Hypothesis: Bariatric surgery performed at US academic centers is safe and associated with low mortality.

Design: Multi-institutional consecutive cohort study.

Setting: Academic medical centers.

Patients and Interventions: We audited the medical records from 40 consecutive bariatric surgery cases performed between October 1, 2003, and March 31, 2004, at each of the 29 institutions participating in the University HealthSystem Consortium Bariatric Surgery Benchmarking Project. All medical records that met inclusion criteria (patient age, >17 and <65 years; and body mass index [calculated as weight in kilograms divided by the square of height in meters], 35-70) and exclusion criteria (previous bariatric surgery) were reviewed and data were collected on a standardized form.

Main Outcome Measures: Demographic data, operative time, blood loss, transfusion requirement, complications, readmission, reoperation, and in-hospital and 30-day mortality.

Results: Data from 1144 bariatric surgery cases were reviewed from 29 University HealthSystem Consortium institutions. The specific bariatric procedures included gastric bypass (91.7%), gastroplasty or gastric banding (8.2%), and biliopancreatic diversion (0.1%). For gastric bypass procedures (n=1049), the mean patient age was 43 years and mean body mass index was 49; 76% of procedures were performed laparoscopically, with a conversion rate of 2.2%; the overall complication rate was 16%, with an anastomotic leakage rate of 1.6%; the 30-day readmission rate was 6.6%; and the 30-day mortality rate was 0.4%. For restrictive procedures (n=94), the mean patient age was 45 years and mean body mass index was 45; 92% of procedures were performed laparoscopically with no conversion; the overall complication rate was 3.2%; the 30-day readmission rate was 4.3%; and the 30-day mortality rate was 0%.

Conclusions: Within the context of the 2004 University HealthSystem Consortium Bariatric Surgery Benchmarking Project, the risk for death within 30 days after bariatric surgery at academic centers is less than 1%. In addition, the practice of bariatric surgery at these centers has shifted from open surgery to predominately laparoscopic surgery. These quality-controlled outcome data can be used as a benchmark for the practice of bariatric surgery at most US hospitals.

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The UHC is an alliance of academic health centers that provides its members with resources to improve performance in clinical, operational, and financial services. The 2004 UHC Bariatric Surgery Benchmarking Project was initiated to evaluate the practice and outcomes of bariatric surgery at academic medical centers. A steering committee consisting of bariatric surgeons, medical directors, quality improvement personnel, administrators, and allied health professionals developed a standardized bariatric data form.

We conducted a multi-institution consecutive cohort study. All UHC institutions were invited to participate in this benchmarking project, and 29 of 93 institutions agreed to participate. Participating institutions were asked to perform a retrospective review of the medical records of 40 consecutive bariatric surgery cases performed between October 1, 2003, and March 31, 2004. All consecutive patient records meeting the inclusion and exclusion criteria were reviewed by quality improvement personnel, and data were collected on a standardized form. Inclusion criteria included patient aged older than 17 years and younger than 65 years, body mass index (BMI) (calculated as weight in kilograms divided by the square of height in meters) between 35 and 70, and routine or elective procedure. Exclusion criteria included revisional bariatric surgery and emergency procedures. Medical records were examined based on the following International Classification of Diseases, Ninth Revision (ICD-9) procedure codes: 44.31 (high gastric bypass), 44.39 (gastroenterostomy without gastrectomy), 44.69 (other repair of stomach), and 44.99 (other operations on stomach). To prevent selection bias, cases were examined in consecutive reverse chronologic order according to the discharge date until a target of 40 cases per institution was identified.

Outcome measures included demographic data, BMI, preoperative comorbidities, type of bariatric procedure performed, additional procedures performed, method of surgery (laparoscopy vs open), conversion from laparoscopy to open surgery, operative time, blood loss, perioperative transfusion requirement, intraoperative and postoperative complications, readmission within 30 days, and 30-day mortality. The operative time was the time elapsed from when the patient entered the operating room until the patient left the operating room. The American Society of Anesthesiologists (ASA) physical status was recorded as P1 (healthy), P2 (mild systemic disease), P3 (severe systemic disease), P4 (severe systemic disease that is a constant threat to life), or P5 (patient moribund). Postoperative complications were categorized as follows: cardiac, pulmonary, infection, vascular or cerebrovascular, gastrointestinal, and other. The types of intraoperative complications and the reasons for reoperation and readmission were also recorded. Length of hospital stay was defined as the period from the index procedure to hospital discharge.

Thirty-day readmission was defined as readmission for any reason within 30 days of discharge after the index procedure. The 30-day readmission data reflect only patients who were readmitted to the institution in which they underwent their operation. In-hospital mortality was defined as the percentage of patients who died before being discharged from the hospital. Thirty-day mortality was defined as death occurring within 30 days after the index procedure.

The UHC Clinical Database was used to examine the volume of bariatric surgical procedures performed at each of the 29 participating institutions in 2003. All hospitalizations during which a bariatric procedure was performed for the treatment of morbid obesity were identified using appropriate ICD-9 diagnosis and procedure codes. All data are expressed as mean±SD.

Data for 1144 bariatric surgery cases were collected at 29 UHC institutions. Race/ethnicity of the study population was as follows: white, 78.0%; African American, 13.5%; Hispanic, 1.9%; Asian, 0.1%; and other, 6.5%. The most common preoperative comorbidities were hypertension (58.7%), followed by degenerative joint disease (37.4%), sleep apnea (31.9%), gastroesophageal reflux disease (31.1%), diabetes (30.8%), depression (21.3%), asthma (21.2%), coronary artery disease (3.9%), venous stasis disease (2.9%), and cirrhosis (0.3%). Primary payers included private insurance (79.2%), Medicare (7.6%), Medicaid (7.4%), and other (5.8%). Most patients had a preoperative ASA status of P2 (37.1%) or P3 (59.7%). Fifty-one (4.5%) of 1144 patients were smokers, and 27% had undergone previous abdominal surgery. The types of bariatric procedures performed included gastric bypass (91.7%), restrictive procedures (vertical banded gastroplasty or gastric banding, 8.2%), and biliopancreatic diversion (0.1%). Additional procedures performed in conjunction with the bariatric procedure included liver biopsy (8.4%), cholecystectomy (8.1%), gastrostomy (2.4%), and ventral hernia repair (2.3%). Using the UHC Clinical Database, the mean number of bariatric cases performed in 2003 at each of the 29 institutions participating in the study was 218±120 cases.

Of the 1144 bariatric surgery cases, 1049 were Roux-en-Y gastric bypass operations. The mean patient age was 43±10 years, and mean BMI was 49±7. Eighty-two percent of patients were female. Seventy-six percent of procedures were performed laparoscopically, with a conversion rate of 2.2%. The mean operative time (time elapsed from when the patient entered the operating room until the patient left the operating room) was 3.8±1.2 hours. The mean blood loss was 125±161 mL. Intensive care unit stay was required for 7.7% of patients. The mean length of hospital stay was 3.3±3.5 days. Postoperative transfusion was required in 22 (2.1%) of 1049 patients. The overall complication rate was 16%, with an anastomotic leakage rate of 1.6%. Other complications included wound infection (2.6%), pneumonia (1.9%), cardiac arrhythmia (1.7%), bowel obstruction (1.5%), urinary tract infection (1%), gastrointestinal tract or intra-abdominal hemorrhage (1.0%), and deep venous thrombosis/pulmonary embolism (0.3%). The rate of reoperation was 4.0%. Reasons for reoperation...
The number of bariatric surgery procedures performed in the United States has increased dramatically in recent years. Several factors have contributed to this upsurge in weight-reduction procedures. First, there has been an increase in the number of obese persons in the United States. According to the 1999-2000 National Health and Nutrition Examination Survey, 4.7% of US adults are considered morbidly obese (BMI >40), almost a 40% increase from the 2.9% noted between 1988 and 1994. Another factor that has contributed to the increasing number of bariatric operations is the recognition of surgery as an effective therapy for morbid obesity, with consequent improvement or resolution of obesity-related comorbidities. Last, the introduction of laparoscopy has attracted patients to a surgical option who were previously reluctant to undergo open bariatric surgery. The exponential growth in the number of bariatric operations requires definition of benchmark rates of morbidity and mortality associated with bariatric surgery so that individual surgeons may compare their results with a national standard.

The outcome of bariatric surgery is not uniform across the United States. Outcome of bariatric surgery at the regional and national levels has only been examined using administrative discharge databases. For example, national administrative databases have reported a low mortality rate, ranging from 0% to 0.7%. Using the Nationwide Inpatient Samples database, Santry et al reported that the adjusted in-hospital mortality rate after bariatric surgery ranged from 0.1% to 0.2% between 1998 and 2002. Similarly, Trus et al reported a slight upward trend in unadjusted in-hospital mortality rate, from 0.2% in 1990 to 0.5% in 2000 with data obtained from the Nationwide Inpatient Samples database. In a study examining inpatient surgery in California, Liu et al reported that the in-hospital mortality rate after gastric bypass decreased from 0.7% in 1990 to 0.2% in 2000.

In contrast to these data, a recent statewide study demonstrated that the in-hospital mortality rate was 1.0%. Further, Flum and Dellinger found that in-hospital mortality underestimated true mortality. These authors found that 30-day mortality was 4 times higher than reported in most published case series and was highest when bariatric surgery was performed by surgeons with a low volume of cases. In another study examining the outcome of bariatric surgery for Medicare beneficiaries based on the Medicare National Claims data, the 30-day mortality rate was 2.0%. The higher mortality among Medicare beneficiaries may represent the outcome of bariatric surgery in a group of disabled patients at high risk. In a study examining the outcome of bariatric surgery in California between 1995 and 2004, Zingmond et al substantiated the finding that the in-hospital mortality rate after gastric bypass in Medicare beneficiaries was higher compared with that in the entire cohort (0.6% vs 0.2%, respectively).

The discrepancy in mortality statistics after bariatric surgery among these different state and national databases underscores the limitations of administrative data. With administrative discharge data, there is a lack of clinical or physiologic bariatric-specific variables such as weight and BMI, which are important in determining the risk in the study population. Other factors that have been shown to be associated with higher morbidity and mortality after gastric bypass include male sex, older age, high BMI (>60), and surgeons on the learning curve of the laparoscopic approach (first 75 procedures). There can also be inaccuracy with the use of certain diagnostic and procedure codes. For example, there is no discrete code for laparoscopic bariatric procedures. There are also missing data with any administrative database, and there is difficulty in tracking readmissions, postdischarge complications, and postdischarge deaths. The 30-day mortality reported in the article by Flum and Dellinger required linking of data from the Washington State Comprehensive Hospital Abstract Reporting System database and the Washington Vital Statistics database. Reliability in the process of linking data between databases comes into question. Despite the limitations of administrative data, they are currently the only source of national population-based statistics in the absence of a comprehensive national bariatric surgery registry.

In an effort to understand the safety of bariatric surgery at the national level, the UHC Bariatric Surgery Benchmarking Project was initiated with the goal of capturing a snapshot of the outcome of bariatric surgery being performed at academic medical centers. Unlike data derived from administrative discharge databases, the data from this project were obtained from record review by quality improvement personnel. The most important finding from our study is that bariatric surgery performed in 2004 at academic centers is safe and associated with low mortality. The in-hospital mortality rate was 0.2% and
the 30-day mortality rate was 0.4%, which is comparable to published data from many single-institution experiences.\textsuperscript{1-6} The mortality data from this study must be viewed in the context of the inclusion and exclusion criteria used, which excluded patients 65 years or older and patients with BMI higher than 70. In addition, only 7% of the study population had Medicare as the primary payer, and most of the 29 UHC institutions are considered high-volume bariatric centers.

Another important finding from this study is that the practice of bariatric surgery has shifted from open surgery to laparoscopic surgery. To our knowledge, this is the first study to document greater use of laparoscopic bariatric surgery than open bariatric surgery. Laparoscopy was used in 76% of gastric bypass procedures and in 92% of restrictive procedures. Using administrative data from the Nationwide Inpatient Samples database, Nguyen et al\textsuperscript{18} reported the increased use of laparoscopic bariatric surgery, which had grown from 2.1% of all bariatric procedures in 1998 to 17.9% in 2002. A major limitation with the use of administrative data is the lack of a procedural code for the laparoscopic bariatric procedure. To estimate the number of laparoscopic bariatric procedures, secondary codes for laparoscopic cholecystectomy, laparoscopic lysis of adhesions, and diagnostic laparoscopy were used. Our study also found that gastric bypass continues to be the primary bariatric surgical procedure of choice (92%), but this may only be a reflection of the cohort of participating institutions. Only 1 of the 29 participating UHC institutions performed more restrictive operations than gastric bypass procedures. In our study, the outcome of restrictive procedures is better than that of gastric bypass insofar as operative time, blood loss, length of stay, and overall complications.

There are several limitations to our study. First, the data are from academic centers only and may not be generalizable to other institutions. The distribution of patients at high risk may differ between academic and community-based centers.\textsuperscript{21} We examined only patients with a BMI between 35 and 70, with a mean BMI of 49 for the study group. Second, this study was retrospective, and certain data points, such as intraoperative and postoperative complications, can be difficult to identify by medical record review. Thus, our results may underestimate the complication rate. Third, most institutions in this study performed a high volume of bariatric surgical procedures; therefore, our results may not be applicable to low-volume institutions. Despite these limitations, to our knowledge, this study represents the first attempt to examine the outcome of bariatric surgery at the national level by auditing consecutive medical records to ensure data accuracy. In addition, unlike data derived from administrative databases, our study was able to obtain specific perioperative and postoperative data that would otherwise be unobtainable from analysis of administrative discharge data.

**CONCLUSIONS**

The 2004 UHC Bariatric Surgery Benchmarking Project represents the first national audit of bariatric surgery being performed at US academic centers. This analysis demonstrates that bariatric surgery at predominately high-volume academic centers and in a subset of patients with BMI of 35 to 70 is associated with low morbidity and mortality. The practice of bariatric surgery at academic centers has shifted from open surgery to laparoscopic surgery, with gastric bypass the primary bariatric surgical procedure. Data from this quality-controlled study can be used as a benchmark for the practice of bariatric surgery at most US hospitals. In the future, there should be emphasis toward a prospective, clinically derived database for collection of bariatric surgery outcomes as a vehicle for quality improvement.

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Wayne H. Schwesinger, MD, San Antonio, Tex: Aside from providing simply an audit, benchmarking gives us a standard of care against which practitioners and institutions can compare their outcomes. In this way, it provides an opportunity to continue improvement in patient care. Benchmarks can do other things as well. They can be used by regulatory agencies such as the Joint Commission on Accreditation of Healthcare Organizations, and likely will be. At the other end of the spectrum, they can be used for marketing by comparing the concordance of an individual experience with that reported by the benchmarking group. To serve any of these purposes, the benchmark itself must be accurate, thorough, and representative. Looking at the current study with those issues in mind, one senses some notable strengths and some limitations. Some have been addressed by the authors.

One of the primary strengths of this study is that the study population is reasonably large, greater than 1000, and the reporting period is relatively recent, ending in March 2004. In addition, the study appears to have a reasonably representative national base, with a third of the UHC programs participating. But, clearly, this is not full participation.

There are also several obvious limitations to this study. One of the problems is that it is a retrospective review. All of us who have done prospective studies know how difficult they can be in terms of data collection. Prospective studies are better, as has been demonstrated by the National Surgical Quality Improvement Project (NSQIP) Veterans Administration (VA) study, but they are more demanding in time and cost. Another limitation is that there is a generous degree of heterogeneity in this study, which, if nothing else, is somewhat distracting. The inclusion of vertical banded gastroplasties detracts from the study and, in my mind, does not warrant subset analysis.

The real question is, given the balance in the strengths and the limitations of this study, can we trust and use the data that have been provided? I would give a qualified yes, at least until something better comes along. It may be that better data will eventually come from the same group. What would be better would be a prospective study looking at the same and other issues in a more representative group.

I have several questions related to this study. First, you did not report on changes in quality-of-life measures. Are there any benchmarks used in this study or others that look at quality of life? Second, have you been able to adequately involve your nonsurgical colleagues in either the development of this benchmarking effort or in its results? What do you see as their role in benchmarking? And third, benchmarking itself is not a static tool; it is one that can be used continuously. Are there efforts to continue this benchmarking protocol, and are you going to revisit the issues already raised?

Dr Stemmer: Improvement in the quality of life following operation is an important consideration. It is the main reason the operation is being done. It was not studied here because to do that we would have needed to know what the quality of life was before the operation. Since this was a retrospective study, we were unable to document that.

Dr Schwesinger asked if there is a plan to continue this study. The answer is yes. While the current study is not an ongoing study, there is a plan to implement a bariatric registry by the Society of American Gastrointestinal Endoscopic Surgeons to follow up on a more long-term basis. I think that, because of all the publicity that this operation has attracted recently in the media and in the surgical literature, it is important that further reviews of this procedure be conducted.

While arguments can be made that procedures of this kind do not need to be done, there is clearly a patient demand for the procedures. The real solution is to be able to do bariatric surgery and to do it well, obviously not without risks, but to do it as well as it can be done, and hopefully to improve it.

Dr Schwesinger mentioned the NSQIP study at the VA. I am a strong supporter of this approach to quality control. One of the outcomes of the NSQIP studies has been that, overall, the mortality and morbidity decreased for the VA as a whole. That might well happen here as these studies are continued.
James R. DeBord, MD, Peoria, Ill: Your wound infection rate was extremely low, but more than 75% of your procedures were done laparoscopically. Do you have any data on the wound infection rate in patients who have undergone open gastric bypass? Do you think you were able to capture that data on wound infections that occurred outside the hospital? My second question is, did you notice any difference in your outcomes between the morbidly obese and the so-called super-morbidly obese in whom the BMI may have been higher than 60 or 70?

Dr Stemmer: To answer the last question first, the study was restricted to people with a certain BMI. Thus, neither the super-morbidly obese nor older patients were included. So that is a question that needs yet to be answered. It is true that the wound infection rate was higher in those patients undergoing open gastric bypass.

Thomas A. Stellato, MD, Cleveland, Ohio: This paper is an important attempt to look at a way to benchmark this operation. I think it would be used as a benchmark if most of the centers participated. Can you give us any insight as to why only 29 members of the consortium participated in this study and what you might have done to improve that?

Dr Stemmer: If the question is why more members did not participate, participation was voluntary. The remaining institutions chose not to. If there was a reason, I do not know what it was.

Ravi Moonka, MD, Seattle, Wash: I have 2 questions. I think one of them has been preempted to some extent. But maybe you could tell us, of the hospitals in the consortium, how many do bariatric surgery? That would give us an idea of how many centers did not participate. If you reported just the centers that wanted to contribute, which, presumably, are the centers that think they have good results, then what you are giving us is the benchmark of what excellent centers do and not what the average center does.

I have a second comment: I do not think these benchmarks should apply to me. As an open bariatric surgeon, I think I operate on larger patients, I operate on more men, and I operate on people with a generally disadvantageous distribution of fat. I am curious as to whether you have generated any way to risk adjust a population of patients so that different practices can be compared with one another.

Dr Stemmer: I mentioned that participation was voluntary. All I can say is that this is what was done and the results were as presented.

In terms of this study being a benchmark that can be applied to others, all we have at this point are the data that Dr Nguyen presented. I think it is a good step in the right direction, at least to provide some answers. I think that eventually, when the study is done prospectively, the concept of benchmarking can be addressed more appropriately.