 (9)	80	80	...	...	47 (6)	47 (6)	5 (10.0)	7 (14.0)	7 (14.0)	10 (20.0)
Westling and Gustavsson, <sup>21</sup> 2001	30	21	...	...	...	...	...	...	41 (4)	44 (4)	0	1 (4.8)	7 (23.3)	0
de Wit et al, <sup>24</sup> 1999	25	25	...	...	68	68	152.2 (31.4)	146.4 (19.9)	51 (10)	50 (6)	3 (12.0)	0	4 (16.0)	2 (8.0)
Sundbom and Gustavsson, <sup>22</sup> 2004	25	25	37 <sup>a</sup>	38 <sup>a</sup>	92	88	...	...	44 <sup>a</sup>	45 <sup>a</sup>	...	...	...	...

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); LAP, laparoscopic.  
<sup>a</sup>Median.

**Table 2. Study Design and Operative Characteristics Reported in Included Randomized Controlled Trials**

Source	Country	Sample Size		Lost to Follow-up, No. (%)	Maximum Follow-up Period, mo	Type of Procedure		Mean (SD)			
		LAP	Open			LAP	Open	Operative Time, min		Length of Hospital Stay, d	
								LAP	Open	LAP	Open
Nguyen et al, <sup>20</sup> 2001	United States	79	76	...	23	GBP	GBP	225 (40)	195 (41)	3	4
Luján et al, <sup>25</sup> 2004	Spain	53	51	...	...	GBP	GBP	186	202	5	8
van Dielen et al, <sup>23</sup> 2005	Netherlands	50	50	2 (2.0)	24	GB	VBG	...	...	4 (2)	7 (10)
Westling and Gustavsson, <sup>21</sup> 2001	Sweden	30	21	0	...	GBP	GBP	245 <sup>a</sup>	100 <sup>a</sup>	5 (1)	6 (4)
de Wit et al, <sup>24</sup> 1999	Netherlands	25	25	1 (2.0)	12	GB	GB	150 (48)	76 (20)	6	7
Sundbom and Gustavsson, <sup>22</sup> 2004	Sweden	25	25	0	12	GBP <sup>b</sup>	GBP	150 <sup>a</sup>	85 <sup>a</sup>	6 <sup>a</sup>	6 <sup>a</sup>

Abbreviations: GB, gastric banding; GBP, gastric bypass; LAP, laparoscopic; VBG, vertical banded gastroplasty.

<sup>a</sup>Median.

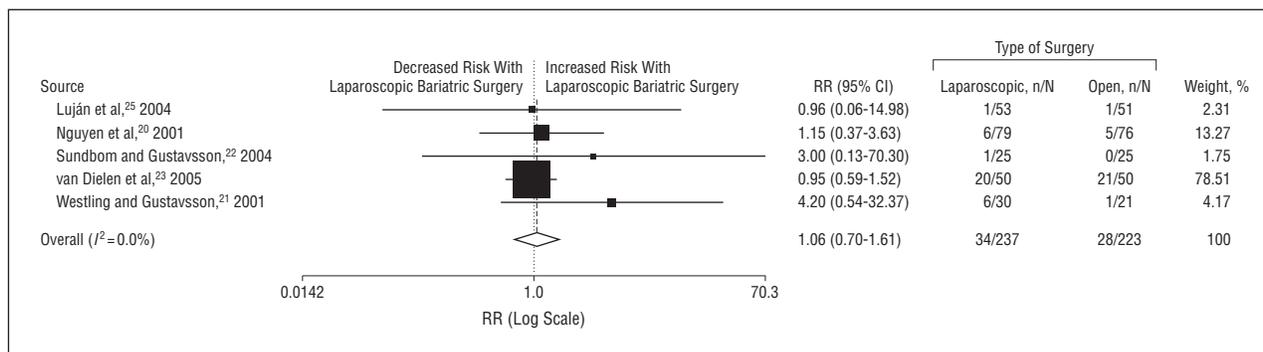
<sup>b</sup>Hand-assisted laparoscopic GBP.

**Table 3. Complications Reported in Included Randomized Controlled Trials**

Source	Sample Size		No. (%)									
	LAP	Open	Reoperation		Wound Infection		Incisional Hernia		Anastomotic Leak		All-Cause Mortality	
			LAP	Open	LAP	Open	LAP	Open	LAP	Open	LAP	Open
Nguyen et al, <sup>20</sup> 2001	79	76	6 (7.6)	5 (6.6) <sup>a</sup>	1 (1.3)	8 (10.5)	0	6 (7.9)	1 (1.3)	1 (1.3)	0	0
Luján et al, <sup>25</sup> 2004	53	51	1 (1.9)	1 (2.0)	0	4 (7.8)	0	10 (19.6)	2 (3.8)	0	2 (3.8)	1 (2.0)
van Dielen et al, <sup>23</sup> 2005	50	50	20 (40.0)	21 (42.0)	0	1 (2.0)	0	8 (16.0)	0	6 (6.0)	0	2 (4.0)
Westling and Gustavsson, <sup>21</sup> 2001	30	21	6 (20.0)	1 (4.8)	0	3 (14.3)	0	1 (4.8)	0	1 (4.8)	0	0
de Wit et al, <sup>24</sup> 1999	25	25	...	...	0	1 (4.0)	0	3 (12.5)	...	...	0	0
Sundbom and Gustavsson, <sup>22</sup> 2004	25	25	1 (4.0)	0	1 (4.0)	1 (4.0)	0	1 (4.0)	...	...	0	0

Abbreviation: LAP, laparoscopic.

<sup>a</sup>The article by Nguyen et al reported in their table that there were 6 reoperations in the laparoscopic group and 5 reoperations in the open group. However, the data in their table do not match their data reported in the text. A description of complications in the text included 6 reoperations in the laparoscopic group but only 1 reoperation in the open group. We conducted a sensitivity analyses using these data and obtained treatment effects (relative risk = 1.63, 95% CI = 0.68-3.90) that were consistent with those of our primary analysis.



**Figure 3.** Relative risk (RR) of reoperation in laparoscopic vs open bariatric surgery. The point estimate suggests that the risk of reoperation is similar for laparoscopic vs open bariatric surgery; however, the 95% CI is wide and does not preclude an effect. Diamond indicates overall summary estimate for the analysis (width of the diamond represents the 95% CI); width of the solid square, studies weight within the meta-analysis; and dot, the study-specific point estimate.

operation (**Table 4**). The incidence of wound infection ranged from 0 to 1 in the laparoscopic group vs 1 to 8 in the open group. The risk of wound infection was substantially lower in the laparoscopic group (RR, 0.21;

95% CI, 0.07-0.65) (**Figure 4**). The incidence of incisional hernia was 0 in the laparoscopic group and ranged from 1 to 10 in the open group. The risk of incisional hernia was substantially lower in the laparo-

**Table 4. Reasons for Reoperation and Causes of Mortality**

Source	Sample Size		Reasons for Reoperation		Causes of Mortality	
	LAP	Open	LAP	Open	LAP	Open
Nguyen et al, <sup>20</sup> 2001	79	76	Intestinal obstruction (n = 3), anastomotic leak (n = 1), gastrointestinal hemorrhage (n = 1), hypopharyngeal injury (n = 1)	Unknown causes (n = 4), retained laparotomy sponge (n = 1) <sup>a</sup>	No mortality	No mortality
Luján et al, <sup>25</sup> 2004	53	51	Intestinal obstruction (n = 1)	Intestinal obstruction (n = 1)	Intestinal obstruction (n = 1), sudden death (n = 1) <sup>b</sup>	Evisceration (n = 1)
van Dielen et al, <sup>23</sup> 2005	50	50	Pouch dilations or slippage (n = 12), band erosions (n = 2), band leakages (n = 2), painful access ports (n = 2), infection around access port (n = 1), port leakage (n = 1)	Staple line disruptions (n = 15), anastomotic leak (n = 3), narrow gastric outlet (n = 2), insufficient weight loss (n = 1)	No mortality	Pneumonia (n = 1), sepsis (n = 1)
Westling and Gustavsson, <sup>21</sup> 2001	30	21	Intestinal obstruction (n = 6)	Anastomotic leak (n = 1)	No mortality	No mortality
de Wit et al, <sup>24</sup> 1999	25	25	No reoperations	No reoperations	No mortality	No mortality
Sundbom and Gustavsson, <sup>22</sup> 2004	25	25	Anastomotic leak (n = 1)	No reoperations	No mortality	No mortality

Abbreviation: LAP, laparoscopic.

<sup>a</sup>The article by Nguyen et al reported in their table that there were 6 reoperations in the laparoscopic group and 5 reoperations in the open group. However, the data in their table do not match the data reported in their text. A description of complications in the text included 6 reoperations in the laparoscopic group but only 1 reoperation in the open group.

<sup>b</sup>Unrelated to the operation.

scopic group (RR, 0.11; 95% CI, 0.03-0.35) (**Figure 5**). The incidence of anastomotic leak ranged from 0 to 2 in the laparoscopic group and from 0 to 3 in the open group. The risk of anastomotic leak was lower in the laparoscopic group (RR, 0.64; 95% CI, 0.14-2.95); however, the 95% CI was wide (**Figure 6**). Finally, the incidence of all-cause mortality ranged from 0 to 2 in the laparoscopic group and from 0 to 2 in the open group. Although the point estimate suggested that the risk of all-cause mortality was similar for both groups, the result is debatable because of the wide 95% CI (RR, 0.86; 95% CI, 0.22-3.28) (**Figure 7**).

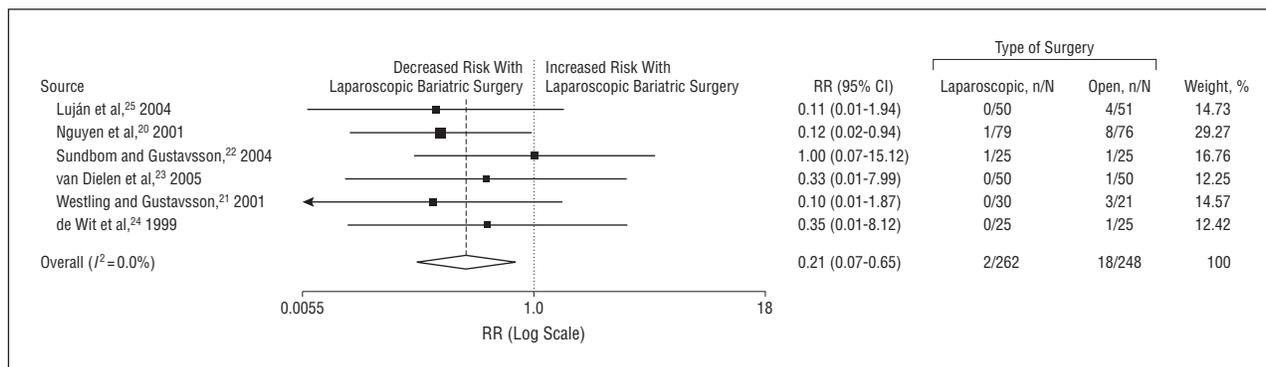
#### WEIGHT LOSS OUTCOMES

Weight loss outcomes at 12 months' follow-up were reported in 5 of 6 RCTs (**Table 5**). Four RCTs reported the mean change in body mass index, which ranged from -11.6 to -15.0 in the laparoscopic group and from -10.6 to -15.5 in the open group. Two RCTs reported the mean weight loss in kilograms, which ranged from -35.0 to -39.0 kg in the laparoscopic group and from -34.4 to -41.0 kg in the open group. Only 1 study<sup>25</sup> reported the mean (SD) percentage change in excess body weight, which was -68% (-15%) for the laparoscopic group and -62% (-14%) for the open group.

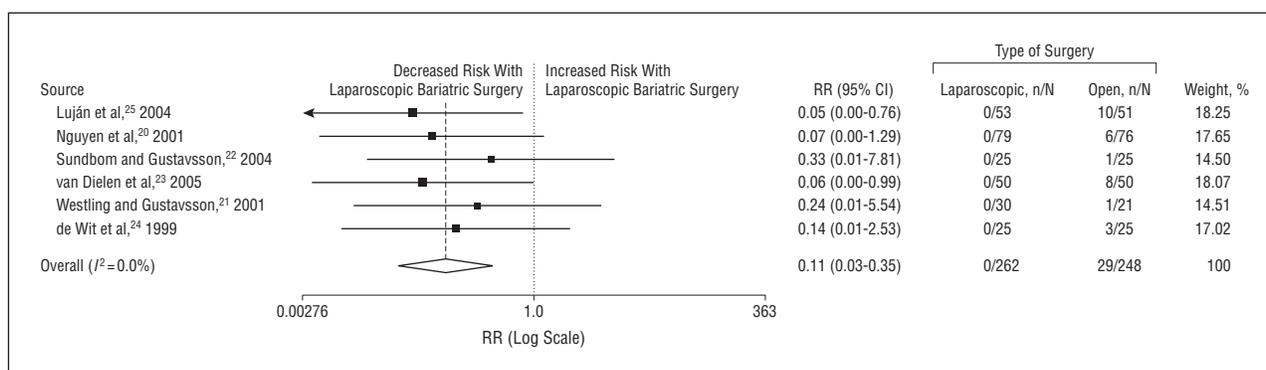
#### COMMENT

Several review articles<sup>26-28</sup> have examined laparoscopic and open bariatric surgery. A Cochrane Collaboration study<sup>26</sup> published in 2009 reviewed data on mortality, reoperation, complications, and weight loss; however, this study did not statistically pool data to provide comparative treatment effects. Two other articles<sup>27,28</sup> reviewed data from observational studies and RCTs examining complications and found that rates of wound infection and incisional hernia were lower with laparoscopic surgery, whereas the rate of small-bowel obstruction was higher with laparoscopic surgery. Most important, these reviews did not directly compare laparoscopic and open bariatric surgical procedures, and no comparative treatment effects were available.

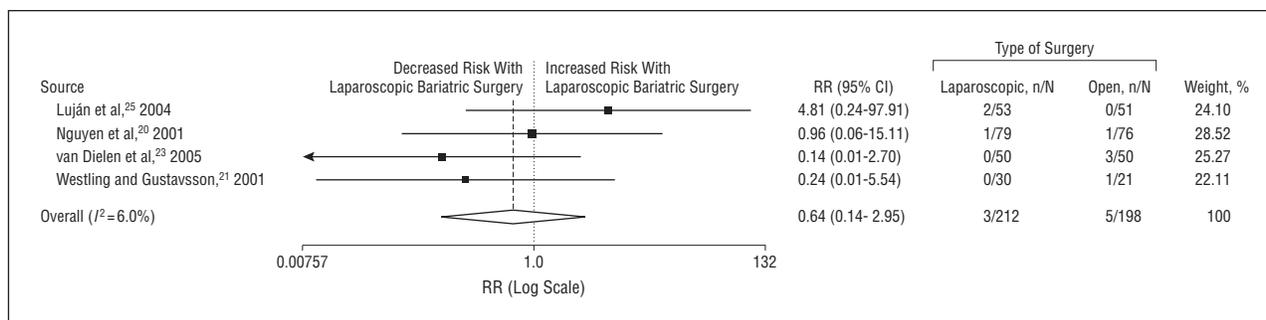
Two previous meta-analyses<sup>29,30</sup> examined laparoscopic and open bariatric surgery. Buchwald et al<sup>29</sup> showed that the absolute risk of mortality was low, similar to that reported herein. Maggard et al<sup>30</sup> pooled data on weight loss, complications, and mortality for laparoscopic and open bariatric surgery groups. The risks of wound infection and incisional hernia were lower in the laparoscopic group compared with the open group. However, this meta-analysis included observational and RCT data, complicating interpreta-



**Figure 4.** Relative risk (RR) of wound infection in laparoscopic vs open bariatric surgery. Laparoscopic surgery is associated with a lower risk of wound infection compared with open bariatric surgery (RR, 0.21; 95% CI, 0.07-0.65). See the legend to Figure 3 for an explanation of the symbols in the Forest plot.



**Figure 5.** Relative risk (RR) of incisional hernia in laparoscopic vs open bariatric surgery. Laparoscopic surgery is associated with a lower risk of incisional hernia compared with open bariatric surgery (RR, 0.11; 95% CI, 0.03-0.35). See the legend to Figure 3 for an explanation of the symbols in the Forest plot.



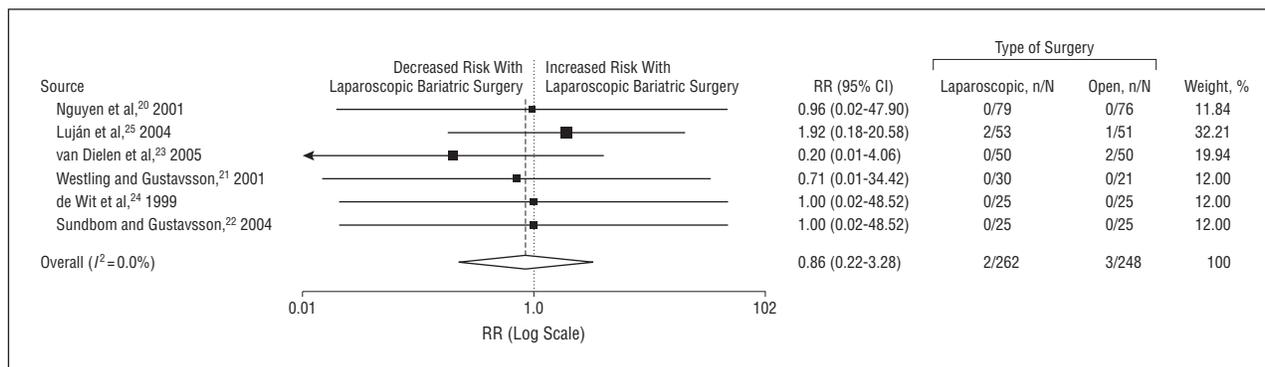
**Figure 6.** Relative risk (RR) of anastomotic leak in laparoscopic vs open bariatric surgery. The point estimate suggests that the risk of anastomotic leak is similar for laparoscopic vs open bariatric surgery; however, the 95% CI is wide and does not preclude an effect. See the legend to Figure 3 for an explanation of the symbols in the Forest plot.

tion of their results. Our study provides evidence based exclusively on RCTs to avoid the possible selection bias associated with observational studies.

Our study was designed to compare the risk of complications associated with laparoscopic vs open bariatric surgery. We found that laparoscopic surgery lowered the risk of wound infection by 79% and the risk of incisional hernia by 89% compared with open surgery. The risks of reoperation, anastomotic leak, and all-cause mortality were similar for the 2 types of surgery. Too few investigations have been conducted to conclude that there is no difference in the risk of these complications; therefore, additional studies may be necessary. We were unable to pool weight loss data at 12

months' follow-up because of the heterogeneous reporting. However, RCTs reporting weight loss showed no clinically important difference between laparoscopic and open surgery. Our results suggest that laparoscopic surgery is the operation of choice for patients undergoing bariatric surgery because it reduces the risk of wound infection and incisional hernia. However, we were unable to include in our study other important complications, such as pulmonary findings, small-bowel obstruction, hemorrhage, and gastrointestinal tract results.

Because laparoscopic bariatric surgery is characterized by smaller incisions, reducing the healing time and exposure to microorganisms, it is not surprising that it is associated with a lower risk of wound infection and



**Figure 7.** Relative risk (RR) of all-cause mortality in laparoscopic vs open bariatric surgery. The point estimate suggests that the risk of all-cause mortality is similar for laparoscopic vs open bariatric surgery; however, the 95% CI is wide and does not preclude an effect. See the legend to Figure 3 for an explanation of the symbols in the Forest plot.

**Table 5. Weight Loss Outcomes at 12 Months' Follow-up Reported in Included Randomized Controlled Trials**

Source	Sample Size		Mean (SD)							
	LAP	Open	Baseline BMI		Follow-up BMI		Weight Loss, kg		BMI Change	
			LAP	Open	LAP	Open	LAP	Open	LAP	Open
Nguyen et al. <sup>20</sup> 2001	79	76	48 (5)	48 (5)	...	...	...	...	...	...
Luján et al. <sup>25</sup> 2004	53	51	49	52	...	...	...	...	...	...
van Dielen et al. <sup>23</sup> 2005	50	50	47 (6)	47 (6)	35 (7)	31 (6)	...	...	-12.0	-16.0
Westling and Gustavsson, <sup>21</sup> 2001	30	21	41 (4)	44 (4)	27 (4)	31 (4)	...	...	-14.0 (3.0)	-13.0 (3.0)
de Wit et al. <sup>24</sup> 1999	25	25	51 (10)	50 (6)	40 (9)	39 (8)	-35.0	-34.4	-11.0	-11.0
Sundbom and Gustavsson, <sup>22</sup> 2004	25	25	44	45	29	30	-39.0	-41.0	-15.0	-15.0

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); LAP, laparoscopic.

incisional hernia compared with open surgery. Observational cohort studies<sup>12,31-37</sup> have corroborated this hypothesis. Given the inherent limitations of observational studies, such as potential selection bias, confounding, and investigator bias, it was necessary to evaluate the risk of these complications in RCTs. The sample sizes of the individual RCTs included in our meta-analysis were too small to provide reliable conclusions about the safety of laparoscopic vs open bariatric surgery. By pooling data across RCTs, we obtained more precise 95% CIs. Hence, we showed a decrease in the risk of wound infection and incisional hernia among patients undergoing laparoscopic bariatric surgery compared with those undergoing open bariatric surgery.

The risk of reoperation was similar in the laparoscopic and open surgery groups. However, given the wide 95% CIs and the few studies reporting reoperation in our meta-analysis, more studies may be needed to confirm this. Previous observational studies<sup>36,37</sup> found no difference in the risk of reoperation between laparoscopic and open bariatric surgery. In contrast, a cross-sectional study<sup>38</sup> of more than 19 000 patients undergoing bariatric surgery in 2005 found increased reoperation in the open surgery group compared with the laparoscopic surgery group (odds ratio [OR], 3.71; 95% CI, 2.47-5.59). Hence, a difference in the risk of reoperation between laparoscopic and open bariatric surgery remains debatable. The information available herein and in the literature about anastomotic leak is inconclusive.<sup>31,33,35,36</sup> However, the risk of anastomotic leak decreases as bariatric surgeons gain more experience.<sup>31</sup> Although no firm conclusions can be drawn, our results suggest that lapa-

roscopic and open bariatric surgical procedures are associated with a similar risk of anastomotic leak.

Our findings indicate that bariatric surgery is a safe method of weight loss, as there was little mortality associated with laparoscopic and open procedures among a low-risk young population. Previous high-quality trials<sup>6-8,39</sup> have illustrated the potential benefits of obesity surgery. The improvements gained with bariatric surgery far outweigh the small risk of mortality associated with the procedure.

We were unable to pool the weight loss data at 12 months' follow-up because of a large variability in the types of weight loss outcomes reported. Four RCTs reported the mean change in body mass index, which was the most common weight loss outcome reported, but only 1 RCT provided the standard deviation. Furthermore, 12-month weight loss data may be too short to be indicative of end results for bariatric surgery. The included RCTs did not report long-term weight loss data; therefore, additional RCTs may be necessary.

Our meta-analysis has several potential limitations. First, because of the limited number of RCTs comparing laparoscopic with open bariatric surgery, our meta-analysis did not have sufficient precision to conclusively compare the effects of laparoscopic and open surgery on the risks of reoperation, anastomotic leak, or all-cause mortality. Second, owing to heterogeneous reporting, we were unable to pool weight loss data. A standard weight loss outcome is necessary to effectively compare weight loss between these surgical procedures. Furthermore, additional RCTs with longer follow-up data are needed to provide meaningful weight loss outcomes for

bariatric surgery. Third, owing to inconsistent reporting of complications, we were unable to address the risk associated with other complications (eg, pulmonary findings, cardiovascular events, bowel obstructions, hemorrhage, or gastrointestinal symptoms). More information on these complications is required to provide a more complete comparison of laparoscopic and open bariatric surgery. Fourth, as is true for most systematic reviews and meta-analyses, our meta-analysis may have been affected by publication bias. However, we assessed for publication bias using the modified test for small-study effects by Harbord et al<sup>16</sup> and found no effect. Fifth, one of our included RCTs used a hand-assisted laparoscopic technique. The hand-assisted technique makes use of a larger incision than traditional laparoscopic surgery, and it may not be appropriate to pool these techniques. However, a previous prospective study<sup>40</sup> of 272 patients compared hand-assisted with laparoscopic gastric bypass and found no difference in the risk of complications. Therefore, we included the hand-assisted technique in the laparoscopic bariatric surgery group.

In conclusion, although data from RCTs are limited, our meta-analysis demonstrates that laparoscopic bariatric surgery is associated with a substantially lower risk of wound infection and incisional hernia compared with open bariatric surgery. The differences between laparoscopic and open bariatric surgery with regard to the risks of reoperation, anastomotic leak, and all-cause mortality remain unknown. However, the risk of all-cause mortality is low in both groups among this young population. Weight loss may be similar between the 2 groups at 12 months. Further research using a standardized method of reporting weight loss and a longer follow-up period is needed to conclusively determine the most efficacious technique for bariatric surgery. Given the current information, we believe that laparoscopic and open bariatric surgical procedures are safe, but laparoscopic bariatric surgery seems to be the technique of choice.

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## INVITED CRITIQUE

# Bandwagon Forward

In the article by Reoch et al<sup>1</sup> in this issue of the *Archives*, the authors have followed strict criteria in describing RCTs of laparoscopic vs open bariatric surgery. Their “usable” RCTs require adult patients, at least 12 months’ follow-up, a listing of weight loss outcomes and certain potential complications, and publication in the English language. Thereby, more than 2400 articles on outcomes of bariatric surgery have been reduced to 6 studies that meet their RCT criteria. Yet, these 6 had variable and inconsistent reporting methods, so that pooling of weight loss data and risk reporting of certain complications were impossible. Commendably, the RCTs are real comparisons of 2 techniques rather than large observational studies of bariatric surgical experience by a single surgeon or institution.

The authors address a major technological change in bariatric surgery that started by 1994 and became timely and popular during the last 10 years. This is the technical shift to laparoscopic surgery that has occurred in almost all of general surgery and in many of the surgical subspecialties. As such, the consumer has concluded that a “bandwagon” is rolling and that they and all surgical personnel should get on it. Therein lies the purpose of this “Invited Critique.” The readers (and myself) should conclude that the laparoscopic bandwagon is safe and appropriate for their bariatric surgery (if needed), given that their surgeon under consideration has prowess. Indeed, as the authors of this meta-analysis disclose, the laparoscopic approach reduces the number of wound infection and incisional hernia complications, which have a recognized incidence in open operations. However, both laparoscopic and open operations have risks, whereby anastomotic and anatomical difficulties may occur, and perioperative mortality from varied causes has a low but real potential. The hospital stay with the laparoscopic procedure should indeed be shorter, and the patient’s return to work or to preoperative activity should be speedier. This is why the patients are excited,

their employers and insurance carriers are enthusiastic, and the bandwagon is rolling.

The other prime issue is effectiveness of the major lifestyle undertaking associated with bariatric surgery. The long-term results are important. The present study fails (and was not set up) to provide a long-term assessment because it is restricted to RCTs that are published with only 1-year weight loss results. Mervyn Deitel, MD, founder and an early editor of *Obesity Surgery*, frequently complained when he sent me manuscripts for review that weight loss results that did not reach well beyond 3 years had limited claim on final outcomes. Brolin et al<sup>2</sup> and my own study<sup>3</sup> have claimed and clarified that 1- or 2-year weight loss data are an inadequate overall picture, partly because of recidivism, and that 4- or 5-year outcomes are desirable and are more likely representative of the operation’s worth. Long-term data are available, of course, with results of open procedures in large observational studies.

Yet, the anatomical changes constructed for laparoscopic and open approaches to the same bariatric operation (eg, Roux-en-Y gastric bypass) should provide equivalent weight loss results. Time will tell.

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