Comparing the 5-Year Diabetes Outcomes of Sleeve Gastrectomy and Gastric Bypass

The National Patient-Centered Clinical Research Network (PCORNet) Bariatric Study

Kathleen M. McTigue, MD et al

Aim of Study

Question:

How do type 2 diabetes (T2DM) outcomes compare across the 2 most common bariatric procedures?

- **sleeve gastrectomy (SG)** and **Roux-en-Y gastric bypass (RYGB)**
  - Mixed evidence in terms of T2DM outcomes, especially in the longer term.
  - Unclear how the choice between them is likely to affect T2DM.
- SG has begun to supplant RYGB as the dominant bariatric procedure over the past decade, despite limited long-term comparative data

Methodology

Recruitment

- PCORnet sites store standardized **electronic health record data** and sometimes other data (eg, claims data), in PCORnet data marts.
- Recruited participants using **59 million patient records** through National Patient-Centered Clinical Research Network (PCORNet) that underwent a primary bariatric procedure at 34 PCORnet-affiliated health systems
- Included **9710 adults**, primarily **female** (7051 female patients [72.6%]) with a mean (SD) age of 49.8 (10.5) years

Inclusion Criteria

- HbA1c level of **6.5%** or more
- **T2DM medication prescription** in the year before surgery
- Patients on **metformin, thiazolidinedione, or liraglutide**
    - needed an ICD-9-CM or Systematized Nomenclature of Medicine (SNOMED) code for T2DM
    - HbA1c level of 6.5% or more in the year before surgery

Exclusion Criteria

- **80 years** or older
- **No T2DM**
- Individuals **without** relevant outcomes **data**

Follow-up

- T2DM remission was calculated from the **index procedure date** to the **last observable data point** following surgery
    - During follow up period, participants medical records from coordinating sites were collected for analysis
        - Eg: , weight, blood pressure, HbA1c laboratory value, or diabetes prescription
    - **Excluded HbA1c measurements** from **admission date to 90 days after discharge** and medication orders from admission dates to the day before discharge

- **Censoring events (events leading to exclusion from final analysis) included:**
    - Death
    - Conversion to a second bariatric procedure (eg, SG to RYGB),
    - Pregnancy (at the delivery date minus 270 days),
    - 18-month lapse in diabetes-specific health care at participating sites. (loss to follow up)

Results

Primary outcome	Secondary outcomes
Remission of Type 2 Diabetes Mellitus	Total weight loss percentages
	Time taken for T2DM relapse
	Changes in Hba1c in 6 months, 1 year, 3 years and 5 years

Important definitions
- **Remission of T2DM**: Hba1c levels of lower than 6.5% for 6 months without consumption of oral hypoglycemics or insulin
- **Total weight loss percentage:** (weight during surgery-weight at any post operative point)/weight during surgery x 100
- **T2DM relapse**.: The occurrence of levels of 6.5% or more and/or a prescription for T2DM medication after remission

Figure 2. Cumulative Incidence Rates of Type 2 Diabetes Remission and Relapse Across 5 Years in the National Patient-Centered Clinical Research Network Bariatric Study Cohort
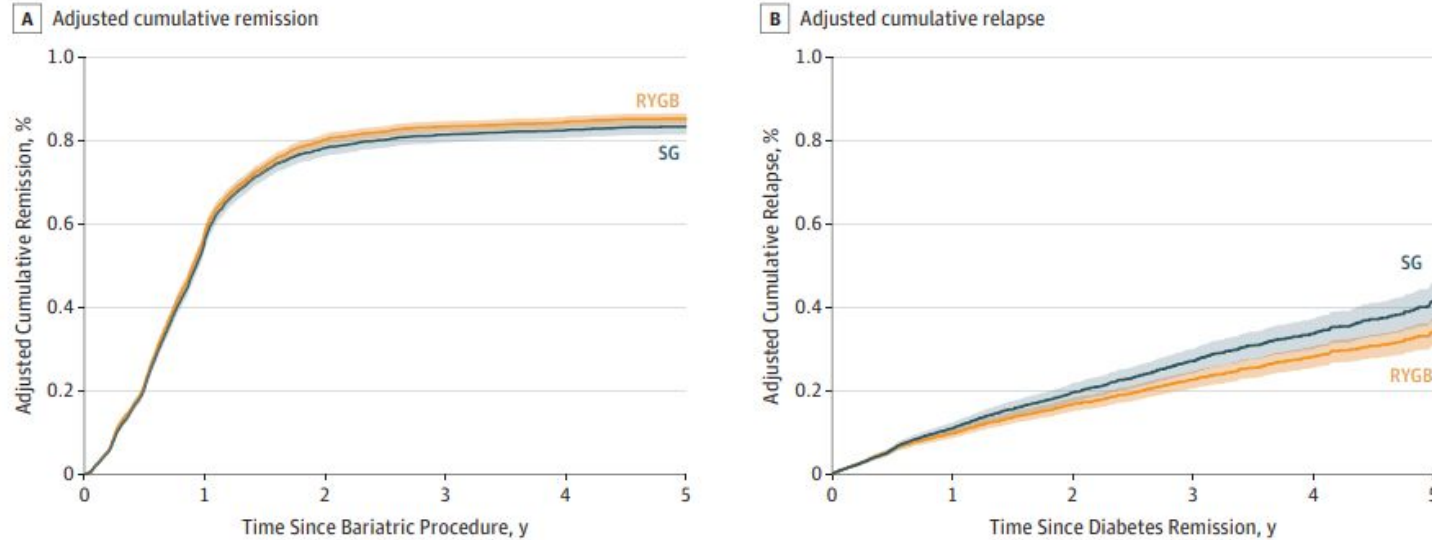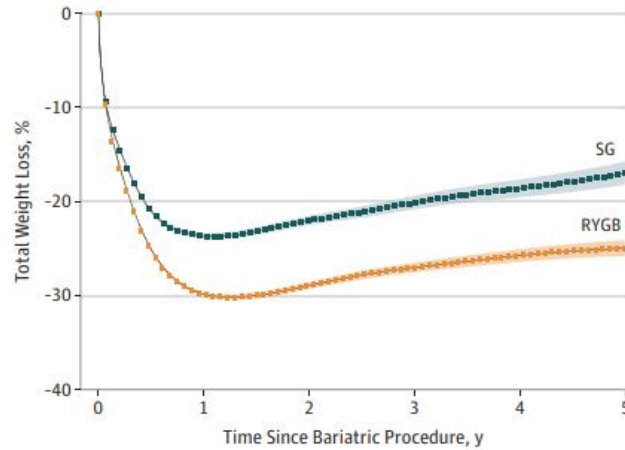
Shaded areas represent 95% pointwise CIs for procedure-specific rates. RYGB indicates Roux-en-Y gastric bypass; SG, sleeve gastrectomy.

- **Remission occurred primarily first 2 years**
- **RYGB showed slightly higher T2DM remission rates than those who had SG (hazard ratio, 1.10 [95% CI, 1.04-1.16];**

Figure 1. Adjusted Total Weight Loss and Change in Hemoglobin A$_{1c}$ Level by Procedure Over 5 Years of Follow-up

A Estimated total weight loss for RYGB and SG procedures

B Estimated change in hemoglobin A$_{1c}$ level for all procedures
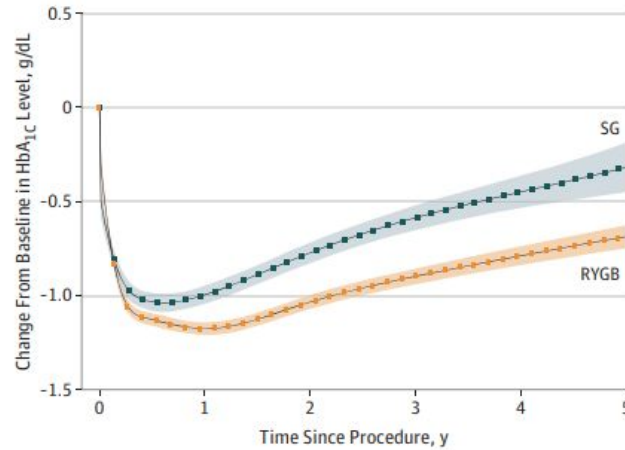
Shaded areas represent 95% pointwise CIs for procedure-specific changes in hemoglobin A$_{1c}$ levels. RYGB indicates Roux-en-Y gastric bypass; SG, sleeve gastrectomy.

- **RYGB group** reflected 6.2% to 8.1% **more total body weight loss than the SG group** at each point
- **10.2-kg difference** (95% CI, 8.3-12.1 kg; $P < .001$) in **weight loss between RYGB and SG at 5 years**
- Patients who underwent **RYGB** experienced **larger and more sustained HbA1c reduction**s than those using SG

Table 2. Comparative Effectiveness of Gastric Bypass and Sleeve Gastrectomy for Percentage of Total Weight Loss and Absolute Difference in Hemoglobin A$_{1c}$ Level Among Adults With Diabetes With 1, 3, and 5 Years of Follow-up[a]

| | Time Since Bariatric Procedure | | | | | |
| | 1 y | | 3 y | | 5 y | |
Group	Patients, No.	Finding	Patients, No.	Finding	Patients, No.	Finding
Total weight loss, %						
Sleeve gastrectomy	2404	−22.8 (−23.1 to −22.5)	2404	−19.2 (−20.0 to −18.5)	2404	−16.1 (−17.3 to −14.8)
Roux-en-Y gastric bypass	4025	−29.1 (−29.3 to −28.8)	4025	−26.2 (−26.7 to −25.7)	4025	−24.1 (−25.0 to −23.3)
Difference	NA	6.2 (5.8-6.7)	NA	7.0 (6.1-7.9)	NA	8.1 (6.6-9.6)
P Value	NA	<.001	NA	<.001	NA	<.001
Hemoglobin A$_{1c}$ mean difference (95% CI), %[a]						
Sleeve gastrectomy	2935	−0.89 (−0.93 to −0.86)	2935	−0.56 (−0.64 to −0.49)	2935	−0.35 (−0.51 to −0.19)
Roux-en-Y gastric bypass	5428	−1.12 (−1.14 to −1.09)	5428	−1.01 (−1.06 to −0.97)	5428	−0.80 (−0.88 to −0.72)
Difference	NA	−0.22 (−0.26 to −0.18)	NA	−0.45 (−0.54 to −0.36)	NA	−0.45 (−0.63 to −0.27)
P Value	NA	<.001	NA	<.001	NA	<.001

Abbreviations: *ICD-9-CM*, International Classification of Diseases, Ninth Revision, Clinical Modification; NA, not applicable; SNOMED, Systematized Nomenclature of Medicine.

[a] Difference is the baseline value minus the end point value; the model was adjusted for age, sex, race, Hispanic ethnicity, body mass index (calculated as weight in kilograms divided by height in meters squared), hemoglobin A$_{1c}$ value, blood pressure, number of inpatient hospital days in the year prior to surgery, number of diabetes medications excluding insulin, insulin use, Charlson/Elixhauser comorbidity score, year of procedure, days from hemoglobin A$_{1c}$ measurement to baseline, having an *ICD-9-CM* or SNOMED code for diabetes, smoking, having an *ICD-9-CM* or SNOMED code for other comorbidities (hypertension, dyslipidemia, sleep apnea, osteoarthritis, nonalcoholic fatty liver disease, gastroesophageal reflux disease, depression, anxiety, eating disorder, substance use, psychosis, kidney disease, infertility, polycystic ovarian syndrome, deep-vein thrombosis, and pulmonary embolism), having *ICD-9-CM* or SNOMED codes for specific diabetes medications (biguanides, glucagon-like peptide-1 agonists, sulfonylureas, thiazolidinediones, and others), site, and propensity-score deciles.

greater reduction in both percentage of total weight loss and absolute difference in hba1c level throughout the 5 years in RYGA compared to sleeve gastrectomy

Summary of Results

Remission rate

Year	RYGB	Sleeve
1 year	59%	56%
5 year	86%	84%

But many will relapse ...

	RYGB	Sleeve
In 5 years	33%	42%

Summary of Results

HBA1c reduction from 7.2% (baseline)

	RYGB	Sleeve
In 5 years	0.8%	0.35%

Diarem Score

- **Diabetes can be complex in management**

- **Predict the likelihood a patient will experience remission following surgery (preoperative probability)**

- **Higher Diarem Score = more advanced disease = overall lower remission rate**

Among individuals with DiaRem scores in the 13-point to 17-point range, **83.4% of patients who had RYGB** had experienced T2DM remission by 5 years vs **76.6% who had SG**

RYGB better remission for more advanced T2DM

Variable	Score
Age (yr)	
<40	0
40–49	1
50–59	2
≥60	3
HbA1c (%)	
<6.5	0
6.5–6.9	2
7.0–8.9	4
≥9.0	6
Other diabetes drugs	
No sulfonylureas or insulin-sensitizing agents other than metformin	0
Sulfonylureas and insulin-sensitizing agents other than metformin	3
Treatment with insulin	
No	0
Yes	10
Overall score (sum of the four components)	0–22
Probability of remission in each DiaRem score subgroup*	
0–2	87 (83–90)
3–7	66 (61–70)
8–12	32 (24–40)
13–17	16 (12–21)
18–22	5 (0–9)

Values are presented as probability (%) with 95% confidence interval.
*Including both partial and complete remissions.
HbA1c, glycosylated hemoglobin.
Adapted from Still CD, et al. Lancet Diabetes Endocrinol 2014;2:38-45, with permission from Elsevier.[31]

Data Differ from Other Studies

- **Some RCT say no differences**
  - Smaller sample size despite longer follow up
  - Current study
    - Author larger sample is able to see all subgroups,generalizing all dr and patient
    - Standardization using PCORnet also reduce data quality issue

- **BUT there are still similarities**
  - Remission rate is consistent with most bariatric studies at 80%
  - Relapse data→ not much, published but stated those 25-53% , consistent with relapse rate

Author Conclusion

Roux en Y > Sleeve

- Similar rates of remission
  - Outcomes similar for those with similar rates
- Larger and more persistent improvement in glycemic control
  - 25% lower
- More advanced disease (high Diarem Score) better improvements

In the end, depends on

- Patient situation
- Adverse effect
- Patient choice
- How it affect life long

Thanks!

Statistical Analysis

- Possible confounding was addressed with direct adjustment for specific factors and deciles of an estimated
- **Primary outcome**
  - Cox proportional hazard models
- **Secondary outcomes**
  - Total weight loss percentages: Linear mixed effects modelling
  - Time taken for T2DM relapse: Cox proportional hazard models
  - Changes in Hba1c: Linear mixed effects modelling

Sensitivity Analysis

- Considered **9-month and 12-month** alternative lags from the last observed T2DM medication order to define remission (HbA1c level <6.5%).

- Additional sensitivity analyses assessed 2 alternate censoring scenarios for inpatient stays:
  (1) no removal of inpatient medications or HbA1c values
  (2) censoring follow-up at the day of admission

Summary of Results

RYGB have
- Slightly higher but similar rates of remission
  - Lower relapse rate
- More reduction in HbA1c
- More weight reduction and maintenance of weight reduction

→ better long term outcome

Those with lower preoperative probability of remission(11-33%) - DiaRem score
- Higher % of remission in RYGB and better improvement

Limitations

- Observational
  - Procedure might be affected by unmeasured factors that affect the surgery
- Using ICD 9 coding
  - Underestimated comorbidity?
- Pbs definition → Relapse and remission relies on medication prescription data
  - Ordered outside the health system
  - Undiagnosed dm is really common
- All dates were normalized to the date of surgery
 - cannot differentiate finish and dropped out

Comparing the 5-Year Diabetes Outcomes of Sleeve Gastrectomy and Gastric Bypass

The National Patient-Centered Clinical Research Network (PCORNet) Bariatric Study

Kathleen M. McTigue, MD et al

Aim of study

- Question → How do type 2 diabetes (T2DM) outcomes compare across the 2 most common bariatric procedures?
- Studies focusing on the 2 most common bariatric procedures: sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB)
  - Mixed evidence in terms of T2DM outcomes, especially in the longer term.
  - Unclear how the choice between them is likely to affect T2DM.
- SG has begun to supplant RYGB as the dominant bariatric procedure over the past decade, despite limited long-term comparative data
- OBJECTIVE→ To evaluate associations of bariatric surgery with T2DM outcomes
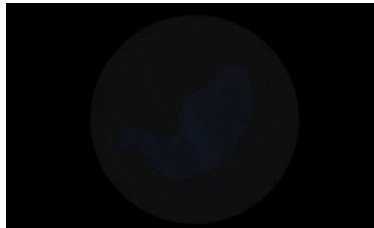
Methodology

Recruitment

- Recruited participants using 59 million patient records through National Patient-Centered Clinical Research Network (PCORNet) that underwent a primary bariatric procedure at 34 PCORnet-affiliated health systems
- Included 9710 adults, primarily female (7051 female patients [72.6%]) with a mean (SD) age of 49.8 (10.5) years
- PCORnet sites store standardized electronic health record data and sometimes other data (eg, claims data), in PCORnet datamarts.Programming queries from the PCORnet Coordinating Center extracted relevant deidentified data from PCORnet datamarts on eligible individuals.
- Race/ethnicity, as recorded in electronic health records, was included, reflecting stakeholder input.

Inclusion criteria : (ICDM-9 - diabetes)
- HbA1c level of 6.5% or more
- T2DM medication prescription in the year before surgery
- Patients on metformin, thiazolidinedione, or liraglutide
  - needed an ICD-9-CM or Systematized Nomenclature of Medicine (SNOMED) code for T2DM or an HbA1c level of 6.5% or more in the year before surgery

Exclusion criteria :

- 80 years or older
- No T2DM
- Individuals without relevant outcomes data

Follow-up

- T2DM remission was calculated from the index procedure date to the last observable data point following surgery
    - I.E. →last observed visit, weight, blood pressure, HbA1c laboratory value, or diabetes prescription
    - Excluded HbA1c measurements from admission date to 90 days after discharge and medication orders from admission dates to the day before discharge
- Remission analyses censoring events included
    - Death
    - Conversion to a second bariatric procedure (eg, SG to RYGB),
    - Pregnancy (at the delivery date minus 270 days),
    - 18-month lapse in diabetes-specific health care at participating sites.
- Relapse analyses censoring event
    - Lapse in provision of any care
        - Patients in remission from T2DM were not necessarily expected to receive HbA1c measures or T2DM prescriptions but needed to receive care in the system to be observed for relapse.
    - More than 18 months without any recorded HbA1c levels, body weight measurement, blood pressure, diagnosis code, or procedure code.

Results- Primary and secondary outcomes

Primary outcome	Secondary outcomes
Remission of Type 2 Diabetes Mellitus	Total weight loss percentages
	Time taken for T2DM relapse
	Changes in Hba1c in 6 months, 1 year, 3 years and 5 years

Important definitions:
- Remission of T2DM: Hba1c levels of lower than 6.5% for 6 months without consumption of oral hypoglycemics or insulin

- Total weight loss percentage: (weight during surgery-weight at any post operative point)/weight during surgery x 100

- The occurrence of levels of 6.5% or more and/or a prescription for T2DM medication after remission defined T2DM relapse.

Statistical Analysis

Statistical analysis used for each outcome

- Possible confounding was addressed with direct adjustment for specific factors and deciles of an estimated propensity score
- Primary outcome: Cox proportional hazard models
- Secondary outcomes:
    - Total weight loss percentages: Linear mixed effects modelling
    - Time taken for T2DM relapse: Cox proportional hazard models
    - Changes in Hba1c: Linear mixed effects modelling

Sensitivity analysis

- considered 9-month and 12-month alternative lags from the last observed T2DM medication order to define remission (HbA1c level <6.5%).

- Additional sensitivity analyses assessed 2 alternate censoring scenarios for inpatient stays: (1) no removal of inpatient medications or HbA1c values and (2) censoring follow-up at the day of admission

Diarem Score

Variable	Score
Age (yr)	
<40	0
40–49	1
50–59	2
≥60	3
HbA1c (%)	
<6.5	0
6.5–6.9	2
7.0–8.9	4
≥9.0	6
Other diabetes drugs	
No sulfonylureas or insulin-sensitizing agents other than metformin	0
Sulfonylureas and insulin-sensitizing agents other than metformin	3
Treatment with insulin	
No	0
Yes	10
Overall score (sum of the four components)	0–22
Probability of remission in each DiaRem score subgroup*	
0–2	87 (83–90)
3–7	66 (61–70)
8–12	32 (24–40)
13–17	16 (12–21)
18–22	5 (0–9)

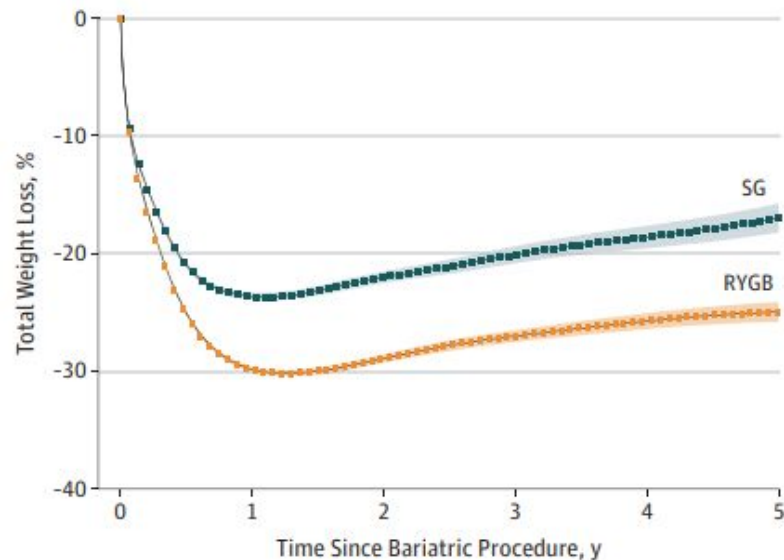Values are presented as probability (%) with 95% confidence interval.
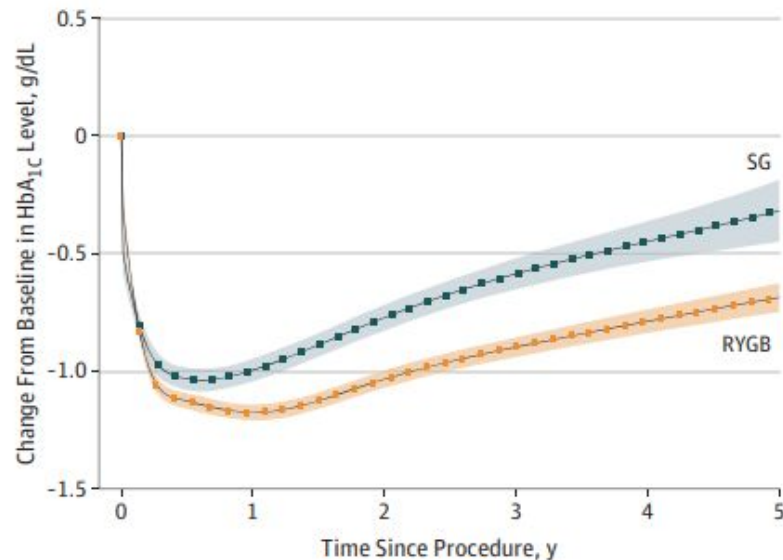*Including both partial and complete remissions.
HbA1c, glycosylated hemoglobin.
Adapted from Still CD, et al. Lancet Diabetes Endocrinol 2014;2:38-45, with permission from Elsevier.[31]

Figure 1. Adjusted Total Weight Loss and Change in Hemoglobin A$_{1c}$ Level by Procedure Over 5 Years of Follow-up

Shaded areas represent 95% pointwise CIs for procedure-specific changes in hemoglobin A$_{1c}$ levels. RYGB indicates Roux-en-Y gastric bypass; SG, sleeve gastrectomy.

Table 2. Comparative Effectiveness of Gastric Bypass and Sleeve Gastrectomy for Percentage of Total Weight Loss and Absolute Difference in Hemoglobin A$_{1c}$ Level Among Adults With Diabetes With 1, 3, and 5 Years of Follow-up[a]

Group	Time Since Bariatric Procedure					
	1 y		**3 y**		**5 y**	
	Patients, No.	Finding	Patients, No.	Finding	Patients, No.	Finding
Total weight loss, %						
Sleeve gastrectomy	2404	−22.8 (−23.1 to −22.5)	2404	−19.2 (−20.0 to −18.5)	2404	−16.1 (−17.3 to −14.8)
Roux-en-Y gastric bypass	4025	−29.1 (−29.3 to −28.8)	4025	−26.2 (−26.7 to −25.7)	4025	−24.1 (−25.0 to −23.3)
Difference	NA	6.2 (5.8-6.7)	NA	7.0 (6.1-7.9)	NA	8.1 (6.6-9.6)
P Value	NA	<.001	NA	<.001	NA	<.001
Hemoglobin A$_{1c}$ mean difference (95% CI), %[a]						
Sleeve gastrectomy	2935	−0.89 (−0.93 to −0.86)	2935	−0.56 (−0.64 to −0.49)	2935	−0.35 (−0.51 to −0.19)
Roux-en-Y gastric bypass	5428	−1.12 (−1.14 to −1.09)	5428	−1.01 (−1.06 to −0.97)	5428	−0.80 (−0.88 to −0.72)
Difference	NA	−0.22 (−0.26 to −0.18)	NA	−0.45 (−0.54 to −0.36)	NA	−0.45 (−0.63 to −0.27)
P Value	NA	<.001	NA	<.001	NA	<.001

Abbreviations: *ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification*; NA, not applicable; SNOMED, Systematized Nomenclature of Medicine.

[a] Difference is the baseline value minus the end point value; the model was adjusted for age, sex, race, Hispanic ethnicity, body mass index (calculated as weight in kilograms divided by height in meters squared), hemoglobin A$_{1c}$ value, blood pressure, number of inpatient hospital days in the year prior to surgery, number of diabetes medications excluding insulin, insulin use, Charlson/Elixhauser comorbidity score, year of procedure, days from hemoglobin A$_{1c}$ measurement to baseline, having an *ICD-9-CM* or SNOMED code for diabetes, smoking, having an *ICD-9-CM* or SNOMED code for other comorbidities (hypertension, dyslipidemia, sleep apnea, osteoarthritis, nonalcoholic fatty liver disease, gastroesophageal reflux disease, depression, anxiety, eating disorder, substance use, psychosis, kidney disease, infertility, polycystic ovarian syndrome, deep-vein thrombosis, and pulmonary embolism), having *ICD-9-CM* or SNOMED codes for specific diabetes medications (biguanides, glucagon-like peptide–1 agonists, sulfonylureas, thiazolidinediones, and others), site, and propensity-score deciles.

Figure 2. Cumulative Incidence Rates of Type 2 Diabetes Remission and Relapse Across 5 Years in the National Patient-Centered Clinical Research Network Bariatric Study Cohort
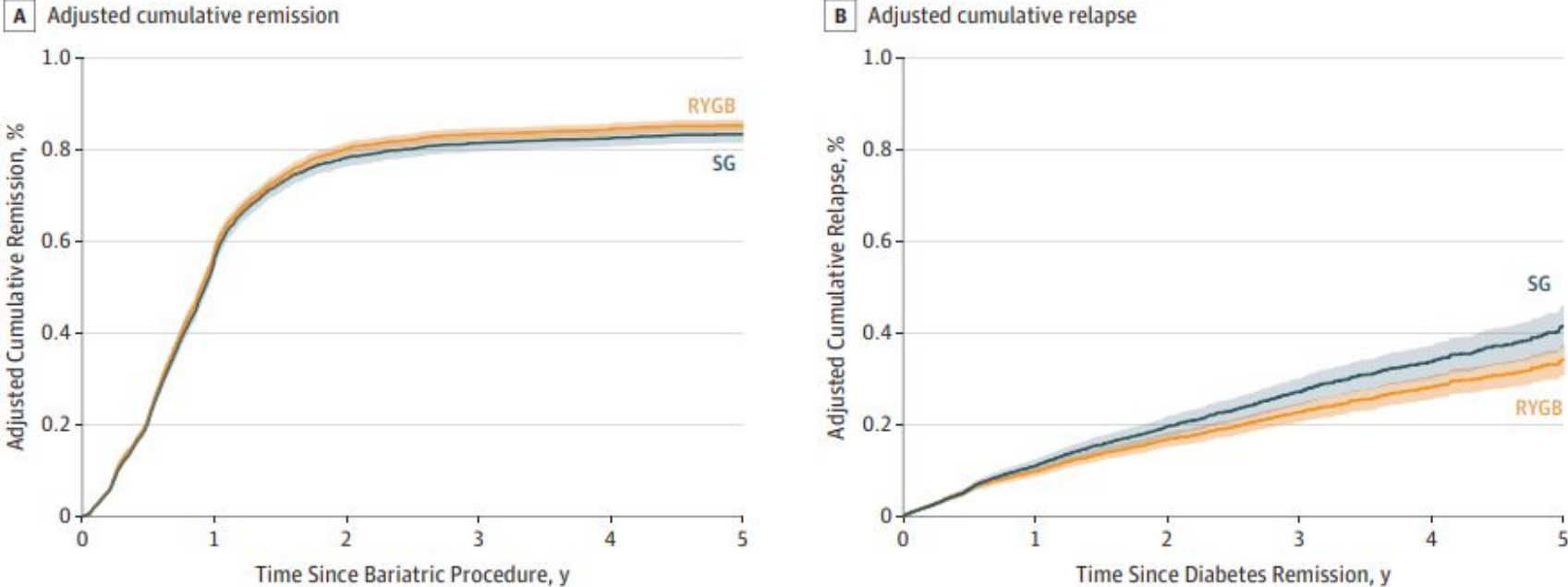
Shaded areas represent 95% pointwise CIs for procedure-specific rates. RYGB indicates Roux-en-Y gastric bypass; SG, sleeve gastrectomy.

Author discussion

Remission rate

Year	RYGB	Sleeve
1year	56%	59%
5 year	84%	86%

But many will relapse

	RYGB	Sleeve
In 5 years	33%	42%

HBA1c reduction from 7.2%

	RYGB	Sleeve
In 5 years	0.8%	0.35%

There is also more weight lost and maintenance with RYGB

In summary

RYGB have

- Slightly lower but similar rates of remission
  - Lower relapse rate
- More reduction in hba1c
- More weight reduction and maintenance of weight reduction

→ better long term outcome

Those with lower preoperative probability of remission(11-33%)

- Higher % in RYGB and better improvement

Lower preoperative%(diarem scoring) → Preoperative insulin use, older age, higher HbA1c level, and more complex T2DM medication regimens

Data differ from other studies

- Some RCT say no difference
  - Smaller sample size despite longer follow up
    - Author larger sample is able to see all subgroups,generalizing all dr and patient
    - Standardization using PCORnet also reduce data quality issue
  - Consider surgeon skill differences

BUT

- Remission rate is consistent with most bariatric studies at 80%
- T2DM remission data→ not much,published but stated those 25-53% , consistent with remission rate

Limitations

- Observational
  - Procedure might be affected by unmeasured factors that affect the surgery
- Using ICD 9 coding
  - Underestimated comorbidity?
- Pbs definition → Relapse and remission relies on medication prescription data
  - Ordered outside the health system
  - Undiagnosed dm is really common
- All dates were normalized to the date of surgery
  - cannot differentiate finish and dropped out

Author conclusion

Roux en Y > Sleeve

- Similar rates of remission
  - Outcomes similar for those with similar rates
- Larger and more persistent improvement in glycemic control
  - 25% lower
- More complicated patient better improvements

In the end,depends on

- Patient situation
- Adverse effect
- Patient choice
- How it affect life long