Original article

Diabetes remission and reduced cardiovascular risk after gastric bypass in Asian Indians with body mass index <35 kg/m²

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Abstract

Background: Roux-en-Y gastric bypass (RYGB) benefits patients with type 2 diabetes mellitus (T2DM) and a body mass index (BMI) >35 kg/m²; however, its effectiveness in patients with T2DM and a BMI <35 kg/m² is unclear. Asian Indians have a high risk of T2DM and cardiovascular disease at relatively low BMI levels. We examined the safety and efficacy of RYGB in Asian Indian patients with T2DM and a BMI of 22–35 kg/m² in a tertiary care medical center.

Methods: A total of 15 consecutive patients with T2DM and a BMI of 22–35 kg/m² underwent RYGB. The data were prospectively collected before surgery and at 1, 3, 6, and 9 months postoperatively.

Results: Of the 15 patients, 8 were men and 7 were women (age 45.6 ± 12 years). Their preoperative characteristics were BMI 28.9 ± 4.0 kg/m², body weight 78.7 ± 12.5 kg, waist circumference 100.2 ± 6.8 cm, and duration of T2DM 8.7 ± 5.3 years. At baseline, 80% of subjects required insulin, and 20% controlled their T2DM with oral hypoglycemic medication. The BMI decreased postoperatively by 20%, from 28.9 ± 4.0 kg/m² to 23.0 ± 3.6 kg/m² (P <.001). All antidiabetic medications were discontinued by 1 month after surgery in 80% of the subjects. At 3 months and thereafter, 100% were euglycemic and no longer required diabetes medication. The fasting blood glucose level decreased from 233 ± 87 mg/dL to 89 ± 12 mg/dL (P <.001), and the hemoglobin A1c decreased from 10.1% ± 2.0% to 6.1% ± 0.6% (P <.001). Their waist circumference, presence of dyslipidemia, and hypertension improved significantly. The predicted 10-year cardiovascular disease risk (calculated using the United Kingdom Prospective Diabetes Study equations) decreased substantially for fatal and nonfatal coronary heart disease and stroke. No mortality, major surgical morbidity, or excessive weight loss occurred.

Conclusion: RYGB safely and effectively eliminated T2DM in Asian Indians with a BMI <35 kg/m². Larger, longer term studies are needed to confirm this benefit. (Surg Obes Relat Dis 2010;6:332–339.) © 2010 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Gastric bypass; Metabolic surgery; Bariatric surgery; Diabetes; Mortality; Cardiovascular risk; Ghrelin; Coronary heart disease

Obesity, which affects ≥250 million people worldwide, is a major public health problem contributing to morbidity and mortality. The average body weight and prevalence of obesity are increasing so rapidly that the World Health Organization (WHO) has declared a global obesity epidemic [1]. Because excess adiposity predisposes to type 2 diabetes mellitus (T2DM), the spread of obesity is driving a parallel pandemic of diabetes, a disease that increases a patient’s cardiovascular disease (CVD) risk by 200–400% [2].

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T2DM is a particular problem in East Asia and the Indian subcontinent, where its prevalence has recently burgeoned 3–6-fold within 20–25 years [3]. It has been predicted that cases of T2DM will increase from 240 million in 2007 to 380 million by 2025 and that ~60% of those cases will be in Asia [3].

In Asian populations, the risks associated with T2DM and CVD occur at a lower body mass index (BMI) than in whites [4–6]. This has been attributed, in part, to differences in body composition and insulin sensitivity. Persons of Asian descent, such as Asian Indians, typically have a greater proportion of body fat than do whites. For any given BMI, the body fat percentage will be 3–5% greater in Asians than in whites, even though the average absolute BMI levels are 3–4 kg/m² lower than in whites [7,8]. Furthermore, Indians store a greater proportion of their body fat viscerally, a distribution that confers increased insulin resistance and CVD risk [9,10]. The greater percentage and central distribution of body fat among Asian Indians places them at particular risk of developing T2DM and CVD [6,11]. It is not uncommon for Indian people to have clinically significant insulin resistance and T2DM at BMI levels that would be considered lean in other populations [6]. Consequently, the WHO has advocated lower values to define a normal BMI for Asian Indians than for whites. For Asian Indians, the proposed classification for an overweight adult BMI is only 23–25 kg/m², and for obesity, it is >25 kg/m² (compared with >30 kg/m² for other populations) [5].

When lifestyle modifications and medications fail to promote adequate weight loss and glycemic control, surgical interventions can provide substantial, long-term benefits. In particular, Roux-en-Y gastric bypass (RYGB) is one of the most effective operations to ameliorate obesity and associated metabolic diseases in severely obese individuals. It has been well documented that in patients with T2DM and a BMI >35 kg/m², RYGB promotes marked and sustained weight loss, with clear improvements in hyperglycemia, dyslipidemia, hypertension, other co-morbidities, and all-cause mortality [12–15]. Consequently, RYGB is considered appropriate for those with a BMI >35 kg/m² and serious obesity-related co-morbidities, such as T2DM [16]. Approximately 84% of obese diabetic patients who undergo RYGB will experience a full remission of T2DM, maintaining euglycemia without any diabetes medication for ≥14 years after surgery [12,17,18]. Increasing evidence has indicated that these remarkable effects result not only from weight loss, but also from weight-independent antidiabetic mechanisms [19].

Accordingly, the use of RYGB to treat T2DM in less obese, or even nonobese, patients has been increasingly considered [20–22], especially among populations with enhanced diabetes risk at lower degrees of adiposity, such as Asians [4–8,11]. However, the benefits of RYGB in patients with T2DM and a BMI <35 kg/m² have not been well documented. Therefore, we conducted a prospective study to evaluate the effects of RYGB on T2DM and estimated CVD risk factors in Asian Indian patients with a BMI of 22–35 kg/m².

Methods

From December 2006 to December 2007, we studied 15 consecutive patients with T2DM who were scheduled to undergo RYGB and had a BMI of 22–35 kg/m². To ensure that we did not inadvertently study patients with type 1 diabetes mellitus, the study candidates were excluded if they had any of the following features: positive anti-glutamic acid decarboxylase or anti-islet cell antibodies, C-peptide <1 ng/mL, a family history of diabetes diagnosed before 30 years of age, or evidence of maturity-onset diabetes of the young in the individual or family. Enrolled subjects were examined prospectively for 9 months after surgery. The Institutional Ethics Committee of the Ruby Hall Medical Center, Pune, India approved the present study, and all participants provided written informed consent.

Laparoscopic RYGB

All RYGB operations were performed laparoscopically by the same surgical team, using a 5-trocar approach. This procedure was executed as follows. With the patient under general anesthesia, a pneumoperitoneum was created by inserting an optic trocar to the left of the midline, above the umbilicus. After insufflation, additional 12-mm working trocars were introduced under direct visualization. A Roux loop of jejunum and a jejunojejunostomy were constructed. The procedure began by creating a 25–30 cm³ gastric pouch from the proximal portion of the stomach, leaving the left gastric artery blood supply intact. The greater omentum was divided in the center, and the jejunum was divided 50 cm distal to the ligament of Treitz. The distal jejunal end was anastomosed to the gastric pouch (linear stapling followed by hand-sewn gastrojejunostomy closure) using an antecolic, antegastric route. Using a stapler, ~150 cm of the alimentary limb was anastomosed (antecolic, antegastric jejunojejunostomy) with 50–70 cm of the proximal jejunum (biliopancreatic limb), completing the Roux-en-Y configuration. Dilute methylene blue was used to test the anastomoses. The mesenteric defect and the space behind the Roux limb were closed. A drain was left in place in the left hypochondrium. The average operative time was 1.5 hours. A Gastrografin contrast study was performed 24 hours postoperatively. If the findings were negative, enteral feeding was initiated with clear liquids. The average hospital stay was 3–4 days.

Postoperative management

All study participants received daily multivitamins, calcium citrate, and mineral supplements, and they were instructed to consume a high-protein, low-fat, calorie-re-
restricted diet. The participants also received vitamin B$_{12}$ and cholecalciferol injections. Iron supplements were prescribed for premenopausal women.

The patients were evaluated postoperatively in the clinic every week for 1 month and again at 3, 6, and 9 months. Each follow-up visit included a complete medical and laboratory workup, with evaluation by a surgeon, internist, and dietitian. T2DM management was performed by an endocrinologist.

United Kingdom Prospective Diabetes Study risk engine

With the recognition that hyperglycemia is a risk factor for coronary heart disease (CHD), the United Kingdom Prospective Diabetes Study (UKPDS) risk engine was introduced in 2001, incorporating glycemic parameters (hemoglobin A1c [HbA1c] and duration of diabetes) into a model to calculate the risk of CHD and stroke [23]. We used this method to predict the CVD risk before and after surgery, because the model uses diabetes-specific equations and corrects for the ethnic features of Asian Indians. The risk engine is available from the Diabetes Trials Unit, Oxford University Centre for Diabetes, Endocrinology, and Metabolism (available from www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/).

Statistical analysis

Continuous data are presented as the mean ± standard deviation. Changes from baseline in efficacy and risk parameters were evaluated using the Student t test. Statistical analyses were conducted using the Statistical Package for Social Sciences for Windows, version 16.0 (SPSS, Chicago, IL). P values <.05 were considered significant.

Results

The study group consisted of 7 women and 8 men, with the following mean preoperative characteristics: age 45.6 ± 12 years, BMI 28.9 ± 4.0 kg/m$^2$, body weight 78.7 ± 12.5 kg, and waist circumference 100.2 ± 6.8 cm. The average duration of T2DM was 8.7 ± 5.3 years. The baseline glycemic indexes and other metabolic parameters are summarized in Table 1.

The average operative time was 1.5 hours. The patients were assisted to ambulate the evening of their operation and given water orally within 12 hours postoperatively. They stayed in the hospital for 3–4 days. No major surgical complications or mortality occurred in this series.

Significant and sustained improvements occurred in all participants in the glycemic parameters, which changed from values consistent with poorly controlled T2DM to values in the normal, nondiabetic range. For example, the fasting blood glucose (FBG) decreased from 233 ± 87 mg/dL to 89 ± 12 mg/dL (P <.001), and HbA1c decreased from 10.1% ± 2.0% to 6.1% ± 0.4% (P <.001; Table 2 and Figs. 1 and 2). The BMI decreased 20%, from 28.9 ± 4.0 kg/m$^2$ to 23.0 ± 3.6 kg/m$^2$ (P <.001). Significant improvements also occurred in body weight, waist circumference, blood pressure, and lipid profiles (Table 2).

Although all 15 subjects had preoperative diabetic-level

| Table 2 |
|---------------------|---------------------|---------------------|---------------------|
| Change in glycemia and other parameters after surgery |
| Parameter | Baseline (n = 15) | Follow-up (n = 15) | Change | P value* |
|---------------------|---------------------|---------------------|---------------------|
| BMI (kg/m$^2$) | 28.9 | 23.0 | −5.9 | <.001 |
| Body weight (kg) | 78.7 | 62.7 | −16.0 | <.001 |
| Waist circumference (cm) | 100.2 | 83.3 | −16.9 | <.001 |
| Fasting blood glucose (mg/dL) | 233 | 89 | −144 | <.001 |
| HbA1c (%) | 10.1 | 6.1 | −4.0 | <.001 |
| Systolic blood pressure (mm Hg) | 136 | 116 | −20 | <.001 |
| Total cholesterol (mg/dL) | 175 | 135 | −40 | <.001 |
| High-density lipoprotein (mg/dL) | 37 | 50 | +13 | <.001 |

BMI = body mass index; HbA1c = hemoglobin A1c.

* Compared with baseline; P value statistically significant at ≤.05.

Fig. 1. There was significant and sustained reduction in FBG throughout the 9 months following RYGB (* after surgery).
Fatal Stroke 3.7

UKPDS 10-year cardiovascular risk predictions before and after RYGB

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n = 15)</th>
<th>Follow-up (n = 15)</th>
<th>Absolute risk reduction (%)</th>
<th>95% CI</th>
<th>Relative risk reduction (%)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD</td>
<td>14.9 ± 12.7</td>
<td>4.7 ± 3.8</td>
<td>-10.1</td>
<td>5.1–15.2</td>
<td>69</td>
<td>.001</td>
</tr>
<tr>
<td>Fatal CHD</td>
<td>9.8 ± 11.1</td>
<td>2.5 ± 2.6</td>
<td>-7.3</td>
<td>2.7–12.0</td>
<td>75</td>
<td>.004</td>
</tr>
<tr>
<td>Stroke</td>
<td>3.7 ± 4.4</td>
<td>2.5 ± 2.7</td>
<td>-1.2</td>
<td>.2–2.2</td>
<td>32</td>
<td>.03</td>
</tr>
<tr>
<td>Fatal Stroke</td>
<td>.6 ± .7</td>
<td>.3 ± .3</td>
<td>-.3</td>
<td>.03– .5</td>
<td>50</td>
<td>.03</td>
</tr>
</tbody>
</table>

UKPDS = United Kingdom Prospective Diabetes Study; RYGB = Roux-en-Y gastric bypass; CI = confidence interval; CHD = coronary heart disease.

* P value statistically significant at ≤.05.

Discussion

Because RYGB typically promotes complete remission of T2DM in severely obese patients [12,17,18] and because mounting evidence has indicated that this results from hormonal and metabolic mechanisms beyond just those related to weight loss [19], the use of RYGB to treat T2DM in less obese patients has been increasingly considered [20–22]. This concept is particularly germane for populations with an enhanced risk of diabetes and CVD at lower BMI levels, such as Asian Indians [4–8,11]. Accordingly, we examined the effects of RYGB in a series of Asian Indian patients with T2DM and a BMI of 22–35 kg/m². These patients had BMI levels that were less than the minimal cutoff for bariatric surgery according to the 1991 National Institutes of Health Consensus Conference [16], but they would generally have been deemed overweight or mildly to moderately obese by the Indian-specific WHO criteria [5].

Fig. 2. There was significant and sustained reduction in HbA1c throughout the 9 months following RYGB (* after surgery).
Our patients experienced marked and rapid improvement in glycemia, allowing them, without exception, to discontinue all diabetes medications and thereafter manifest non-diabetic FBG and HbA1c levels. This complete remission of T2DM, which had occurred in every patient by 3 months after surgery (and typically by only 1 month), was particularly remarkable because the study cohort had relatively severe baseline T2DM. They had had a mean duration of known disease of 9 years, poor initial glycemic control (mean preoperative HbA1c of 10.1%), and insulin use required by 80% (with oral diabetes medications for the remainder). The impressive improvement in glycemic control we observed was accompanied by substantial reductions in other obesity-related co-morbidities, including hypertension and dyslipidemia. These metabolic benefits produced major reductions in the predicted CVD risk, including the probabilities of fatal and nonfatal CHD and stroke. Our salutary results were achieved without mortality, significant surgical morbidity, excessive weight loss, or malnutrition, emphasizing the safety and efficacy of RYGB in Asian Indian patients with T2DM and a BMI <35 kg/m².

Although we did not directly compare RYGB in diabetic patients with a BMI less than versus greater than the traditional BMI cutoff of 35 kg/m², a comparison of our results with historical controls suggests that RYGB is at least as effective against T2DM among less obese persons as it is among patients obese enough to qualify for bariatric surgery using the existing National Institutes of Health guidelines [16]. Patients with a BMI >35 kg/m² typically lose approximately one third of their total body weight, with complete T2DM remission in ~84% of cases [12,13,17,18]. Although our patients with a BMI <35 kg/m² lost only approximately one fifth of their body weight during the follow-up period, they experienced 100% T2DM remission (and all have since remained euglycemic, without weight regain, during the period when this report was being prepared and reviewed). For patients with a BMI >35 kg/m², the few whose T2DM has not remitted after RYGB have been characterized by a longer duration of the disease, for example >5 years [24]. All of our subjects with a BMI <35 kg/m² experienced complete T2DM remission, despite an average 9-year duration of known disease. Our observation that T2DM improves at least as much or more among less obese patients with lesser weight loss compared with more obese patients with greater weight loss suggests that weight loss is not the only determinant of T2DM improvement after RYGB and that additional weight-independent antidiabetes mechanisms are engaged [19]. Consistent with this assertion, we found no correlations between the amount of weight lost and the degree of glycemic improvement (i.e., the magnitude of decrease in FBG or HbA1c) or the rapidity of T2DM remission (data not shown).

One of our most important findings was that RYGB markedly improved the predicted CVD risk, as calculated using the UKPDS risk engine. The Framingham risk scores have also been used to predict CVD risk, but the latter method has important limitations [25]. The UKPDS risk equations are specific for patients with T2DM, and they correct for glycemic control and Indian ethnicity [23,26]. Thus, the UKPDS risk predictions should provide more accurate estimates for our study population. Our patients’ improvements in metabolic parameters in addition to glycemia, such as total and high-density lipoprotein cholesterol, have been included in the UKPDS risk equations, and they contributed to the decrease in CVD risk. It has been demonstrated that in patients with a BMI >35 kg/m², RYGB reduces the predicted CVD risk and actual observed long-term mortality [14,15,27]. Our findings have extended these observations to show reductions in the predicted CVD risk among patients with a BMI <35 kg/m², at least in Asian Indians with T2DM.

Our positive findings regarding RYGB for patients with T2DM and a BMI <35 kg/m² complement the small extant data on bariatric surgery performed in less obese patients with metabolic disease. Other preliminary investigations of RYGB for patients with a BMI <35 kg/m² have also found favorable effects on T2DM and dyslipidemia in Chinese [21] and Brazilian [20,22] populations, both of which have relatively high metabolic disease risks. Importantly, as in our cohort, excessive post-RYGB weight loss was not observed in these studies of less obese patients. Early explorations of gastric banding, biliopancreatic diversion, and experimental gastrointestinal operations to treat T2DM among patients with a BMI <35 kg/m² have also reported desirable results [20,28–30], although additional studies are required to judge the balance of risks and benefits among these approaches.

Notable limitations of our work included the modest sample size, absence of control groups, and relatively short duration of follow-up. To our knowledge, however, this is the first study to evaluate RYGB as a treatment of T2DM among Asian Indian patients with a BMI <35 kg/m². We believe that our promising results help justify larger and longer term investigations in this area.

If corroborated by more definitive clinical trials, our findings would have important implications for T2DM care, at least among persons of Indian descent. Diet, exercise, and medications remain the cornerstones of primary T2DM therapy. However, the long-term adherence and success rates of lifestyle modifications can be disappointing, and, despite an ever-increasing armamentarium of pharmacotherapeutic agents, adequate glycemic control often remains elusive. Moreover, most diabetes medications promote weight gain, and using them to achieve tight glycemic control increases the risk of hypoglycemia. In cases in which behavioral and pharmacologic strategies prove insufficient, surgery offers a powerful alternative. Among severely obese patients, RYGB causes profound weight loss and ameliorates virtually all obesity-related co-morbidities, with acceptable surgical mortality and complication rates of <1% and 10–15%, respectively, and decreased long-term mortality [12,14,15,31]. Such encouraging results in pa-
tients with T2DM and a BMI >35 kg/m², along with the continuing evolution of minimally invasive techniques with lower risks, have prompted consideration of RYGB for less obese patients with T2DM [20–22].

This is of special relevance in populations such as Asian Indians, who accumulate more body fat, especially visceral fat, than do whites at comparable BMI levels [4–8,11]. Our data support the use of RYGB for Indian patients with T2DM and a BMI <35 kg/m², although independent corroborations of our findings are required before considering widespread changes in clinical practice.

Conclusion

Our study was impelled by 3 previous observations. First, RYGB is highly beneficial for patients with T2DM and a BMI >35 kg/m², causing T2DM remission in 84% of cases and reducing T2DM-related mortality by 92% [12,15]. Second, the impressive antidiabetic effects of RYGB result from mechanisms beyond just weight loss [19]. Finally, Asian Indians carry significant risks of T2DM and CVD at lower BMI levels than do whites [4–8,11], yet the latter population was primarily used to establish the existing threshold of >35 kg/m² for the use of RYGB in patients with T2DM.

Therefore, we examined the effects of RYGB among Asian Indian patients with T2DM and a BMI <35 kg/m². RYGB caused rapid and complete remission of T2DM in all of our patients, even though they had severe, longstanding disease preoperatively. Other metabolic syndrome features also improved, including dyslipidemia and hypertension, and these benefits markedly decreased the predicted CVD risks from CHD and stroke. No mortality, untoward surgical morbidity, or excessive weight loss occurred.

Our results suggest that RYGB is a safe, effective procedure to ameliorate T2DM and associated co-morbidities, thereby reducing the CVD risk, in Asian Indian patients with T2DM and a BMI <35 kg/m². Given the technical expertise required to perform RYGB, additional data are required from larger and longer term trials before routinely recommending RYGB for patients with a BMI <35 kg/m² and T2DM. However, our favorable preliminary findings help justify such studies designed to clarify whether the indications for RYGB should be broadened, especially for ethnic groups with an enhanced T2DM risk, and whether RYGB might be viewed primarily as “metabolic,” rather than “bariatric,” surgery.

Disclosures

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

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Comment on: Diabetes remission and reduced cardiovascular risk after gastric bypass in Asian Indians with body mass index <35 kg/m²

By this time, everyone involved in healthcare is aware of the twin epidemics of obesity and type 2 diabetes mellitus (T2DM). Tens of millions of humans have one, and often both, of these conditions. Additionally, most predictions have suggested that within the next few decades, the numbers will likely grow into the hundreds of millions. Because the cost of treating the consequences of obesity in America is already >100 billion dollars, the magnitude of the future cost increase is unfathomable. Now, expand this crisis globally because neither disease is the unique property of the United States. In India alone, the prevalence of T2DM will be >100 million before the close of 2010 [1].

It is also well known to most bariatric clinicians and to a growing number of nonbariatric clinicians, that bariatric surgery seems to achieve dramatic beneficial effects against T2DM [2]. Most patients experience a dramatic improvement and even “remission” of this most devastating chronic disease. Currently, private health insurance and Medicare only cover morbidly obese patients (body mass index ≥35 kg/m²) for bariatric surgery. This requirement discriminates against millions of patients with T2DM. The argument against offering surgery to these patients is the lack of published data in this field. To date, only a few reports of gastric bypass [3,4], adjustable gastric banding [5,6], biliopancreatic diversion [7], and hybrid-like procedures [8] have been published. All these studies have reported improvement in T2DM similar to the universal experience with morbidly obese patients and a low frequency of complications. However, all these studies also had a small sample size and short follow-up period.

In the current issue of the Journal, Shah et al. report on the experience in India with gastric bypass surgery for patients with T2DM whose body mass index was 22–35 kg/m². In India, T2DM is associated with obesity at a lower body mass index than that seen in whites or people of African descent [9]. Because medical therapies are expensive and only slow the progression of T2DM, a “one intervention” surgical procedure that could dramatically improve or permit long-term remission would be especially attractive in India. The results of the study by Shah et al. demonstrated complete remission of T2DM in all 15 patients by 9 months of follow-up. Also, no deaths or major morbidity occurred. These results are consistent with those previously published by Cohen et al. [4] for gastric bypass and Angrisani et al. [5] and Dixon et al. [6] for the adjustable gastric band.

Bariatric surgery, used to target metabolic diseases such as T2DM instead of morbid obesity, is a very promising concept. This could have major positive ramifications for the hundreds of millions of patients with T2DM, especially in countries such as India, where the disease is spreading in epidemic proportions. However, before it is clinically introduced to large populations, we need more studies with longer follow-up to validate the risk/benefit ratio and confirm that the effects are sustainable and not fleeting.

Disclosures

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

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