Original article

Effect of Center of Excellence requirement by Centers for Medicare and Medicaid Services on practice trends

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Received May 15, 2007; revised August 26, 2007; accepted November 15, 2007

Abstract

Background: To report the effect of the American Society of Bariatric Surgery or American College of Surgeons–designated Centers of Excellence designation in Michigan on our practice trends and patient populations. As of February 2006, weight loss surgery for Medicare beneficiaries are reimbursed when procedures are performed at American Society of Bariatric Surgery or American College of Surgeons–designated Centers of Excellence.

Methods: Patients who underwent laparoscopic Roux-en-Y gastric bypass surgery by an individual surgeon from June 1 to October 31 in 2004, 2005, and 2006 were stratified according to use of private third-party insurance versus Medicare (MC) insurance. The demographic data, body mass index, numbers of medications and co-morbidities, operative time, lengths of stay, morbidity, and mortality were analyzed. Significance was assessed at $P < .05$.

Results: From June 1 to October 31 in 2004, 2005, and 2006, 255 patients with MC or private third-party insurance underwent laparoscopic Roux-en-Y gastric bypass surgery, with the percentage of MC patients increasing from 15.3% and 10.2% in 2004 and 2005 to 30.9% in 2006. The MC patients were older (56.1 ± 1.3 yr versus 44.1 ± 0.7 yr; mean ± standard error of mean), had more co-morbidities (5.1 ± 0.2 versus 3.5 ± 0.1), required more medications (10.3 ± 0.6 versus 5.6 ± 0.3), had undergone more previous operations (2.1 ± 0.2 versus 1.3 ± 0.1), and had longer operative times (148 ± 11.1 versus 121 ± 3.1 min) than the private third-party insurance patients; the differences were all significant. The differences in gender, body mass index, and length of stay were not significantly different.

Conclusion: The Centers for Medicare and Medicaid Services requirements for Centers of Excellence designation resulted in a significant increase in the Medicare case load within our institution. This population tended to be older and more complex, with longer operative times. The changes present new challenges in patient care, including the coordination of care for the multiple co-morbidities of older obese patients with a multispecialty care team.

Keywords: Roux-en-Y gastric bypass; Medicare; Centers of Excellence

Obesity continues to be an escalating problem in the United States, with an increasing incidence in almost every age group. The rates are increasing most rapidly in the adolescent population, but Arterburn et al. [1] in 2004 estimated that the number of obese people >60 years will increase from 14.6 million in 2000 to an estimated 20.9 million in 2010. This increase will be accompanied by an increase in requests for surgical weight loss procedures by patients >60 years.

In 2004, Medicare removed language categorizing obesity as "not a disease" from the Coverage Policy Manual [2]. Thus, the treatment options for obesity were opened to Medicare patients, including Roux-en-Y gastric bypass (RYGB) procedures. In February 2006, the Centers for
Medicare and Medicaid Services (CMS) modified the requirements for reimbursement of weight loss surgical procedures. The new requirements included that the procedures be performed at Centers of Excellence (COE) certified by either the American Society of Bariatric Surgery or the American College of Surgeons. The requirements to be designated a Bariatric Surgery Center of Excellence are listed in Table 1, and certified facilities are listed on the CMS Web site [3]. The surgical procedures covered by Medicare include open and laparoscopic RYGB, laparoscopic adjustable gastric banding, and open and laparoscopic biliopancreatic diversion with duodenal switch.

At the time the CMS changes took effect, the Spectrum Health/Michigan Medical, P.C. Bariatric Program was the only certified COE in Michigan. As a result, a rapid influx of Medicare patients into this center occurred. The goal of this study was to review the effect of the CMS requirements on the patient population, demographics, and complexity of care in our private/university-affiliated practice.

**Methods**

Data were prospectively gathered on all patients undergoing laparoscopic RYGB by an individual surgeon. The data included patient demographics, operative technique, operative time, length of stay, insurance type, and outcomes. The CMS guidelines were released on February 21, 2006. The average time between the first patient evaluation in our office and the date of surgery has been 3 months, and, by November 2006, 4 additional COEs had been designated within Michigan. Therefore, the period from June 1, 2006 to October 31, 2006 was compared with the same periods in 2004 and 2005.

The specific demographics included age, gender, body mass index, number of co-morbidities, number of medications, and number of previous intra-abdominal operations. Insurance was divided into private insurance (PI) and Medicare (MC) patients. The MC patients were then further subdivided into patients ≥65 years and those <65 years. The private-pay patients and Medicaid patients were excluded. The outcome variables included operative time, length of stay, morbidity, return to the operating room, and mortality. Differences between the groups were tested for significance with the Student t test. P values <.05 were considered statistically significant.

**Results**

The demographic and clinical data are described in Table 2. In the periods listed (15 months total), 266 patients underwent laparoscopic RYGB. Eleven Medicaid and self-pay patients were excluded, leaving a total of 255 patients. Of the MC and PI patients, 13 and 72 underwent RYGB in June to October of 2004, 9 and 80 in June to October of 2005, and 25 and 56 patients in June to October of 2006, respectively. The percentage of MC patients increased from 15.3% in 2004 and 10.2% in 2005 to 30.9% in 2006.

The gender distribution and body mass index between the MC and PI groups did not differ significantly; 12.8% versus 20.2% were men, and the body mass index was 50.3 ± 1.7 (mean ± standard error of the mean) versus 50.1 ± 1.1, respectively. The differences in the length of stay also were not significant (1.7 ± 0.2 versus 1.5 ± 0.1 days, respectively). The average age was older in the Medicare group (56.1 ± 1.3 years versus 44.1 ± 0.7 years). The MC patients also had an increased number of co-morbidities (5.1 ± 0.2 versus 3.5 ± 0.1; Fig. 1 and Table 3) and were taking more medications (10.3 ± 0.6 versus 5.6 ± 0.3; Fig. 2). The number of previous intra-abdominal operations was significantly greater in the MC group (2.1 ± 0.2 versus 1.3 ± 0.1). Finally, the operative time was significantly longer in the MC group (148 ± 11.1 minutes versus 121 ± 3.1 minutes).

The number and type of adverse events did not differ significantly between the groups. The events included 1 death (in the PI group), 2 repeat operations for a staple line leak (1 each in the MC and PI groups), 4 obstructions (1 in the MC and 3 in the PI group), 3 port site hematomas (1 in the MC and 2 in the PI group), and 5 repeat admissions for abdominal pain and/or nausea (2 in the MC and 3 in the PI group).

The MC patients were subdivided into 2 groups, those <65 years (n = 33) and those ≥65 years (n = 14). When...
Comparing the subgroups, only age differed significantly, the remaining categories were all similar between the 2 groups.

Discussion

Our practice, as a certified COE, noted a significant change with the new CMS requirements. The percentage of Medicare recipients increased nearly threefold, and, with this increase, significant changes in patient demographics followed, with increasing age and complexity of cases, as evidenced by the greater number of co-morbidities, more medications, and more previous surgeries, with the resultant longer operative times. Despite this, morbidity and mortality in these groups remained stable.

The concept of limiting surgical procedures to high-volume centers is not novel and has been described, not only for weight-loss surgical procedures, but also for other procedures, including esophageal and pancreatic surgery [4]. Nguyen et al. [5] reviewed the relationship between the hospital volume of bariatric procedures and outcomes of those procedures. Their findings showed that, compared with low-volume centers (<50 cases/yr), high-volume centers (>100 cases/yr) had shorter lengths of stay, lower overall complications, and lower costs. In addition, they also found a decreased postoperative mortality rate in patients >65 years at high-volume centers compared with little mortality difference between centers for patients ≤55 years. They did recognize that a component of the more efficient care at the high-volume centers included the presence of structural characteristics and formalized processes for the postoperative care, as well as the greater experience of the surgeons. They also supported selected referral of patients >55 years to high-volume centers.

The growing number of Medicare recipients undergoing bariatric surgery is a relatively new phenomenon. Davis et al. [6] found a steadily increasing number of patients undergoing surgical weight loss procedures, but the private pay sector was handling an increasing share of the costs. Reviewing the periods of 1996–2002, the percentage of Medicare recipients undergoing bariatric procedures declined. Our data support the opposite phenomenon: increasing Medicare recipients without a concomitant increase (and even a slight decrease) in private-insurer patients, resulting in a greater proportion of Medicare patients.

Obesity is an escalating problem in the elderly, with prevalence rates projected to be as great as 37.4% by 2010 [1]. It is then not surprising that we find increasing numbers of older patients and Medicare patients undergoing surgical weight loss procedures. When examining bariatric procedures between 1998 and 2002, Santry et al. [7] found a steadily increasing proportion of patients aged 50–64 years, as well as an increased average age of bariatric patients. These investigators also noted increased co-morbidities and a greater risk with increasing age. They found that the proportion of patients ≥65 years remained stable; however, that study had been completed before the CMS changes and coverage of bariatric surgery.

The effect of patient age on outcomes after bariatric surgery has been extensively investigated. Early data suggested increased morbidity and mortality in patient popula-

Table 3
Co-morbidities

<table>
<thead>
<tr>
<th>Co-morbidities</th>
<th>Medicare</th>
<th>Private</th>
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<tr>
<td>Hypertension*</td>
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<td>Hyperlipidemia†</td>
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<td>Diabetes mellitus†</td>
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<tr>
<td>Osteoarthritis†</td>
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<tr>
<td>Depression/anxiety†</td>
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<tr>
<td>Gastroesophageal reflux disease†</td>
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<tr>
<td>Obstructive sleep apnea</td>
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<td>Asthma/chronic obstructive pulmonary disease</td>
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<td>Urinary incontinence</td>
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<td>Coronary artery disease/myocardial infarction</td>
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<td>Chronic musculoskeletal pain</td>
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<td>Endometriosis</td>
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<tr>
<td>Fibromyalgia</td>
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* Present in >50% of patients.
† Present in >25% of patients.
tions aged ≥65 years [8]. However, more recent publications have suggested that RYGB is not only effective, but safe in selected patients aged ≥65 years [9–13]. Varela et al. [13] in 2006 reported lower than expected risk-adjusted mortality in patients >60 years versus younger patients after RYGB and advocated for surgery in this population in programs prepared to comprehensively manage the co-morbidities. Nelson et al. [12] and Fatima et al. [10] both found evidence that RYGB is not only effective with significant weight loss and resolution of co-morbidities, but also that the procedure was safe with much less mortality than previously reported; Nelson et al. reported a 1.3% in-hospital mortality rate and Fatima et al., a <1% 30-day mortality and 5% 5-year mortality rate.

As shown, the outcomes of patients >65 years have been extensively studied. Although the Medicare population is composed of patients qualifying by age, another younger subdivision exists, those qualifying for Medicare because of disability. Although this group is, on average a younger population, no significant differences were found in the remaining patient demographics, including co-morbidities, number of medications required, and number of previous surgeries. This demonstrates a population of patients with an advanced physiologic age, behaving similar to that of an older population secondary to co-morbidities. Therefore, higher risk Medicare patients are not only limited to the elderly population.

Conclusion

Our results have demonstrated that the CMS requirements resulted in a shift toward more complex patients. The changes have resulted in new challenges, including the coordination of care of the multiple co-morbidities with a multispecialty care team. As demonstrated by our initial data, with recognition and proper treatment of these complex patients, adverse events can be maintained at a level equivalent to their counterpart group. We predict that older and more complex obese patients will continue to occupy a greater percentage of the bariatric patient population, and the effects of this change are only starting to be realized. Finally, recent changes in CMS requirements have allowed for increased coverage for surgical weight-loss procedures to Medicare beneficiaries; however, access is limited by the few centers that have been approved as COEs. Considering the evidence of the significant improvements in co-morbidities and quality of life of patients after RYGB, the CMS changes have been beneficial to Medicare recipients in gaining the opportunity to undergo a potentially life-saving procedure; however, access will only improve as more centers become approved COEs.

Acknowledgments

The authors thank Alan T. Davis, Ph.D., for his assistance with the statistical analysis of our data and for reviewing our manuscript.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

References