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Original article

Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database

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Abstract

Background: The Bariatric Outcomes Longitudinal Database (BOLD) is a registry of self-reported bariatric surgery patient information from the American Society for Metabolic and Bariatric Surgery Bariatric Surgery Center of Excellence participants. The present study was undertaken to define the baseline characteristics of the patients with data entered into BOLD.

Methods: The data submitted by >800 surgeons and >450 facilities using BOLD before May 20, 2009, were analyzed.

Results: A total of 57,918 research-consented patients with surgical procedure data were included. Of the 57,918 patients, 41,243 were adults aged 26–55 years, with few patients aged ≤18 years (.14%) or ≥66 years (5.67%). Females constituted a significant majority of the study population (45,619 [78.76%]). Of the 57,918 patients, 78.12% registered were described as Caucasian, 10.52% as African-American, 6.02% as Hispanic, .20% as Asian, and .46% as Native American. The most common bariatric surgical procedure was some form of gastric bypass (31,668 [54.68%]), followed by some form of gastric banding (22,947 [39.62%]), sleeve gastrectomy (1,328 [2.29%]), and biliopancreatic diversion (517 [.89%]). The vast majority of index procedures were completed using laparoscopic surgery techniques, except for biliopancreatic diversion, which was primarily done with an open approach. Through May 2009, 78 deaths were reported at any point after the index procedure, for a mortality rate of .13%. The 90-day mortality rate was .11%, and the 30-day mortality rate was .09%.

Conclusion: This is the first report of data from BOLD. The data have revealed important characteristics of patients undergoing bariatric surgery across the United States in centers participating in the Bariatric Surgery Center of Excellence program. Future analyses of BOLD data are likely to have a major effect on the specialty of bariatric surgery. (Surg Obes Relat Dis 2010;6: 347–355.)

Keywords: Bariatric surgery; Demographics; Gastric bypass; Adjustable gastric band; Sleeve gastrectomy; Duodenal switch; Mortality; Complications; Patient selection

The steady increase in the number of bariatric surgery operations performed each year has mandated the development of national benchmarks for quality and patient safety. Identifying these benchmarks, with the goal of establishing guidelines for best clinical practices, requires a broad collection of clinical data from a large population of patients. Surgical Review Corporation (SRC) was created under the auspices of the American Society for Metabolic and Bariatric Surgery to advance the safety, efficacy, and efficiency of bariatric and metabolic surgical care.

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Two key objectives of SRC are to identify the processes and practices that promote patient safety and lead to excellent short- and long-term outcomes, as well as to recognize bariatric surgery programs that have enacted such practices by designating them as Bariatric Surgery Centers of Excellence (BSCOE). To monitor compliance and quantify the effect of the BSCOE program on patient outcomes, SRC developed a mechanism, the Bariatric Outcomes Longitudinal Database (BOLD), to collect and report perioperative data from BSCOE participants. This information includes procedures, medications, demographic characteristics, weight loss and maintenance, complications, co-morbidities, and outcomes. Such data can provide powerful evidence for the best practices in bariatric surgery.

BOLD was developed under the guidance of SRC's Research Advisory Committee. Efforts were made to keep the BOLD data elements and definitions common with the National Institutes of Health Longitudinal Assessment of Bariatric Surgery (LABS) program and other national databases. BOLD uses standardized patient encounter forms rather than narrative operative reports to promote consistent, high-quality data collection.

The baseline characteristics of the research-consented patients entered into the BOLD during the 23-month period between its launch in June 2007 and May 2009 have been reported in the present study.

Methods

BOLD background and data entry

BOLD is a proprietary, Internet-based software product developed by SRC to collect prospective data for all bariatric surgery patients treated by American Society for Metabolic and Bariatric Surgery BSCOE participants for the purpose of assessing outcomes and quality of care. The present report has included perioperative patient data entered into BOLD from the time it opened for patient data entry in June 2007 to May 2009, representing approximately 23 months of data accrual. All BSCOE participants have been required to enter patient data into BOLD since January 2008. As of May 2009, >450 facilities and >800 surgeons were using BOLD.

Data entry into BOLD occurs by way of a secure, Web-based application and is performed by designated individuals at each facility. Training and weekly live Webinars are available but are not currently required for those who enter data into BOLD. The submitted information is typically collected during routine clinical patient encounters, and hard copy forms of BOLD data entry screens can be used by participants to facilitate data capture during these encounters. The entry of patient-identifying information is not required; however, programs that choose to use BOLD as their primary mechanism for data collection can enter patient-identifying information. BOLD also interfaces with select third-party electronic medical record systems, enabling participants currently using these software systems to directly transmit their data into BOLD to minimize duplicate data entry.

The baseline data collected before bariatric surgery include patient demographics, anthropomorphic measurements, medications, co-morbid conditions, and previous bariatric surgical procedures. Although BOLD requires the data to be entered for only a single preoperative encounter, more preoperative encounters can be entered and might ultimately facilitate research related to the possible contribution of preoperative weight loss and co-morbidity improvement in reducing surgical risk. The baseline demographic data include the patient's age, race, gender, employment status, and insurance status. BOLD uses basic anthropomorphic values (height and weight) to calculate the body mass index (BMI), ideal body weight, and excess body weight. Co-morbidity severity is assessed using a modified version of the scoring system developed by Ali et al. [1]. This 6-point scoring system assigns a numerical value (0–5) to each of a number of medical conditions according to the relative severity of the condition (e.g., diabetes mellitus and hypertension). A value of 0 indicates that the condition is absent. As the numerical value increases, so does the severity of the medical co-morbidity, such as the requirement for multiple medications to treat the condition and/or the presence of known complications related to the condition. The detailed data collection found in BOLD regarding preoperative co-morbidities have been mentioned for completeness in the overview of BOLD. However, these are still being analyzed and have not been reported in the present study.

Information specific to the surgical procedure and perioperative patient treatment, including complications/adverse events, are entered at the hospital encounter. Postoperatively, the data are collected at regular intervals to assess body mass, co-morbidities, and complications. Table 1 provides a list of the >130 complications that can be recorded in BOLD during the facility stay and postoperative visits. To accommodate individualized preferences in case management, data entry is acceptable within a range of postoperative intervals (<30 days, 3–6 months, 9–12 months, and annually after surgery).

Several quality measures have been implemented to exclude invalid, inaccurate, and inconsistent data from BOLD. Business and validation rules have been built into the database to flag or reject potential errors at the point of data entry. Automated data quality reports alert users and SRC of unacceptable trends after data capture. SRC also uses site inspections to verify the data entered into BOLD, including key outcomes indicators, such as mortality, reoperations, and readmissions.

Table 1
Complications/adverse events listed in BOLD

Acute asthma exacerbation
Adrenal insufficiency
Alopecia
Anastomotic, hemorrhage
Anastomotic, leakage
Anemia, cause other than iron deficiency
Angina
Anoxic brain injury
ARDS/noncardiogenic pulmonary edema
Arrhythmia
Atelectasis
Bacteremia
Bleeding/hemorrhage, intra-abdominal
Blindness
Calcium deficiency/osteopenia/osteoporosis
Cardiac failure
Cholecystitis
Common bile duct obstruction
Death from accident
Death from suicide
Death from bleeding
Death from sepsis from an anastomotic leak
Death from sepsis from other abdominal source
Death from pulmonary embolus
Death from cardiac failure
Death from myocardial infarction
Death from cerebrovascular accident (stroke)
Death from bowel obstruction
Death from evisceration
Death from pneumonia
Death from respiratory failure, including ARDS
Death from other cause
Death cause indeterminate
Decubitus ulceration of skin/underlying tissues
Deep venous thrombosis
Dehiscence
Dehydration
Delirium (altered mental status)
Diarrhea
Drug reaction
Electrolyte imbalance requiring treatment
Erosion
Esophageal dilation
Evisceration
Fluid leak from device
Folate deficiency
Gall stones
Gastroesophageal reflux disease
Gastrogastric fistula/gastric pouch staple line disruption
Gastrointestinal bleeding
Heart failure and/or pulmonary edema
Hemodialysis
Hernia, surgical incision site
Hyperglycemia
Hyperparathyroidism
Hypoglycemia
Hypovolemia
Paralytic ileus
Infection, device related
Injury of esophagus
Injury of intestine, including duodenum, jejunum, colon
Injury of liver
Injury of pancreas

Table 1
Continued

Injury of spleen
Injury of stomach
Internal hernia
Intestinal obstruction
Intolerance, device related
Intra-abdominal abscess
Iron deficiency/resulting anemia
Lead malfunction or displacement
Liver failure
Magnesium deficiency
Malfunction, device related
Mesenteric arterial thrombosis
Mesenteric ischemia
Mesenteric ischemia/bowel ischemia/infarction
Mesenteric venous thrombosis (e.g., portal)
Multisystem organ failure
Myocardial infarction
Nausea/vomiting
Neisidioblastosis/hyperinsulinemia
Nerve injury
Neuropathy
Nutritional support required using total parenteral nutrition
Nutritional support required, enteral nutrition using feeding tube
Obstruction
Obstruction, device related
Open conversion from minimal access procedure
Pancreatitis, all other etiologies
Pancreatitis, gallstone etiology
Panniculitis
Pleural effusion
Pneumonia
Pneumothorax
Pouch dilation
Procedure intolerance requiring reversal
Protein deficiency/protein malnutrition
Psychosis
Pulmonary embolism
Renal calculus/kidney stone
Renal failure
Respiratory failure
Rhabdomyolysis
Roux limb, ischemia
Roux limb, obstruction
Sepsis from anastomotic leak
Sepsis from other abdominal source
Severe weakness/motor dysfunction, including Guillain-Barré syndrome
Slippage, gastric band, adjustable
Slippage, gastric band, nonadjustable
Slippage, banded gastric bypass
Stricture
Stroke/cerebrovascular accident
Superficial phlebitis
Surgical site infection
Surgical wound infection/soft tissue abscess
Systemic inflammatory response syndrome
Thyroid dysfunction, hyper or hypo
Ulcer
Urinary infection
Vitamin A deficiency
Vitamin B_1 (thiamin) deficiency, peripheral neuropathy
Vitamin B_1 (thiamin) deficiency, Wernicke-Korsakoff syndrome
Vitamin B_{12} deficiency
Vitamin D deficiency

Table 1
Continued

Vitamin E deficiency
Vitamin K deficiency
Wound complications
Zinc deficiency
Other

BOLD = Bariatric Outcomes Longitudinal Database; ARDS = acute respiratory distress syndrome.

Access to data

The policies and procedures for those entities requesting access to BOLD data are governed by the Data Dissemination Policies and Procedures as approved by SRC's Board of Directors and under the oversight of SRC's Data Dissemination Committee. In brief, bariatric centers contributing data to BOLD have free, unrestricted access to their own patient data. Reports of aggregate national data are provided regularly to participating centers. These are expected to provide a useful benchmark to improve overall performance by comparison with individual center data.

Quality assessment

Identifying methods to improve quality and patient safety are the major objectives of the BSCOE initiative. The institution of mandatory data reporting by BSCOE participants has set the stage for comparisons of individual program data to aggregate national benchmarks. Such comparisons will eventually become a critical component of the re-evaluation process for BSCOE designation. To accomplish the goal of comparing outcomes, it is first essential to develop sophisticated surgical risk stratification methods, and BOLD was developed with this in mind. The introduction of quality measures such as the observed/expected complication ratios for appropriately risk-stratified patient populations is a primary objective of the quality assessment process.

Research

In addition to its expected role in improving patient safety and quality of care for bariatric surgery patients, BOLD can also be used for research. On enrollment in BOLD, patients are requested to sign a consent form approved by an institutional review board to allow their data to be used for research purposes. No patient data are made available to the research database unless informed consent has been noted in the patient record. As an additional protection for patient privacy, no patient-identifying information is made available to the research database. Only aggregate data are reported as a result of research efforts using BOLD; individual patients, surgeons, and programs are not identified.

The utility of the BOLD as a national data repository also extends to investigators and other entities who wish to use the de-identified, aggregate BOLD research data to answer research questions. No program- or surgeon-identified data are available for such research purposes. The parties interested in research must complete an application process, followed by review and approval of the application by the SRC's Data Access Committee. The approval for dissemination and publication of BOLD data is granted by SRC's Data Dissemination Committee.

Results

Participating centers have reported data on 57,918 research-consented bariatric surgery patients in BOLD between June 2007 and May 2009. This population of patients was the focus of the present study.

Preoperative patient characterization

The distribution of patients by age before bariatric surgery is listed in Table 2. The gender and race characteristics of the population are listed in Table 3. Most patients were identified as female (45,619 [78.76%]). Male gender was reported for 12,299 patients (21.24%). Most patients were identified as Caucasian (45,248 [78.12%]). African-American patients constituted 10.52% (6,094) of the total population, followed by Hispanics (6.02% [3,489]), and Native Americans (.46% [265]). The reported employment status of the patients was primarily full-time (58.53%), followed by retired (7.74%), disabled (7.01%), and unemployed (5.92%).

The mean BMI of the study population was 46.46 kg/m^2. The patient BMI ranges are reported in Table 4. The American Society of Anesthesiologists classification of patients undergoing the 4 most frequent types of bariatric surgery

Table 2
Preoperative age distribution in 57,918 patients undergoing bariatric surgery with data entered in BOLD

Age (yr)	Patients (n)
<14	27 (.05)
15–18	50 (.09)
19–25	1,678 (2.90)
26–35	8,964 (15.48)
36–45	15,987 (27.60)
46–55	16,292 (28.13)
56–65	11,508 (19.97)
66–75	3,177 (5.49)
>75	107 (.18)
NA*	128 (.22)
Total	57,918 (100)

BOLD = Bariatric Outcomes Longitudinal Database; NA = not applicable.

Data in parentheses are percentage of total.

Mean age of study population was 46.65 ± 11.77 years.

* Data judged to be in error as defined by age <3 years or >100 years and those with data entered before introduction of business rules requiring age be entered before proceeding to next field for data entry.

Table 3
Gender and race distribution in 57,918 patients undergoing bariatric surgery with data entered into BOLD

Variable	Patients (n)
Gender	
Female	45,619 (78.76)
Male	12,299 (21.24)
Race	
African-American	6,094 (10.52)
Asian	113 (.20)
Caucasian	45,248 (78.12)
Hispanic	3,489 (6.02)
Native American	265 (.46)
Pacific Islander/Hawaiian	80 (.14)
Other*	2,893 (4.99)

BOLD = Bariatric Outcomes Longitudinal Database.

Data in parentheses are percentage of total.

* Reflects patients of multiracial origin and patients for which a race was not identified; users were permitted to select >1 race when entering a patient into BOLD; therefore, the sum of patients identified by race is >57,918.

(i.e., gastric bypass, adjustable gastric band, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch) is listed in Table 5. Across all procedures, most patients were identified as American Society of Anesthesiologists class III, defined as severe systemic disease (but not incapacitating).

Surgical procedures and outcomes

Table 6 provides information regarding the various types of bariatric surgical procedures performed. The most common procedure performed during the study period was various forms of gastric bypass (31,668 [54.68%]). Roux-en-Y gastric bypass (RYGB) accounted for the vast majority of gastric bypass procedures (30,864). A much smaller group of patients underwent banded gastric bypass (717), gastric bypass with distal gastrectomy (78), or gastric bypass with loop reconstruction (9). Laparoscopic access was used successfully in the vast majority of RYGB procedures (27,363 [88.66%]), followed by 2,618 open RYGB operations (8.48%), 293 robotically assisted RYGB procedures, and 135 hand-assisted RYGB procedures. Conversion to an open approach was uncommon and reported for only 274 procedures (.89%).

Table 4
Body mass index for 57,918 patients undergoing bariatric surgery with data entered in BOLD

BMI (kg/m^2)	Patients (n)
<35	1,297 (2.24)
35–39.9	9,936 (17.16)
40–49.9	30,962 (53.46)
50–59.9	12,007 (20.73)
≥60	3,512 (6.06)
NA*	204 (.35)

BMI = body mass index; BOLD = Bariatric Outcomes Longitudinal Database.

Mean BMI for population was 46.46 ± 8.37 kg/m^2.

Data in parentheses are percentage of total.

* Refers to data judged to be in error as defined by BMI <10 or >100 kg/m^2 and those with data entered before introduction of business rules mandating entry of height and weight data into BOLD.

Table 5
American Society of Anesthesiologists classification of patients with bariatric surgery data entered in BOLD

ASA class	RYGB	AGB	Sleeve	BPD/DS
I	3.84	5.60	4.97	1.40
II	23.53	31.35	26.66	15.83
III	67.36	60.27	61.9	73.95
IV	5.17	2.73	6.33	8.82
V	.09	.05	.15	0

BOLD = Bariatric Outcomes Longitudinal Database; ASA = American Society of Anesthesiologists; RYGB = Roux-en-Y gastric bypass; AGB = adjustable gastric banding; Sleeve = sleeve gastrectomy; BPD/DS = biliopancreatic diversion with duodenal switch.

Data presented as percentage of total population undergoing each of 4 most commonly performed bariatric procedures found in BOLD.

Various forms of gastric banding were reported for 22,947 patients, making it the second most commonly performed type of bariatric surgery in the present study (39.62%). Adjustable gastric banding accounted for most cases, and 99.42% of the adjustable gastric banding procedures were performed laparoscopically. A small group of 168 patients (.73% of all patients treated with some form of gastric banding) were treated using vertical banded gastroplasty. An even smaller group of 64 patients (.28%) were treated with nonadjustable gastric bands.

Sleeve gastrectomy was performed in 1,328 patients (2.29%), with most of these cases performed laparoscopically (94.58%). Biliopancreatic diversion (BPD) represented a very small component of bariatric surgical procedures performed, with only 517 procedures (.89%) reported. BPD with or without duodenal switch represented the only category of bariatric surgical procedure for which open access (69.33%) was used more often than laparoscopic access (29.86%). Approximately 2% of patients indicated having undergone a previous bariatric surgical procedure. These patients were not excluded from the present analysis.

Table 7 lists the perioperative and hospital discharge data for the patients who underwent a bariatric surgical procedure. Most patients had received ≥2 deep venous thrombosis prophylaxis measures, with anticoagulation and intermittent venous compression device use the most common. Blood transfusion was uncommon, occurring in .56% of all bariatric surgical procedures (data not shown). The mean length of hospital stay was 2.5 days, with 98.79% of patients discharged to their residence without the need for placement in a facility to provide ongoing care.

Table 8 lists the complication rates for the most commonly performed types of bariatric surgery. BOLD captures

Table 6
Bariatric procedures reported in BOLD for 57,918 research-consented patients

Procedure	Laparoscopic	Open	Open conversion*	Hand†	Robot‡	Other	Total
All forms of gastric bypass							
Roux-en-Y	27,363	2,618	274	135	293	181	30,864
Banded	582	95	6	0	33	1	717
With distal gastrectomy	45	27	5	0	1	0	78
Loop configuration	3	4	1	1	0	0	9
Total	27,993 (88.4)	2,744 (8.6)	286 (.9)	136	327	182	31,668
Gastric banding							
VBG	134	32	1	0	0	1	168
Adjustable	22,584	21	23	23	64	0	22,715
Nonadjustable	63	1	0	0	0	0	64
Total	22,781 (99.1)	54 (.23)	24 (.1)	23	64	1	22,947
Sleeve gastrectomy	1,256 (94.6)	45 (3.4)	8 (.6)	19	0	0	1,328
Biliopancreatic diversion							
With duodenal switch	141	337	9	4	8	0	499
Without duodenal switch	10	8	0	0	0	0	18
Total	151 (29.2)	345 (66.7)	9 (1.7)	4	8	0	517
Other							
Intragastric balloon	0	0	0	0	0	82	82
Gastric pacing	1	0	0	0	0	0	1
Miscellaneous/not identified	333	108	11	1	0	872	1,325

VBG = vertical banded gastroplasty; BOLD = Bariatric Outcomes Longitudinal Database.
Data presented as absolute number of procedures, with percentage of category of procedure in parentheses.
Fifty patients (.09%) had their procedure cancelled after anesthesia induction and were excluded from Table 6.
* Patients undergoing initial laparoscopic access followed by conversion to open access.
† Hand-assisted laparoscopic surgery technique.
‡ Robotically assisted laparoscopic technique.

data on >130 complications, spanning a wide range of severity, from major to minor. Overall, 10.77% of patients experienced ≥1 complications after surgery. Complications were most commonly reported for patients undergoing BPD/duodenal switch (25.65%), followed by RYGB (14.87%). Most complications occurred after discharge and were judged to be relatively minor. The most commonly reported complication after discharge was nausea/vomiting (data not shown). Additional data analysis is underway to characterize the various types and severities of the complications.

Table 9 lists the mortality data, including the frequency and timing of the deaths reported in BOLD through May 2009. The mortality rates were low. The 30-day all-cause mortality rate was .09%, and the 90-day all-cause mortality rate was .11%. These mortality rates were calculated with the assumption that all deaths occurring in the BOLD population during the specified periods were reported in BOLD. If the mortality rate was determined solely from those patients who had had a recorded follow-up encounter, the 90-day mortality rate would be .22%.

Discussion

The number of bariatric surgery procedures in the United States has increased tremendously as the obesity epidemic has continued to grow. The case volume for bariatric surgery has been estimated at >200,000 procedures annually [2], making it one of the most commonly performed abdominal operations. Despite the increase in popularity for bariatric surgery as a treatment of obesity, very few large clinical studies evaluating population-based outcomes of surgery using clinically rich data sets have been published. Many healthcare insurance carriers have refused to allow coverage or to remove barriers to bariatric surgical care for their insured patients. Around the year 2000, bariatric surgery came under attack for issues surrounding liability, cost effectiveness, and risk.

To provide a mechanism for resolving these issues, the American Society for Metabolic and Bariatric Surgery founded SRC in 2003 as an independent, nonprofit organization governed by the industry stakeholders. SRC's charge was to develop and administer a national, evidence-based bariatric surgery program focused on healthcare quality and patient safety, supported by a centralized outcomes database. SRC would also work to protect and expand health plan coverage of bariatric surgery, lower medical malpractice premiums, and improve access to quality care.

Additional support for the development of the center of excellence (COE) concept came in 2006 when the Centers for Medicare and Medicaid Services issued a National Coverage Determination in favor of bariatric surgery as an appropriate treatment of morbid obesity according to the available data [3]. Application was limited to identified COEs as designated by SRC and the American College of Surgeons. Recognizing the need for large, population-

Table 7
Perioperative, operative, and hospital discharge data for 57,918 patients undergoing bariatric surgery procedures with data entered in BOLD

Variable	Value
Mean duration of surgery (min)	91.8
Mean duration of anesthesia (min)	129.6
Mean estimated blood loss (mL)	41.7
Mean length of hospital stay (d)	2.5
Surgical resident participated (%)	10.1
Surgical fellow participated (%)	8.4
Concurrent procedures (%)	34.6
Use of DVT prophylaxis (n)	
None reported	4,205 (7.26)
1 method	11,536 (19.92)
≥2 methods	42,177 (72.83)
DVT prophylaxis methods (n)	
Anticoagulation	46,571
Foot pump	1,387
Intermittent compression	45,080
TED stocking	11,720
Intraoperative complications (n)	550 (.95)
Predischarge complications (n)	2,097 (3.62)
Discharge location (n)	
Residence	57,217 (98.79)
Rehabilitation facility	76 (.13)
Skilled nursing facility	48 (.08)
Another hospital	12 (.02)
Deceased	35 (.06)
Other/not specified	530 (.92)

BOLD = Bariatric Outcomes Longitudinal Database; DVT = deep venous thrombosis; TED = thromboembolic deterrent.
Data in parentheses are percentages.

based studies with clinically relevant data, the Centers for Medicare and Medicaid Services charged both of the neophyte certification programs with collecting and reporting patient data to improve care and document treatment outcomes.

Table 9
Deaths reported in BOLD for 57,918 bariatric surgical procedures

Variable	Deaths (n)
Intraoperative	5 (6.41)
Before discharge	25 (32.05)
After discharge (d)	
0–30	22 (28.21)
30–90	13 (16.67)
>90	13 (16.67)
Total	78
All reported mortality (%)	.135
90-d All-cause mortality (%)	.112
30-d All-cause mortality (%)	.089
Predischarge mortality (%)	.052

BOLD = Bariatric Outcomes Longitudinal Database.
Data in parentheses are percentage of total deaths.

The present study is the first publication of data collected from BSCOE participants using BOLD. Originally, data collected and published by SRC included data submitted to the organization in aggregate form by individual centers seeking BSCOE designation [4]. This information was maintained in SRC's "application database." Although useful for the purposes of center designation, the application data format allowed for few comparative and research opportunities because of its aggregate nature. Recognizing these limitations, SRC developed BOLD to capture prospective, longitudinal patient data.

Since BOLD opened for data entry in June 2007, 116,984 patients have been registered through May 2009, a number that includes preoperative patients evaluated for bariatric surgery who had not yet undergone the procedure and patients who had not granted permission to use their information for research purposes. Of the registered patients, 75,050 (64.15%) signed an institutional review

Table 8
Complications/adverse events

Variable	All procedures	RYGB	AGB	Sleeve	BPD/DS
Total					
Procedures	57,918	30,864	22,715	1,328	499
Complications	9,967	7,494	1,433	235	256
Patients with ≥1 complication	6,240 (10.77)	4,588 (14.87)	1,050 (4.62)	144 (10.84)	128 (25.65)
Intraoperative complications					
Complications (n)	634	448	92	18	24
Patients (n)	550	385	88	16	17
Predischarge complications					
Complications (n)	2,687	2,078	326	74	63
Patients (n)	2,097	1,613	283	52	43
Postdischarge complications					
Complications (n)	6,646	4,968	1,015	143	169
Patients (n)	4,170	3,060	724	87	90

Abbreviations as in Table 5.
Data in parentheses are percentages.
Overall, 9,967 complications were reported in 6,240 patients during the following periods: intraoperatively, postoperatively but before discharge, and within 1 year of discharge (some patients experienced complications in >1 period).
Conversion from laparoscopic to open surgical access was not included as a complication.

board-approved consent form to allow their data to be studied for research purposes. The present study population constituted a subset of 57,918 research-consented patients with data entered in BOLD for a bariatric surgical procedure through May 2009.

The data analyzed in the present study were self-reported by BSCOE participants, with resulting inherent limitations. Data are entered into BOLD by designated individuals at the various sites, many of whom are involved in patient care, including nurses, bariatric coordinators, and surgeons. Some participants provide data entry access to hospital staff for the entry of intraoperative data; others enter the intraoperative data at the surgical practice. No research has yet been conducted to determine whether one of these methods produces more accurate data entry. Additionally, the practices are responsible for entering all postdischarge complications related to surgery, even if the complications have been treated by another healthcare provider. These postdischarge events are potentially underrepresented in the database.

As of May 2009, >450 facilities and >800 surgeons were participating in the BSCOE program. Effective January 2008, BSCOE participants have been required to enter data into BOLD as a part of their participation agreement. Also, data submission is required for centers to maintain their BSCOE status. The accrual rate of new patients registered in BOLD is >5,000 monthly, with >3,000 agreeing to research participation.

Several multi-institutional, clinically oriented bariatric surgery research databases have demonstrated more limited data accrual, requiring many years of data collection to reach significant numbers of patients available for study. The International Bariatric Surgery Registry, launched by Mason in 1979, was the first large international data collection initiative. A 2006 International Bariatric Surgery Registry report provided data for >30,000 patients undergoing bariatric surgery during an 18-year period [5]. The Italian Society of Obesity Surgery National Registry [6], University HealthSystem Consortium [7], Society of American Gastrointestinal and Endoscopic Surgeons Bariatric Outcome Initiative [8], and the American College of Surgeons National Surgical Quality Improvement Program [9] have reported bariatric surgery patient accrual rates significantly lower than those for BOLD. The National Institutes of Health-funded Longitudinal Assessment of Bariatric Surgery projects (LABS-1 and LABS-2) have collected a substantial amount of clinical and laboratory data on 2,000–5,000 patients spread across 6 academic centers [10–12]. However, this relatively small patient cohort has not allowed the LABS to test certain hypotheses, particularly regarding low-frequency events. BOLD was developed with input from the LABS team to enable collaboration and enhance the analytical power of each data collection effort. BOLD's tremendous enrollment and rapid rate of patient accrual will allow investigators to exponentially increase the power that can be applied to statistical analyses of the data to answer critical bariatric surgery outcome questions previously out of reach.

Previous attempts to analyze large databases for factors that determine bariatric surgery outcomes have predominantly used administrative databases. Bradley and Sharma [13] used a payor database to demonstrate that outcomes such as 30-day readmission rates were significantly improved for patients who underwent surgery at the Blue Cross and Blue Shield of North Carolina COE programs compared with the outcomes of those who underwent surgery at non-COE programs. In a separate study, Flum and Dellinger [14] reviewed the outcomes on a statewide level and found the mortality rate for bariatric surgery to be much greater than anticipated from single-institution studies. These efforts, although supportive of outcomes research, have lacked important clinical parameters known to correlate with surgical risk, such as knowledge of co-morbid conditions and the specific details of the operation.

The composition of the BOLD patient population reported in the present study closely resembled that of other bariatric surgery populations described previously [15,16]. Most patients were female, Caucasian, aged 36–55 years, with a baseline BMI of 40–50 kg/m^2. RYGB was the most common bariatric surgical procedure performed, followed by adjustable gastric banding, sleeve gastrectomy, and BPD. Consistent with the trend toward less-invasive surgical approaches, most procedures were completed using laparoscopic techniques, with the exception of BPD, which was primarily performed as an open procedure.

The overall mortality rate after bariatric surgery in the BOLD patient population was .14%, and the all-cause 30- and 90-day mortality rates were .09% and .11%, respectively. Death before discharge from the index procedure hospitalization occurred in .05% of the population. These statistics represent an additional significant decrease in mortality from the .36% reported by SRC in 2008 using validated data from its application database [4]. The present report is not the first to suggest a progressive decline in bariatric surgery mortality in recent years. The Agency for Healthcare Research and Quality reported a dramatic 79% reduction in bariatric surgery mortality from 1998 to 2004 [17]. A recent review of data from the 2005 National Inpatient Survey found a mortality rate of .17% in a group of 24 COE-designated hospitals [18]. Encinosa et al. [19] analyzed the MarketScan Commercial Claims and Encounter Database for 2001–2002 and 2005–2006, noting that although patients undergoing surgery were older and sicker in 2005–2006 than in 2001–2002, the 180-day mortality rate remained low at .05%, and the risk-adjusted rate of complications and readmissions related to complications was significantly decreased [19]. The investigators identified the increased use of laparoscopic techniques, increased use of gastric banding instead of gastric bypass, and increased surgical volume as likely reasons for the improved out-

comes. The American Society for Metabolic and Bariatric Surgery BSCOE program, which was introduced during their study period, might have also contributed to the improvement in outcomes.

Conclusion

The present study has provided the first descriptive report of the baseline characteristics of the population of research-consented bariatric surgery patients entered into BOLD by BSCOE participants since its launch in June 2007 through May 2009. BOLD has quickly emerged as the largest prospective database for bariatric surgery worldwide. Access to this repository of clinical information is likely to make a tremendous contribution to our understanding of bariatric surgery procedures and outcomes.

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Disclosures

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