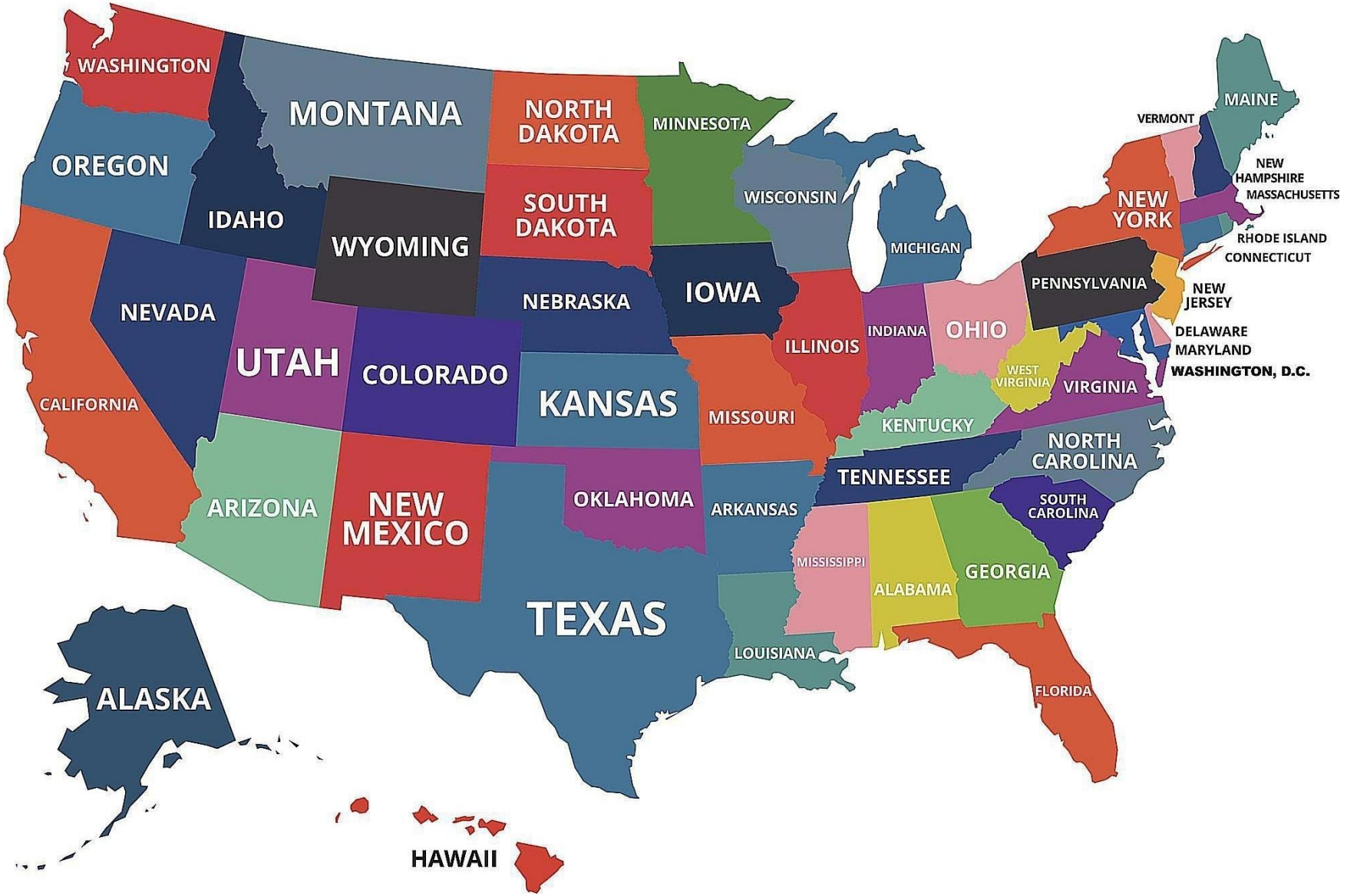
# Bariatric & Metabolic Surgery for Diabetes (type 2 & type 1)

**Ali Aminian, MD, FACS, FASMBS**
Associate Professor of Surgery
Cleveland Clinic

Cleveland Clinic


WASHINGTON
OREGON
CALIFORNIA
IDAHO
NEVADA
MONTANA
WYOMING
UTAH
ARIZONA
COLORADO
NEW MEXICO
NORTH DAKOTA
SOUTH DAKOTA
NEBRASKA
KANSAS
OKLAHOMA
TEXAS
MINNESOTA
IOWA
MISSOURI
ARKANSAS
LOUISIANA
WISCONSIN
ILLINOIS
MICHIGAN
INDIANA
OHIO
KENTUCKY
TENNESSEE
MISSISSIPPI
ALABAMA
GEORGIA
FLORIDA
SOUTH CAROLINA
NORTH CAROLINA
VIRGINIA
WEST VIRGINIA
PENNSYLVANIA
NEW YORK
MAINE
VERMONT
NEW HAMPSHIRE
MASSACHUSETTS
RHODE ISLAND
CONNECTICUT
NEW JERSEY
DELAWARE
MARYLAND
WASHINGTON, D.C.
ALASKA
HAWAII


3.2 million patient visits
36,000 employees
2,800 physicians
$252M in research funding

Cleveland Clinic

## U.S. News 2018-19 Best Hospitals Honor Roll

| RANK | NAME | POINTS |
|---|---|---|
| 1 | Mayo Clinic, Rochester, Minnesota | 414 |
| 2 | Cleveland Clinic | 385 |
| 3 | Johns Hopkins Hospital, Baltimore | 355 |
| 4 | Massachusetts General Hospital, Boston | 354 |
| 5 | University of Michigan Hospitals-Michigan Medicine, Ann Arbor | 324 |
| 6 | UCSF Medical Center, San Francisco | 296 |
| 7 | UCLA Medical Center, Los Angeles | 267 |

| Specialty | National Rank | Overall Score |
|---|---|---|
| Cancer | #5 | 80.9/100 |
| Cardiology & Heart Surgery | #1 | 100/100 |
| Diabetes & Endocrinology | #4 | 80.5/100 |
| Ear, Nose & Throat | #11 | 90.4/100 |
| Gastroenterology & GI Surgery | #2 | 89.1/100 |
| Geriatrics | #5 | 87.5/100 |
| Gynecology | #5 | 83.8/100 |
| Nephrology | #2 | 93.6/100 |
| Neurology & Neurosurgery | #4 | 88.5/100 |
| Ophthalmology | #9 | 8.1/100 |
| Orthopedics | #3 | 71.4/100 |
| Pulmonology | #3 | 88.5/100 |
| Rheumatology | #2 | 39.6/100 |
| Urology | #1 | 100/100 |

# Disclosure

- Nothing related to this lecture

# Outline

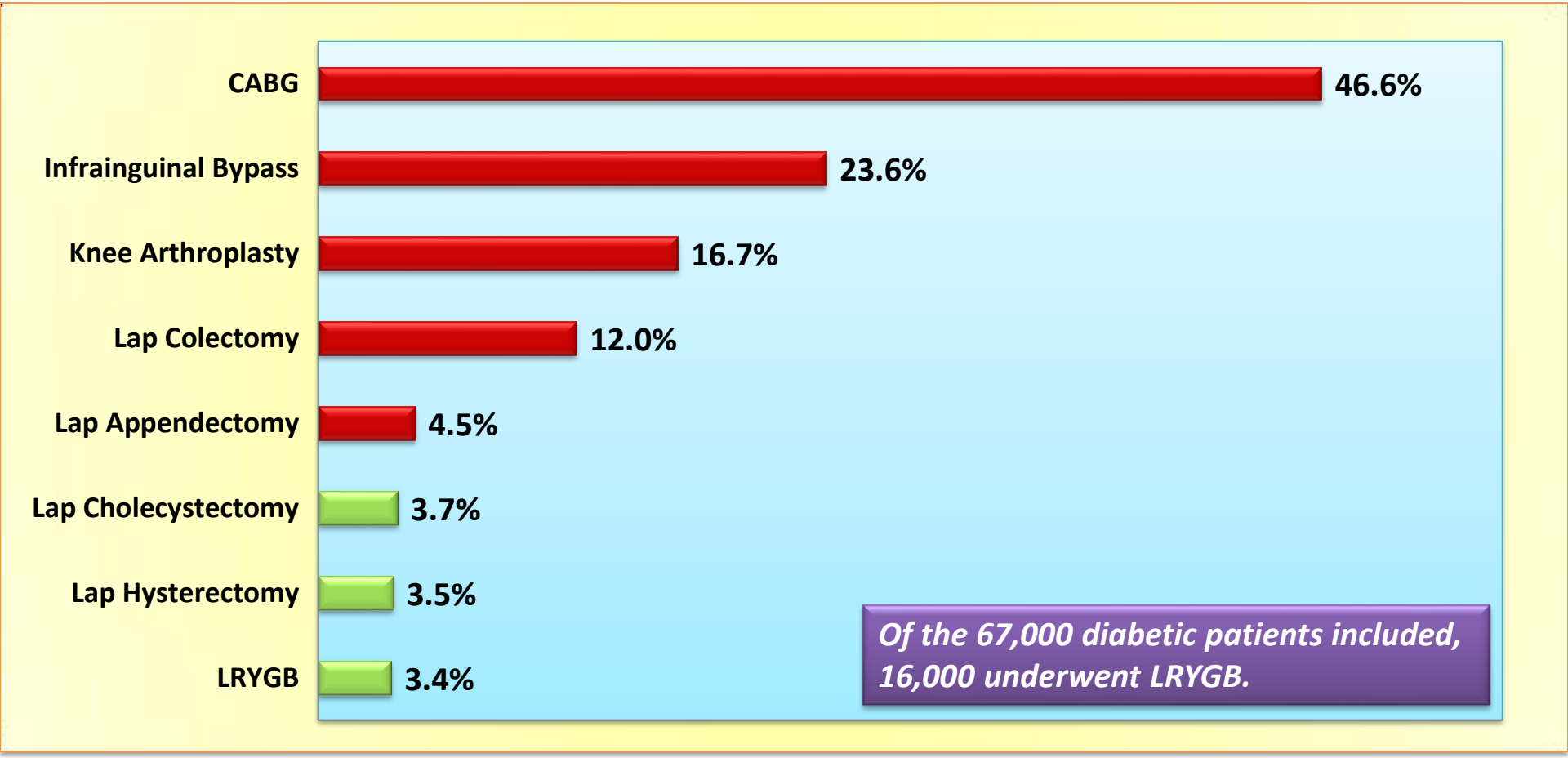
- **Surgery for T2DM:**
- **Safety**
- **Efficacy**
  - Glucose control
  - Metabolic profile
  - End organ complications
  - QoL
  - Survival
- **Guidelines**
- **Which procedure?**
- **Surgery for T1D:**
- **Efficacy**
- **Safety**

Diabetes Obes Metab. 2015 Feb;17(2):198-201. doi: 10.1111/dom.12405. Epub 2014

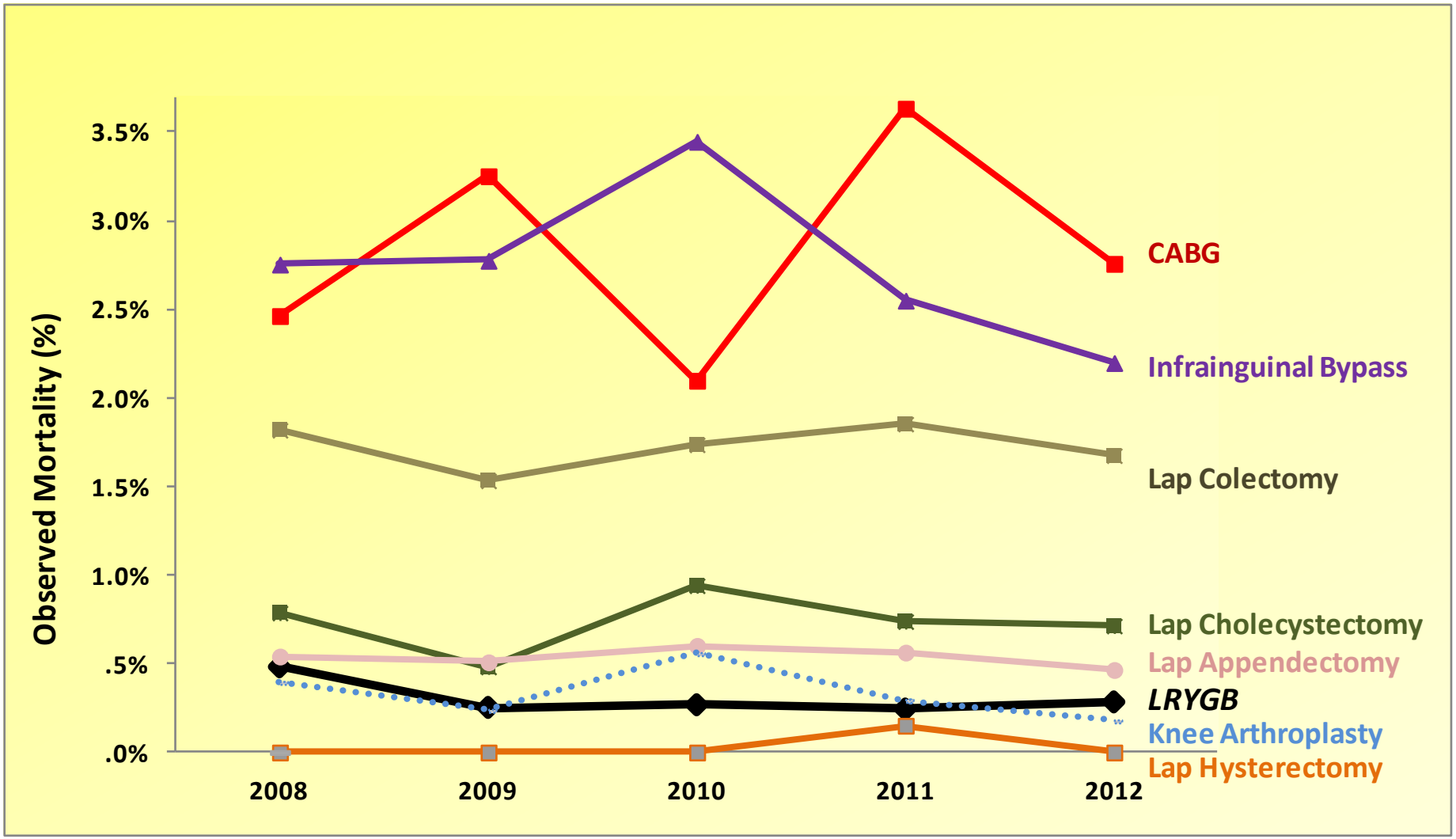
**How safe is metabolic/diabetes surgery?**

Aminian A[1], Brethauer SA, Kirwan JP, Kashyap SR, Burguera B, Schauer PR.

# US National Data of Postoperative Composite Complication Rate (%) of 8 Procedures in Patients with Type 2 Diabetes



# Mortality Rates (%) of 8 Procedures in Diabetics, 2008-2012




***Mortality Rate of LRYGB = 3 in 1000***

ELSEVIER

CrossMark

SURGERY FOR OBESITY AND RELATED DISEASES

Surgery for Obesity and Related Diseases 12 (2016) 1163–1170

Diabetes special issue

# A nationwide safety analysis of bariatric surgery in nonseverely obese patients with type 2 diabetes

Ali Aminian, M.D.[a,*], Amin Andalib, M.D., M.S.[b], Zhamak Khorgami, M.D.[a], Sangeeta R. Kashyap, M.D.[c], Bartolome Burguera, M.D., Ph.D.[a,c], Philip R. Schauer, M.D.[a], Stacy A. Brethauer, M.D.[a]

| Baseline Characteristics | n=1,300 |
|---|---|
| Gender (female), % | 74.3 |
| Age (year), mean±SD | 53.2±10.1 |
| BMI (kg/m$^2$), mean±SD | 33.5±1.6 |
| BMI < 30, n (%) | 46 (4.6) |
| Insulin use, % | 40 |
| Hypertension, % | 78 |
| Cardiac disease, % | 9 |
| Surgical Procedures, (%) | RYGB (54%), AGB (18%), Sleeve (26%), DS (1%) |

# Surgical outcomes of bariatric surgery in patients with type 2 diabetes and only mild obesity

| OUTCOMES | Whole Cohort (n=1300) |
|---|---|
| Composite Complication, % | 4.2 |
| Operative time (min), mean±SD | 110.3±51.6 |
| LOS (days), mean±SD | 2.0±1.7 |
| Reoperation, % | 1.6 |
| Mortality, % | 0.2 |

| OUTCOMES | RATE (%) |
|---|---|
| *Composite Morbidity & Mortality* | 4.2 |
| Blood Transfusion | 1.6 |
| Organ/Space SSI | 0.5 |
| Deep Vein Thrombosis | 0.2 |
| Pulmonary Embolism | 0 |
| Pneumonia | 0.2 |
| Myocardial Infarction | 0 |
| Acute Renal Failure | 0.1 |
| Stroke | 0 |
| Sepsis | 0.1 |
| Septic Shock | 0.3 |
| Unplanned Intubation | 0.3 |
| Ventilation >48 hours | 0.1 |
| Cardiac Arrest | 0.1 |
| Hospital Stay >7 days | 0.6 |
| Reoperation | 1.6 |
| Mortality | 0.2 |

| OUTCOMES | RYGB (n=574) | AGB (n=227) | Sleeve (n=189) |
|---|---|---|---|
| *Composite Morbidity & Mortality* | 5.0 | 3.1 | 3.2 |
| Blood Transfusion | 2.4 | 0 | 1.1 |
| Organ/Space SSI | 0.3 | 0.4 | 1.1 |
| Deep Vein Thrombosis | 0.3 | 0 | 0 |
| Pulmonary Embolism | 0 | 0 | 0 |
| Pneumonia | 0.2 | 0.4 | 0 |
| Myocardial Infarction | 0 | 0 | 0 |
| Acute Renal Failure | 0.2 | 0 | 0 |
| Stroke | 0 | 0 | 0 |
| Sepsis | 0.2 | 0 | 0 |
| Septic Shock | 0.3 | 0.4 | 0 |
| Unplanned Intubation | 0.2 | 0.9 | 0 |
| Ventilation >48 hours | 0.2 | 0 | 0 |
| Cardiac Arrest | 0 | 0 | 0.5 |
| Hospital Stay >7 days | 0.9 | 0 | 0.5 |
| Reoperation | 1.7 | 1.3 | 1.6 |
| Mortality | 0.3 | 0 | 0 |

- **A 2-hour surgical procedure requiring a two-day hospital stay that is associated with low morbidity and mortality can lead to remission of a chronic, progressive and disabling disease.**

- Based on these findings, bariatric surgery can be considered a relatively safe option for managing T2DM in patients with mild obesity.

# RCTs of Surgery *vs* Medical Rx for T2DM

**Metabolic surgery for type 2 diabetes mellitus: Randomized controlled clinical trials**

| Study | Pts with BMI < 35 kg/m² | Study design | No. pts | Follow-up (mo) | Remission criteria | Remission[a] or change in HbA1c (%) | *P* value |
|---|---|---|---|---|---|---|---|
| Dixon[28] | 22% | LAGB vs control | 60 | 24 | HbA1c < 6.2% | 73 vs 13 | < .001 |
| Schauer[29,30,43] | 36% | RYGB vs SG vs control | 150 | 60 | HbA1c ≤ 6.0% | 22 vs 15 vs 0 | < .05 |
| Mingrone[31,32] | 0% | RYGB vs BPD vs control | 60 | 60 | HbA1c ≤ 6.5% | 42 vs 68 vs 0 | .003 |
| Ikramuddin[33,34] | 59% | RYGB vs control | 120 | 24 | HbA1c < 6.0% | 44 vs 9 | < .001 |
| Liang[35] | 100% | RYGB vs control | 101 | 12 | HbA1c < 6.5% | 90 vs 0 vs 0[b] | < .0001 |
| Halperin[36] | 34% | RYGB vs control | 38 | 12 | HbA1c < 6.5% | 58 vs 16 | .03 |
| Courcoulas[37,38] | 43% | RYGB vs LAGB vs control | 69 | 36 | HbA1c < 6.5% | 40 vs 29 vs 0 | .004 |
| Wentworth[39] | 100% | LAGB vs control | 51 | 24 | FBG < 7.0 mmol/L | 52 vs 8 | .001 |
| Parikh[40] | 100% | RYGB/LAGB/SG vs control | 57 | 6 | HbA1c < 6.5% | 65 vs 0 | .0001 |
| Ding[41] | 34% | LAGB vs control | 45 | 12 | HbA1c < 6.5% | 33 vs 23[c] | .46 |
| Cummings[42] | 25% | RYGB vs control | 43 | 12 | HbA1c < 6.0% | 60 vs 5.9 | .002 |
| Shah[44] | 85 | RYGB vs control | 80 | 24 | HbA1c < 6.5% | 60 vs 2.5 | < .001 |

CCJM Supplement 1, July

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes

Philip R. Schauer, M.D., Deepak L. Bhatt, M.D., M.P.H., John P. Kirwan, Ph.D., Kathy Wolski, M.P.H., Ali Aminian, M.D., Stacy A. Brethauer, M.D., Sankar D. Navaneethan, M.D., M.P.H., Rishi P. Singh, M.D., Claire E. Pothier, M.P.H., Steven E. Nissen, M.D., and Sangeeta R. Kashyap, M.D., for the STAMPEDE Investigators*

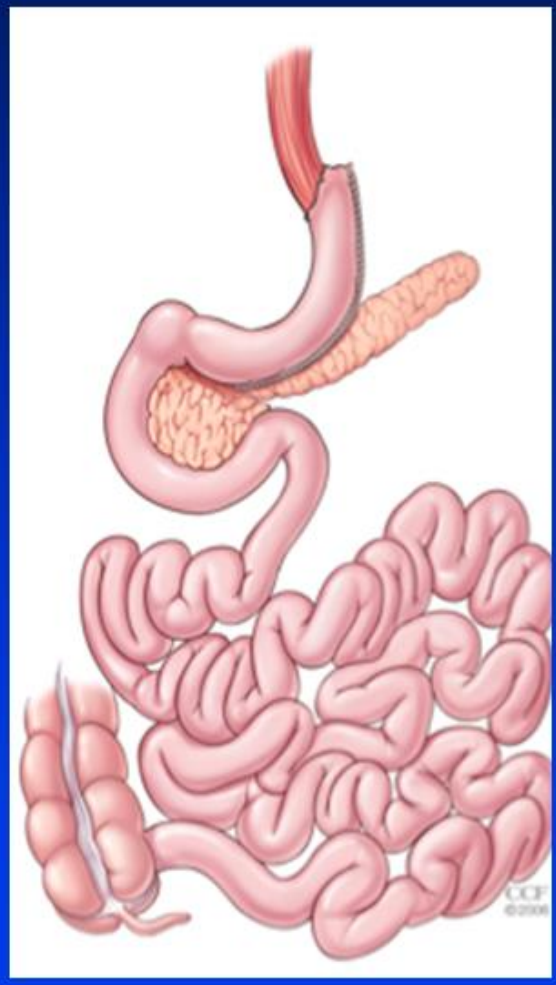
# Treatment Arms

**Intensive Medical Therapy**

- ADA guidelines
- Lifestyle intervention
- Drug RX Goal: **A1c ≤6.0%**
  - Oral agents
  - GLP1 agonists
  - Insulin
- Scheduled visits with
  - Endocrinology
  - Psychology
  - Nutrition
- Follow–up visits
  - Q 3 months years 1-2
  - Q 6 months thereafter

**Gastric Bypass**


**Sleeve Gastrectomy**



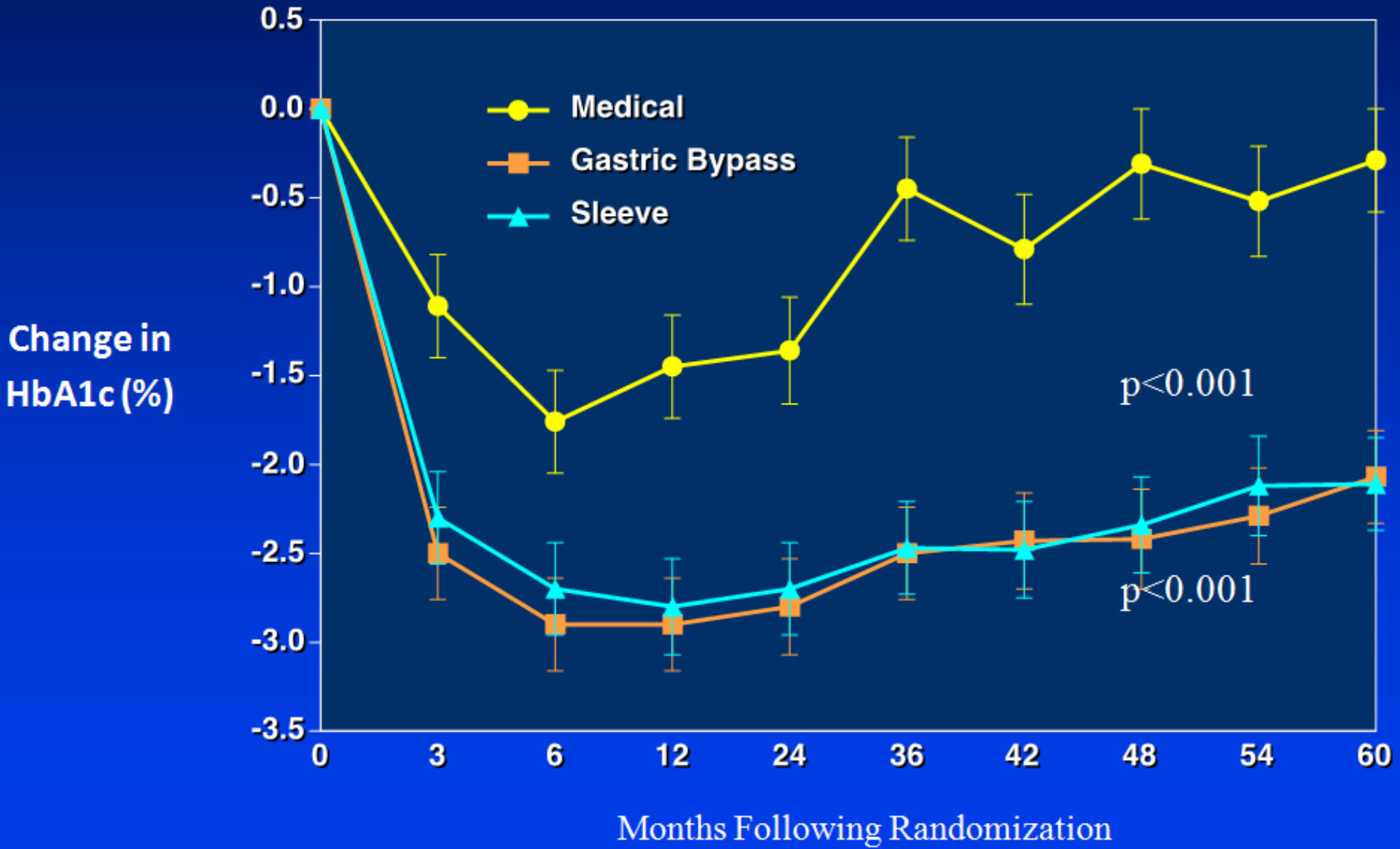
Kashyap S, Schauer P, Bhatt D; Diabetes Obesity Metabolism 2010 Sep;12(9):833

# Baseline Characteristics

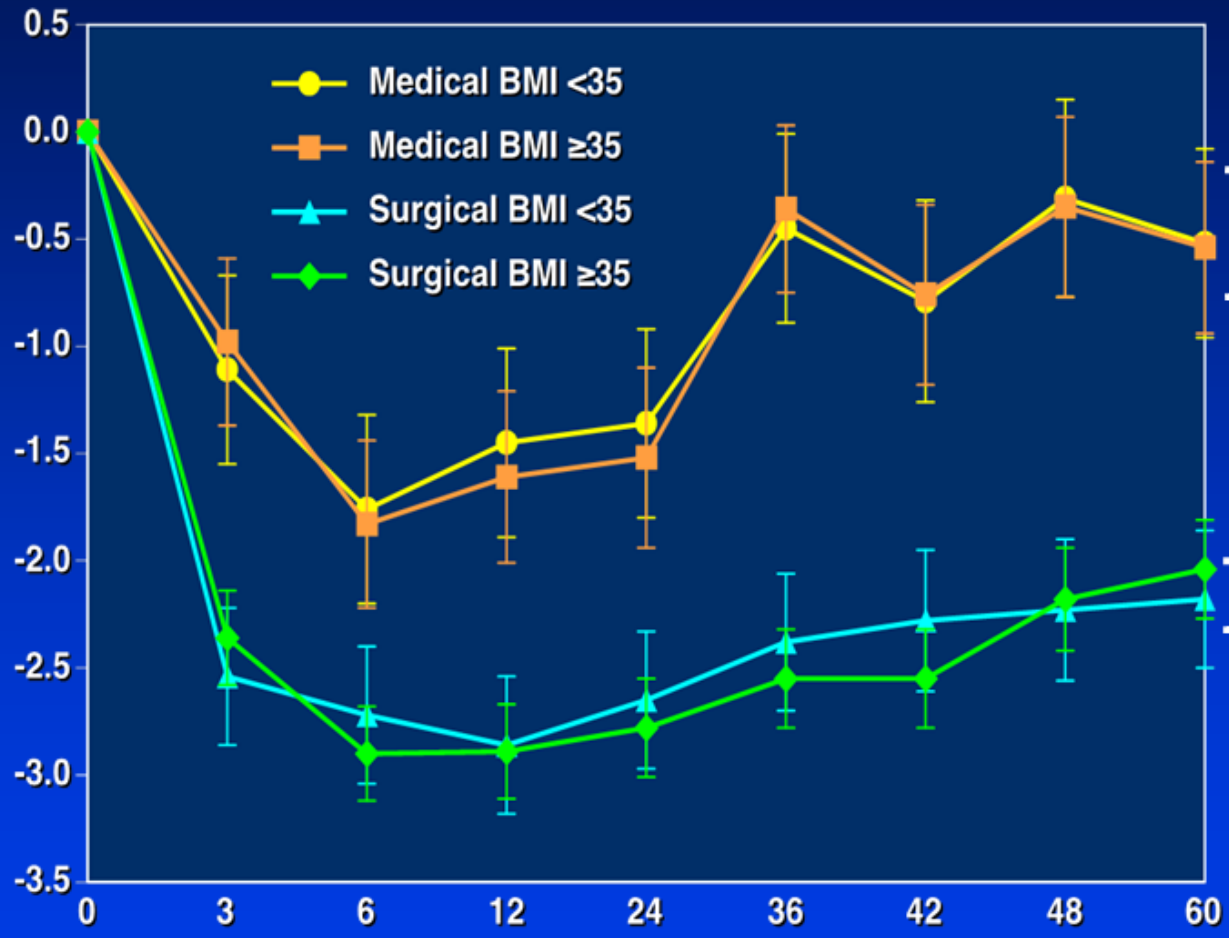
| Parameter | Medical Therapy (n=38) | Bypass (n=49) | Sleeve (n=47) |
|---|---|---|---|
| Age (yrs) | 50.2 | 48.2 | 48.1 |
| Females | 66% | 57% | 77% |
| Duration of diabetes (yrs) | 8.8 | 8.2 | 8.3 |
| HbA1c (%) | 8.8 | 9.3 | 9.5 |
| Body Mass Index ($kg/m^2$) | 36.4 | 37.0 | 36.0 |
| ≥ 3 diabetes medications | 61% | 53% | 47% |
| Insulin use | 53% | 47% | 45% |

Advanced Type 2 Diabetes

# STAMPEDE: Change in HbA1c Over 5 Years

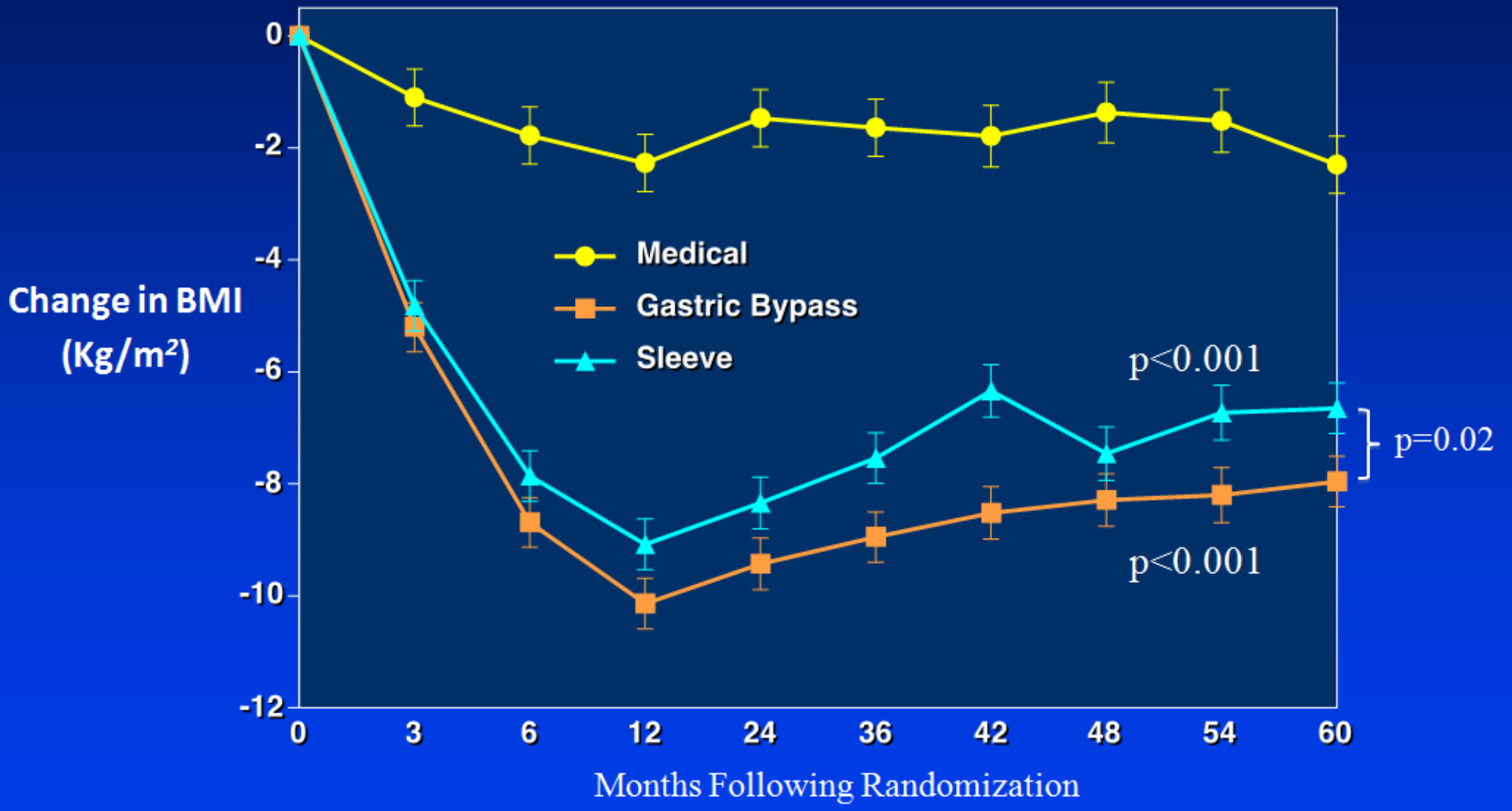


# *5-Year* Evidence from a Superlative RCT: STAMPEDE

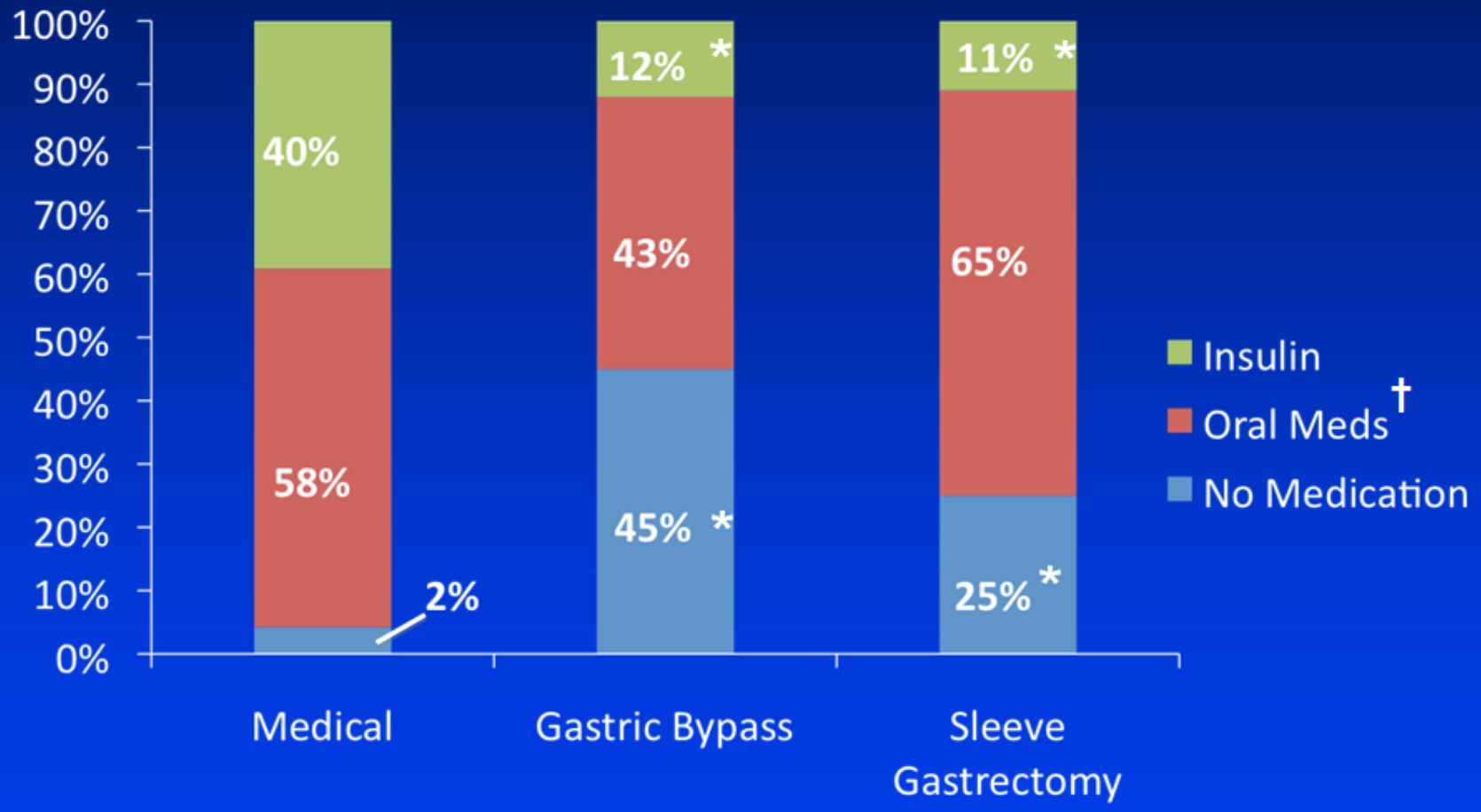



Schauer PR et al.
*NEJM* (2017)

# Change in BMI Over 5 years



# Diabetes Medications at 5 Years




* P<0.05 compared to medical therapy

† Includes injectables such as GLP-1 agonists

# Adverse Events Over 5 Years

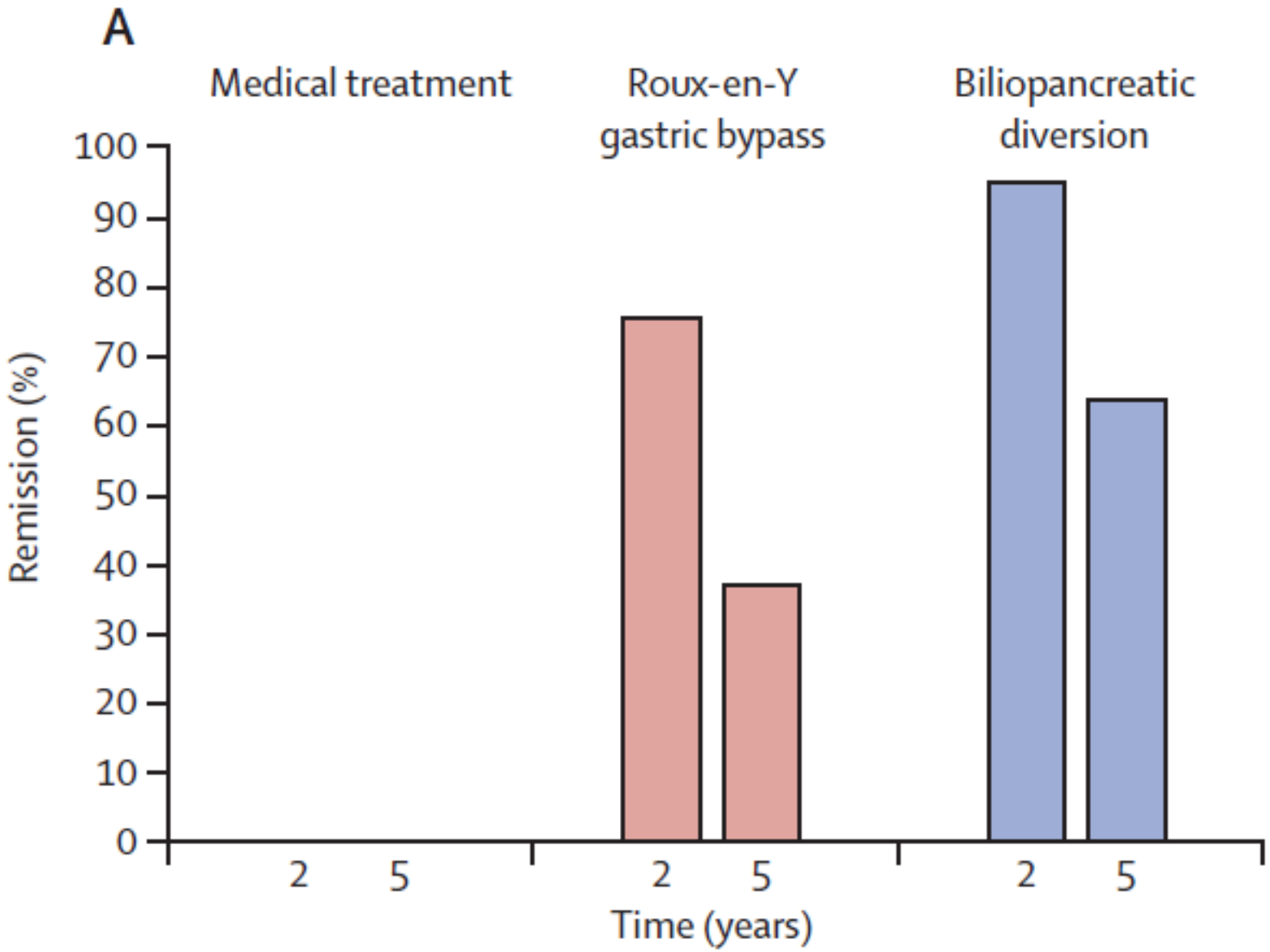
| Parameter | Medical Therapy (n=43) | Bypass (n=50) | Sleeve (n=49) |
|---|---|---|---|
| Fatal myocardial infarction | 1 (2%) | 0 | 0 |
| Stroke | 0 | 0 | 1 (2%) |
| Nephropathy | 6 (14%) | 11 (22%) | 9 (18%) |
| Bowel obstruction | 1 (2%) | 1 (2%) | 1 (2%) |
| Stricture | 0 | 1 (2%) | 1 (2%) |
| Gastric Fistula | 0 | 0 | 1 (2%) |
| Ulcer | 1(2) | 4 (8%) | 1(2%) |
| Severe hypoglycemia | 0 | 2 (4) | 0 |
| Anemia (mild) | 7 (16%) | 14 (28%) | 24 (49%)* |
| Weight gain >5% | 8 (19%) | 0 * | 0 * |
| Re-operation | NA | 3 (6%) | 4(8%) |

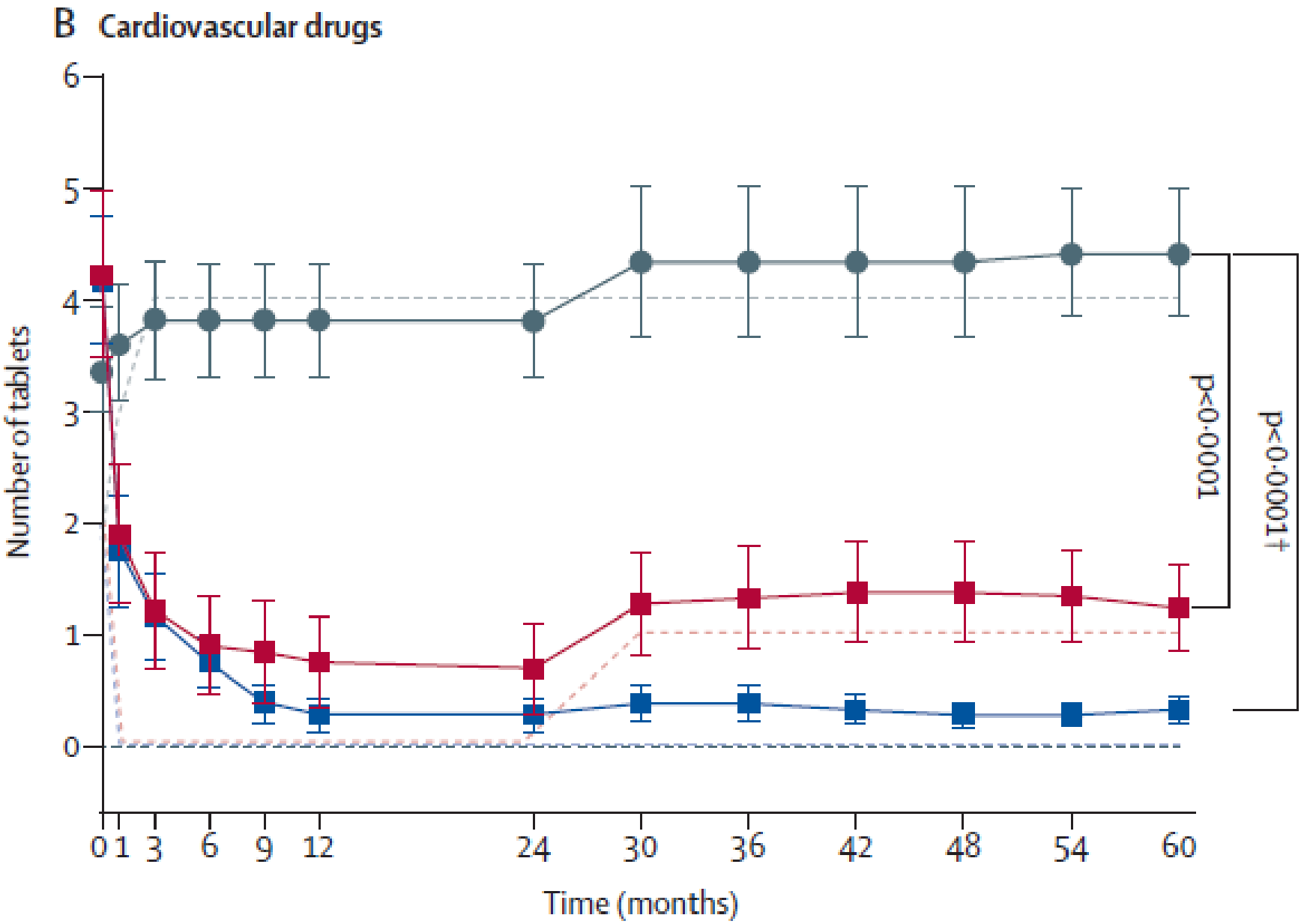
* $p<0.05$ compared to medical therapy group

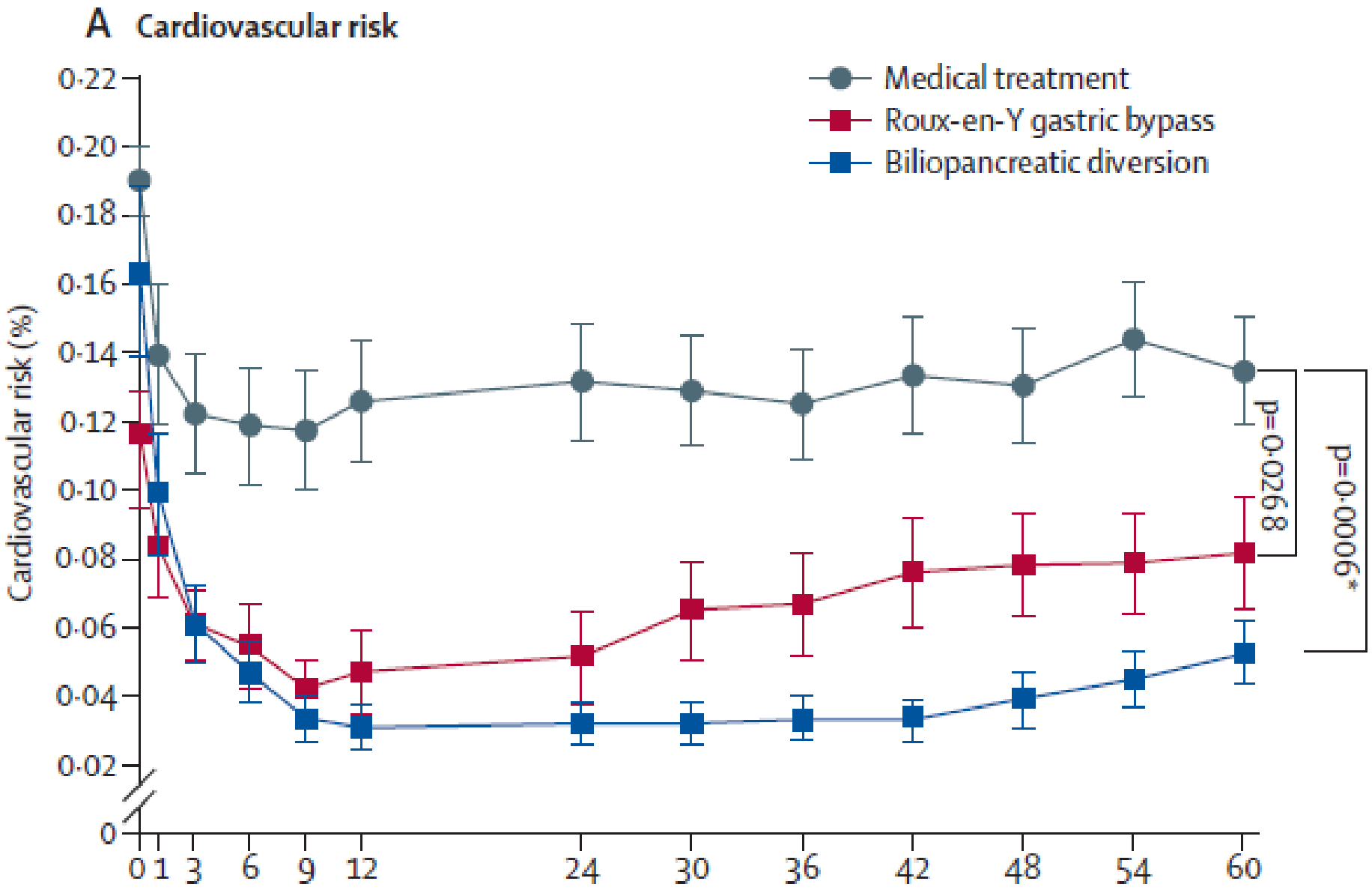
THE LANCET

# Bariatric–metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial

*Geltrude Mingrone, Simona Panunzi, Andrea De Gaetano, Caterina Guidone, Amerigo Iaconelli, Giuseppe Nanni, Marco Castagneto, Stefan Bornstein, Francesco Rubino*


A
Medical treatment
Roux-en-Y gastric bypass
Biliopancreatic diversion
Remission (%)
100
90
80
70
60
50
40
30
20
10
0
2
5
2
5
2
5
Time (years)

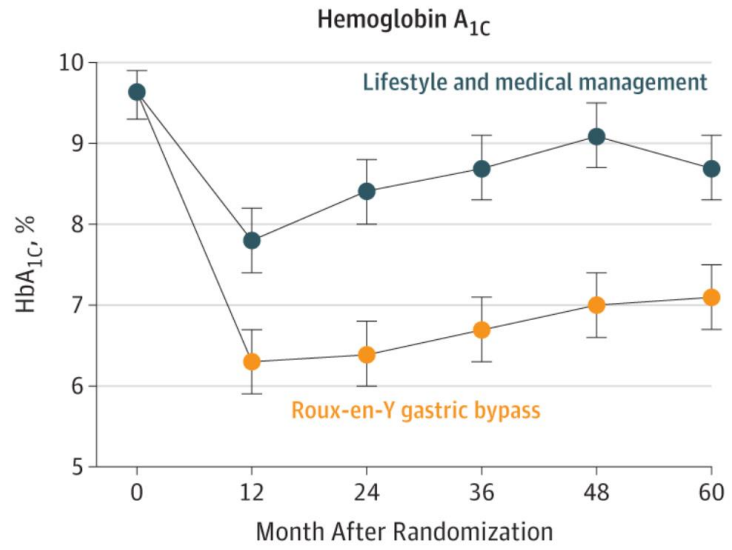

B Cardiovascular drugs
Number of tablets
0
1
2
3
4
5
6
0 1 3 6 9 12 24 30 36 42 48 54 60
Time (months)
p<0·0001
p<0·0001†


A Cardiovascular risk
Medical treatment
Roux-en-Y gastric bypass
Biliopancreatic diversion
Cardiovascular risk (%)
0·22
0·20
0·18
0·16
0·14
0·12
0·10
0·08
0·06
0·04
0·02
0
0 1 3 6 9 12 24 30 36 42 48 54 60
p=0·0268
*p=0·0006

JAMA | Original Investigation

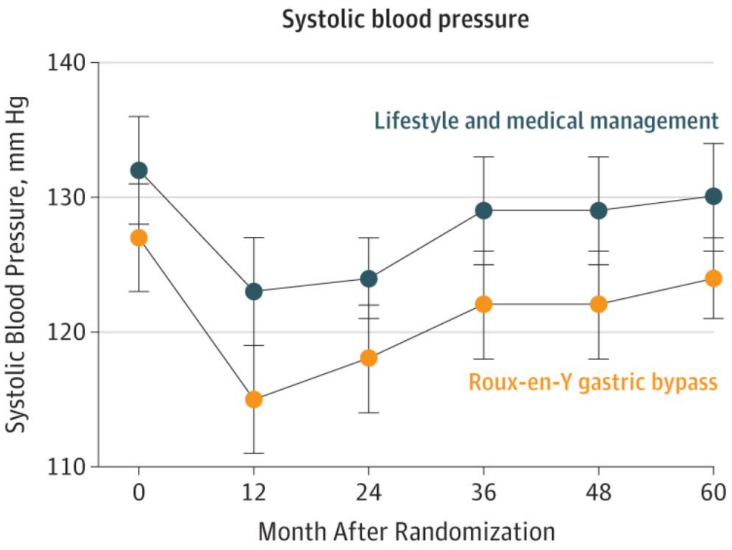
# Lifestyle Intervention and Medical Management With vs Without Roux-en-Y Gastric Bypass and Control of Hemoglobin $A_{1c}$, LDL Cholesterol, and Systolic Blood Pressure at 5 Years in the Diabetes Surgery Study

Sayeed Ikramuddin, MD, MHA; Judith Korner, MD, PhD; Wei-Jei Lee, MD, PhD; Avis J. Thomas, MS; John E. Connett, PhD; John P. Bantle, MD; Daniel B. Leslie, MD; Qi Wang, MS; William B. Inabnet III, MD; Robert W. Jeffery, PhD; Keong Chong, MD; Lee-Ming Chuang, MD, PhD; Michael D. Jensen, MD; Adrian Vella, MD; Leaque Ahmed, MD; Kumar Belani, MD; Charles J. Billington, MD



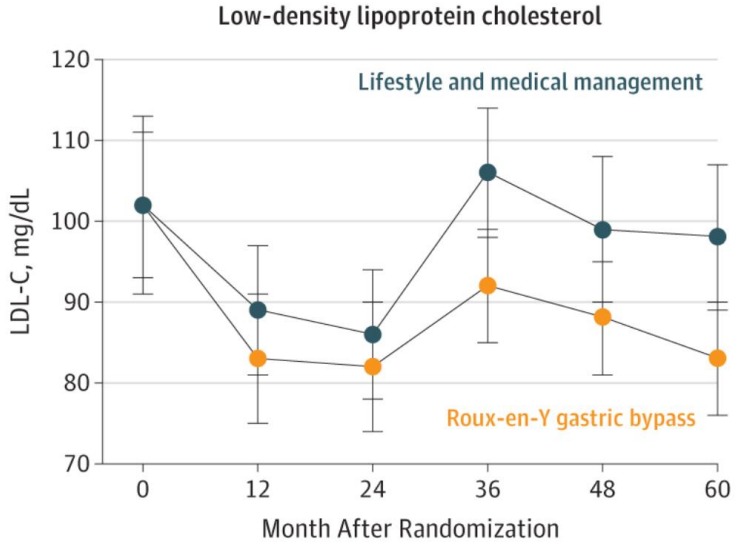

No. of patients

| | | | | | | |
|---|---|---|---|---|---|---|
| Lifestyle and medical management | 56 | 56 | 54 | 44 | 42 | 43 |
| Roux-en-Y gastric bypass | 57 | 57 | 56 | 55 | 54 | 55 |



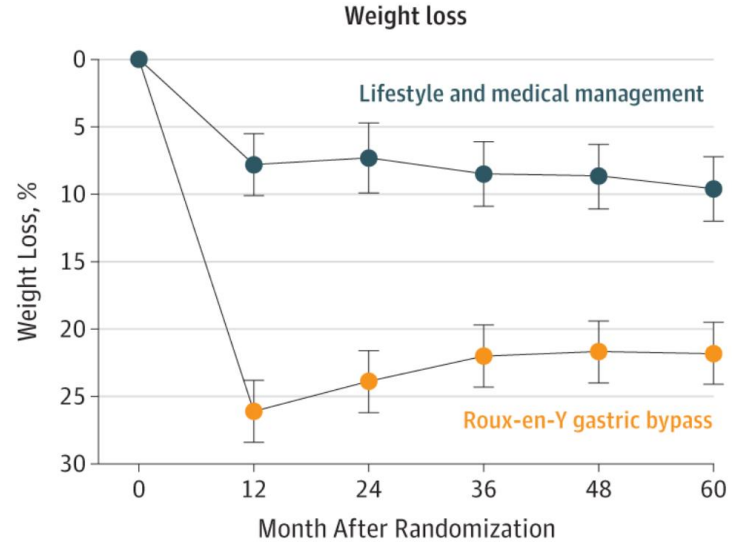

No. of patients

| | | | | | | |
|---|---|---|---|---|---|---|
| Lifestyle and medical management | 56 | 56 | 54 | 44 | 42 | 43 |
| Roux-en-Y gastric bypass | 57 | 57 | 56 | 55 | 54 | 55 |




No. of patients

| | | | | | | |
|---|---|---|---|---|---|---|
| Lifestyle and medical management | 56 | 56 | 54 | 44 | 42 | 43 |
| Roux-en-Y gastric bypass | 57 | 57 | 56 | 55 | 54 | 55 |




No. of patients

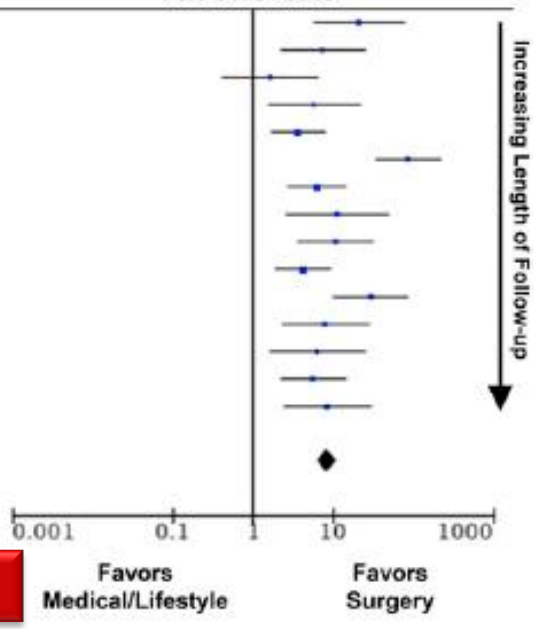
| | | | | | | |
|---|---|---|---|---|---|---|
| Lifestyle and medical management | 56 | 56 | 54 | 44 | 42 | 43 |
| Roux-en-Y gastric bypass | 57 | 57 | 56 | 55 | 54 | 55 |

**Rubino et al. Diabetes Care 2016**

**B**

| Study (Operation) [Follow-up; $HbA_{1c}$ end point] | Surgery Glyc. Endp. | Surgery N | Medical/Lifestyle Glyc. Endp. | Medical/Lifestyle N | Weight | Peto, Fixed, 95% CI |
|---|---|---|---|---|---|---|
| Parikh 2014 (RYGB/LAGB/SG) [6 mo; ≤6.5% off meds] (18) | 13 | 20 | 0 | 24 | 4.5% | 21.15 [5.85, 76.51] |
| Courcoulas 2014 (RYGB/LAGB) [12 mo; ≤6.5% off meds] (14) | 18 | 41 | 0 | 17 | 5.1% | 7.51 [2.24, 25.21] |
| Ding 2015 (LAGB) [12 mo; ≤6.5%] (22) | 6 | 18 | 5 | 22 | 3.9% | 1.68 [0.42, 6.66] |
| Halperin 2014 (RYGB) [12 mo; ≤6.5% off meds] (15) | 11 | 19 | 3 | 19 | 4.4% | 5.82 [1.59, 21.39] |
| Ikramuddin 2013 (RYGB) [12 mo; ≤7.0%] (13) | 28 | 57 | 11 | 57 | 12.5% | 3.72 [1.72, 8.04] |
| Liang 2013 (RYGB) [12 mo; ≤7.0% off meds] (16) | 28 | 31 | 0 | 70 | 8.4% | 86.76 [33.89, 222.08] |
| Schauer 2012 (RYGB/SG) [12 mo; ≤6.0%] (12) | 34 | 99 | 0 | 41 | 10.4% | 6.39 [2.74, 14.88] |
| Cummings 2016 (RYGB) [12 mo; ≤6.5% off meds] (23) | 9 | 15 | 1 | 17 | 3.4% | 11.48 [2.63, 50.13] |
| Dixon 2008 (LAGB) [24 mo; ≤6.2% off meds] (10) | 22 | 29 | 4 | 26 | 6.7% | 10.83 [3.79, 30.96] |
| Ikramuddin 2015 (RYGB) [24 mo; ≤7.0%] (21) | 26 | 60 | 8 | 59 | 11.8% | 4.25 [1.92, 9.38] |
| Mingrone 2012 (RYGB/BPD) [24 mo; ≤6.5% off meds] (11) | 34 | 40 | 0 | 20 | 6.4% | 30.08 [10.28, 88.06] |
| Wentworth 2014 (LAGB) [24 mo; ≤7.0%] (17) | 12 | 23 | 2 | 25 | 4.9% | 8.11 [2.37, 27.84] |
| Courcoulas 2015 (RYGB/LAGB) [36 mo; ≤6.5% off meds] (24) | 14 | 37 | 0 | 14 | 4.0% | 6.44 [1.65, 25.21] |
| Schauer 2014 (RYGB/SG) [36 mo; ≤6.0%] (19) | 27 | 97 | 0 | 40 | 8.7% | 5.73 [2.28, 14.42] |
| Mingrone 2015 (RYGB/BPD) [60 mo; ≤6.5% off meds] (20) | 19 | 38 | 0 | 15 | 4.9% | 8.44 [2.46, 29.01] |
| **Fixed-Effects Model** | | **624** | | **466** | **100.0%** | **8.45 [6.44, 11.10]** |

Heterogeneity: $Chi^2 = 45.43$, df = 14 ($P < 0.0001$); $I^2 = 69\%$
Test for overall effect: Z = 15.36 ($P < 0.00001$)

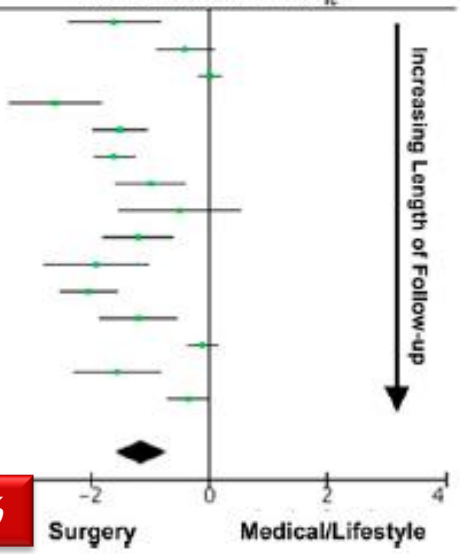



***OR of main glycemic end points: 8.4***

**C**

| Study (Operation) [Follow-up; $HbA_{1c}$ end point] | Surgery Mean | Surgery SD | Surgery N | Medical/Lifestyle Mean | Medical/Lifestyle SD | Medical/Lifestyle N | Weight | IV, Random, 95% CI |
|---|---|---|---|---|---|---|---|---|
| Parikh 2014 (RYGB/LAGB/SG) [6 mo; ≤6.5% off meds] (18) | 6.2 | 0.9 | 20 | 7.8 | 1.7 | 24 | 6.1% | -1.60 [-2.39, -0.81] |
| Courcoulas 2014 (RYGB/LAGB) [12 mo; ≤6.5% off meds] (14) | 6.6 | 0.8 | 41 | 7 | 0.9 | 17 | 6.9% | -0.40 [-0.89, 0.09] |
| Ding 2015 (LAGB) [12 mo; ≤6.5%] (22) | 7.17 | 0.3 | 18 | 7.15 | 0.28 | 22 | 7.5% | 0.02 [-0.16, 0.20] |
| Halperin 2014 (RYGB) [12 mo; ≤6.5% off meds] (15) | 6.2 | 1.4 | 19 | 8.8 | 1 | 19 | 6.1% | -2.60 [-3.37, -1.83] |
| Ikramuddin 2013 (RYGB) [12 mo; ≤7.0%] (13) | 6.3 | 0.9 | 57 | 7.8 | 1.5 | 57 | 7.0% | -1.50 [-1.95, -1.05] |
| Liang 2013 (RYGB) [12 mo; ≤7.0% off meds] (16) | 6 | 0.3 | 31 | 7.6 | 1.4 | 70 | 7.3% | -1.60 [-1.94, -1.26] |
| Schauer 2012 (RYGB/SG) [12 mo; ≤6.0%] (12) | 6.5 | 0.95 | 99 | 7.5 | 1.8 | 41 | 6.7% | -1.00 [-1.58, -0.42] |
| Cummings 2016 (RYGB) [12 mo; ≤6.5% off meds] (23) | 6.4 | 1.6 | 15 | 6.9 | 1.3 | 17 | 5.3% | -0.50 [-1.52, 0.52] |
| Dixon 2008 (LAGB) [24 mo; ≤6.2% off meds] (10) | 6 | 0.8 | 30 | 7.2 | 1.4 | 30 | 6.7% | -1.20 [-1.78, -0.62] |
| Ikramuddin 2015 (RYGB) [24 mo; ≤7.0%] (21) | 6.5 | 1.6 | 56 | 8.4 | 2.9 | 54 | 5.8% | -1.90 [-2.78, -1.02] |
| Mingrone 2012 (RYGB/BPD) [24 mo; ≤6.5% off meds] (11) | 5.65 | 0.95 | 20 | 7.69 | 0.57 | 20 | 7.0% | -2.04 [-2.53, -1.55] |
| Wentworth 2014 (LAGB) [24 mo; ≤7.0%] (17) | 6.1 | 0.8 | 23 | 7.3 | 1.4 | 25 | 6.5% | -1.20 [-1.84, -0.56] |
| Courcoulas 2015 (RYGB/LAGB) [36 mo; ≤6.5% off meds] (24) | 7.1 | 0.4 | 38 | 7.2 | 0.4 | 14 | 7.5% | -0.10 [-0.35, 0.15] |
| Schauer 2014 (RYGB/SG) [36 mo; ≤6.0%] (19) | 6.85 | 1.3 | 97 | 8.4 | 2.2 | 40 | 6.3% | -1.55 [-2.28, -0.82] |
| Mingrone 2015 (RYGB/BPD) [60 mo; ≤6.5% off meds] (20) | 6.55 | 0.5 | 38 | 6.9 | 0.6 | 15 | 7.3% | -0.35 [-0.69, -0.01] |
| **Random-Effects Model** | | | **602** | | | **465** | **100.0%** | **-1.14 [-1.57, -0.71]** |

Heterogeneity: $Tau^2 = 0.63$; $Chi^2 = 200.88$, df = 14 ($P < 0.00001$); $I^2$
Test for overall effect: Z = 5.20 ($P < 0.00001$)



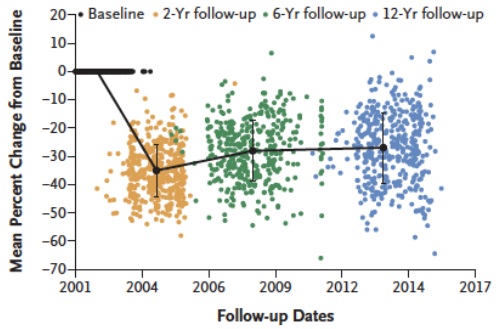

***Mean Differences of A1C: 1.1%***

# Weight and Metabolic Outcomes 12 Years after Gastric Bypass

Ted D. Adams, Ph.D., M.P.H., Lance E. Davidson, Ph.D., Sheldon E. Litwin, M.D., Jaewhan Kim, Ph.D., Ronette L. Kolotkin, Ph.D., M. Nazeem Nanjee, Ph.D., Jonathan M. Gutierrez, B.S., Sara J. Frogley, M.B.A., Anna R. Ibele, M.D., Eliot A. Brinton, M.D., Paul N. Hopkins, M.D., M.S.P.H., Rodrick McKinlay, M.D., Steven C. Simper, M.D., and Steven C. Hunt, Ph.D.

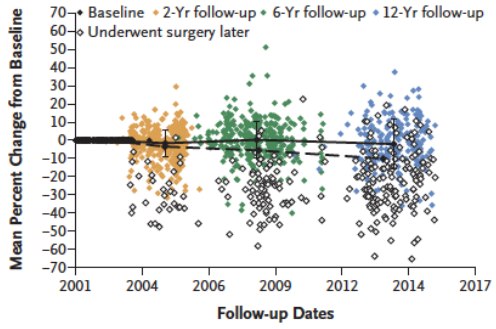
NEJM Sept 2017

**A** Mean Percent Change in Body Weight from Baseline to Years 2, 6, and 12 in the Surgery Group




| No. of Patients | Baseline | 2 Yr | 6 Yr | 12 Yr |
|---|---|---|---|---|
| Surgery group | 418 | 409 | 379 | 387 |
| Deaths | — | 3 | 9 | 14 |
| Total | 418 | 412 | 388 | 401 |

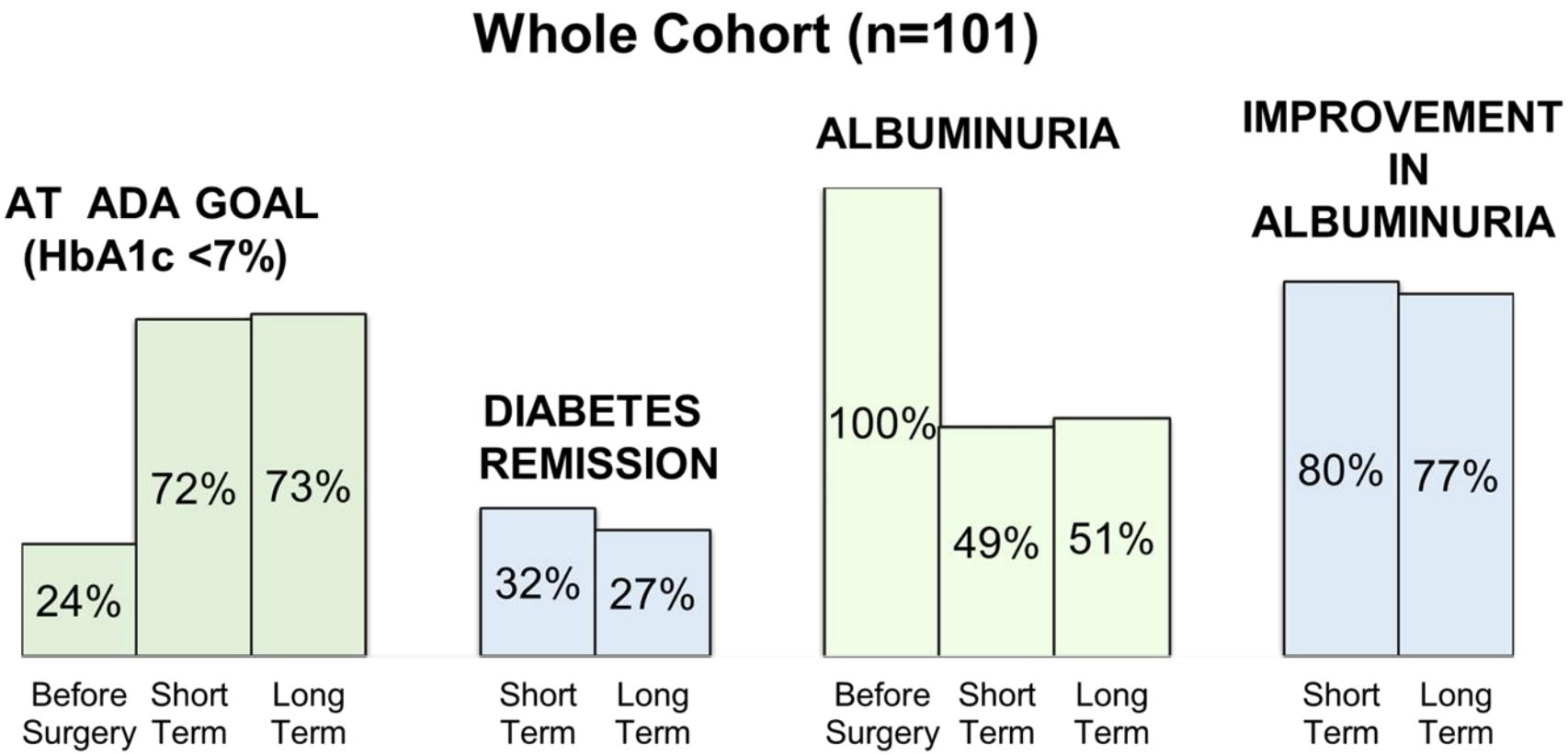
**B** Mean Percent Change in Body Weight from Baseline to Years 2, 6, and 12 in Nonsurgery Group 1




| No. of Patients | Baseline | 2 Yr | 6 Yr | 12 Yr |
|---|---|---|---|---|
| Nonsurgery group 1 | 417 | 373 | 294 | 217 |
| Underwent surgery later | — | 28 | 89 | 146 |
| Deaths | — | 3 | 11 | 25 |
| Total | 417 | 404 | 394 | 388 |

Cleveland Clinic

# Impact of Bariatric Surgery in Diabetic Nephropathy




Aminian et al. Surg Endo sc 2018

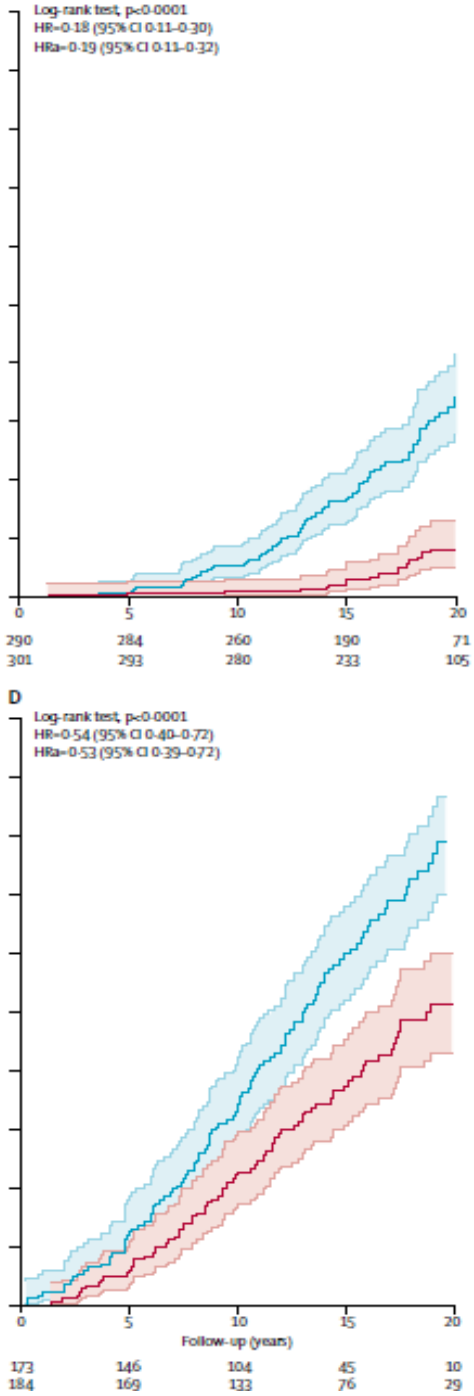
# Long-term incidence of microvascular disease after bariatric surgery or usual care in patients with obesity, stratified by baseline glycaemic status: a post-hoc analysis of participants from the Swedish Obese Subjects study

*Lena M S Carlsson, Kajsa Sjöholm, Cecilia Karlsson, Peter Jacobson, Johanna C Andersson-Assarsson, Per-Arne Svensson, Ingrid Larsson, Stephan Hjorth, Martin Neovius, Magdalena Taube, Björn Carlsson, Markku Peltonen*

THE LANCET
Diabetes & Endocrinology

- 374 incident cases of microvascular disease in control group and 224 in surgery group (HR 0·6, 95%CI 0·5–0·6; p<0·0001).

- Bariatric surgery was associated with reduced risk of microvascular complications.



# Gastric Bypass Surgery Produces a Durable Reduction in Cardiovascular Disease Risk Factors and Reduces the Long-Term Risks of Congestive Heart Failure

Peter N. Benotti, MD; G. Craig Wood, MS; David J. Carey, PhD; Vishal C. Mehra, MD, PhD; Tooraj Mirshahi, PhD; Michelle R. Lent, PhD; Anthony T. Petrick, MD; Christopher Still, DO; Glenn S. Gerhard, MD; Annemarie G. Hirsch, PhD

JAHA
Journal of the American Heart Association

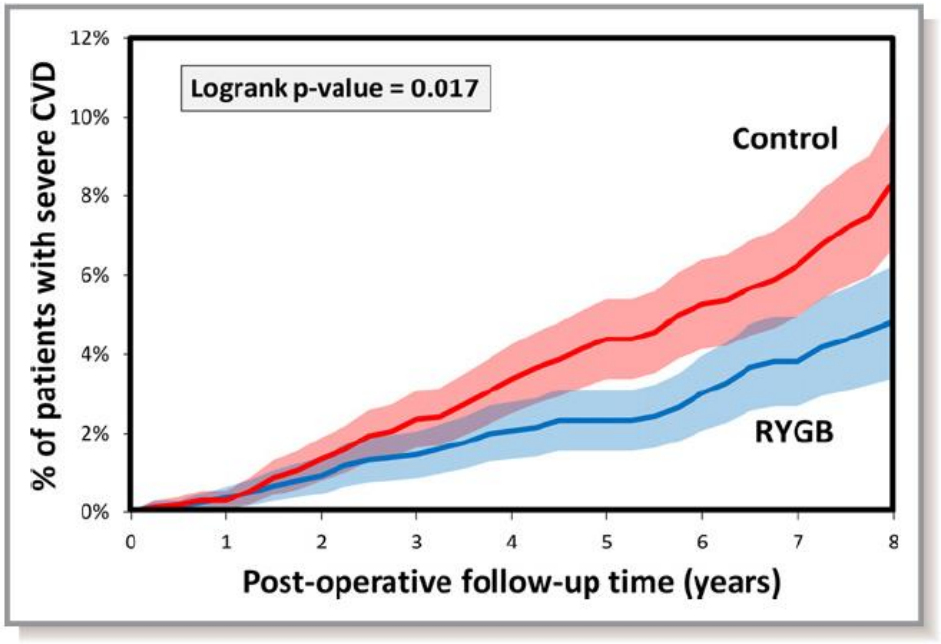



**Figure 2.** Kaplan–Meier curve estimated severe CVD rates in RYGB patients (n=1724) and controls (n=1724). CVD indicates cardiovascular disease; RYGB, Roux-en-Y gastric bypass surgery.

ORIGINAL RESEARCH

Annals of Internal Medicine

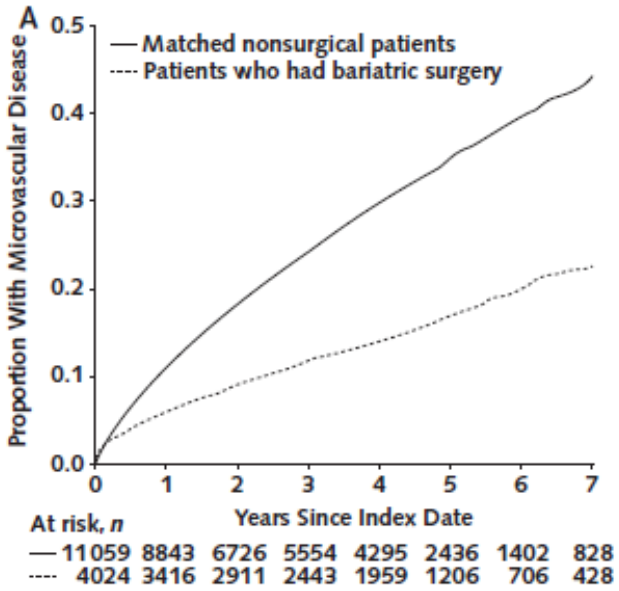
# Microvascular Outcomes in Patients With Diabetes After Bariatric Surgery Versus Usual Care

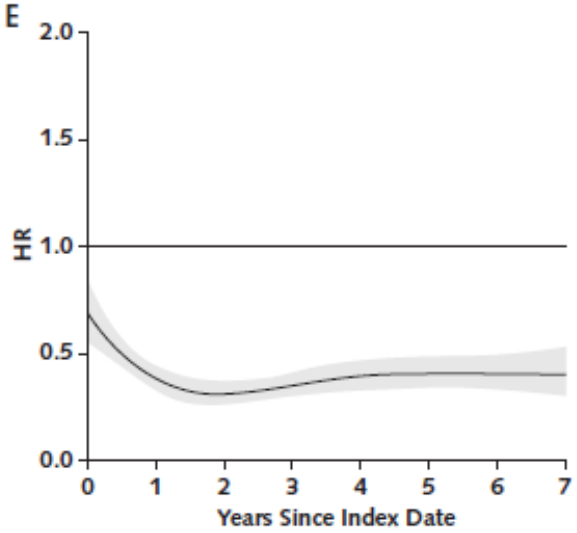
## A Matched Cohort Study

Rebecca O'Brien, MD; Eric Johnson, MS; Sebastien Haneuse, PhD; Karen J. Coleman, PhD; Patrick J. O'Connor, MD, MA, MPH; David P. Fisher, MD; Stephen Sidney, MD, MPH; Andy Bogart, MS; Mary Kay Theis, MA, MS; Jane Anau, BS; Emily B. Schroeder, MD, PhD; and David Arterburn, MD, MPH

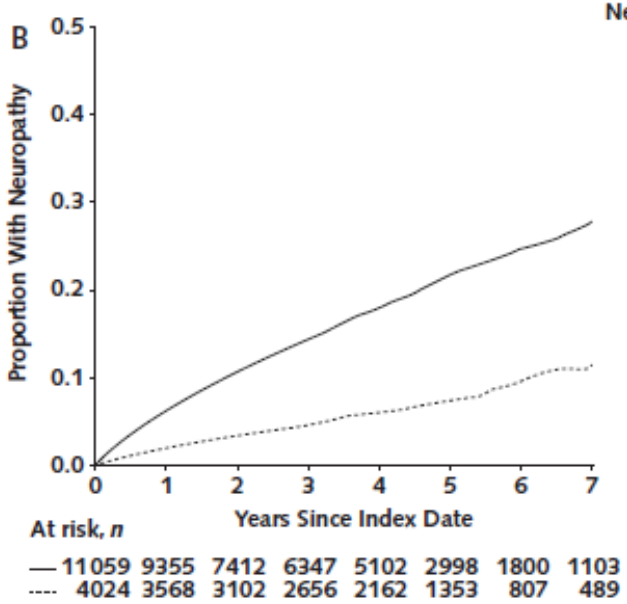
*Ann Intern Med. 2018;169:300-310.*

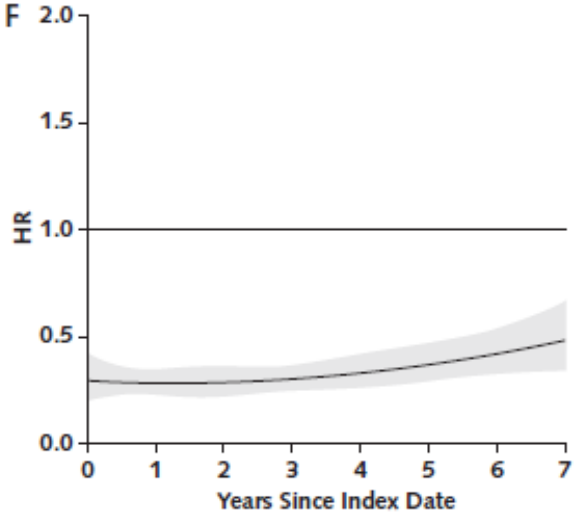
All Microvascular Disease

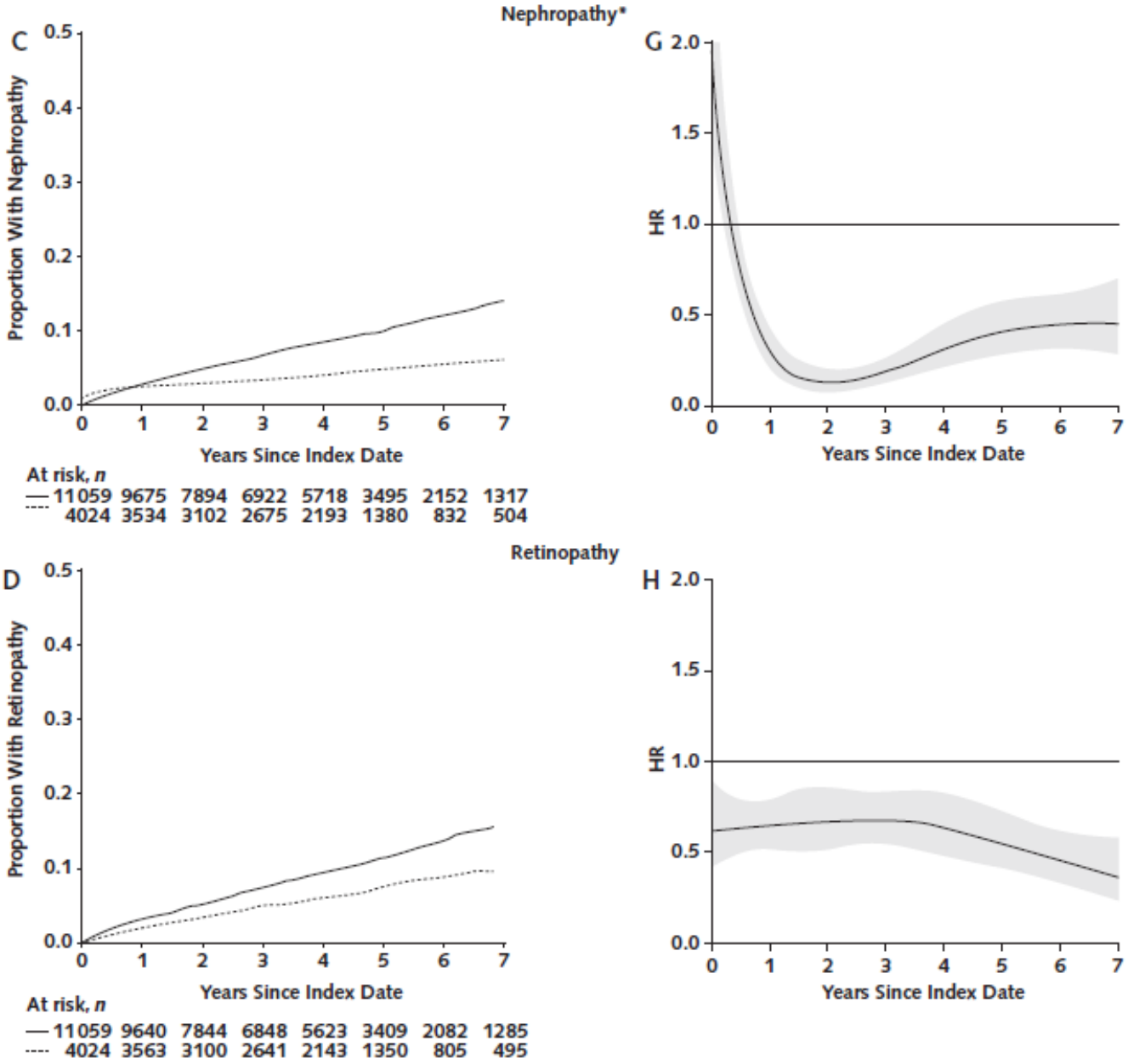



Neuropathy




Nephropathy*
C
Proportion With Nephropathy
0.5
0.4
0.3
0.2
0.1
0.0
0 1 2 3 4 5 6 7
Years Since Index Date
At risk, n
11059 9675 7894 6922 5718 3495 2152 1317
4024 3534 3102 2675 2193 1380 832 504
G
HR
2.0
1.5
1.0
0.5
0.0
0 1 2 3 4 5 6 7
Years Since Index Date
Retinopathy
D
Proportion With Retinopathy
0.5
0.4
0.3
0.2
0.1
0.0
0 1 2 3 4 5 6 7
Years Since Index Date
At risk, n
11059 9640 7844 6848 5623 3409 2082 1285
4024 3563 3100 2641 2143 1350 805 495
H
HR
2.0
1.5
1.0
0.5
0.0
0 1 2 3 4 5 6 7
Years Since Index Date

ELSEVIER
CrossMark
Surgery for Obesity and Related Diseases 10 (2014) 576–583
SURGERY FOR OBESITY AND RELATED DISEASES

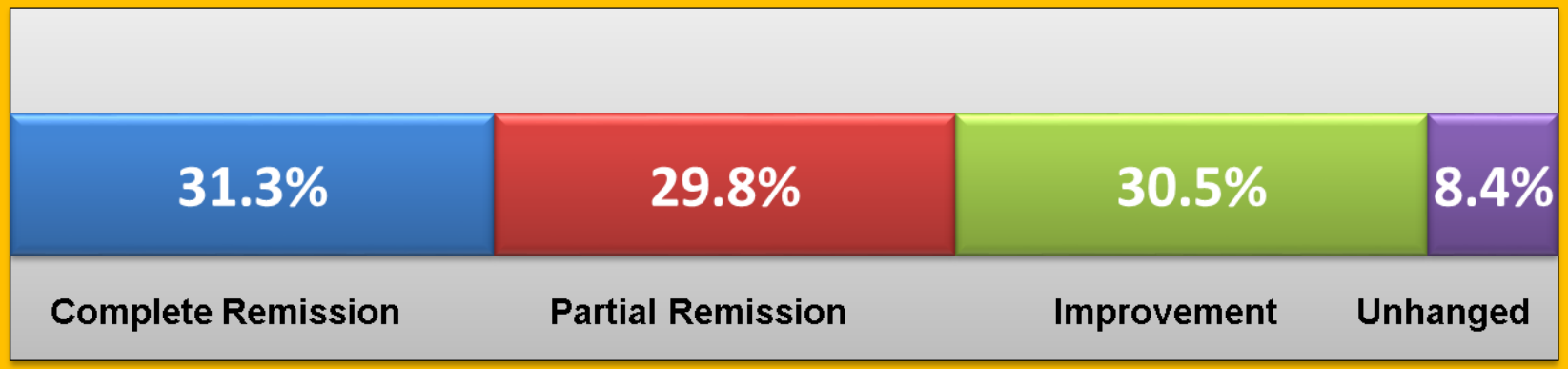
Original article

# Risk prediction of complications of metabolic syndrome before and 6 years after gastric bypass

Ali Aminian, M.D.[a], Christopher R. Daigle, M.D.[a], Héctor Romero-Talamás, M.D.[a], Sangeeta R. Kashyap, M.D.[b], John P. Kirwan, Ph.D.[b], Stacy A. Brethauer, M.D.[a], Philip R. Schauer, M.D.[a,*]

- **N=131, T2DM**
- **RYGB (2004-2007)**
- **F/U: median of 6 years (range, 5-9)**
- **% EWL 61±25%**

## Long-term diabetes status after gastric bypass (n=131)

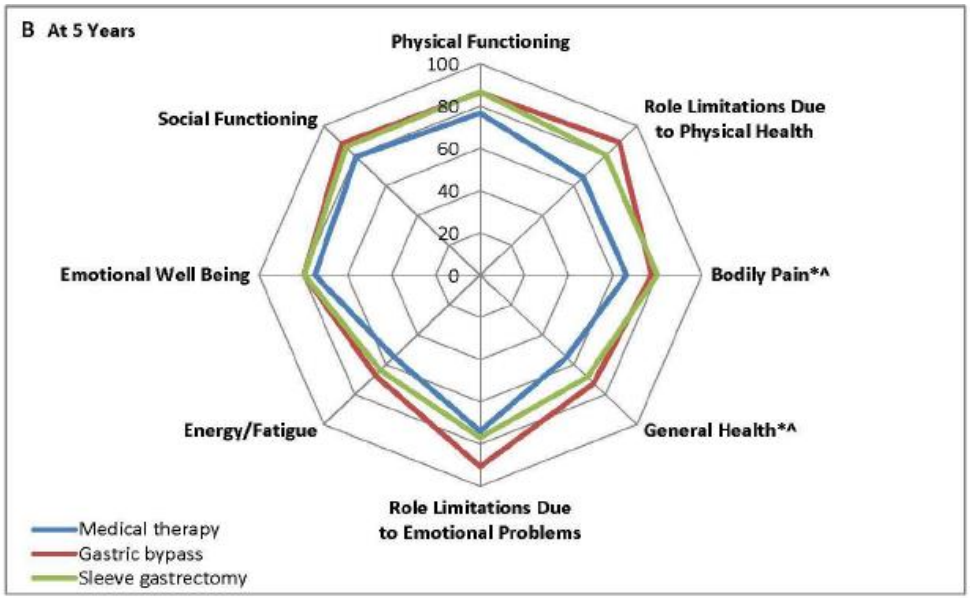


# Predicted Risk of End Organ Complications

| Metabolic Syndrome-Related Complications | Risk Assessment Tools | % Risk Reduction | P value |
|---|---|---|---|
| Overall risk of CHD, stroke, and PVD | Framingham (10-yr risk) | 27 | <0.001 |
| Coronary Heart Disease | UKPDS (10-yr risk) | 20 | 0.002 |
| Myocardial Infarction | PROCAM ( 10-yr risk) | 40 | <0.001 |
| Stroke | ARIC (10-yr risk) | 42 | 0.001 |
| Nephropathy | QKidney (5-yr risk) | 45 | <0.001 |
| Retinopathy | Semeraro's nomogram (4-yr risk) | - | 0.006 |
| Intermittent Claudication | Framingham (4-yr risk) | 47 | <0.001 |
| Cardiovascular Mortality | DECODE (5-yr risk) | 18 | 0.048 |

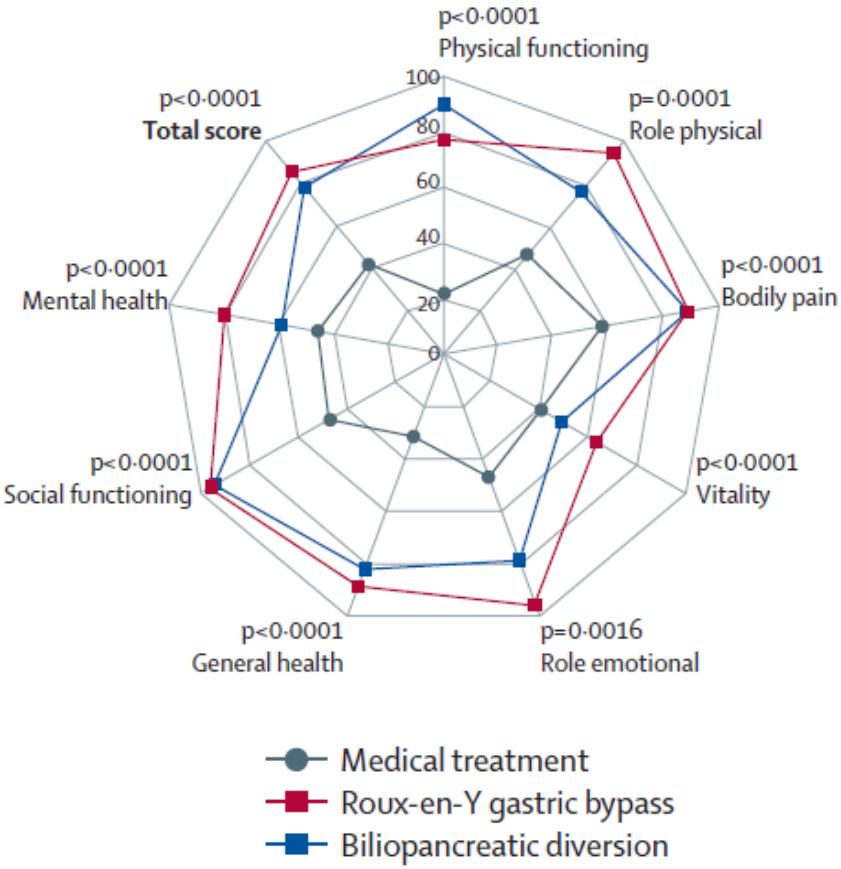
# QUALITY OF LIFE

## STAMPEDE




*p<0.05 for change from baseline between gastric-bypass group and medical therapy group
^p<0.05 for change from baseline between sleeve-gastrectomy and medical therapy group

## Mingrone/Rubino



# Long-term Mortality Following Bariatric Surgery

- **41** published studies (to date)
- 18 report on CVD-caused mortality
- Methods vary by surgery type, follow-up time, control group selection, matching and BMI
- Lower all-cause mortality for surgery group when compared to SO controls (all studies; 1 study NS)

***Courtesy of Dr Ted Adams***

# Bariatric Surgery & Reduced All-Cause Mortality (%) versus Severely Obese Controls

| Study Reference | % Reduction |
|---|---|
| MacDonald, KG. J Gastrointest Surg 1997;1:213-220 | 88 |
| Flum, DR. J Am Coll Surg 2004;199:543-551 | 33 |
| Christou, NV. Ann Surg 2004;240:416-424 | 89 |
| Sowemino, OA. Surg Obes Relat Dis 2007;3:73-77 | 63 |
| Sjöström, L. NEJM 2007;357:741-752 | 29 |
| Adams. T. NEJM 2007;357:753-761 | 40 |
| Busetto, L. Surg Ob Rel Dis 2007;3:496-502 | 60 |
| Peeters, A. Ann Surg 2007;246:1028-1033 | 72 |
| Miranda, WR. Gastrointest Surg 1997;1:213-220 | 88 |

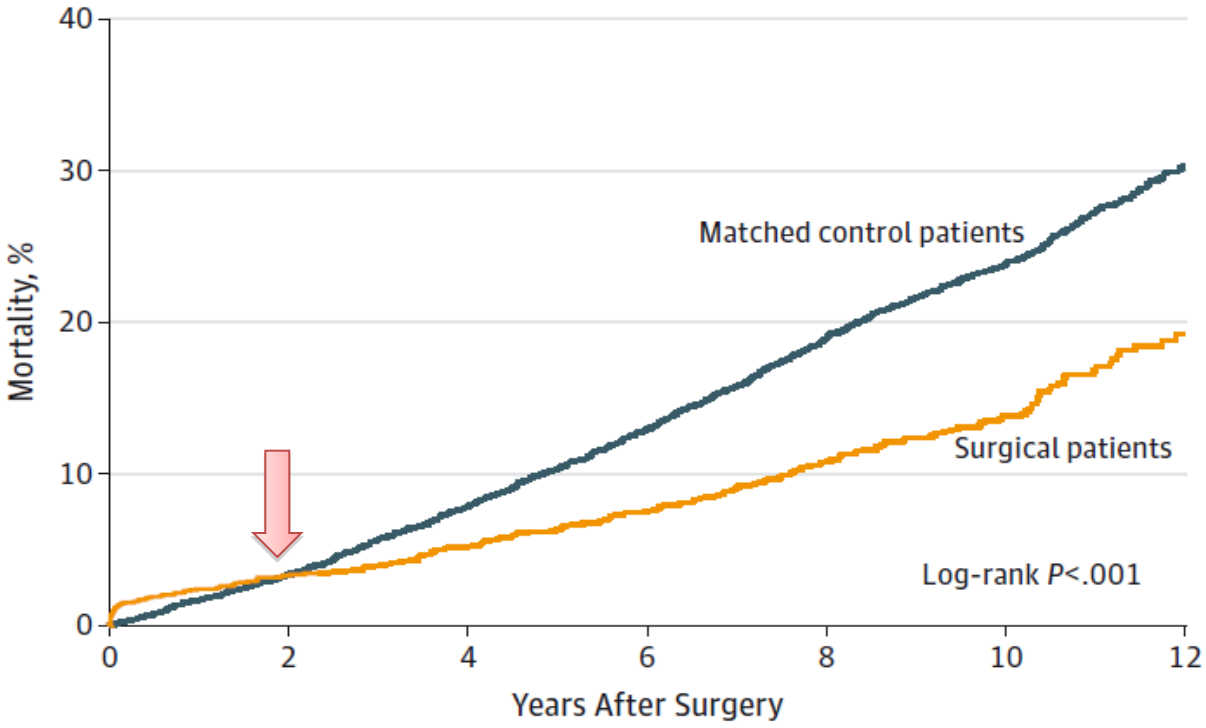
# Bariatric Surgery & Reduced All-Cause Mortality (%) versus Severely Obese Controls

| Study Reference | % Reduction |
|---|---|
| Johnson, RJ. Am Surg 2012;78:685-692 | 40 |
| Arterburn, DE. JAMA 2015;313:62-70 | 53 |
| Perry, CD. Ann Surg 2008;247:21-27 | 50 |
| Maciejewski, ML. JAMA 2011;305:2419-2426 | 36 |
| Maciejewski, ML. JAMA 2011;305:2419-26 - propensity | NS |
| Arterburn DE, JAMA 2015;313:62-70 | 54 |
| Guidry, CA. Am J Surg 2015;209:463-467 | 52 |
| Scott, JD. Surg Obes Rel Dis 2013;9:32-41 | 40 |
| Eliasson, B, Lancet Diabetes Endocrin 2015;3:847-54 | 58 |

# Bariatric Surgery & Reduced All-Cause Mortality (%) versus Severely Obese Controls

| Study Reference | % Reduction |
|---|---|
| Mirinda, WR. Eur Heart J 2012;33:494 | 24 |
| Maggard-Gibbons, M. Evid Based Med 2015;20:148 | 53 |
| Schauer, DP. Ann Surg 2015;261:914-9 | Significant |
| Pontiroli, AE. Cardiovasc Diabetol 2016;15:39 | 26 |
| Flanagan, E. Am Surg 2016;82:166-70 | 75 |
| Jakobsen, GS. JAMA 2018;319:291-301 | 58-66 |
| Reges, O. JAMA 2018;319:279-290 | 50 |

## Kaplan-Meier Estimated Mortality Curves for Surgical Patients and Matched Control Patients



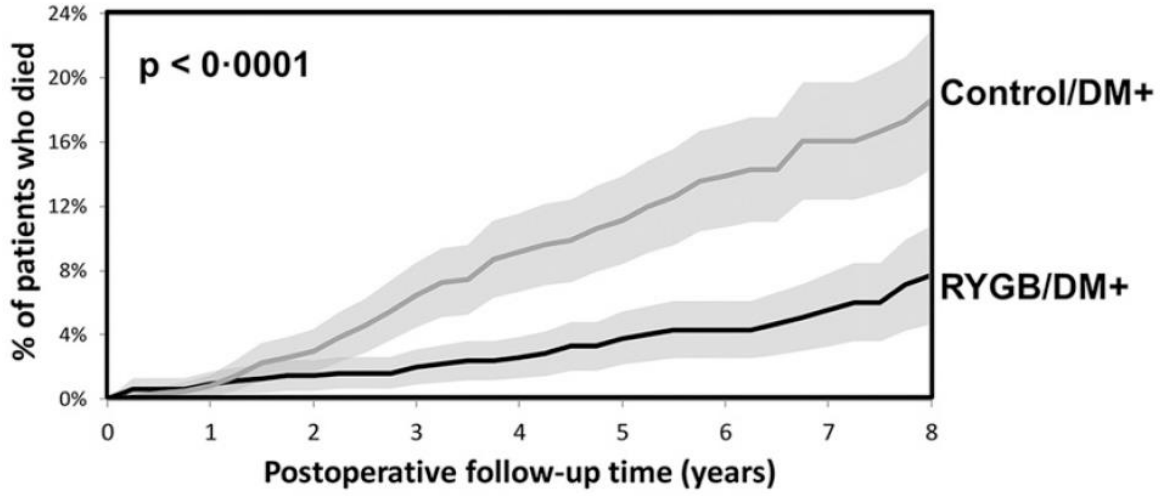

| No. at risk | | | | | | | |
|---|---|---|---|---|---|---|---|
| Matched control patients | 7462 | 7114 | 5306 | 3878 | 2641 | 1407 | 472 |
| Surgical patients | 2500 | 2416 | 1868 | 1412 | 1004 | 552 | 185 |

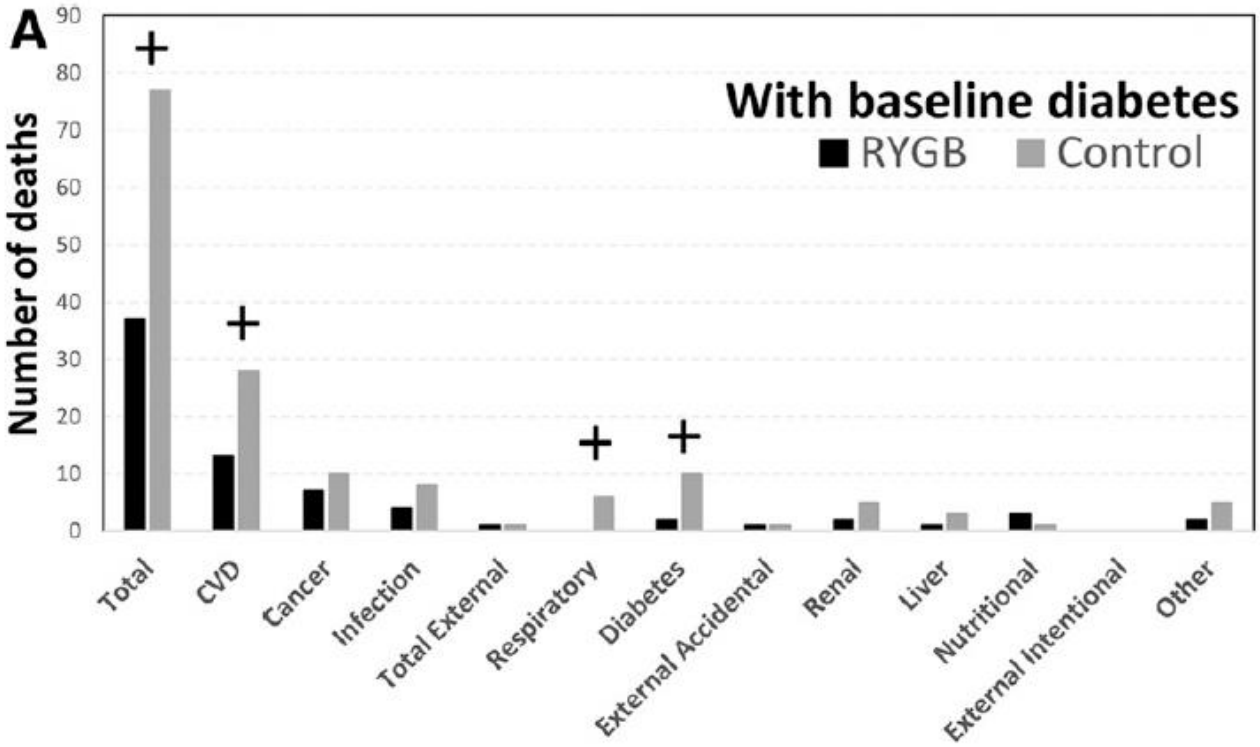
Entire cohort includes 2500 surgical patients and 7462 matched control patients; follow-up was censored at December 31, 2013. Estimated mortality rates were 2.4% at 1 year, 6.4% at 5 years, and 13.8% at 10 years for surgical patients; for matched control patients, 1.7% at 1 year, 10.4% at 5 years, and 23.9% at 10 years.

Arterburn DE, et al. Association between bariatric surgery and long-term survival. JAMA. 2015 6;313:62-70.

# All-Cause and Specific-Cause Mortality Risk After Roux-en-Y Gastric Bypass in Patients With and Without Diabetes

*Michelle R. Lent,[1,2] Peter N. Benotti,[1] Tooraj Mirshahi,[3] Glenn S. Gerhard,[4] William E. Strodel,[5] Anthony T. Petrick,[5] Jon D. Gabrielsen,[5] David D. Rolston,[6] Christopher D. Still,[1] Annemarie G. Hirsch,[7] Fahad Zubair,[8] Adam Cook,[1] David J. Carey,[3] and G. Craig Wood[1]*



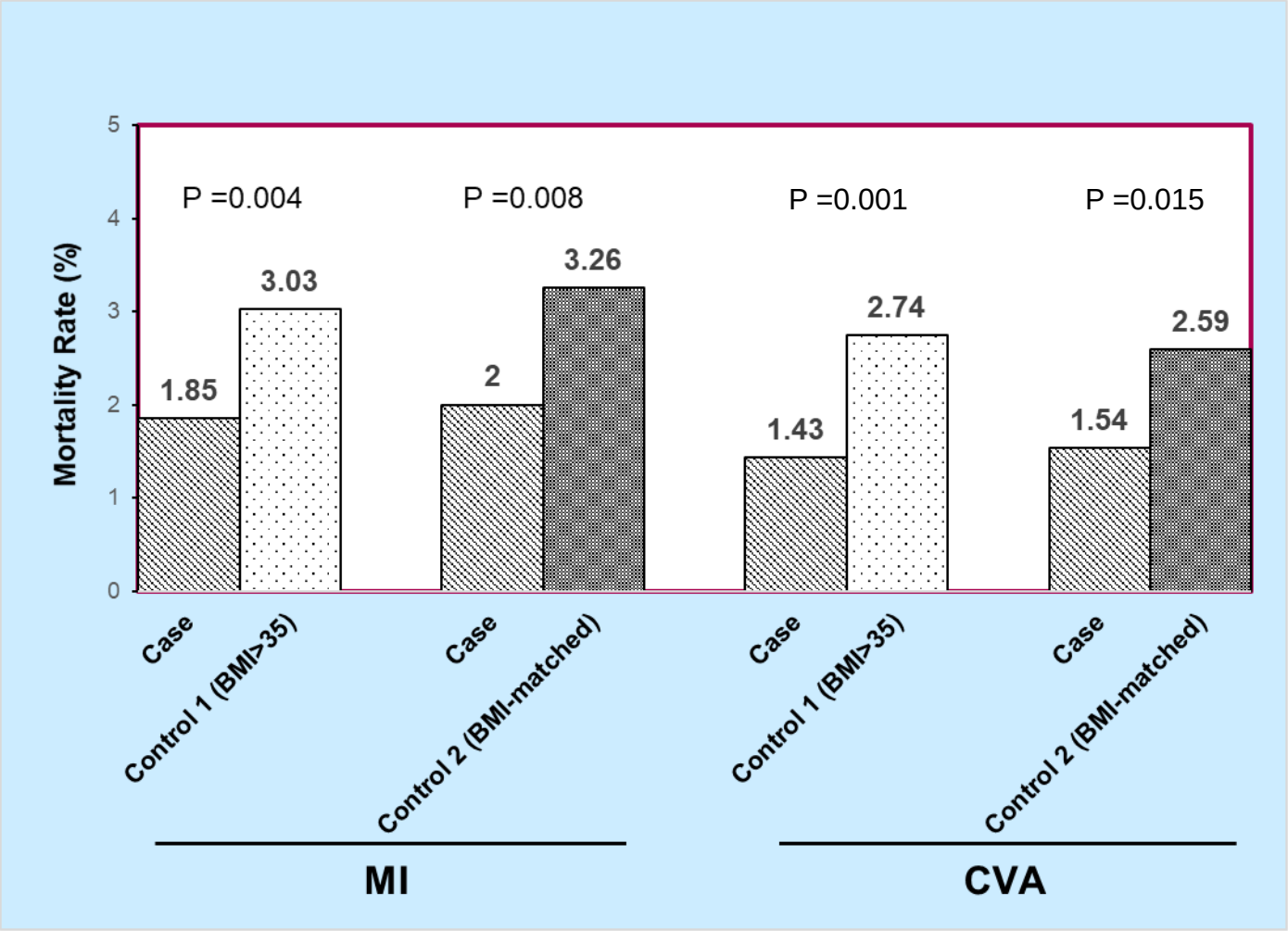

Cleveland Clinic

# Bariatric Surgery is Associated with a Lower Rate of Death after Heart Attack and Stroke: a Nationwide Study

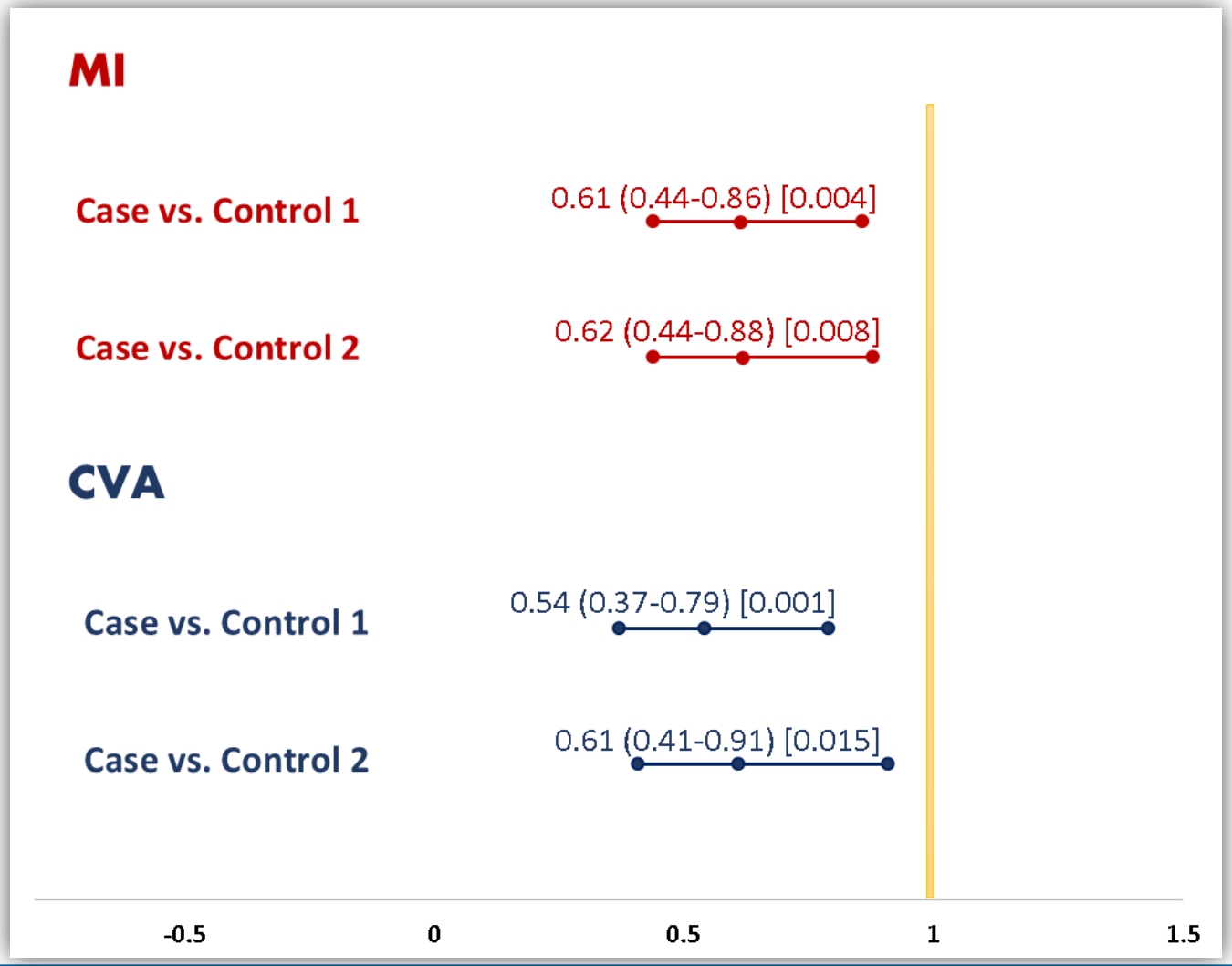

Ali Aminian
Essa Aleassa
Chao Tu
Zhamak Khorgami
Christopher Daigle
Deepak Bhatt
Stacy Brethauer
Philip Schauer

Cleveland Clinic

# Propensity-matched comparison of Mortality



# Odds Ratio (95% CI) [P Value] of Mortality after MI & CVA



# Surgery for Obesity Indications/Contraindications

- Indications
  - BMI ≥40 kg/m$^2$ with or without comorbidity
  - BMI 35–39 kg/m$^2$ with comorbidity
- Contraindications
  - Incompetent mentally to understand procedure
  - Inability or unwillingness to change lifestyle
  - Uncontrolled substance abuse
  - Psychologically unstable

**2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults**

# Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations

*Diabetes Care 2016;39:861–877 | DOI: 10.2337/dc16-0236*

*Francesco Rubino,[1] David M. Nathan,[2] Robert H. Eckel,[3] Philip R. Schauer,[4] K. George M.M. Alberti,[5] Paul Z. Zimmet,[6] Stefano Del Prato,[7] Linong Ji,[8] Shaukat M. Sadikot,[9] William H. Herman,[10] Stephanie A. Amiel,[1] Lee M. Kaplan,[2] Gaspar Taroncher-Oldenburg,[11] and David E. Cummings,[12] on behalf of the Delegates of the 2nd Diabetes Surgery Summit**

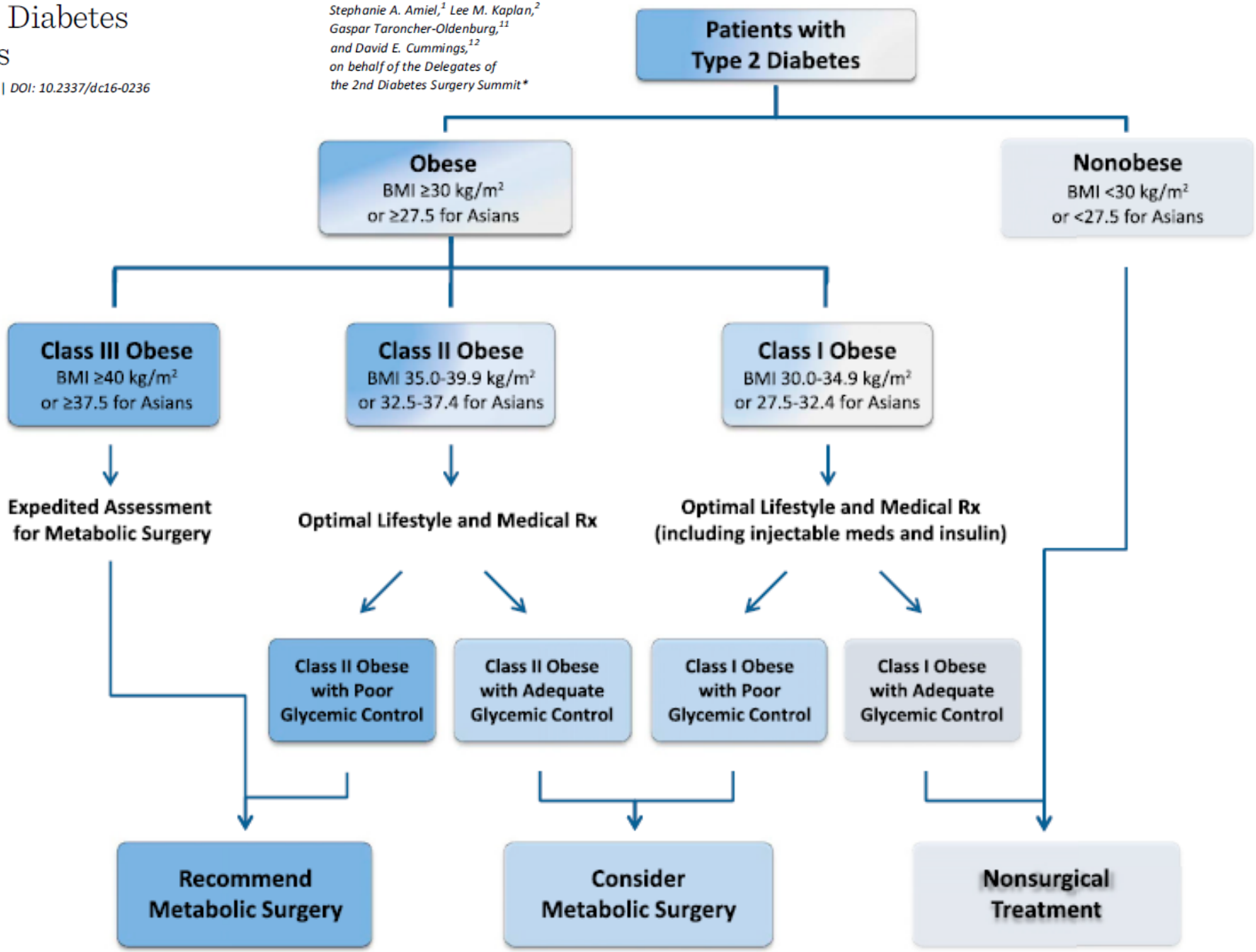
## Metabolic Surgery for patients with T2DM should be

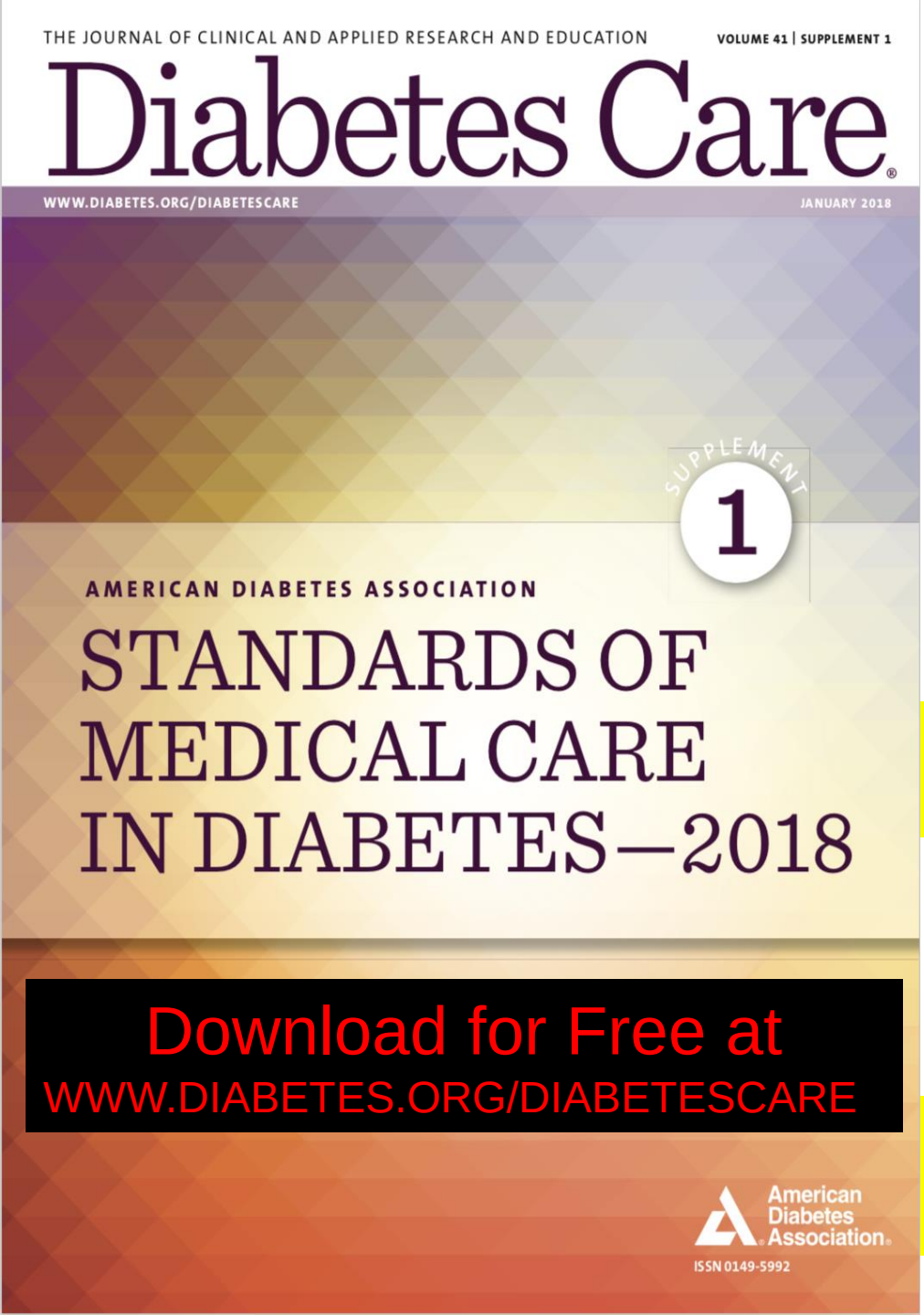
- **Recommended** for BMI $\geq$ 40 regardless of glycemic control
- **Recommended** for BMI $\geq$ 35 with inadequately controlled hyperglycemia
- **Considered** for BMI 30-34.9 with inadequately controlled hyperglycemia
- **Considered** for Asians with BMI as low as 27.5 with inadequately controlled hyperglycemia

# Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations

*Francesco Rubino,[1] David M. Nathan,[2] Robert H. Eckel,[3] Philip R. Schauer,[4] K. George M.M. Alberti,[5] Paul Z. Zimmet,[6] Stefano Del Prato,[7] Linong Ji,[8] Shaukat M. Sadikot,[9] William H. Herman,[10] Stephanie A. Amiel,[1] Lee M. Kaplan,[2] Gaspar Taroncher-Oldenburg,[11] and David E. Cummings,[12] on behalf of the Delegates of the 2nd Diabetes Surgery Summit**

*Diabetes Care 2016;39:861–877 | DOI: 10.2337/dc16-0236*






**Recommendations**

recommended for BMI > 40

appropriate surgical candidates with BMI ≥40 kg/m$^2$ (BMI ≥37.5 kg/m$^2$ in Asian Americans), regardless of the level of glycemic control or com-

recommended for BMI 35-39 if not well controlled with meds

Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy. A

- Metabolic surgery should be con-

should be considered for BMI 30-35 If not well controlled with meds

cans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin). B

- Metabolic surgery should be per-

Should be performed in high volume centers

and gastrointestinal surgery. C

ELSEVIER

Check for updates

Surgery for Obesity and Related Diseases 14 (2018) 1071–1087

SURGERY FOR OBESITY AND RELATED DISEASES

ASMBS statements/guidelines

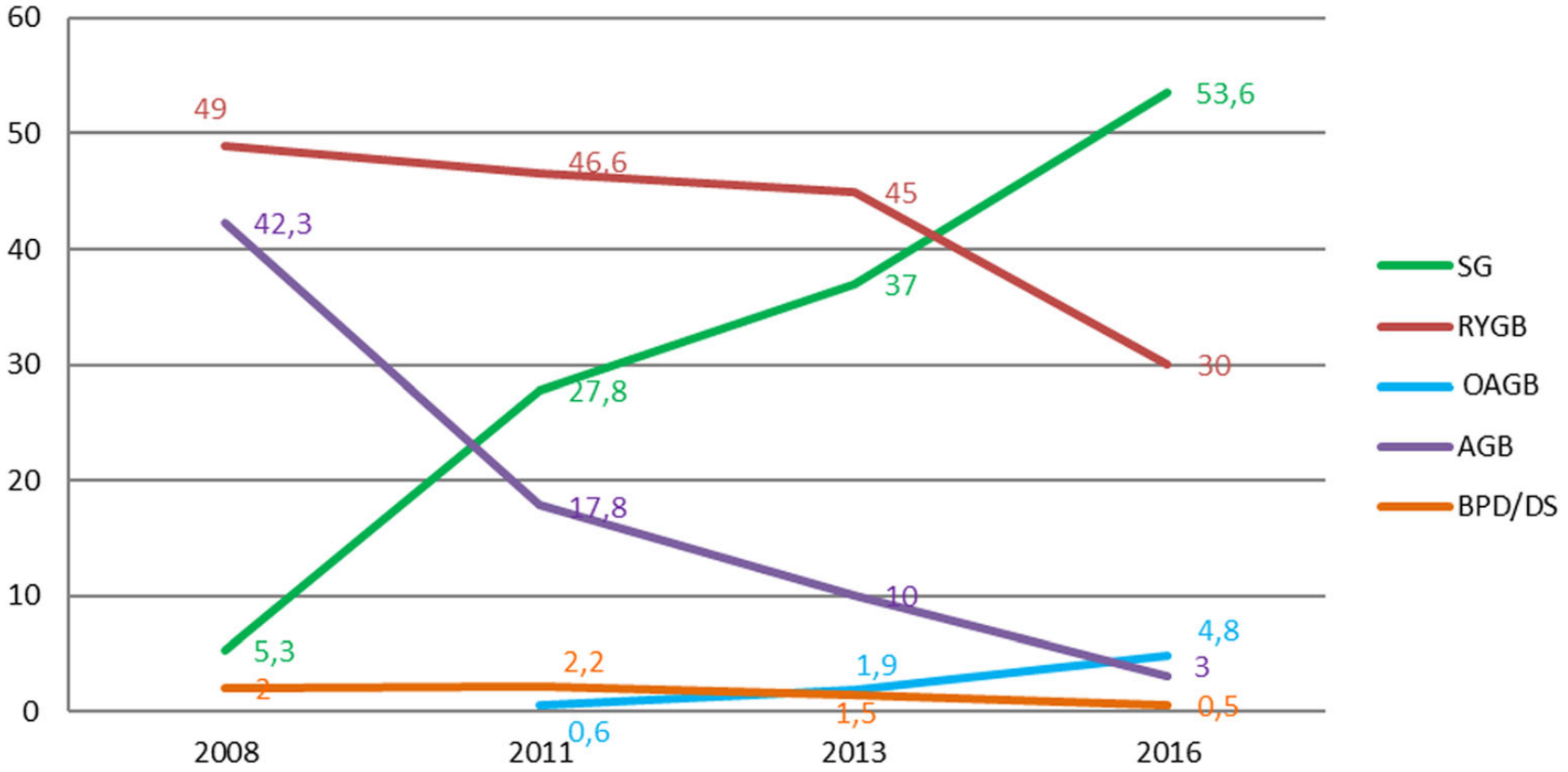
# ASMBS updated position statement on bariatric surgery in class I obesity (BMI 30–35 kg/m$^2$)

Ali Aminian[a,*], Julietta Chang[a], Stacy A Brethauer[a], Julie J. Kim[b], for the American Society for Metabolic and Bariatric Surgery Clinical Issues Committee

4. For patients with BMI 30 to 35 kg/m$^2$ and obesity-related co-morbidities who do not achieve substantial, durable weight loss and co-morbidity improvement with reasonable nonsurgical methods, bariatric surgery should be offered as an option for suitable individuals. In this population, surgical intervention should be considered after failure of nonsurgical treatments.
5. Particularly given the presence of high-quality data in patients with type 2 diabetes, bariatric and metabolic surgery should be strongly considered for patients with BMI 30 to 35 kg/m$^2$ and type 2 diabetes.

# Procedure Selection for Diabetes

# Estimate of Bariatric Surgery Numbers from IFSO




Angrisani L, et al. Obes Surg. 2018.

# Estimate of Bariatric Surgery Numbers from ASMBS

| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|---|---|
| **Total** | **158,000** | **173,000** | **179,000** | **193,000** | **196,000** | **216,000** | **228,000** |
| **Sleeve** | 17.80% | 33.00% | 42.10% | 51.70% | 53.61% | 58.11% | **59.39%** |
| **RYGB** | 36.70% | 37.50% | 34.20% | 26.80% | 23.02% | 18.69% | **17.80%** |
| **Band** | 35.40% | 20.20% | 14.00% | 9.50% | 5.68% | 3.39% | **2.77%** |
| **BPD-DS** | 0.90% | 1.00% | 1.00% | 0.40% | 0.60% | 0.57% | **0.70%** |
| **Revision** | 6.00% | 6.00% | 6.00% | 11.50% | 13.55% | 13.95% | **14.14%** |
| **Other** | 3.20% | 2.30% | 2.70% | 0.10% | 3.19% | 2.63% | **2.46%** |
| **Balloons** | — | — | — | — | 0.36% | 2.66% | **2.75%** |

**>95% in T2DM: SG & RYGB**

English et al. SOARD 2018

# Bariatric Procedure Selection

| Condition | Choice |
|---|---|
| High risk patient | SG |
| High BMI | SG |
| Crohn's disease | SG |
| Transplant recipient/candidate | SG |
| Active smoker | SG |
| NSAID user | SG |
| GERD, Barrett's | RYGB |
| Diabetes | 22 |

## Procedure Selection for Diabetes

# Efficacy & Risk Gradient

**DS ≥ SADI > SAGB ≥ RYGB ≥ SG > AGB**

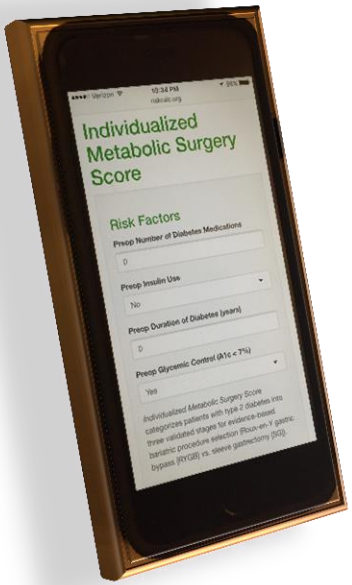
# Long-term Response Differs According to Severity of Diabetes

ANNALS OF SURGERY
A Monthly Review of Surgical Science Since 1885

# Individualized Metabolic Surgery Score: Procedure Selection Based on Diabetes Severity

*Ali Aminian, MD,* Stacy A. Brethauer, MD,* Amin Andalib, MD, MSc,† Amy S. Nowacki, PhD,‡ Amanda Jimenez, MD, PhD,§ Ricard Corcelles, MD, PhD,§ Zubaidah Nor Hanipah, MD,*¶ Suriya Punchai, MD,*|| Deepak L. Bhatt, MD, MPH,** Sangeeta R. Kashyap, MD,†† Bartolome Burguera, MD, PhD,*†† Antonio M. Lacy, MD, PhD,§ Josep Vidal, MD, PhD,§‡‡ and Philip R. Schauer, MD**

**Ann Surg 2017;266:650–657**




**BariatricCalc**

Available on the App Store

Get it on Google play

# Objective

- To construct and externally validate an individualized scoring system for evidence-based selection of metabolic surgery *(RYGB and SG)* for T2DM based on disease severity.

# Methods

- T2DM
- Primary RYGB or SG (2004-2011) with at least 5-yr data
- Training dataset: n=659 from *Cleveland Clinic*
- Validation dataset: n=241 from *Hospital Clínic Universitari*

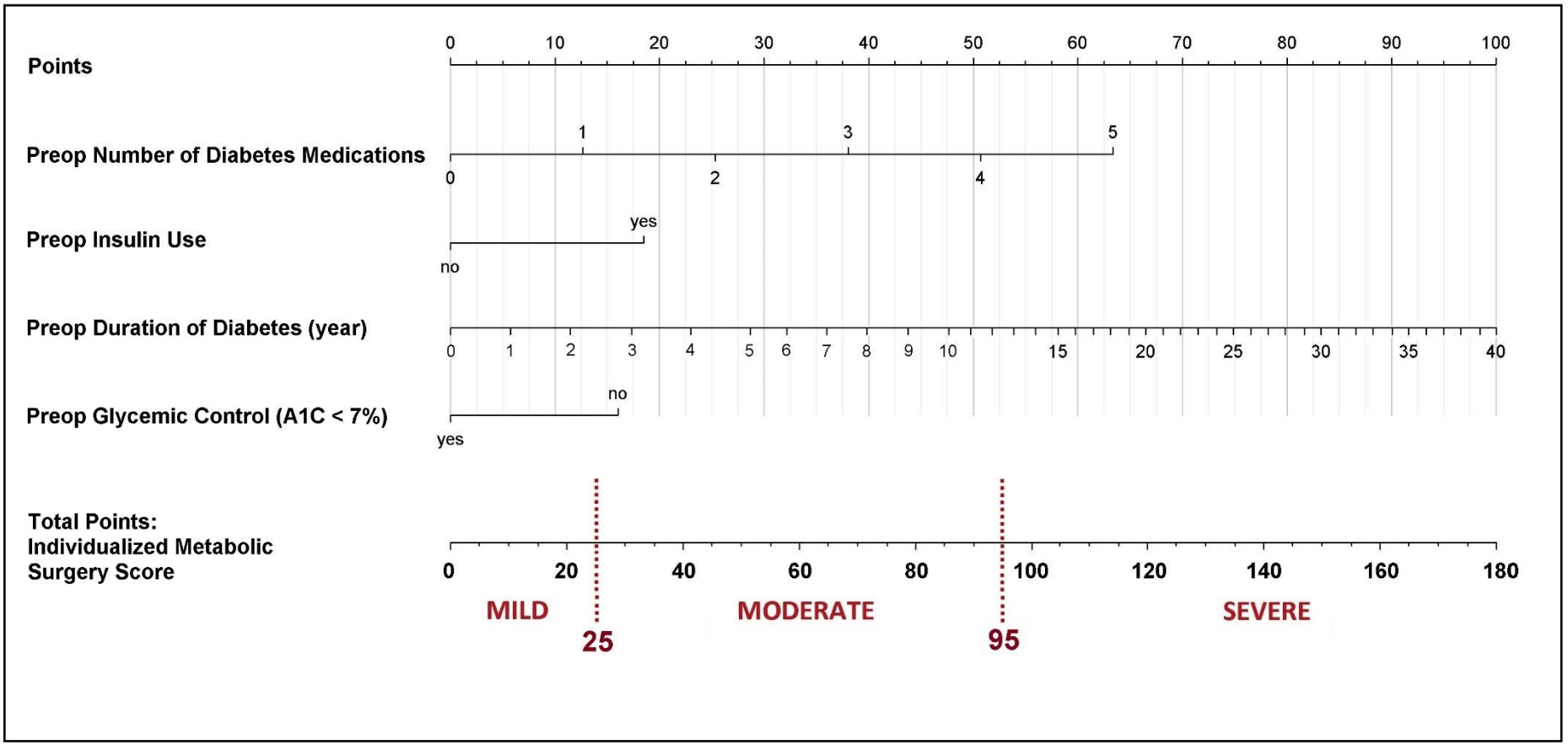
# Statistical Analysis

- Logistic regression model based on diabetes remission
- Nomogram
- Individualized Metabolic Surgery (IMS) score
- Online IMS score calculator

# Independent Predictors of Remission

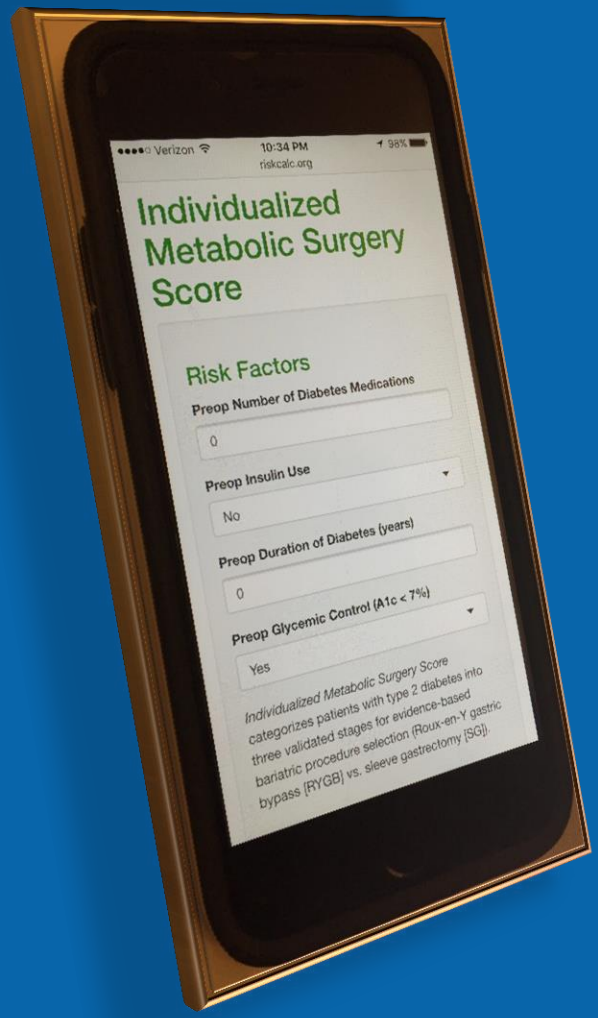
- # of Diabetes Meds ($p < 0.0001$)
- Insulin Use ($p = 0.002$)
- Duration of Diabetes ($p < 0.0001$)
- Glycemic control ($p = 0.002$)

***Functional Beta Cell Reserve***




| | | | |
|---|---|---|---|
| Remission after RYGB vs. SG (Model Generating Data) | 92% vs. 74% | 60% vs. 25% | 12% vs. 12% |
| Remission after RYGB vs. SG (Validation Data) | 91% vs. 91% | 70% vs. 56% | 8% vs. 3% |
| **Recommendation in Average Risk Patients** | **RYGB is suggested.** Both procedures are highly effective. | **RYGB is recommended.** SG is less effective. | **SG is suggested.** Both procedures are less effective. |

# http://riskcalc.org/Metabolic_Surgery_Score/




**BariatricCalc**

Available on the App Store

Get it on Google play

# Bariatric Procedure Selection

| Condition | Choice |
|---|---|
| High risk patient | SG |
| High BMI | SG |
| Crohn’s disease | SG |
| Transplant recipient/candidate | SG |
| Active smoker | SG |
| NSAID user | SG |
| GERD, Barrett’s | RYGB |

## Diabetes

# Bariatric Procedure Selection

| Condition | Choice |
|---|---|
| High risk patient | SG |
| High BMI | SG |
| Crohn's disease | SG |
| Transplant recipient/candidate | SG |
| Active smoker | SG |
| NSAID user | SG |
| GERD, Barrett's | RYGB |
| **Diabetes** | |
| Mild (IMS Score≤25) | RYGB is suggested. |

# Bariatric Procedure Selection

| Condition | Choice |
|---|---|
| High risk patient | SG |
| High BMI | SG |
| Crohn's disease | SG |
| Transplant recipient/candidate | SG |
| Active smoker | SG |
| NSAID user | SG |
| GERD, Barrett's | RYGB |
| **Diabetes** | |
| Mild (IMS Score≤25) | RYGB is suggested. |
| Severe (IMS score >95) | SG is suggested. |

# Bariatric Procedure Selection

| Condition | Choice |
|---|---|
| High risk patient | SG |
| High BMI | SG |
| Crohn's disease | SG |
| Transplant recipient/candidate | SG |
| Active smoker | SG |
| NSAID user | SG |
| GERD, Barrett's | RYGB |

## Diabetes

| | |
|---|---|
| Mild (IMS Score≤25) | RYGB is suggested. |
| Moderate (25 < IMS score ≤ 95) | RYGB is recommended. |
| Severe (IMS score >95) | SG is suggested. |

# Individualized Metabolic Surgery (IMS) Score:

## Bariatric Procedure Selection Based on Diabetes Severity

**Surgery for Type 2 Diabetes:**

Roux-en-Y Gastric Bypass

*VS.*

Sleeve Gastrectomy

**4 Predictors of Diabetes Remission:**

- Diabetes Duration
- Diabetes Med #
- Insulin Use
- Glycemic Control

NOMOGRAM

**3 Stages of Diabetes Severity:**

**Mild** (IMS Score ≤25) → ***Suggestion:***

**Moderate** (25< IMS ≤95) → ***Recommendation:***

**Severe** (IMS score >95) → ***Suggestion:***

**Procedure of Choice:**

**BariatricCalc**

Available on the App Store

Get it on Google play

ANNALS OF SURGERY
A Monthly Review of Surgical Science Since 1885

Aminian et al. *Ann Surg.* 2017


Cleveland Clinic