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CLINICAL RESEARCH

# A Model for Predicting the Resolution of Type 2 Diabetes in Severely Obese Subjects Following Roux-en Y Gastric Bypass Surgery

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**Abstract**

*Background* Severely obese type 2 diabetics who undergo Roux-en Y gastric bypass surgery have significant improvements in glycaemic control. Little work has been undertaken to establish the independent predictors of such resolution or to develop a predictive model. The aim of this study was to develop a mathematical model and establish independent predictors for the resolution of diabetes.

*Methods* A consecutive sample of 130 severely obese type 2 diabetics who underwent gastric bypass surgery for weight loss from November 1997 to May 2007 with prospective pre-operative documentation of biochemical and clinical measurements was followed up over 12 months. Logistic discrimination analysis was undertaken to identify those variables with independent predictive value and to develop a predictive model for resolution of type 2 diabetes. Consecutive samples of 130 patients with body mass index (BMI)≥35 with type 2 diabetes were selected. One hundred and twenty-seven patients completed the study with a sufficient data set. Patients were deemed unresolved if (1) diabetic medication was still required after surgery; (2) if fasting plasma glucose (FPG) remained >7 mmol/L; or (3) HbA1c remained >7%.

*Results* Resolution of diabetes was seen in 84%, while diabetes remained but was improved in 16% of patients. Resolution was rapid and sustained with 74% of those on medication before surgery being able to discontinue this by the time of discharge 6 days following surgery. Five pre-operative variables were found to have independent predictive value for resolution of diabetes, including BMI, HbA1c, FPG, hypertension and requirement for insulin. Two models have been proposed for prediction of diabetes resolution, each with 86% correct classification in this cohort of patients.

*Conclusions* Type 2 diabetes resolves in a very high percentage of patients undergoing gastric bypass surgery for severe obesity. The key predictive variables include pre-operative BMI, HbA1c, FPG, the presence of hypertension and diabetic status.

**Keywords** Mathematical model · Diabetes resolution · Gastric bypass surgery

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## Introduction

The positive effects of bariatric surgery on type 2 diabetes mellitus (T2DM) have been increasingly recognized over the past 15 years. Roux-en Y gastric bypass surgery is noted for the rapid and sustained resolution of T2DM in most severely obese diabetics. Resolution often occurs within 6 days of surgery, well before weight loss could contribute to glycaemic control [1–3]. RYGB surgery has been shown to improve fasting plasma glucose, insulin levels and glycated haemoglobin in almost all severely obese diabetic patients and achieve normalization of these parameters in 75–85% of diabetics, without the need to take medication [4].

Given that not all those with T2DM will come off medication and return to what effectively appears to be a non-diabetic state, it would be both desirable and informative to investigate those features which reliably and independently predict resolution of T2DM. To date, no major effort appears to have gone into such an exercise. However, it has been suggested by both Pories and Schaeur that diabetes is more likely to remain unresolved post-operatively if the duration of T2DM diagnosis is greater than 5–8 years [5, 6]. In addition, Schauer noted that those with T2DM requiring insulin, with higher HbA1c and lower excess weight loss after surgery had a reduced likelihood of resolution of diabetes [6]. Lee reported that a C-peptide of >3 ng/ml seemed to be predictive of resolution in 20 non-obese T2DM patients following sleeve gastrectomy [7]. The pre-operative factors identified to date to have predictive value are: (1) severity and duration of T2DM, (2) pre-operative HbA1c, (3) weight loss after surgery and potentially, pre-operative fasting C-peptide level of >3 ng/mL . The purpose of this study was to systematically examine a range of pre-operative parameters in severely obese diabetics undergoing Roux-en Y gastric bypass surgery, to determine their predictive value for the attainment of glycaemic control or resolution of T2DM following surgery. Having done so, a mathematical model for predicting glycaemic control without need for medication has been developed.

## Patients and Methods

The study group consisted of all patients with T2DM who underwent gastric bypass surgery by a single surgeon (RS) at Wakefield Hospital between November 1997 and May 2007 and who have received a minimum of 12-months follow-up. During this period, two similar forms of gastric bypass surgery were performed. The first was a silastic ring Roux-en Y gastric bypass and the second was a modification of this technique, the Fobi pouch gastric bypass, where a gastric transection was performed to overcome subsequent staple-line disruption. Both of these forms of gastric bypass surgery were initially described by Fobi [8, 9].

The diagnosis of T2DM was established in two ways. In the first, patients had clear prior documentation of the diagnosis and/or were receiving treatment for T2DM. In the second, the diagnosis was established by oral glucose tolerance test which was routinely performed in those without a known history of diabetes. In this context a fasting glucose≥7.0 mmol/L and/or a 2 h glucose≥ 11.1 mmol/L led to the patient being designated as having previously unrecognized diabetes. Therefore, patients with T2DM were classified into one of four T2DM groups: previously unrecognized, diet controlled, those requiring oral hypoglycaemic drugs and insulin requiring T2DM.

Consent was obtained from all patients for collection of data including; weight, height, body mass index, existence of co-morbidities and follow-up data. Pre-operative blood tests included fasting insulin, fasting glucose, HbA1c, and fasting lipid profiles (high-density lipids (HDL), low-density lipids (LDL), triglycerides and total cholesterol). Fasting plasma levels of glucose, insulin and C-peptide were again measured on the morning of surgery, prior to the operation and 6 days post-operatively. Percentage excess body weight loss (%EWL) was calculated using ideal body weight figures from the New York Metropolitan Life Insurance Company tables (1985). Insulin and C-peptide assays were conducted by Canterbury Health Laboratories (Christchurch) using a Roche Elecsys 2010 automated analyzer (coefficient of variation 3.1% and 11% respectively). For insulin assays, plasma was extracted with an equal volume of 25% PEG 6000 to precipitate immunoglobulins prior to analysis. Day of surgery and 6-day post surgery samples were analysed in the same batch. Plasma glucose was assayed using a standard Abbott reagent with coefficient of variation of 1%.

Patients were assessed at 3-monthly intervals after surgery for a minimum of 12 months with collection of data including weight, changes in medication and co-morbidities. A battery of blood tests was undertaken prior to each follow-up visit which included fasting plasma insulin, fasting plasma glucose, HbA1c and fasting lipid profile (HDL, LDL, triglycerides and total cholesterol).

At each time point post-operatively, patients were classified to one of three groups according to glycaemic control:

- Resolution: fasting plasma glucose <6.0 mmol/L and HbA1c<6.0% without requirement for medication
- Indeterminate: fasting plasma glucose is≥6 but≤ 7 mmol/L and/or HbA1c≥6 but≤7% without requirement for medication
- Unresolved: fasting plasma glucose >7.0 mmol/L and/or HbA1c>7.0%, or requirement for antidiabetic medication

At 12 months or the nearest follow-up time point to 12 months, each patient was classified in one of two groups (a) resolved or (b) unresolved. Patients classified as indeterminate were included in the resolved group because with their level of fasting plasma glucose and HbA1c, without the need for medication, a secure diagnosis of diabetes could not be made. Repeat oral glucose tolerance tests were not undertaken because these are poorly and unreliably tolerated after gastric bypass surgery. Despite this allocation into resolved and unresolved groups, the indeterminate group was included for documentation purposes, to acknowledge the uncertainty of status of some diabetic subjects after gastric bypass.

Thirteen pre-operative parameters were examined for their independent role in predicting glycaemic outcome following the gastric bypass. Three of these were categorical variables; diabetes status and presence of or treatment for either hypertension or dyslipidaemia. The remaining ten were continuous variables and included duration of diabetes, age at surgery, BMI, HbA1c and fasting levels of glucose, insulin, C-peptide, LDL, HDL and triglyceride. Each of the continuous variables has been expressed as mean ± standard deviation.

We have used the pre-operative attributes measured on each individual to predict the outcome following surgery for that particular individual. This is known as a supervised learning technique. The data is used as the training data to derive a rule that can be used to classify new individuals. A variety of techniques were used including logistic regression, decision tree learning and logistic model trees.

### Attribute Selection

The wrapper method [10] was used for attribute (or variable) selection. Tenfold cross-validation was employed in this process. The selection endeavors to eliminate all except the most relevant attributes prior to classification. This was undertaken because it is known that the performance of most machine learning algorithms is degraded by irrelevant or distracting attributes.

### The Analysis

A variety of statistical and data mining techniques were applied to the data. In particular, the Weka workbench [10] was used to apply several classification algorithms to the data. Weka has two classifier functions (logistic and simple logistic) that build logistic regression models. Both classifiers were used. The Weka algorithm JRIP was used to build a rule based learner. This algorithm implements a propositional rule learner, Repeated Incremental Pruning to Produce Error Reduction (RIPPER) [11]. The decision tree algorithm J48 [10] was used to derive a decision tree or set of rules that can be used for predicting the outcome. The Naive Bayes classifier which is often considered as a reference method in classification studies was also used.

## Results

There were 708 patients who underwent gastric bypass surgery between November 1997 and May 2007. Of these, 130 (18.3%) met the criteria for having T2DM prior to surgery. However, three of these were excluded from further involvement in the study, because of incomplete data collection, leaving 127 patients with T2DM as the subjects of this report. Patient characteristics can be seen in Table 1. The majority of patients ($n=115$) underwent a Fobi pouch gastric bypass as their first bariatric operation. Eight patients underwent silastic ring gastric bypass and four patients, who had previously undergone gastroplasty procedures, were revised to a Fobi pouch gastric bypass.

After 12 months, the BMI of the 127 patients was 30±6 with an EWL of 73±17%. At 12 months, 107 (84%) had resolution of their T2DM (by our definition) whilst 20 patients (16%) remained unresolved. Furthermore, 57 (83%) of the 69 patients requiring antidiabetic medications pre-operatively had these discontinued by 12 months. Following discontinuation of diabetic medication, no patient required recommencement within the 12-month follow-up period. The patient characteristics and variables of the resolved and unresolved groups can be seen in Table 2.

Improvement in mean HbA1c was seen in all patients at 12 months, irrespective of diabetic status prior to surgery. Patients least likely to experience resolution of their diabetes were those taking insulin prior to surgery (Fig. 1). Indeed, 16 (50%) of those taking insulin prior to surgery remained diabetic following surgery, although control was improved and the requirement for insulin was reduced. Only six of 32 patients continued to require insulin by 12 months.

**Table 1** Pre-operative patient characteristics/variables of 127 severely obese diabetic individuals undergoing gastric bypass surgery

| Characteristic/variables | |
|---|---|
| Age (years) | 48.5±10.1 |
| Gender | 82 females (65%) |
| | 45 males (35%) |
| BMI | 46.8±9.4 |
| Duration of diabetes (years) | 4.5±5 |
| Diabetes status | |
| Previously unrecognised | 24 (19%) |
| Diet controlled | 11 (9%) |
| Oral hypoglycaemics | 60 (60%) |
| Requiring insulin | 32 (25%) |
| HbA1c (%) | 7.7±1.7 |
| Fasting plasma insulin (pmol/L) | 175±109 |
| Fasting plasma glucose (mmol/L) | 8.7±4 |
| Fasting LDL cholesterol (mmol/L) | 3.0±1.1 |
| Fasting HDL cholesterol (mmol/L) | 1.16±0.28 |
| Fasting C-peptide (pmol/L) | 1322±615 |
| Fasting serum triglyceride (mmol/L) | 2.5±2.9 |
| Hypertension ($n$) | 88 |

**Table 2** Patient characteristics before surgery and variables before and after according to whether there was resolution of diabetes after 12 months

| | Resolved ($n$=107) | | Unresolved ($n$=20) | |
|---|---|---|---|---|
| Characteristics | | | | |
| Age at surgery (years) | 48±10 | | 51±8 | |
| Gender ($n$) | 70 Females | | 12 Females | |
| | 37 Males | | 8 Males | |
| BMI | 47±10 | | 41±6 | |
| Duration of diabetes (years) | 3.68±4.41 | | 9.31±4.62 | |
| Diabetes status (resolved/total) | | | | |
| Previously unrecognized | 24/24 | | 0/24 | |
| Diet controlled | 11/11 | | 0/11 | |
| Oral hypoglycaemic agents | 56/60 | | 4/60 | |
| Insulin requiring | 16/32 | | 16/32 | |
| Variables | Pre-operative | 12 months | Pre-operative | 12 months |
| Plasma Insulin (pmol/L) | 170.81±105.02 | 43.41±28.52 | 194.42±122.91 | 44.31±32.64 |
| HbA1c | 7.35±1.45 | 5.55±0.52 | 9.78±1.52 | 7.74±2.12 |
| Fasting glucose (mmol/L) | 8.56±3.47 | 4.90±0.67 | 10.11±2.93 | 7.71±2.01 |
| Cholesterol (mmol/L) | 5.21±1.12 | 4.75±1.72 | 5.51±1.58 | 4.91±1.38 |
| LDL cholesterol (mmol/L) | 3.03±0.97 | 2.56±0.65 | 3.34±1.52 | 3.06±0.92 |
| HDL cholesterol (mmol/L) | 1.21±0.34 | 1.47±0.44 | 1.15±0.27 | 1.47±0.37 |
| C-peptide (pmol/L) | 1,389.96±562.24 | Not tested | 1,002.73±743.84 | Not tested |
| Triglyceride (mmol/L) | 2.57±3.16 | 1.28±0.56 | 2.75±1.71 | 1.52±0.64 |
| Hypertension ($n$) | 53 (50%) | 21 (20%) | 15 (75%) | 7 (35%) |

## Logistic Regression

In all the models in which patients were classified as either resolved or unresolved, the classifier meta.AttributeSelectedClassifier selected five variables as being important attributes for predicting outcome. These included diabetic status, presence of hypertension, fasting plasma glucose (FPG), HbA1c and BMI. Table 3 details the proportion of patients correctly and incorrectly classified by the various models employed. There is very little difference between the various models proposed. We have selected the J48 trees model and the simple logistic model as being practical for use in the Clinic. The former uses four attributes and is shown in Fig. 2. The latter allows for the calculation of a probability of a particular patient being resolved of their diabetes on the basis of the following formula. Only two attributes are used in this model; the diabetic status and the pre-operative HbA1c.

For the simple logistic model, the model is $\frac{e^{\log \mathrm{it}}}{1+e^{\log \mathrm{it}}}$

Class Resolved :

logit is $5.86 - 1.96 \times$ [diabetes status] $- 0.44 \times$ [HbA1c]

Class Not Resolved :

logit is $-5.86 + 1.96 \times$ [diabetes status] $+ 0.44 \times$ [HbA1c].

Where diabetes status is 1 if the patient is taking insulin and 0 for all other groups. The patient is deemed likely to resolve if the probability of "Class Resolved" is greater that the probability of "Class Not Resolved".

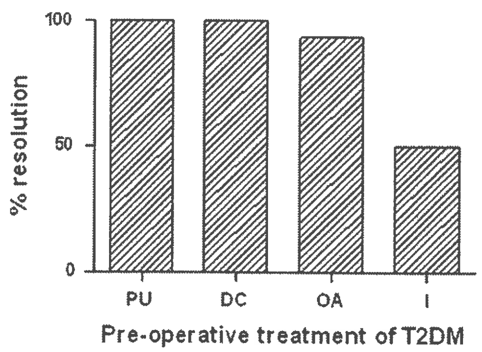


**Fig. 1** Percentage of patients resolving their T2DM at 12 months following surgery categorised according to pre-operative treatment. *PU* previously unrecognised, *DC* diet controlled, *OA* oral hypoglycaemic, *I* insulin requiring)

## Discussion

Type 2 diabetes is an epidemic with the worldwide prevalence set to more than double from 171 million in 2000 to 366 million by 2030 [12, 13]. Diabetic subjects face both the development of the microvascular and neuropathic complications of diabetes and an increased risk

**Table 3** Mathematical models explored for predicting resolution or otherwise of diabetes 12 months after surgery and the attributes they employ, showing the percentage of patients correctly or incorrectly classified by the model

| Model | Attributes in model | Correctly classified (%) | Misclassified (%) |
|---|---|---|---|
| Naïve Bayes | Diabetes, FPG, HbA1c, BMI, hypertension | 82.7 | 17.3 |
| J48 trees | Diabetes, FPG, HbA1c, hypertension | 87.4 | 12.6 |
| Logistic regression | Diabetes, FPG, HbA1c, BMI, hypertension | 85.8 | 14.2 |
| Simple logistic | Diabetes, pre HbA1c | 86.6 | 13.4 |
| Logistic Model trees | Diabetes, pre HbA1c | 86.6 | 13.4 |
| JRIP | Diabetes, pre HbA1c | 84.2 | 15.8 |

in overall mortality. At present, a target HbA1c of ~7% is advised because this has been shown to be associated with fewer long-term microvascular complications [14]. Unfortunately, only some 37% of adults are able to achieve this HbA1c target through medical therapy [15]. Somewhat surprisingly, attempts to optimise glycaemic control even further to an HbA1c of nearer to 6%, such as was done in several large recently reported international trials (VADT, ACCORD and ADVANCE), have not been shown to reduce mortality from cardiovascular complications [16–18], and in one study, there was even increased mortality [16].

The difficulties encountered in achieving glycaemic targets using medical therapy contrast sharply with the glycaemic improvements noted immediately following gastric bypass surgery in the severely obese with type 2 diabetes. Although all forms of bariatric surgery have been shown to lead to resolution of T2DM, biliopancreatic diversion and gastric bypass procedures have been shown to have a greater benefit in this respect than restrictive type procedures [4]. While the explanation for this remains unknown, it is almost certainly linked to the mechanism by which resolution or improvement occurs. Reduced energy intake and weight loss play an undisputed role in this process, but neither seems to be the key explanation, as although the former can be expected to improve glycaemic control, it would be unusual for resolution to be accomplished by this means. Furthermore, weight loss per se is

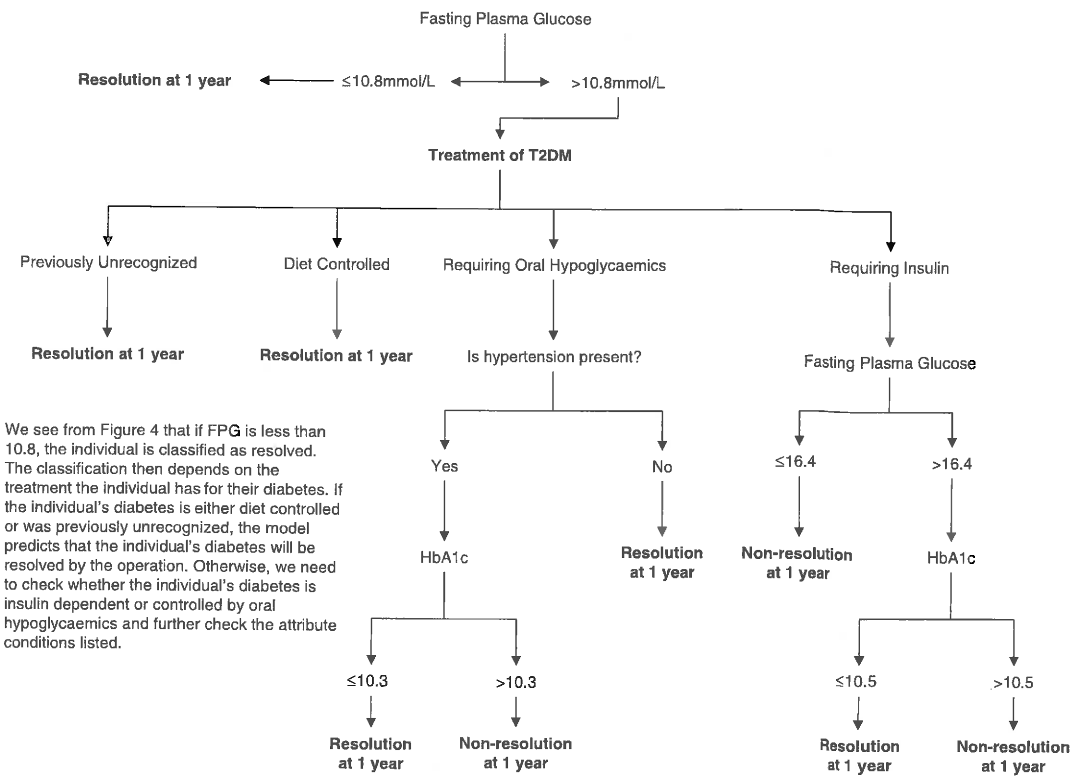


**Fig. 2** J48 decision tree for the two group model for predicting the resolution of diabetes at 1 year

not the major explanation, because, as demonstrated in this series and others [2, 3, 6], resolution of the diabetes generally occurs within one week of surgery, during which time minimal weight loss has been achieved. Nevertheless, where resolution has not been achieved by 1 week, it may yet be achieved over the coming 12 months indicating that weight loss does have a role to play, as shown in several patients in this reported experience. The more interesting and potentially important explanation would seem to link with the dramatic early resolution of insulin resistance which we have shown occurs within 6 days of gastric bypass [1]. While a number of authors have attempted to explain the early occurrence of resolution, by creating and referring to the "foregut hypothesis" [19] and the "hindgut hypothesis" [20], the mechanism remains unproven. Its clarification will, however, herald a major advance in our understanding of insulin resistance and the role of the gut in its development. It is also likely that such an understanding will ultimately lead to a new approach and even paradigm for the management of T2DM. The meta-analysis by Buchwald, defining resolution by the discontinuation of treatment, indicates that gastric bypass surgery results in resolution in 80.5% of patients [21]. This is consistent with our results for gastric bypass where we noted an 84% resolution rate, and with stricter definitions of resolution. We have defined resolution where both the HbA1c (percentage) and fasting glucose (millimoles per liter) are less than 7, in the absence of any antidiabetic medication. This definition has been used because it is not possible to reliably perform oral glucose tolerance testing in patients who have undergone gastric bypass surgery because of variable tolerance to the 75-g oral glucose load and because the time course of oral absorption of glucose will be altered by such surgery. Notwithstanding use of this definition, it must be acknowledged that an "indeterminate" group does exist, which for pragmatic reasons may be considered "resolved". Current consensus statements concerning treatment describe an algorithm of firstly, diet control, then metformin and finally commencement of insulin in the severely obese diabetic [22]. This stepwise escalation of standard treatment is a reminder of the progressive natural history of type 2 diabetes. Not surprisingly, we and others observe resolution rates of T2DM after gastric bypass which parallel these treatment groups. Thus, virtually all newly diagnosed diabetics and those controlled with diet alone can expect resolution. Most of those requiring oral medication can also expect resolution, but in our experience only around 50% of those requiring insulin can expect such an outcome after gastric bypass surgery. Recognition of this is important, not just for what it tells us about our patients, but for the reporting of resolution rates after different types of bariatric surgery. Failure to report severity of diabetes pre-operatively in this way, and to carefully define resolution, is a common weakness in the reported literature and makes comparison between reports and operations problematic if not relatively meaningless.

In this study, we sought to determine the independent predictive factors of diabetes resolution. We used a cohort of 130 diabetics with a 98% follow-up rate over 12 months to examine 13 possible predictors of resolution. The pre-operative factors found to be independently predictive of resolution were: low HbA1c, low fasting plasma glucose, no hypertension, high BMI and no requirement for insulin therapy. The two strongest predictors of resolution were a low HbA1c and no requirement for insulin therapy. Together, these two factors correctly predicted resolution in 86.6% of our patients using a simple logistic model. The addition of hypertension and fasting plasma glucose as factors improved the successful prediction rate to 87.4% using a J48 decision tree. One of the strengths of the methodology used in this study is that it employed a tenfold validation technique. This entailed repeated utilization (in rotation) of 90% of the patient group to develop a model that was then tested in the remaining 10% of the group, before determining the best models for prediction.

Careful examination of the independent predictors of resolution of T2DM after gastric bypass, as undertaken in this study, is important for several reasons. It may help clinicians and patients decide on the merit of proceeding with gastric bypass surgery, where this is principally being considered for resolution of T2DM. At a more fundamental level it may help us develop a better understanding of the mechanisms involved, and contribute to the development and future of metabolic surgery. For instance, it was an unexpected but important finding of our study, that low BMI is a negative predictor of diabetes resolution. This has implications for the development of metabolic surgery undertaken to correct diabetes in non-obese diabetics, and provides some explanation for the considerably lower rates of resolution (16–33%) so far noted when a variety of surgeries have been applied to overweight, but non-obese diabetic subjects [23–25]. This serves as a reminder that currently at least, the startling benefits of surgery can currently only be recommended for the subset of diabetics who are severely obese.

Gastric bypass surgery is not without risk and carries significant disadvantage in terms of future quality of eating. Sacrifice is therefore involved for the prospective patient and it is right that they should have as much information as can be given regarding the prospect and magnitude of benefit. For those who may wish to undergo surgery primarily for resolution of T2DM, current information and predictions based on HbA1c, duration and severity of diabetes [6] are imprecise and have not previously been quantified. The information provided by the present study and the models proposed may be helpful in this respect. We note in passing that the younger age of a patient, which has previously been proposed as a possible predictive factor for resolution, [5, 26] is not supported by our study.

Resolution of T2DM and the knowledge of reduced disease-specific mortality in this group of severely obese patients [27] coupled with knowledge of the ongoing morbidity and risks faced by severely obese diabetics makes bariatric surgery an important option which needs to be discussed with all such patients. Some indication of the expected prospect of resolution of diabetes should be part of that discussion. The finding that the strongest independent negative predictors of resolution are a requirement for insulin therapy and a high HbA1c, makes it desirable that such a discussion take place even in otherwise reasonably controlled diabetics, before the disease progresses to poor control.

**Conflict of Interest** The authors declare that they have no conflict of interest.

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