Mortality After Bariatric Surgery

Analysis of 13,871 Morbidly Obese Patients From a National Registry

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Objective: To define mortality rates and risk factors of different bariatric procedures and to identify strategies to reduce the surgical risk in patients undergoing bariatric surgery.

Summary Background Data: Postoperative mortality is a rare event after bariatric surgery. Therefore, comprehensive data on mortality are lacking in the literature.

Methods: A retrospective analysis of a large prospective database was carried out. The Italian Society of Obesity Surgery runs a National Registry on bariatric surgery where all procedures performed by members of the Society should be included prospectively. This Registry represents at present the largest database on bariatric surgery worldwide.

Results: Between January 1996 and January 2006, 13,871 bariatric surgical procedures were included: 6122 adjustable silicone gastric bandings (ASGB), 4215 vertical banded gastroplasties (VBG), 1106 gastric bypasses, 1988 biliopancreatic diversions (BPD), 303 biliointestinal bypasses, and 137 various procedures. Sixty day mortality was 0.25%. The type of surgical procedure significantly influenced ($P < 0.001$) mortality risk: 0.1% ASGB, 0.15% VBG, 0.54% gastric bypasses, 0.8% BPD. Pulmonary embolism represented the most common cause of death (38.2%) and was significantly higher in the BPD group (0.4% vs. 0.07% VBG and 0.03% ASGB). Other causes of mortality were the following: cardiac failure 17.6%, intestinal leak 17.6%, respiratory failure 11.8%, and 1 case each of acute pancreatitis, cerebral ischemia, bleeding gastric ulcer, intestinal ischemia, and internal hernia. Therefore, 29.4% of patients died as a result of a direct technical complication of the procedure. Additional significant risk factors included open surgery ($P < 0.001$), prolonged operative time ($P < 0.05$), preoperative hypertension ($P < 0.01$) or diabetes ($P < 0.05$), and case load per Center ($P < 0.01$).

Conclusions: Mortality after bariatric surgery is a rare event. It is influenced by different risk factors including type of surgery, open surgery, prolonged operative time, comorbidities, and volume of activity. In defining the best bariatric procedure for each patient the different mortality risks should be taken into account. Choice of the procedure, prevention, early diagnosis, and therapy for cardiovascular complications may reduce postoperative mortality.

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Bariatric surgery remains the only proven mechanism for inducing both sustained and profound weight loss for morbidly obese individuals.[1–4] Postoperative mortality, the most feared outcome of bariatric surgery, is a rare event: published rates of postoperative mortality range from 0.05% to 2%.[5–7]

Detecting small (but clinically important) differences in mortality between different bariatric procedures and identifying perioperative risk factors are difficult tasks to perform in traditional cohort studies and randomized controlled trials. A recent large cohort study reported a 1.5% mortality rate after gastric bypass and identified anastomotic leak, pulmonary embolus, preoperative weight, and preoperative hypertension as associated with postoperative mortality.[6] However, relatively few deaths were available for analysis and robust regression modeling. Furthermore, no studies have compared large series of different bariatric procedures in terms of mortality rates. The only comparative data resulted from small randomized controlled trials[8–12] enrolling no more than 100 patients in each group and therefore reporting only occasional deaths.

The charge of identifying differences in mortality rates and risk factors for mortality in different bariatric procedures may be ideally suited to the use of a large dataset such as a National Registry. The Italian Society of Obesity Surgery (SICOB) runs a National Registry on bariatric surgery where all procedures performed by members of the Society are included prospectively. This Registry represents, to our knowledge, the largest prospective database on bariatric surgery worldwide.

The aim of this study was to define mortality rates and risk factors of different bariatric procedures by analyzing data of the first 10 years of activity of the SICOB Registry, to identify strategies to reduce the surgical risk in patients undergoing bariatric surgery.

METHODS

The study consists of a retrospective analysis of a prospective database.

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SICOB is the Italian surgical society devoted to bariatric surgery and was founded in 1991. In January 1996, SICOB initiated a prospective database to include all surgical bariatric procedures performed by SICOB members from January 1, 1996 onward: the “SICOB Registry”. In 1996 the Registry included 13 Centers; the number of Centers affiliated to the Registry increased progressively, reaching in 2005 a total number of 55. It was mandatory for SICOB members to enroll all bariatric cases in the Registry. Data were collected by filling a specific form, prepared and approved by SICOB Scientific Committee. Data collection was centralized at the Department of Surgery of the University of Turin. Because our study used existing data with encrypted identifiers, written consent from subjects was not required.

Patients were considered eligible for surgery for obesity according to the 1991 National Institutes of Health Consensus Conference guidelines[13] if their body mass index (BMI) was $>$35 kg/m^2 associated with obesity related comorbidity or $>$40 kg/m^2 with or without comorbidity.

The database maintained information on age, gender, preoperative weight, preoperative BMI, patient comorbidities (hypertension, diabetes mellitus, hyperlipemia), previous surgical procedures, operative time, type of surgery, associated surgical procedures, and complications. After reviewing recent studies,[1,14–18] we classified complications, that occurred during admissions for a bariatric surgical procedure, by codes into 2 categories: technical and systemic. Technical complications included unexpected reoperations for surgical complications, splenic injury, hemorrhage, intestinal leak (defined as any anastomotic disruptions, intestinal perforations, or staple line disruptions), occlusion, and wound complications. Systemic complications included respiratory tract, cardiac, neurologic, thromboembolic, genitourinary tract, and multisystemic (shock) complications.

The data were evaluated to find factors related to early death. Early deaths were defined as deaths that occurred within 60 days of the initial procedure. The complete clinical report of each patient who died was examined to identify cause of death, perioperative pharmacological and anesthesiological protocols, interval between surgery, the occurrence of the complication and death, etc.

Each SICOB Center was identified by a progressive number and each death was correlated to the Center’s global experience in bariatric procedures and in the specific procedure that lead to patient death; furthermore, mortality rates were correlated to each Center global bariatric case load. Centers were divided into 2 groups: a high case volume hospital was defined as one that included $>$100 cases, a low volume hospital was defined as one that included $<$100 cases.

Statistical Analysis

Prospective data were collected and managed using Microsoft Excel (Microsoft Corp., Redmond, WA). This analysis was essentially a descriptive evaluation of mortality rates after bariatric procedures among different groups within the SICOB Registry cohort, and no a priori power calculation were performed.

An independent investigator examined the Registry data and the complete clinical report of each dead patient.

Preoperative patient risk factors and postoperative mortality and complications rate were compared between the different bariatric procedures and surgical approaches using χ^2 or Fisher exact test tests for categorical variables. Two-tailed *t*-tests or Wilcoxon 2-sample tests were used for continuous variables depending on distribution. All *P* values were 2-sided. Stepwise logistic regression analysis was performed to know which predictor variables were statistically significant and correlated to the patients mortality risk. Many predictor variables were included into the analysis: sex, gender, BMI, hypertension, diabetes, hyperlipemia, surgical access, operative time, previous surgery, associated surgical procedures, and type of procedure. Some of them are dichotomous and some are continuous predictor variables. The results of analysis will be presented in a term of *z*-statistic from the Wald test and its *P* value, the standardized odds ratio, and the standard deviation of variable. A *P* value of 0.05 or less was considered statistically significant. Data were analyzed on an intention-to-treat basis. All calculations were done with SYSTAT (SYSTAT Software Inc., Richmond, CA).

RESULTS

Between January 1996 and January 2006, 13,871 patients submitted to bariatric surgery were enrolled in the SICOB Registry: 6122 adjustable silicone gastric bandings (ASGB), 4215 vertical banded gastroplasties (VBG), 1106 gastric bypasses (GBP), 1988 biliopancreatic diversions (BPD), 303 biliointestinal bypasses, and 137 miscellaneous procedures. Mean number of patients included per Center was 252 (range 20–1245); mean number of bariatric procedures performed each year per Center was 36 $\pm$ 33 (range 5–156). Patients submitted to biliointestinal bypasses or to miscellaneous procedures were excluded from the study because their number was insufficient for statistical analysis (no mortality occurred in this group of patients).

A total of 13,431 bariatric procedures have been included in the present study. Four thousand eight hundred fourteen (36%) procedures were performed by open surgery and 8617 (64%) by laparoscopy. Percentage of open and laparoscopic access were 3.2% (200 of 6122) and 96.8% (5922 of 6122) for ASGB; 59% (2476 of 4215) and 41% (1739 of 4215) for VBG; 38% (425 of 1106) and 62% (681 of 1106) for GBP; and 86% (1713 of 1988) and 14% (275 of 1988) for BPD, respectively.

There were 34 early deaths leading to an overall mortality of 0.25% (34 of 13,431). The type of surgical procedure influenced significantly ($P < 0.001$) mortality rates: 0.1% (6 of 6122) for ASGB, 0.15% (6 of 4215) for VBG, 0.54% (6 of 1106) for GBP, 0.8% (16 of 1988) for BPD.

Pulmonary embolism represented the commonest cause of death (13 of 34, 38.2%) and was significantly more frequent in the BPD group (0.4% BPD vs. 0.07% VBG, 0.03% ASGB, and 0% GBP) ($P < 0.01$). Other causes of mortality were the following: cardiac failure 6 of 34 (17.6%), intestinal leak 6 of 34 (17.6%), respiratory failure 4 of 34 (11.8%), and 1 case each of acute pancreatitis, cerebral ischemia, bleeding gastric ulcer, intestinal ischemia, and internal hernia. Systemic complications represented the lead-

TABLE 1. Causes of Mortality After Bariatric Surgery

	ASGB (%)	VBG (%)	GBP (%)	BPD (%)	Overall (%)
Pulmonary embolism	33.3 (2/6)	50 (3/6)	—	50 (8/16)	38.2 (13/34)
Respiratory failure	33.3 (2/6)	—	33.3 (2/6)	—	11.8 (4/34)
Cardiac failure	33.3 (2/6)	16.6 (1/6)	16.6 (1/6)	12.5 (2/16)	17.6 (6/34)
Cerebral ischemia	—	—	—	6.2 (1/16)	2.9 (1/34)
Intestinal leak	—	33.3 (2/6)	33.3 (2/6)	12.5 (2/16)	17.6 (6/34)
Bleeding gastric ulcer	—	—	—	6.2 (1/16)	2.9 (1/34)
Acute pancreatitis	—	—	—	6.2 (1/16)	2.9 (1/34)
Internal hernia	—	—	16.6 (1/6)	—	2.9 (1/34)
Intestinal ischemia	—	—	—	2.9 (1/34)	2.9 (1/34)
Systemic complications (total)	100 (6/6)	66.6 (4/6)	50 (3/6)	68.8 (11/16)	70.6 (24/34)
Technical complications (total)	0 (0/6)	33.3 (2/6)	50 (3/6)	31.2 (5/16)	29.4 (10/34)

ASGB indicates adjustable silicone gastric banding; VBG, vertical banded gastroplasty; GBP, gastric bypass; BPD, biliopancreatic diversion.

ing causes of death after bariatric surgery (24 of 34, 70.6%) whereas 10 of 34 (29.4%) patients died for a technical complication. Specific causes of death for each procedure are analyzed in Table 1.

Deaths occurred a mean of 20.2 ± 18.2 days from surgery (range 0–59). Systemic complications caused patients' death after a mean of 17.4 ± 19.9 days from surgery (range 0–59). Patients with technical complications were all submitted to a reoperation a mean of 12.8 ± 13.7 days from surgery (range 4–44) and died a mean of 27 ± 14 days from the first surgical procedure (range 5–48).

The laparoscopic access reduced significantly the risk of mortality in the overall group ($P < 0.001$) (Table 2). In the laparoscopic group a conversion to open surgery represented a significant risk of mortality overall and among ASGB, VBG ($P < 0.001$), and GBP ($P < 0.05$) (Table 2). In particular, the laparoscopic access reduced significantly mortality because of pulmonary embolism ($P < 0.01$) and systemic complications ($P < 0.01$) (Table 3) whereas in the laparoscopic group a conversion increased significantly mortality caused by both systemic ($P < 0.001$) and technical ($P < 0.01$) complications (Table 3).

A prolonged operative time represented a significant risk factor for early deaths: mean time of surgical procedures for patients who died was 183 ± 74 minutes versus 112 ± 65 minutes ($P < 0.05$) (Table 4).

Sex, preoperative BMI, previous surgical, and associated surgical procedures did not significantly influence post-

TABLE 2. Correlation Between Mortality Risk and Surgical Approach

	Open Surgery Death (%)	Laparoscopy Death (%)	*P*	Successful Laparoscopy Death (%)	Converted Laparoscopy Death (%)	*P*
ASGB	0.5 (1/200)	0.08 (5/5922)	0.06	0.07 (4/5844)	1.3 (1/78)	<0.001
VBG	0.12 (3/2476)	0.17 (3/1739)	NS	0.06 (1/1680)	3.4 (2/59)	<0.001
GBP	0.47 (2/425)	0.58 (4/681)	NS	0.45 (3/661)	5 (1/20)	<0.05
BPD	0.93 (16/1713)	0 (0/275)	<0.05	0 (0/254)	0 (0/21)	NS
Overall	0.46 (22/4814)	0.14 (12/8617)	<0.001	0.09 (8/8439)	2.25 (4/178)	<0.001

ASGB indicates adjustable silicone gastric banding; VBG, vertical banded gastroplasty; GBP, gastric bypass; BPD, biliopancreatic diversion; NS, not significant.

TABLE 3. Rate of Different Lethal Complications After Open, Laparoscopic, or Converted Bariatric Procedures

	Open Surgery Death (%)	Laparoscopy Death (%)	*P*	Successful Laparoscopy Death (%)	Converted Laparoscopy Death (%)	*P*
Pulmonary embolism	0.21 (10/4814)	0.03 (3/8617)	<0.01	0.02 (2/8439)	0.56 (1/178)	<0.001
Other systemic complications	0.12 (6/4814)	0.06 (5/8617)	NS	0.05 (4/8439)	0.56 (1/178)	<0.01
Total systemic complications	0.33 (16/4814)	0.09 (8/8617)	<0.01	0.07 (6/8439)	1.1 (2/178)	<0.001
Technical complications	0.12 (6/4814)	0.05 (4/8617)	NS	0.04 (3/8439)	0.56 (1/178)	<0.01
Total	0.45 (22/4814)	0.14 (12/8617)	<0.001	0.1 (9/8439)	1.7 (3/178)	<0.001

ASGB indicates adjustable silicone gastric banding; VBG, vertical banded gastroplasty; GBP, gastric bypass; BPD, biliopancreatic diversion; NS, not significant.

TABLE 4. Influence of Different Parameters on Mortality

	ASGB		VBG		GBP		BPD		Overall	
	A	D	A	D	A	D	A	D	A	D
Age (yr, mean ± SD)	39 ± 11	49 ± 8*	39 ± 11	38 ± 11	41 ± 12	45 ± 11	39 ± 11	43 ± 11	39 ± 11	43 ± 10
Female (%)	81.1	66.6	81.3	66.6	75.6	66.6	69.2	75	79	70.6
Preoperative BMI (mean ± SD)(kg/m^2)	43 ± 6	45 ± 7	44 ± 6	41 ± 5	48 ± 6	49 ± 7	49 ± 8	52 ± 9	44 ± 7	48 ± 8
Previous abdominal surgery (%)	35.6	16.6	54.6	33.3	53.8	16.6	49.3	50	48	41.2
Associated surgical procedures (%)	9.7	0	16.3	33.3	22.6	33.3	29.4	12.5	15.8	17.6
Operative time (mean ± SD) (min)	83 ± 47	155 ± 132	96 ± 41	177 ± 80*	191 ± 51	187 ± 12	196 ± 60	194 ± 59	112 ± 65	183 ± 74*

*$P < 0.05$.
ASGB indicates adjustable silicone gastric banding; VBG, vertical banded gastroplasty; GBP, gastric bypass; BPD, biliopancreatic diversion; A, alive; D, dead; SD, standard deviation.

TABLE 5. Correlation Between Mortality and Preoperative Comorbidities

	Mortality Rate					
	With Hypertension (%)	Without Hypertension (%)	With Diabetes (%)	Without Diabetes (%)	With Hyperlipemia (%)	Without Hyperlipemia (%)
ASGB	0.7 (5/702)	0.06* (1/1621)	0.9 (3/320)	0.2† (3/1831)	0.4 (2/518)	0.2 (4/1695)
VBG	0.1 (1/1014)	0.2 (5/2392)	0 (0/408)	0.2 (6/2981)	0 (0/564)	0.2 (6/2808)
GBP	2 (5/255)	0.3† (1/383)	0.9 (1/110)	1 (5/525)	0.7 (1/138)	1 (5/489)
BPD	1.4 (7/501)	1.1 (9/813)	2.3 (5/221)	1 (11/1103)	1.3 (5/373)	1.2 (11/929)
Overall	0.7 (18/2472)	0.3* (16/5209)	0.8 (9/1059)	0.4† (25/6440)	0.5 (8/1593)	0.4 (26/5921)

*$P < 0.01$.
†$P < 0.05$.
ASGB indicates adjustable silicone gastric banding; VBG, vertical banded gastroplasty; GBP, gastric bypass; BPD, biliopancreatic diversion.

operative mortality neither overall nor among single procedures (Table 4). Concerning age there was a significant difference only among patients submitted to ASGB ($P < 0.05$) (Table 4).

Concerning preoperative comorbidities, hypertension ($P < 0.01$) and diabetes mellitus ($P < 0.05$) but not hyperlipemia did significantly influence the risk of mortality (Table 5).

The risk of mortality did significantly correlate with bariatric case load per center: mortality rate in high volume hospitals was 0.19% versus 0.51% in low volume hospitals ($P < 0.01$) (Table 6). Stepwise logistic regression has selected only the pulmonary embolism as statistically significant. The multivariate analysis confirmed this variable as an independent predictor of mortality patients risk (odds ratio 149.2; z 10.6; $P < 0.001$).

DISCUSSION

The analysis of the SICOB Registry identifies an overall mortality risk for bariatric surgery of 0.25% and 5 different factors influencing mortality risk: type of procedure, surgical access (laparoscopic or open), operative time, preoperative comorbidities, and hospital bariatric case volume.

The type of surgical procedure was significantly correlated with the risk of mortality: mortality rates were 0.1% for ASGB, 0.15% for VBG, 0.5% for GBP, and 0.8% for BPD. It is interesting to note that mortality of GBP, the most commonly performed procedure worldwide, in the present study corresponds to the 0.5% 30 days mortality rate reported by Buchwald in a review and meta-analysis of GBP.[7] Complex surgical procedures including intestinal sutures and anastomosis have an increased risk of mortality both from technical and systemic complications. Until now, no studies have compared large series of different bariatric procedures in terms of mortality rates. Recent publications from large administrative dataset have reported contrasting data on early deaths after bariatric surgery. Using the Nationwide Inpatient Sample database, Santry et al[19] reported a 0.2% in-hospital mortality; this mortality rate contrasts with the 1.9% mortality at 30 days for Washington State reported by Flum et al[5] The remarkably low mortality rate from the Nationwide Inpatient Sample study presumably underestimates total postoperative mortality, as this database detects only deaths that occurred during the hospitalization in which the procedure was performed. Nevertheless, these 2 US studies were cen-

TABLE 6. Influence of Case Load Per Center on Mortality Rate (%)

No. Cases Enrolled	<100 Cases	>100 Cases	P
ASGB	0.19 (2/1056)	0.08 (4/5066)	NS
VBG	0.58 (2/345)	0.1 (4/3870)	<0.05
GBP	0.89 (2/225)	0.45 (4/881)	NS
BPD	0.83 (6/724)	0.79 (10/1264)	NS
Overall	0.51 (12/2350)	0.19 (22/11081)	<0.01

ASGB indicates adjustable silicone gastric banding; VBG, vertical banded gastroplasty; GBP, gastric bypass; BPD, biliopancreatic diversion; NS, not significant.

tered on GBP, a procedure that represents 88% of bariatric procedures in the United States[19] but only 8.2% in the present series. In Europe restrictive procedures (particularly ASGB) were extremely popular in the last decade and, in the SICOB Registry, represented 74% of all procedures performed in the study period. The recent introduction and diffusion of laparoscopic ASGB in the United States is at present slowly modifying surgical attitude of US bariatric surgeons and the significant difference in mortality risks between laparoscopic ASGB and laparoscopic GBP (0.1% vs. 0.5%) is a point to be taken into account.

Systemic complications, pulmonary and cardiovascular above all, represent 70% of mortality causes, ranging from 100% for ASGB to 50% for GBP (Table 1). Although all patients included in the Registry underwent perioperative prophylaxis of thromboembolic complications, including low molecular weight heparin and graduate elastic compression stockings, pulmonary embolism represented the commonest single cause of death (38%). Technical complications causing death were essentially related to the presence of intestinal sutures or anastomosis varying from 0% in ASGB to 33% and 37% in VBG and BPD and to 50% in GBP. Among technical complications, intestinal leaks were the most common; accordingly, leaks have been reported as the first cause of death in many GBP series.[6,20]

Different randomized controlled trials have shown that the laparoscopic approach was advantageous for ASGB,[8] VBG,[9,21] and GBP[11,12,22,23] but because of the limited number of patients they all failed to show a reduced mortality rate in laparoscopic patients. The present study shows that the laparoscopic access significantly reduces the mortality risk in bariatric surgery, mainly by reducing systemic complications such as cardiac and respiratory failure and pulmonary embolism.

On the other side, among patients submitted to laparoscopic bariatric surgery conversion represents a significant risk of early deaths (2.25% vs. 0.09%; $P < 0.001$), increasing the rate of all types of systemic and technical complications (Table 3). This figure corresponds to data reported in other applications of laparoscopic surgery such as colorectal[24] and hepatobiliary.[25]

The role of comorbidities in increasing mortality risk after GBP has been shown by Jamal et al[26] and Weller et al[27] among others. Our data clearly show that preoperative hypertension and diabetes are significant risk factors for mortality after all bariatric procedures.

It is well known in abdominal surgery that systemic complications and particularly pulmonary embolism are more frequent after prolonged surgical procedure. The present study identifies prolonged operative time as a further risk factor for bariatric surgery. Therefore, a complex laparotomic operation involving digestive suture and anastomosis with a prolonged operative time presented a high risk for pulmonary embolism, the first cause of death in the present series.

The volume-outcome relationship has been well established in several complex abdominal operations; however, few studies have examined this relationship in patients undergoing bariatric surgery.[5,6,28] In a recent study Nguyen et al[29] demonstrated that bariatric surgery performed at hospitals with more than 100 cases annually is associated with a lower morbidity and mortality (0.3% vs. 1.2%, $P < 0.01$); this volume-outcome relationship was even more pronounced for a subset of patients older than 55 years, for whom in-hospital mortality was 3-fold higher at low-volume compared with high-volume hospitals. The study by Nguyen et al referred uniquely to GBP; the present series, including 74% of restrictive procedures (ASGB and VBG), confirms that case volume load significantly affects mortality rates after bariatric surgery. Specifically, hospitals that performed 1 to 100 procedures during the study period had a mortality rate of 0.51% whereas those who performed >100 procedures had a mortality rate of 0.19% ($P < 0.01$).

In conclusion, this national study confirms that mortality after bariatric surgery is a rare event. Nevertheless, different risk factors, such as, type of procedures, open surgery, prolonged operative time, presence of comorbidities, and low volume hospitals could be identified.

Bariatric surgery is a potentially life-saving procedure in selected patients and in the hands of a qualified surgeon. A correct evaluation of the identified risk factors for early mortality may help to optimize outcomes in these elective procedures.

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Discussions

PROFESSOR R. MARGREITER: Dr Morino and his colleagues should be congratulated, not only for having established what I think is the largest database in bariatric surgery, but also for this careful analysis. The overall mortality is very low. It has to be mentioned, however, that the majority of their procedures were of a restrictive nature. Seventy percent of their deaths were due to systemic complications and about 40% of them were due to pulmonary embolism. According to your manuscript, all patients were given low molecular weight heparin prophylactically. My question is what dosage was used and for how long was it given in these patients, since it has been reported that this complication may occur even late after surgery and that anticoagulation should therefore be given for at least 4 weeks?

Heart failure accounted for about 17% of deaths. Since laparoscopy may impair cardiac function, I would ask whether those 6 cardiac deaths occurred in the open or in the laparoscopic group and did these deaths occur early or later (ie, more than one week or so after surgery?)

There were a few leaks, 6 altogether. How were these leaks managed, by stenting or did you redo the anastomosis? And could you maybe tell us what the leakage rate was in this last series?

You say that volume had an impact on mortality. The handling of these morbidly obese patients is certainly always the same. The various procedures, however, differ in their surgical complexity and it could well be that a single center performed 500 gastric bandings without mortality but the only gastric bypass patient died.

Finally, have you done any multivariate analyses and what was the outcome?

PROFESSOR M. MORINO: Concerning DVT prophylaxis: I cannot give the protocol of every center but most used a standard protocol: 0.4 unit to 0.8 unit of low molecular heparin will be given from the day before surgery up to 20–28 days after surgery. Furthermore, most of groups used compressive stockings. Laparoscopy allowed early mobilization, a goal that is not easy to reach after open surgery in obese patients. I think that the data on pulmonary embolism are very interesting because, while in the majority of procedures laparoscopy did not reduce the rate of pulmonary embolism, in the present series of bariatric surgery pulmonary emboli were significantly reduced after laparoscopy compared with laparotomy. Concerning the heart problem, unfortunately I cannot give you data for each patient but certainly, in every center, the patients are evaluated preoperatively and severe heart problems are a contraindication to laparoscopy in every center. Nevertheless, you must balance the advantages of laparoscopy for an obese patient, with the disadvantages of the risk of left sided cardiac problems. This evaluation is done on a single basis per patient together with the anesthesiologist.

Concerning leaks and their management, in the present series we reported only 6 leaks because 6 leaks led to death. But, as you know, the leaks are in the range of 2% and therefore this should be approximately the overall leakage rate in the SICOB Registry. The main problem is that, in obese patients, a leak has a large variety of clinical impacts. It can be difficult to diagnose a leak in an obese patient. Sometimes they do not have any clinical problem, they seem perfect but they have a leak. In the present series this problem is probably enhanced by the fact that these patients were operated upon a mean of 12 days following surgery. One patient for instance was operated on 44 days after surgery, so, certainly, this patient was treated conservatively in the first instance with a percutaneous drainage and then, because of the persistence of the leak, had to be operated on. It changes very much from one case to another but, certainly, you have to be very, very careful in following these patients. Another point is that with laparoscopy, everybody obtains very early gastro-esophageal x-rays, and sometimes they may be done too early. In the first day you may not see a leak that appears 2 or 3 days later, when the patient is already eating.

As for the volume caseload: your question is correct. The volume caseload is significant for each procedure, even in the bandings, which represent a simple procedure, there are more deaths in the group who with fewer banding.

Concerning the multivariate analysis, the only significant independent risk factor for mortality was pulmonary embolism.

PROFESSOR A. SITGES-SERRA: I have a couple of questions. Do you provide some checking for the honesty and completeness of data? Do you visit the participant centers? How sure are you that everybody reports the deaths? In your country as well as mine, in south Europe, there is much pressure in the media on that and people tend to hide these complications.

Also, are these so-called learning curves included in that study? At what level of expertise do these centers start to include patients because that could also be a bias?

If we eliminate gastric banding, almost all the figures double and then you have increasing mortality figures because gastric banding accounts for almost half of the patients you recruited in the study.

And finally, your paper is a good example of statistical versus clinical significance. The massive series is so huge that even 0.2% or 0.1% differences are significant. However, the relevance of clinical significance versus statistical significance could be a matter of debate.

PROFESSOR M. MORINO: I will start from the last point. In my opinion, the clinical significance of a 0.1% or 0.2% difference in mortality after bariatric surgery is extremely important. Each death in this case means a legal process and means being on the media and on the news. This is a special group of patients.

Certainly checking would be ideal. We discussed this, but we have not gone into checking for the moment. SICOB is more or less a group of friends. We know each other very well. I hope that their data are correct. I must say that, once again, a patient who dies after bariatric procedure, at least in Italy, goes into the newspapers so it is very easy to check because they are in the press and television.

Concerning the learning curve, the main problem is that the Registry represents the results of an expert group of surgeons that covers presumably less than half of bariatric surgery in our country. It would be very interesting to compare our results with the standard results all over the country. Very often in congresses I have heard that gastric banding is abandoned but, in fact, more and more people are doing banding and lap band represents by and large the most common bariatric procedure worldwide. Furthermore, gastric banding is coming to the United States now because they received FDA approval only a few years ago. Even in the United States, the number of bandings is increasing. I think that the mortality data are important in this set. I think that banding will stay with us for a long time in the future.

PROFESSOR N. SENNINGER: I have 3 questions. One relates to Body Mass Index, which you did not mention at all. Is there a relation to Body Mass Index?

The second is, and I think everyone would agree, the 2 major procedures that will evolve are gastric bypass and gastric banding. We know that we see more problems in the early postoperative course after gastric bypass, but we see more problems after gastric banding in the long term. Were you able to study the morbidity of the patients with gastric banding in the long term? During the last year we removed more than 6 gastric bands endoscopically with some problems.

And, finally, what worried me most is that you could show that the time for the reoperation was about 12 days for those patients who died. This is a time when most of our patients, or at least this is the aim, are already discharged from hospital. How many of these patients had to be readmitted, and should this encourage us to keep an eye on these patients for a longer period of time?

Professor M. Morino: BMI is not statistically significant but there is a slight difference. The mean BMI of the whole group was 44 and 48 for the group who died, but it is not statistically significant.

We could stay here for 2 days talking of bypass and bands! We know the problem of banding very well. We described the first series of banding removals in ’95 in the *British Journal of Surgery*. The surgeon and the patient must choose between something very safe and simple that gives inferior results in terms of weight loss and more complication in the long term and a complex procedure with a non-negligible mortality that gives better results in the long term. This is a matter of choice between surgeon and patient.

And finally, regarding time of reoperation, there is a recent series from the United States where many patients were dismissed one or 2 days after surgery, had problems at home, came back and died after rehospitalization. This is not the case in Italy. Our laparoscopic bypass patients stay more or less 4 days in hospital. So, usually, any complications arise during this period. The reason for a mean of 12 days before reoperation is not that the patient was at home and then came back to the hospital, but just because the treatment was, in the first instance, conservative.