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

Methods: Data submitted by more than 800 surgeons and 450 facilities using BOLD prior to May 20, 2009, were analyzed.

Results: 57,918 research-consented patients with surgical procedure data were included. 41,243 were adults between age 26-55 with a minority of patients age ≤ 18 (0.14%) or age ≥ 66 (5.67%). Females comprised a significant majority of the study population (45,619; 78.76%). 78.12% of patients registered were described as Caucasian, 10.52% African-American, 6.02% Hispanic, 0.20% Asian, and 0.46% 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; 0.89%).

The vast majority of index procedures were completed utilizing laparoscopic surgery techniques, except for biliopancreatic diversion, which was primarily done open. Through May 2009, 78 deaths were reported at any point in time following the index procedure for a total mortality of 0.13%. The 90-day mortality was 0.11%, and the 30-day mortality was 0.09%.

Conclusions: This is the first report of data from BOLD. The data reveal important characteristics of patients undergoing bariatric surgery across the United States in centers participating in the BSCOE program. Future analyses of BOLD data are likely to have a major impact on the specialty of bariatric surgery.

Key words: bariatric surgery; demographics; gastric bypass; adjustable gastric band; sleeve gastrectomy; duodenal switch; mortality; complications; patient selection.

Introduction

The steady rise 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 practice, requires a broad collection of clinical data on a large population of patients. Surgical Review Corporation (SRC) was created under the auspices of the American Society for Metabolic and Bariatric Surgery (ASMBS) to advance the safety, efficacy and efficiency of bariatric and metabolic surgical care.

Two key objectives of SRC are to identify processes and practices that promote patient safety and lead to excellent short- and long-term outcomes, as well as recognize bariatric surgery programs that enact such practices by designating them as Bariatric Surgery Centers of Excellence® (BSCOE). To monitor compliance and quantify the impact 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, comorbidities, and outcomes. Such data can provide powerful evidence for best practices in bariatric surgery.

BOLD was developed under the guidance of SRC's Research Advisory Committee. Efforts were made to keep BOLD data elements and definitions common with the National

Institutes of Health (NIH) 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 research-consented patients entered into BOLD over the 23-month period between its launch in June 2007 and May 2009 are reported in the current study.

Materials and Methods

BOLD Background and Data Entry

BOLD is a proprietary, Internet-based software product developed by SRC to collect prospective data on all bariatric surgery patients treated by ASMBS BSCOE participants for the purpose of assessing outcomes and quality of care. The current report includes perioperative patient data entered into BOLD between the time it opened for patient data entry in June 2007 and 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, there were more than 450 facilities and 800 surgeons utilizing BOLD.

Data entry into BOLD occurs via a secure, Web-based application and is performed by designated individuals at the facility. Training and weekly live webinars are available but currently not required for individuals who enter data into BOLD. Submitted information is typically collected during routine clinical patient encounters, and hard copy forms of BOLD data entry screens may be used by participants in order to facilitate data capture during these encounters. Entry of patient-identifying information is not required; however, programs that

choose to utilize BOLD as their primary mechanism for data collection may enter patient-identifying information. BOLD also interfaces with select third-party electronic medical record (EMR) systems, which enables participants currently using these software systems to directly transmit their data into BOLD to minimize duplicate data entry.

Baseline data collected before bariatric surgery include patient demographics, anthropomorphic measurements, medications, comorbid conditions, and previous bariatric surgical procedures. Although BOLD requires data to be entered for only a single preoperative encounter, more preoperative encounters can be entered and may ultimately facilitate research related to the possible contribution of preoperative weight loss and comorbidity improvement in reducing surgical risk. 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 body mass index (BMI), ideal body weight (IBW), and excess body weight (EBW). Comorbidity severity is assessed via a modified version of the scoring system developed by Ali et al.[1] This six-point scoring system assigns a numerical value (zero to five) to each of a number of medical conditions based upon the relative severity of the condition (e.g., diabetes mellitus and hypertension). A value of zero indicates that the condition is not present. As the numerical value increases, so does the severity of the medical comorbidity, such as the requirement of 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 comorbidities are mentioned here for completeness in the overview of BOLD but are still being analyzed and will not be presented in the current report.

Information specific to the surgical procedure and perioperative patient management, including complications/adverse events, are entered at the time of the hospital encounter.

Postoperatively, data are collected at regular intervals to assess body mass, comorbidities, and complications. Table 1 provides a list of the more than 130 complications that can be recorded in BOLD during intraoperative and postoperative visits. To accommodate for individualized preference in patient 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 are 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 utilizes site inspections to verify data entered into BOLD, including key outcomes indicators such as mortality, reoperations, and readmissions.

Access to Data

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 will be 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 ways to improve quality and patient safety are major objectives of the BSCOE initiative. The institution of mandatory data reporting by BSCOE participants sets 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 methodologies, and BOLD was developed with this in mind. Introduction of quality measures such as observed/expected complication ratios for appropriately risk-stratified patient populations is one 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 may also be used for research. Upon enrollment in BOLD, patients are asked to sign a consent form, which has been approved by an Institutional Review Board (IRB), to allow their data to be utilized for research purposes. No patient data are made available to the research database unless informed consent has been noted in the patient record. As a further 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 BOLD as a national data repository also extends to investigators and other entities who wish to use de-identified, aggregate BOLD research data to answer research questions. No program- or surgeon-identified data are available for such research purposes. Parties interested in research must complete an application process, followed by review and

approval of the application by SRC's Data Access Committee. Approval for dissemination and publication of BOLD data falls under the purview of SRC's Data Dissemination Committee.

Results

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

Preoperative Patient Characterization

Distribution of patients by age prior to bariatric surgery is depicted in Table 2. Gender and race characteristics of the population are found in Table 3. The majority of patients were identified as female (45,619; 78.76%). Male gender was reported in 12,299 patients (21.24%). The majority of patients were identified as Caucasian (45,248; 78.12%). African-American patients comprised 10.52% of the total population (6,094), followed by Hispanics (6.02%; 3,489), and Native Americans (0.46%; 265). The reported employment status of 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 various ranges of patient BMI are reported in Table 4. The American Society of Anesthesiologists (ASA) classification of patients undergoing the four highest-frequency types of bariatric surgery (gastric bypass, adjustable gastric band, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch)

is listed in Table 5. Across all procedures, the majority of patients were identified as ASA 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 in the study population. The most common procedure performed during this 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 utilized successfully in the vast majority of RYGB procedures (27,363; 88.66%), compared to 2,618 open RYGB operations (8.48%), 293 robotically assisted RYGB procedures, and 135 hand-assisted RYGB procedures. Conversion to open was uncommon and reported in only 274 procedures (0.89%).

Various forms of gastric banding were reported in 22,947 patients, making it the second most commonly performed type of bariatric surgical procedure in the current study (39.62%). Adjustable gastric banding (AGB) accounted for the majority of cases, and 99.42% of AGB procedures were performed laparoscopically. A small group of 168 patients was treated by vertical banded gastroplasty (VBG), comprising 0.73% of all patients treated by some form of gastric banding procedure. An even smaller group of 64 patients (0.28%) were treated by non-adjustable gastric bands.

Sleeve gastrectomy was performed in 1,328 patients (2.29%), with the majority of these cases performed laparoscopically (94.58%). Biliopancreatic diversion (BPD) represented a very

small component of bariatric surgical procedures performed, with only 517 procedures reported (0.89%). BPD with or without duodenal switch (DS) represented the only category of bariatric surgical procedure where open access (69.33%) was utilized more often than laparoscopic access (29.86%). Approximately 2% of patients indicated having a previous bariatric surgical procedure. These patients are not excluded from the current analysis.

Table 7 presents perioperative and hospital discharge data for patients undergoing bariatric surgical procedures. Most patients received two or more deep venous thrombosis (DVT) prophylaxis measures, with anticoagulation and intermittent venous compression device being the most common. Blood transfusion was uncommon, occurring in 0.56% of all bariatric surgical procedures (data not shown). The mean length of hospital stay was 2.5 days, with 98.79% of patients being discharged to a residence without need for placement in a facility to provide ongoing care.

Table 8 presents complication rates for the most commonly performed types of bariatric surgical procedures. BOLD captures data on more than 130 complications spanning a wide range of severity, from major to minor. Overall, 10.77% of patients experienced one or more complications following surgery. Complications were most commonly reported in patients undergoing BPD/DS (25.65%), followed by RYGB (14.87%). Most complications occurred post-discharge and were judged to be relatively minor. The most commonly reported complication post-discharge was nausea/vomiting (data not shown). Further data analysis is underway to characterize the various types and severity of complications.

Table 9 presents mortality data, including both frequency and timing of mortalities reported in BOLD through May 2009. Mortality rates were low: 30-day all-cause mortality was 0.09% and 90-day all-cause mortality was 0.11%. These mortality rates were calculated based

on the assumption that all deaths occurring in the BOLD population during the specified time periods were reported in BOLD. If the mortality rate was based solely on those patients having a recorded follow-up encounter, the 90-day mortality rate would be 0.22%.

Discussion

The number of bariatric surgery procedures in the U.S. has increased tremendously as the obesity epidemic continues to grow. The case volume for bariatric surgery is estimated at more than 200,000 procedures per year[2], making it one of the most commonly performed abdominal operations. Despite the increase in popularity for bariatric surgery as a treatment for obesity, very few large clinical studies that evaluate population-based outcomes of surgery using clinically rich data sets have been published. Many healthcare insurance carriers have refused to allow coverage or remove barriers to bariatric surgical care for their insured. Around the turn of the century, 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 Surgical Review Corporation in 2003 as an independent, non-profit organization governed by 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.

Further support for the development of the center of excellence (COE) concept came in 2006 when the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination in favor of bariatric surgery as an appropriate treatment for morbid obesity based upon available data[3]. Application was limited to identified COEs as designated by SRC and the American College of Surgeons (ACS). Recognizing the need for large population-based studies with clinically relevant data, CMS charged both of the neophyte certification programs with collecting and reporting patient data to improve care and document treatment outcomes.

The current study is the first publication utilizing data collected from BSCOEs using BOLD. Originally, data collected and published by SRC was comprised of 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 purpose of center designation, the application data format allowed for few comparative and research opportunities due to its aggregate nature. Recognizing these limitations, SRC developed BOLD to capture prospective, longitudinal patient data.

Since BOLD opened for data entry in June 2007, there have been 116,984 patients registered through May 2009, a number that includes preoperative patients being evaluated for bariatric surgery who have not yet undergone the procedure and patients who have not granted permission to utilize their information for research purposes. Of the registered patients, 75,050 (64.15%) have signed an IRB-approved consent form to allow their data to be studied for research purposes. The current study population is a subset of 57,918 research-consented patients in BOLD with data entered for a bariatric surgical procedure through May 2009.

It is important to note that data analyzed in the current study are self-reported by BSCOE participants, which has inherent limitations. Data is entered into BOLD by designated

individuals at the various sites, many of whom are involved in patient care such as nurses, bariatric coordinators, and surgeons. Some participants provide data entry access to hospital staff for the entry of intraoperative data; others enter intraoperative data at the surgical practice. No research has yet been conducted to determine if one of these methods produces more accurate data entry. Additionally, practices are responsible for entering all post-discharge complications related to surgery, even if they are managed by another healthcare provider. These post-discharge events are potentially underrepresented in the database.

As of May 2009, more than 450 facilities and 800 surgeons were participating in the BSCOE program. Effective January 2008, BSCOE participants are required to enter data into BOLD as part of their participation agreement, and data submission is required for centers to maintain their BSCOE status. The accrual rate of new patients registered in BOLD now exceeds 5,000 per month, with more than 3,000 consented for 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 (IBSR), launched by Dr. Edward Mason in 1979, was the first large international data collection initiative. A 2006 IBSR report provided data on more than 30,000 patients undergoing bariatric surgery over an 18-year period[5]. The Italian Society of Obesity Surgery National Registry[6], University HealthSystem Consortium[7], SAGES Bariatric Outcome Initiative[8], and ACS National Surgical Quality Improvement Program (NSQIP)[9] have reported bariatric surgery patient accrual rates that are significantly lower than BOLD. The NIH-funded Longitudinal Assessment of Bariatric Surgery projects (LABS-1 and LABS-2) collect a substantial amount of clinical and laboratory data on 2000-5000 patients spread across six academic centers[10,11,12]. However, this

relatively small patient cohort does not allow 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 data, to answer critical bariatric surgery outcome questions previously out of reach.

Prior attempts to analyze large databases for factors that determine bariatric surgery outcomes have predominantly utilized administrative databases. Bradley and Sharma used a payor database to demonstrate that outcomes such as 30-day readmission rates were significantly improved for patients operated on at Blue Cross and Blue Shield of North Carolina COE programs as compared to non-COE programs[13]. In a separate study, Flum et al. reviewed outcomes on a statewide level and found the mortality rate for bariatric surgery to be much higher than anticipated based upon single institution studies[14]. These efforts, though supportive of outcomes research, are lacking important clinical parameters known to correlate with surgical risk such as knowledge of comorbid conditions and specific details of the operation.

The composition of the BOLD patient population reported in this study closely resembled that of other bariatric surgery populations previously described[15,16]. The majority of patients were female, Caucasian, age 36-55, with a baseline BMI of 40-50. RYGB was the most common bariatric surgical procedure performed, followed by AGB, sleeve gastrectomy, and BPD. Consistent with the trend toward less-invasive surgical approaches, most procedures were completed utilizing laparoscopic techniques, with the exception of BPD, which was primarily performed as an open procedure.

The overall mortality following bariatric surgery in the BOLD patient population was 0.14%, while the all-cause 30- and 90-day mortality were 0.09% and 0.11% respectively. Death before discharge from the index procedure hospitalization occurred in 0.05% of cases. These statistics represent a further significant decrease in mortality from the 0.36% reported by SRC in 2008 using validated data from its application database[4]. This report is not the first to suggest a progressive decline in bariatric surgery mortality in recent years. The Agency for Healthcare Research and Quality (AHRQ) reported a dramatic 79% reduction in bariatric surgery mortality between 1998 and 2004[17]. A recent review of data from the 2005 National Inpatient Survey found a mortality rate of 0.17% in a group of 24 COE-designated hospitals[18]. Encinosa et al. 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 0.05%, while the risk-adjusted rate of complications and readmissions related to complications was significantly decreased[19]. The authors identified the increased use of laparoscopic techniques, increased use of gastric banding over gastric bypass, and increased surgical volume as likely reasons for the improved outcomes. The ASMBS BSCOE program, which was introduced during their study period, may have also contributed to the improvement in outcomes.

Conclusion

In summary, the current study provides the first descriptive report of 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 in the world. Access to this repository of clinical information is likely to make a tremendous contribution to our understanding of bariatric surgery procedures and outcomes. We thank the surgeons and facilities that enter data into BOLD for their participation in this critically important initiative.

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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 / non-cardiogenic pulmonary edema
- Arrhythmia
- Atelectasis
- Bacteremia
- Bleeding / hemorrhage, intra-abdominal
- Blindness
- Calcium deficiency / osteopenia / osteoporosis
- Cardiac failure
- Cholecystitis
- Common bile duct obstruction
- Death due to accident
- Death due to suicide
- Death from bleeding
- Death caused by sepsis from an anastomotic leak
- Death caused by sepsis from other abdominal source
- Death from pulmonary embolus
- Death from cardiac failure
- Death due to myocardial infarction
- Death due to cerebrovascular accident (stroke)
- Death due to bowel obstruction
- Death due to evisceration
- Death due to pneumonia
- Death due to respiratory failure, including ARDS
- Death due to other cause
- Death 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
- GI 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
- 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
- Multi-system organ failure
- Myocardial infarction
- Nausea / vomiting
- Neisidioblastosis / hyperinsulinemia
- Nerve injury
- Neuropathy
- Nutritional support required via TPN
- Nutritional support required, Enteral nutrition via 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 Guillen-Barre syndrome
- Slippage, gastric band, adjustable
- Slippage, gastric band, non-adjustable
- 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 B1 (thiamin) deficiency – Peripheral neuropathy
- Vitamin B1 (thiamin) deficiency – Wernicke-Korsakoff syndrome
- Vitamin B12 deficiency
- Vitamin D deficiency
- Vitamin E deficiency
- Vitamin K deficiency
- Wound complications
- Zinc deficiency
- Other

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

	n	% of total
Age < 14	27	0.05
Age 15-18	50	0.09
Age 19-25	1,678	2.90
Age 26-35	8,964	15.48
Age 36-45	15,987	27.60
Age 46-55	16,292	28.13
Age 56-65	11,508	19.97
Age 66-75	3,177	5.49
Age > 75	107	0.18
N/A*	128	0.22
	57,918	100

Mean age of the study population was 46.65 ± 11.77 (S.D.) years.

* N/A refers to data that was judged to be in error as defined by age < 3 years or age > 100 years as well as those patients with data entered prior to the introduction of business rules requiring that age be entered before proceeding to the next field for data entry.

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

	n	% of total
Gender		
Female	45,619	78.76
Male	12,299	21.24
Race		
African-American	6,094	10.52
Asian	113	0.20
Caucasian	45,248	78.12
Hispanic	3,489	6.02
Native American	265	0.46
Pacific Islander / Hawaiian	80	0.14
Other*	2,893	4.99

* Other reflects patients of multiracial origin as well as patients who have not identified a race. Users are permitted to select more than one race when entering an individual patient into BOLD; therefore, the sum of the patients identified by race is greater than 57, 918.

Table 4
Body mass index (BMI) in kg/m^2 for 57,918 patients undergoing bariatric surgery with data entered in BOLD

	n	% of total
< 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
N/A*	204	0.35

The mean BMI for the population is 46.46 + 8.37 kg/m^2.

* N/A refers to data that was judged to be in error as defined by BMI < 10 or > 100 as well as those patients with data entered prior to the introduction of business rules mandating the entry of both height and weight data into BOLD.

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

	RYGB	AGB	Sleeve	BPD/DS
ASA Class I	3.84	5.60	4.97	1.40
ASA Class II	23.53	31.35	26.66	15.83
ASA Class III	67.36	60.27	61.9	73.95
ASA Class IV	5.17	2.73	6.33	8.82
ASA Class V	0.09	0.05	0.15	0

RYGB = Roux-en-Y gastric bypass; AGB = adjustable gastric banding; Sleeve = sleeve gastrectomy; BPD/DS = biliopancreatic diversion with duodenal switch

The data are presented as percent of the total population undergoing each of the four most commonly performed bariatric procedures found in BOLD, i.e. RYGB, AGB, Sleeve, and BPD/DS.

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

	Laparoscopic	Open	Open Conversion	Hand	Robot	Other	Total
I. **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 (0.9)	136	327	182	31,668
II. **Gastric banding**							
VBG	134	32	1	0	0	1	168
Adjustable	22,584	21	23	23	64	0	22,715
Non-adjustable	63	1	0	0	0	0	64
TOTAL	22,781 (99.1)	54 (0.23)	24 (0.1)	23	64	1	22,947
III.**Sleeve gastrectomy**	1,256 (94.6)	45 (3.4)	8 (0.6)	19	0	0	1,328
IV.**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
V. **Other**							
Intragastric balloon	0	0	0	0	0	82	82
Gastric pacing	1	0	0	0	0	0	1
Misc/not identified	333	108	11	1	0	872	1,325

VBG = vertical banded gastroplasty

Open conversion refers to patients undergoing an initial laparoscopic access followed by conversion to open access. Hand refers to hand-assisted laparoscopic surgery technique. Robot refers to robotically assisted laparoscopic technique.

50 patients had their procedure cancelled after anesthesia induction (0.09%) and were excluded from this table. Data are presented as absolute number of procedures (% of the category of the procedure whether I, II, III, or IV).

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

Mean duration of surgery	91.8 min.
Mean duration of anesthesia	129.6 min.
Mean estimated blood loss	41.7 mL
Mean length of hospital stay (LOS)	2.5 days
Surgical resident participated	10.1%
Surgical fellow participated	8.4%
Concurrent procedures	34.6%

	n	%
Use of DVT prophylaxis		
None reported	4,205	7.26
1 method	11,536	19.92
2 or more methods	42,177	72.83
DVT prophylaxis methods		
Anticoagulation	46,571	
Foot pump	1,387	
Intermittent compression	45,080	
TED stocking	11,720	
Intraoperative complications	550	0.95
Predischarge complications	2,097	3.62
Discharge location		
Residence	57,217	98.79
Rehabilitation facility	76	0.13
Skilled nursing facility	48	0.08
Another hospital	12	0.02
Deceased	35	0.06
Other / not specified	530	0.92

DVT = deep venous thrombosis; TED = thrombo-embolic deterrent

Table 8
Complications/adverse events

	All Procedures	RYGB	AGB	Sleeve	BPD/DS
Totals					
# Procedures	57,918	30,864	22,715	1,328	499
# Complications	9,967	7,494	1,433	235	256
# Patients ≥ 1 Comp	6,240	4,588	1,050	144	128
% Patients ≥ 1 Comp	10.77	14.87	4.62	10.84	25.65
Intraop Comp					
# Comp	634	448	92	18	24
# Patients	550	385	88	16	17
Pre-DC Comp					
# Comp	2,687	2,078	326	74	63
# Patients	2,097	1,613	283	52	43
Post-DC Comp					
# Comp	6,646	4,968	1,015	143	169
# Patients	4,170	3,060	724	87	90

RYGB = Roux-en-Y gastric bypass; AGB = adjustable gastric banding; Sleeve = sleeve gastrectomy; BPD/DS = biliopancreatic diversion with duodenal switch

Overall, 9,967 complications were reported in 6,240 patients during the following time frames: intraoperative (intraop), postoperative but before hospital discharge (pre-DC), or within one year of hospital discharge (post-DC). Complications for the four most commonly performed procedures (RYGB, AGB, Sleeve, and BPD/DS) are reported in this table. Of note, conversion from laparoscopic to open surgical access was not included as a complication. Some patients experienced complications in more than one time frame.

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

	n	% of total mortalities
Intraoperative	5	6.41
Pre-discharge	25	32.05
Post-discharge		
0-30 days	22	28.21
30-90 days	13	16.67
> 90 days	13	16.67
All mortalities	78	100

All reported mortality %	0.135
90 day all-cause mortality %	0.112
30 day all-cause mortality %	0.089
Pre-discharge mortality %	0.052