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DiaRem2: Incorporating duration of diabetes to improve prediction of diabetes remission following metabolic surgery

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Abstract

Background—DiaRem is a validated tool for predicting the likelihood of type 2 diabetes (T2DM) remission after Roux-en-Y gastric bypass (RYGB) surgery.

Objectives—The objective of this study is to determine if the addition of duration of T2DM to DiaRem improves its ability to discriminate between patients with or without T2DM remission and/or to reclassify pre-surgery patients into accurate risk groups.

Setting—Academic Medical Center

Methods—This study included patients consented into a prospective registry of RYGB between July 2009 and November 2015 with known duration of T2DM (n=307). Electronic health record (EHR) derived duration of T2DM was compared with patient reported duration of T2DM in a subset of patients (n=48). DiaRem2 was created using clinical variables from DiaRem and duration of T2DM. Area under the curve (AUC) and the net reclassification index (NRI) were used to assess increased performance of DiaRem2.

Results—Self-reported duration of T2DM was highly concordant with EHR derived T2DM duration (96% agreement). Early T2DM remission occurred in 44% of patients. DiaRem2 included age, hemoglobin A1c, insulin medication use, and duration of T2DM. DiaRem2 had a higher AUC than DiaRem (0.876 versus 0.850, $p=0.026$), reduced the number of remission risk groups from five down to three, and reclassified patients from intermediate to either high or low remission groups (NRI $p<0.0001$).

Conclusions—DiaRem2 simplifies and improves the accuracy of assessing probability of T2DM remission after RYGB. Self-reported duration of T2DM is an acceptable surrogate for T2DM duration derived from clinical data.

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Conflicts of Interest

None

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Keywords

RYGB; diabetes remission; diabetes duration

Introduction

The DiaRem score was designed to provide a simple, preoperative tool for predicting the likelihood of Type 2 diabetes (T2DM) remission after RYGB surgery.⁽¹⁾ The original version of DiaRem (hereafter referred to as DiaRem) used components that are usually known to patients with T2DM and their providers including age, hemoglobin A1c level (A1c), and types of T2DM medications. As compared to other prediction tools, DiaRem is easy to use, has the lowest prediction error⁽²⁾, and it has been validated in multiple and varied RYGB cohorts.^(3–7)

A criticism of DiaRem is the absence of duration of T2DM as a component within the scoring system.^(3,8–9) Longer duration of T2DM is a known risk factor for failure of T2DM remission after bariatric surgery.^(10,11) However, duration of T2DM typically relies on patient self-report. One study reported good concordance between self-reported duration of T2DM with electronic medical records^(12,13) but the accuracy of self-reported duration of T2DM and its utility for research remains uncertain.

The primary objective of this study is to determine if the addition of duration of T2DM to DiaRem improves its ability to discriminate likely success or failure to remit T2DM after RYGB. In addition, we assess whether we can reclassify patients into accurate T2DM remission risk groups. Finally, we sought to determine if self-reported duration of T2DM agrees with the duration of T2DM measured using data from the electronic health record (EHR).

Materials and Methods

Since 2004, patients seeking bariatric surgery at a tertiary Nutrition and Weight Management clinic have been offered participation in an IRB approved research study on outcomes of bariatric surgery. Clinical data from consented patients were extracted from the EHR based on an in-depth standard of care preoperative surgical preparation program.⁽¹⁴⁾ Selection criteria for this IRB approved study included those with a confirmed diagnosis of T2DM at the time of RYGB occurring between July 2009 and November 2015 and with self-reported duration of T2DM (n=377, Figure 1). Patients without adequate post-RYGB follow-up for evaluation of T2DM remission were excluded (n=70). As compared to the 307 patients meeting inclusion and exclusion criteria, the 70 that were excluded were slightly younger at time of surgery (49 years 51 years, p=0.043) but had a similar gender (p=0.797), mean body mass index (p=0.597), mean A1c (p=0.570), and self-reported duration of T2DM (p=0.131).

The duration of T2DM was measured using patient self-report and time since T2DM incidence as derived from the EHR. Self-reported duration of T2DM was consistently recorded at the preoperative surgical evaluation visit and then entered in a clinic note using

standard language (e.g. “the patient was diagnosed with diabetes in ...”). The text notes were extracted into an electronic file, were parsed to identify the year of initial T2DM diagnosis, and then used to calculate the duration of T2DM at time of RYGB. T2DM incidence from the EHR was calculated by manual review of individual patients using the American Diabetes Association (ADA) guidelines for the diagnosis of T2DM (A1c $\geq 6.5\%$ or fasting blood glucose $\geq 125\text{mg/dL}$).⁽¹⁵⁾ Since bariatric surgery patients are commonly referred to this tertiary care hospital from outside the health system, careful review was necessary to distinguish between incident T2DM (i.e. new cases) and prevalent T2DM (i.e. pre-existing T2DM upon entry into EHR). The earliest date of diagnosis or qualifying abnormal lab result was used to define the earliest recorded evidence of T2DM within the EHR. If this date occurred after a minimum of 365 days with active patient encounters and previous normal lab results, the date was considered the incident date of T2DM diagnosis. Otherwise the patient was presumed to have prevalent T2DM at time of entry into the EHR. For patients with ≤ 10 years between time of incident T2DM and RYGB, the duration of T2DM was calculated and recorded as the EHR derived duration of T2DM. However, since the amount of retrospective data was limited, patients with >10 years between the incident T2DM date and RYGB and patients with >10 years of prevalent T2DM were categorized as duration of T2DM >10 years. All others were recorded as unknown EHR derived duration of T2DM.

Remission of T2DM was defined using ADA criteria for partial and complete remission.⁽¹⁶⁾ Partial remission was defined as a consecutive 12-month interval without abnormal laboratory results (A1c $< 6.5\%$ and fasting glucose $\geq 125\text{mg/dL}$) and without use of antidiabetic medications. Complete remission was defined as a consecutive 12 months with normal laboratory results (A1c $< 5.7\%$ and fasting glucose $\geq 100\text{mg/dL}$) without use of antidiabetic medications. Early T2DM remission was recorded when remission criteria were met within the first 2 months after RYGB and lasting for 12 months. Patients with T2DM remission starting ≥ 2 months after RYGB were considered late remissions.

Patient demographics and baseline characteristics were summarized using means with standard deviations and percentages including DiaRem, which was calculated as previously described.⁽¹⁾ The agreement between self-reported duration of T2DM and EHR derived duration of T2DM was evaluated utilizing the percentage of patients with T2DM onset within ± 2 years (if duration was ≤ 10 years) or where both self-report and the EHR derived duration were >10 years. The statistical relationship between early T2DM remission and DiaRem as well as the association between early T2DM remission and duration of T2DM was evaluated using Cochran-Armitage Trend tests. Multiple logistic regression was used to evaluate the association of early T2DM remission with T2DM duration and other patient factors included within DiaRem (age, A1c, T2DM medication types). Interaction terms were used to test for effect modification between duration of T2DM and the DiaRem factors. The odds ratios from a final logistic regression model were used as a guide for a weighting system for a new DiaRem score (hereafter referred to as DiaRem2) that maintains the accuracy of the logistic model. The c-statistic from logistic regression of DiaRem2 was used to evaluate improvement in area under the curve (AUC) as compared to DiaRem. The net reclassification index (NRI) was used to test whether DiaRem2 reclassifies patients into a more accurate risk group (e.g. how often were those with a high probability of remission

based on DiaRem but did not have T2DM remission reclassified to a lower chance of remission using DiaRem2). Kaplan-Meier curves were used to estimate the time until early and late T2DM remission after categorizing DiaRem2 into high remission, intermediate remission, and low remission groups. Data analysis was performed using SAS Version 9.4 (SAS Institute Inc., Cary, NC, USA). P-values<0.05 were considered significant.

Results

The 307 patients with T2DM had a mean age of 51.2 years (SD=10.1), mean baseline body mass index of 49.2 kg/m² (SD=10.3), and included 69% females. The mean DiaRem was 10.4 (SD=6.4) and included 9% with a score of 0–2, 35% with a score of 3–7, 13% with a score of 8–12, 21% with a score of 13–17, and 22% with a score 18. Use of insulin medication was noted in 43% (n=162). The median self-reported duration of T2DM for the 307 patients was 6 years and included 49% with 5 years, 19% with 6–9 years, and 33% with 10 years.

Duration of T2DM from the EHR was identified for 48 of the 307 patients. The remaining 259 patients had unknown EHR derived duration of T2DM (i.e. T2DM developed prior to the patient's initial visit with the health system). The overall rate of agreement between self-reported duration of T2DM and EHR derived duration of T2DM was 96% (Figure 2). Of the 26 patients with 10 years of self-reported duration of T2DM, there were 24 that had an EHR derived duration of T2DM within ± 2 years of the self-reported duration of T2DM. There were 22 patients with >10 years of self-reported duration of T2DM and these all had an EHR derived duration of T2DM >10 years.

Of the 307 study patients, early complete remission of T2DM occurred in 20% (n=62) and another 24% (n=73) patients met the definition of partial T2DM remission (for a total of 44%, n=135, meeting either early partial or complete remission of T2DM). Both measures of remission were significantly associated with DiaRem. The percent of patients with early T2DM remission decreased with each corresponding increase in DiaRem category. For example, the percent with early partial or complete remission was 86% for those with DiaRem 0–2, 74% for those with DiaRem 3–7, 36% for those with DiaRem 8–12, 20% for those with DiaRem 13–17, and 6% for those with DiaRem 18+ (trend test $p<0.0001$). Similarly, in unadjusted analysis, the percent of patients with early T2DM remission decreased with increasing self-reported duration of T2DM. The percent with early partial or complete T2DM remission was 66% for those with 5 years of duration, 46% for those with 6–9 years of duration, and 10% for those with 10 years of duration (trend test $p<0.0001$).

Multiple logistic regression was used to determine which combination of factors within DiaRem and duration of T2DM predict T2DM remission. For models using early partial/complete remission as the outcome, there were significant independent contributions for age ($p=0.0053$), A1c ($p<0.0001$), insulin medication use ($p<0.0001$), duration of T2DM ($p=0.0025$) but not for treatment with sulfonylurea and insulin-sensitizing agent other than metformin ($p=0.661$).

The multiple logistic model was evaluated for improvement after testing for effect modification using interaction terms between DiaRem factors and the duration of T2DM. This analysis revealed increased area under the curve when including interaction terms for T2DM duration with age and T2DM duration with A1c. The interaction term for T2DM duration with insulin medication as not significant and was removed from the model. This model indicated a lower chance of partial/complete remission for older age (with increased risk with T2DM duration >10 years and age >50 years), a lower chance of partial/complete remission for higher A1c (with increased risk with T2DM duration >5 years and A1c >6.5%), and a lower chance of partial/complete T2DM remission for patients using insulin medication (Table 1). A similar analysis was conducted for early complete remission and resulted in a similar pattern of significant findings (data not shown).

The odds ratios of the final logistic model for early partial/complete T2DM remission were used as a guideline for the scoring algorithm for DiaRem2 (Table 2). The percent with early partial/complete T2DM remission for each DiaRem2 score was reviewed to identify categories for high, intermediate, and low remission probabilities. The percent of the cohort within the high, intermediate, and low remission groups was 42%, 21%, and 37%, respectively. The chance of a partial or complete remission at 1-year and 3-years post-RYGB was 94% and 96% for the high remission group, 65% and 86% for the intermediate remission group, and 15% and 25% for the low remission group (Figure 3). Similarly, the chance of complete T2DM remission at 1-year and 3-years post-RYGB was 67% and 80% for the high remission group, 26% and 62% for the intermediate remission group, and 7% and 9% for the low remission group.

When compared with DiaRem, DiaRem2 had superior ability to discriminate patients with early partial or complete T2DM remission from patients without early T2DM remission. For partial or complete remission of T2DM, the AUC for DiaRem2 was higher than the AUC for the DiaRem (Figure 4, 0.876 versus 0.850, $p=0.037$). When limiting to complete remission, the AUC for DiaRem2 was higher than the AUC for DiaRem but was not statistically significant (0.855 versus 0.838, $p=0.156$).

In DiaRem, 70% ($n=215$) of patients classified into one of three intermediate risk groups. However, 21% ($n=64$) of the patients were in the single intermediate risk group for DiaRem2. When comparing DiaRem to DiaRem2, 50% ($n=152$) were classified into the same risk group and the remaining 50% ($n=155$) were reclassified into differing risk groups. For partial or complete remission of T2DM, DiaRem2 correctly reclassified 43% ($n=131$) of patients (e.g. for a patient that did not have remission, DiaRem2 moved the patient to a lower probability of remission category). However, the DiaRem2 incorrectly reclassified 8% ($n=24$) of patients (e.g. for a patient that did not have remission, DiaRem2 moved the patient to a higher probability of remission category). This resulted in a significant net reclassification index (NRI p -value <0.0001). When limiting to complete remission of T2DM, the DiaRem2 score correctly reclassified likelihood of early complete T2DM remission in 36% ($n=111$) of patients but incorrectly reclassified 14% ($n=44$). Although the net reclassification was smaller for complete remission, the resulting NRI was significant ($p<0.0001$).

Discussion

While predicting improvements in co-morbid conditions and extent of weight loss after bariatric surgery has remained challenging, DiaRem is a well validated clinical predictor of T2DM remission after RYGB surgery. We improved DiaRem a clinically useful and scientifically validated tool for prediction of T2DM remission after RYGB surgery by adding duration of diabetes as a factor. Critically, our approach maintains the ease of calculating the chances of diabetes remission while improving both classification and prediction for T2DM remission. DiaRem2 included the clinical variables age, A1c, insulin medication, and duration of T2DM, all of which are routinely available to patients and their surgical providers. These factors were scored and resulted in three remission probability categories including low, intermediate, and high T2DM remission. These remission probability categories subdivide patients into risk groups for early and late remission of T2DM and for varying T2DM remission criteria (i.e. complete and partial/complete remission).

This study adds to the existing literature demonstrating the prognostic value of using duration of T2DM for predicting T2DM remission after RYGB. ^(10, 11) A major challenge in incorporating duration of diabetes into a score has been reliability of duration data, whether obtained from patient oral history, clinic notes or EHR. Using our extensive longitudinal T2DM data in EHR, we demonstrate that self-reported T2DM duration agrees with T2DM duration calculated using a well curated, longitudinal EHR. This finding is consistent with other research and provides more evidence that patient reported medical history is useful for improving their care. ^(12,13) Reliable measure of T2DM duration was not routinely available to the authors at the time of the original DiaRem development. ⁽¹⁾ However, the year of initial T2DM incidence is now collected using standard text at a consistent clinic visit, which results in routine retrieval for clinical care and research.

One of the limiting factors of DiaRem was having too many remission subgroups (n=5). Cotillard et al. selected DiaRem as the best prediction tool for clinicians but suggested using a single remission threshold. ⁽²⁾ Others have shown reduced predictive power and overlap of DiaRem scores in the intermediate groups and in the lowest remission group. ⁽⁷⁻⁹⁾ DiaRem2 reduces the number of risk groups from five down to three. This reduction provides a simpler tool with outcomes that are easier to interpret, greater divergence between remission categories, and consistent surgical expectations to both patients and their care providers.

DiaRem2 not only improved the accuracy of predicting T2DM remission (AUC increase from 0.850 to 0.876, p=0.037), but it also reclassified 72% of the patients in the intermediate remission groups based on DiaRem (group 2-4) into the low or high remission group for DiaRem2 (of which 85% were reclassified correctly). Reclassification to the extreme groups (i.e. lowest and highest risk groups) is preferred to optimize the clinical utility of a T2DM remission prediction algorithm. For example, categorization into the high remission group corresponds to likely successful remission (94% with partial/complete remission and 67% with complete remission by 1-year after surgery) which is helpful information when considering bariatric surgery. Categorization into the low remission group (15% with partial/complete remission and 7% with complete remission by 1-year after surgery) is useful to

manage expectations when considering bariatric surgery and helps patients and their providers plan appropriate courses of action for maintaining glycemic control post-surgery. However, categorization into the intermediate remission group (65% with partial/complete remission and 26% with complete remission by 1-year after surgery) helps identify those with the least certain outcomes. With 79% of this study cohort falling within the high or low remission groups, only 21% of the patients fall into the intermediate group. Given the reduced certainty in remission status in this intermediate group, patients and clinicians should remain vigilant as to the specific outcomes for these individuals. The intermediate group also provides an opportunity to further explore more specific elements that can affect surgical outcome, such as family history, clinical test, or genetics, which can in turn be incorporated into future scores to improve remission prediction.

Our results are comparable to those recently published by Aron-Wisnewsky et al. ⁽¹⁷⁾ These researchers derived the Ad-DiaRem that revised the original DiaRem score by adding two clinical variables (T2DM duration and number of glucose-lowering agents) and restructuring the score weighting system. As a post-hoc analysis, we compared DiaRem2 against Ad-DiaRem and found high agreement (approximately 75% classified into same risk group) and area under the curve was not significantly different (AUC: DiaRem2 = 0.876, Ad-DiaRem = 0.863, $p=0.367$). We found marginal improvement in classification within the DiaRem2 core (65% of the patients classified into different risk groups were classified correctly in the DiaRem2 score, NRI p -value = 0.058). Further research is needed to compare and validate both the DiaRem2 and the Ad-DiaRem.

While other scores that use additional, less frequently available tests (e.g. C-reactive protein) have good predictive value, DiaRem2 maintains a major advantage of simplicity, requiring no additional clinical tests. These findings provide compelling evidence that metabolic surgery programs should make efforts to record the duration of T2DM. Implementation of such a simple program in bariatric centers would facilitate their use of diabetes duration in calculating DiaRem2 as an important part of their preoperative evaluation. DiaRem2 and other evidence based predictive tools are helpful for increasing the personalization of healthcare which will lead to improve patient-centered risk/benefit considerations when discussing surgical decisions.

Conclusions

The use of DiaRem2 improves the prediction of T2DM remission after RYGB and it reclassifies more patients into simple and clinically useful risk groups. There is high agreement between self-reported duration of T2DM and EHR derived duration of T2DM.

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Figure 1:
Study flowchart. RYGB=Roux-en-Y gastric bypass, T2DM=Type 2 diabetes,
EHR=electronic health record

Figure 2:

Bubble plot of the agreement between self-reported duration of T2DM EHR derived duration of T2DM. The circle size is increased with larger sample size (sample sizes are included as labels within each circle). Blue bots represent results that fall within the agreement interval (± 2 years or >10 years for both) and red dots represent results that fall outside of the agreement interval. The agreement rate was 96% (46 of 48 patients). T2DM=Type 2 diabetes, EHR=electronic health record

Figure 3:
Kaplan-Meier curves for time until partial/complete T2DM remission (a) and complete T2DM remission (b) by DiaRem2 remission groups.

Figure 4:
Receiver operator characteristic curves of DiaRem and DiaRem2 for partial or complete remission of T2DM. AUC=area under the curve.

Table 1:

Multiple logistic regression model for early partial/complete remission of T2DM

Parameter	Estimate (SE)	Odds ration (95% CI)	P-value
Intercept	-2.11 (0.52)	-	-
Age and T2DM duration			
Age<40 and T2DM duration <10	Reference	-	-
Age 40–49 and T2DM duration <10	0.31 (0.54)	1.37 [0.47, 3.98]	0.564
Age 50–59 and T2DM duration <10	0.58 (0.52)	1.79 [0.65, 4.91]	0.256
Age 60+ and T2DM duration <10	1.36 (0.63)	3.88 [1.14, 13.23]	0.030
Age 30–49 and T2DM duration 10	−0.13 (0.88)	0.88 [0.16, 4.96]	0.885
Age 50+ and T2DM duration 10	3.02 (0.80)	20.40 [4.25, 97.88]	0.0002
A1c and diabetes duration			
A1c<6.5 and any T2DM duration	Reference	-	-
A1c 6.5–8.9 and T2DM duration <5	0.62 (0.37)	1.86 [0.90, 3.84]	0.093
A1c 9+ and T2DM duration <5	2.75 (1.13)	15.57 [1.69, 143.49]	0.015
A1c 6.5–6.9 and T2DM duration <5	0.67 (0.61)	1.96 [0.59, 6.52]	0.274
A1c 7+ and T2DM duration <5	2.57 (0.55)	13.00 [4.43, 38.14]	<0.0001
Treatment with insulin			
No	Reference	-	-
Yes	1.74 (0.35)	5.71 [2.87, 11.39]	<0.0001

SE=standard error, CI=confidence interval, T2DM=Type 2 diabetes, A1c=Hemoglobin A1c

Table 2:

Scoring algorithm for DiaRem2

Step 1: Calculate DiaRem2 score. Collect patient age, A1c, T2DM medications, and reported duration of T2DM			
	Time with T2DM (years)		
	5	6 – 9	10+
Age (years)			
< 40	0	0	0
40 – 49	1	1	1
50 – 59	2	2	10
60	4	4	10
HbA1c (%)			
<6.5%	0	0	0
6.5 – 6.9%	2	5	5
7.0 – 8.9%	2	10	10
9.0%	10	10	10
Treatment with insulin			
No	0	0	0
Yes	5	5	5
DiaRem2 Score	Sum of above		
Step 2: Assign remission group			
	DiaRem2 Remission group		
DiaRem2 score 0 – 5	High		
DiaRem2 score 6 – 12	Intermediate		
DiaRem2 score 13 – 25	Low		

T2DM=Type 2 diabetes, A1c=Hemoglobin A1