A critical review of outcomes of bariatric surgery

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Association of British Clinical Diabetologists

Principal outcome measures for bariatric surgery

Weight loss

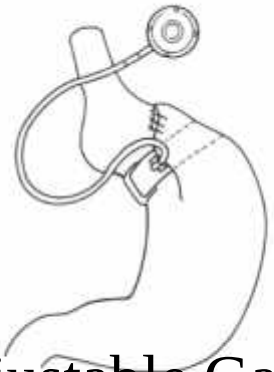
Impact on comorbidity

Quality of life

Safety

Cost

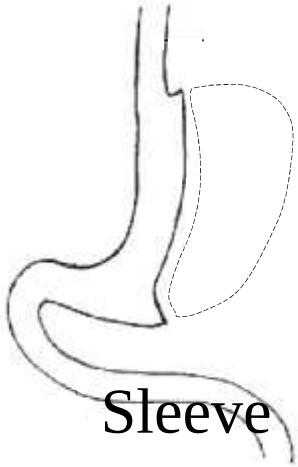
Bariatric surgery



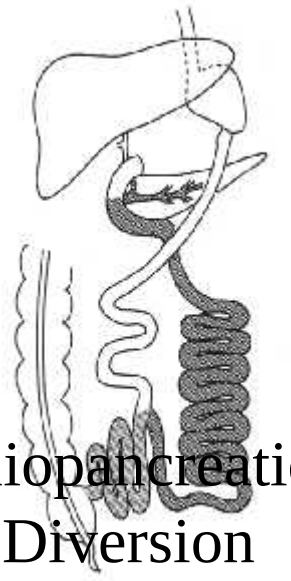
Adjustable Gastric Banding

Roux-en-Y Gastric Bypass

Duodenal Switch

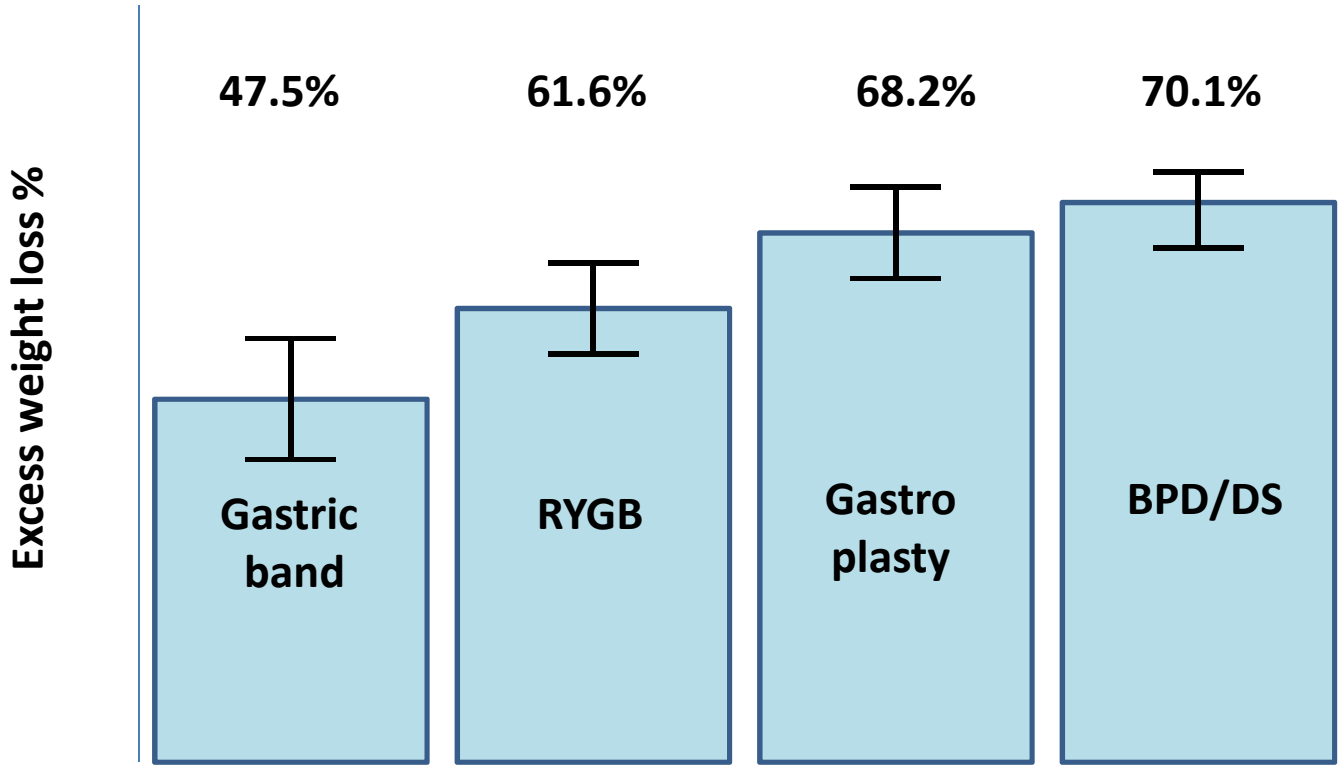


Sleeve Gastrectomy



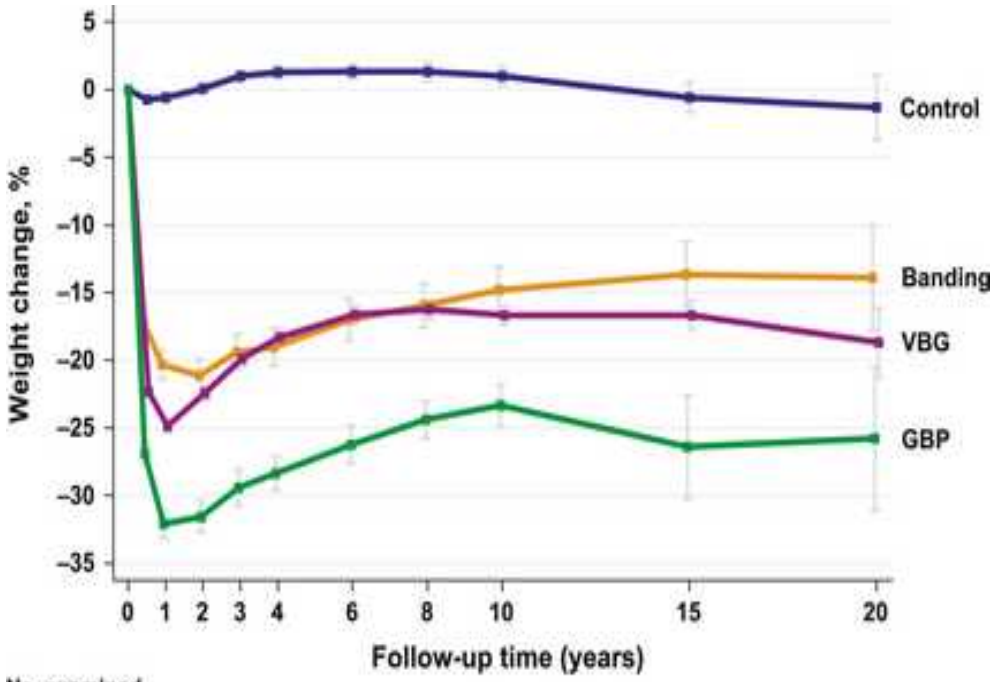
Biliopancreatic Diversion

Weight loss after bariatric surgery



Buchwald H et al. Bariatric surgery: a systematic review and meta-analysis. JAMA 2004 Oct 13;292(14):1724-37.

Weight loss in the Swedish Obese Subjects (SOS)



No. examined

Control	2037	1490	1242	1267	556	176
Banding	376	333	284	284	150	50
VBG	1369	1086	987	1007	489	82
GBP	265	209	184	180	37	13

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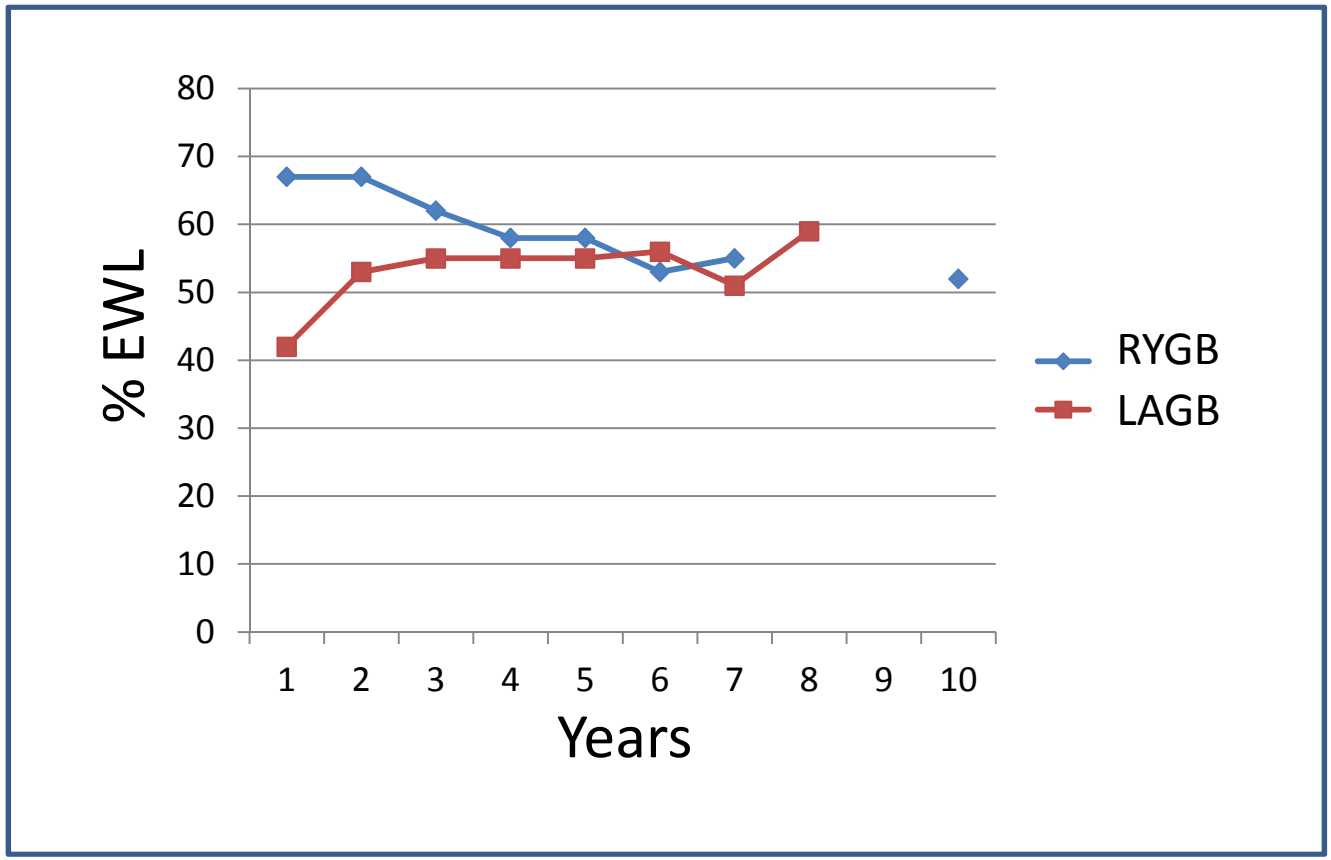
Systematic review of medium term weight loss after RYGB and LAGB



O'Brien P et al. Systematic review of medium-term weight loss after bariatric operations. Obes Surg 2006 16;8:1032-1042.

Metabolic / bariatric surgery worldwide 2011.

	Percentage of procedures		
Year	2003	2008	2011
RYGB	65.1	49.0	46.6
LAGB	24.4	42.3	17.8
SG	0	5.3	27.9
BPD	6.1	4.9	2.1

Roux-en-Y gastric bypass (RYGB) 46.6%; sleeve gastrectomy (SG) 27.8%; adjustable gastric banding (AGB) 17.8%; and biliopancreatic diversion/duodenal switch (BPD/DS) 2.2%. The global trends from 2003 to 2008 to 2011 showed a decrease in RYGB: 65.1 to 49.0 to 46.6%; an increase, followed by a steep decline, in AGB: 24.4 to 42.3 to 17.8%; and a marked increase in SG: 0.0 to 5.3 to 27.89%. BPD/DS declined: 6.1 to 4.9 to 2.1%.

Buchwald H and Oien DM. Obes Surg 2013 Apr;23(4):427-36.

Principal outcome measures for bariatric surgery

Weight loss

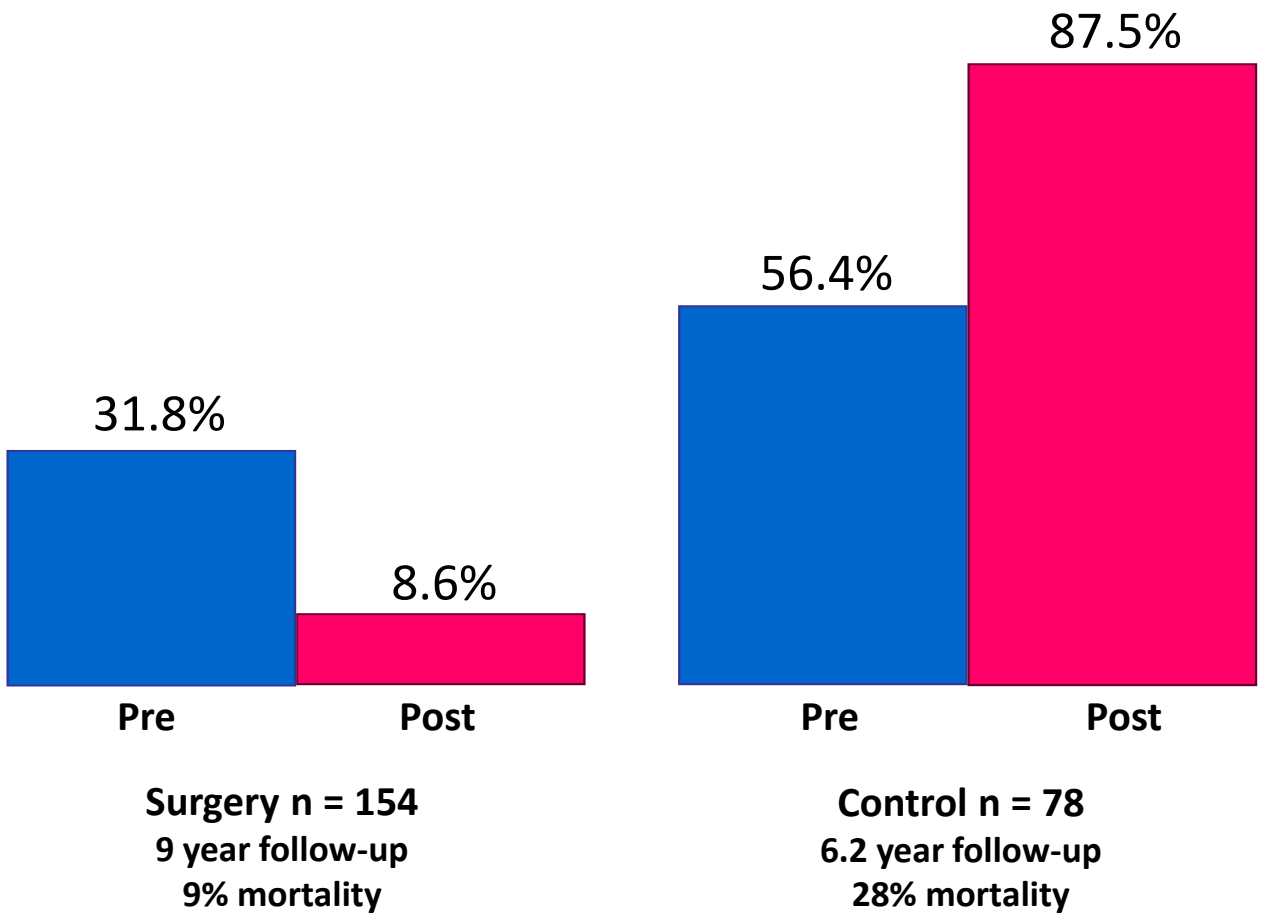
Impact on comorbidity

Quality of life

Safety

Cost

Requirements for oral therapy or insulin in type 2 diabetes after gastric bypass or continued medical management



Modified from MacDonald et al. J Gastroenterol Surg 1997;1:213–220.

“Overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients.
“

Buchwald et al. Am J Med 2009.

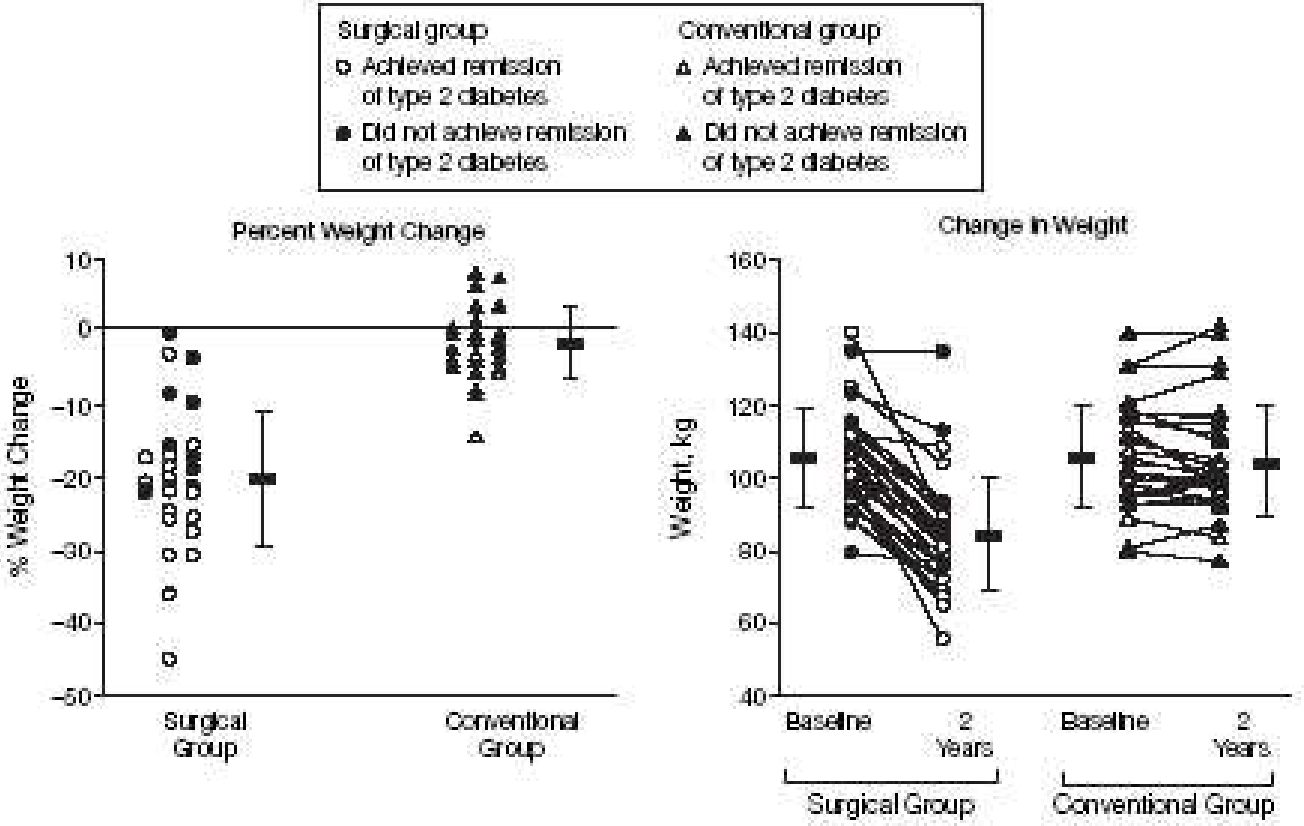
TABLE 3. Resolution of T2DM According to Preoperative Severity and Duration (n = 191)

Number	Improved 33	Resolved 158
Severity*		
IFG (n = 14)	0	100%
DC-T2DM (n = 32)	3%	97%
OA-T2DM (n = 93)	13%	87%
I-T2DM (n = 52)	38%	62%
Duration*		
≤5 years (n = 119)	5%	95%
6 to 10 years (n = 44)	25%	75%
>10 years (n = 28)	46%	54%

* Indicates $P < 0.001$.

Schauer P et al. Ann Surg 2003

Figure 2. Percentage of Weight Loss Achieved Over the 2-Year Study Period (n=60) and Individual Weight Measures at Baseline and at 2 Years



Remission indicates those achieving remission of type 2 diabetes (see "Methods") at 2 years. Data markers with error bars indicate mean (SD).

Dixon J et al. JAMA 2008; 229; 316-323.

Gastric banding versus conventional therapy for type 2 diabetes

	Surgical	Medical
Diabetes remission	22 (73%)	4 (13%)
RR remission	5.5	1
% Weight loss	20.7%	1.4%

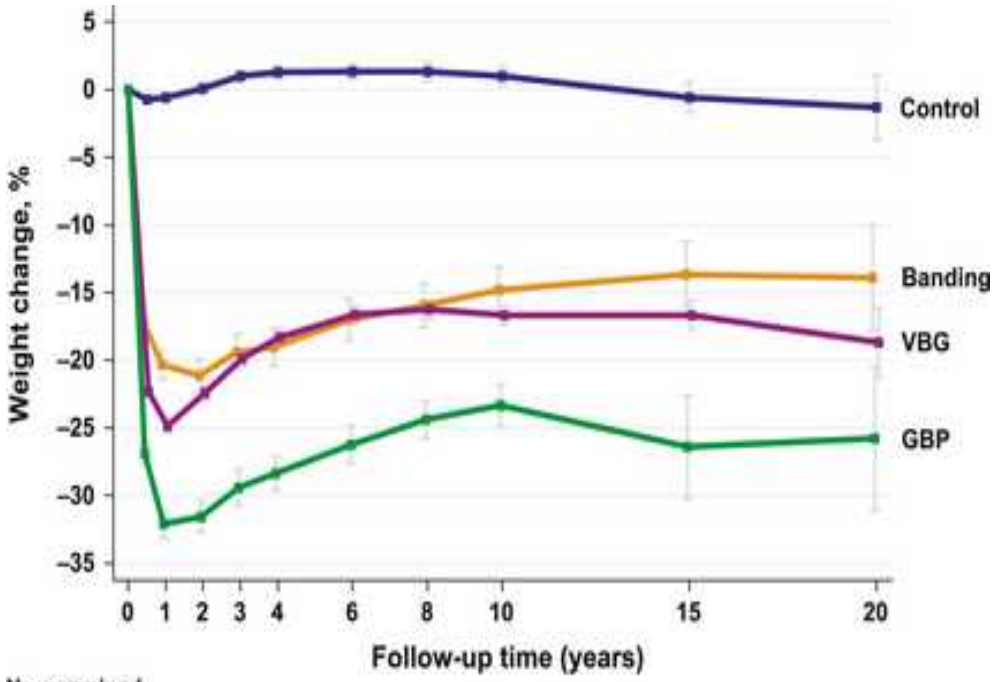
N=60

Remission related to weight loss ($R^2 = 0.46$, $P < .001$) and lower baseline HbA_{1c} levels (combined $R^2 = 0.52$, $P < .001$).

There were no serious complications in either group.

Dixon, J et al. Adjustable Gastric Banding and Conventional Therapy for Type 2 Diabetes A Randomized Controlled Trial. *JAMA.* 2008;299(3):316-323.

Weight loss in the Swedish Obese Subjects (SOS) trial



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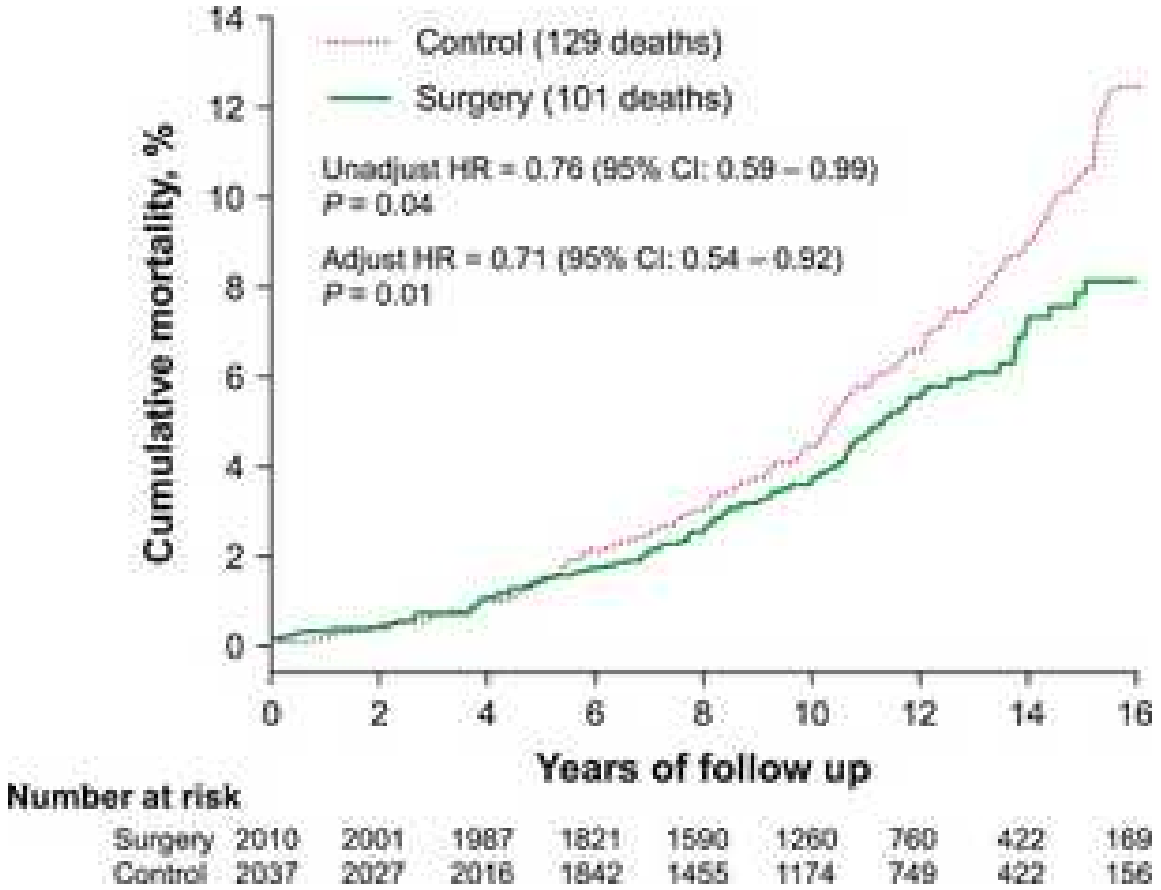
http://onlinelibrary.wiley.com/doi/10.1111/joim.12012/full#joim12012-fig-0001

Mortality in the Swedish Obese Subjects (SOS) trial



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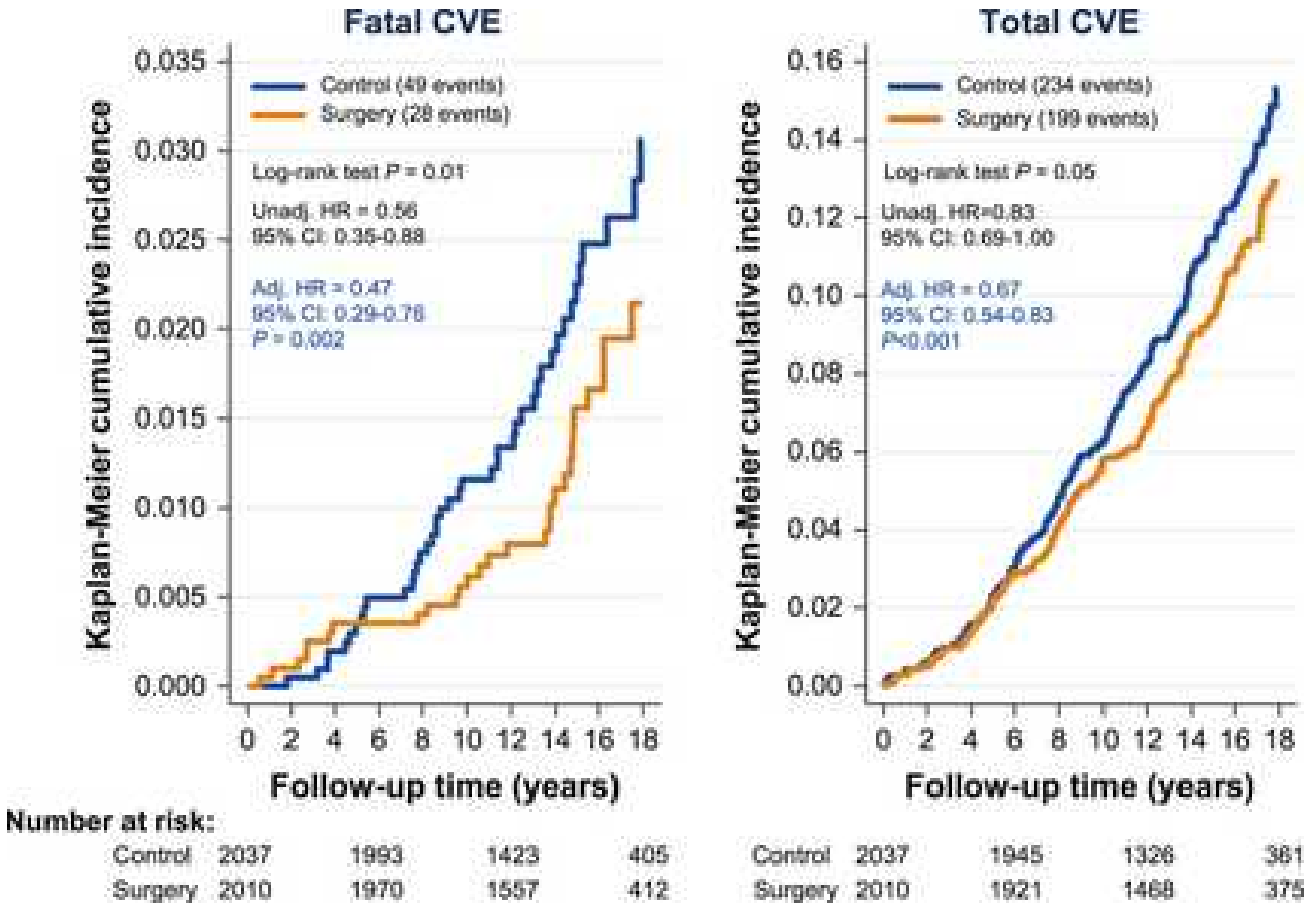
http://onlinelibrary.wiley.com/doi/10.1111/joim.12012/full#joim12012-fig-0002

Cardiovascular events in the Swedish Obese Subjects (SOS) trial



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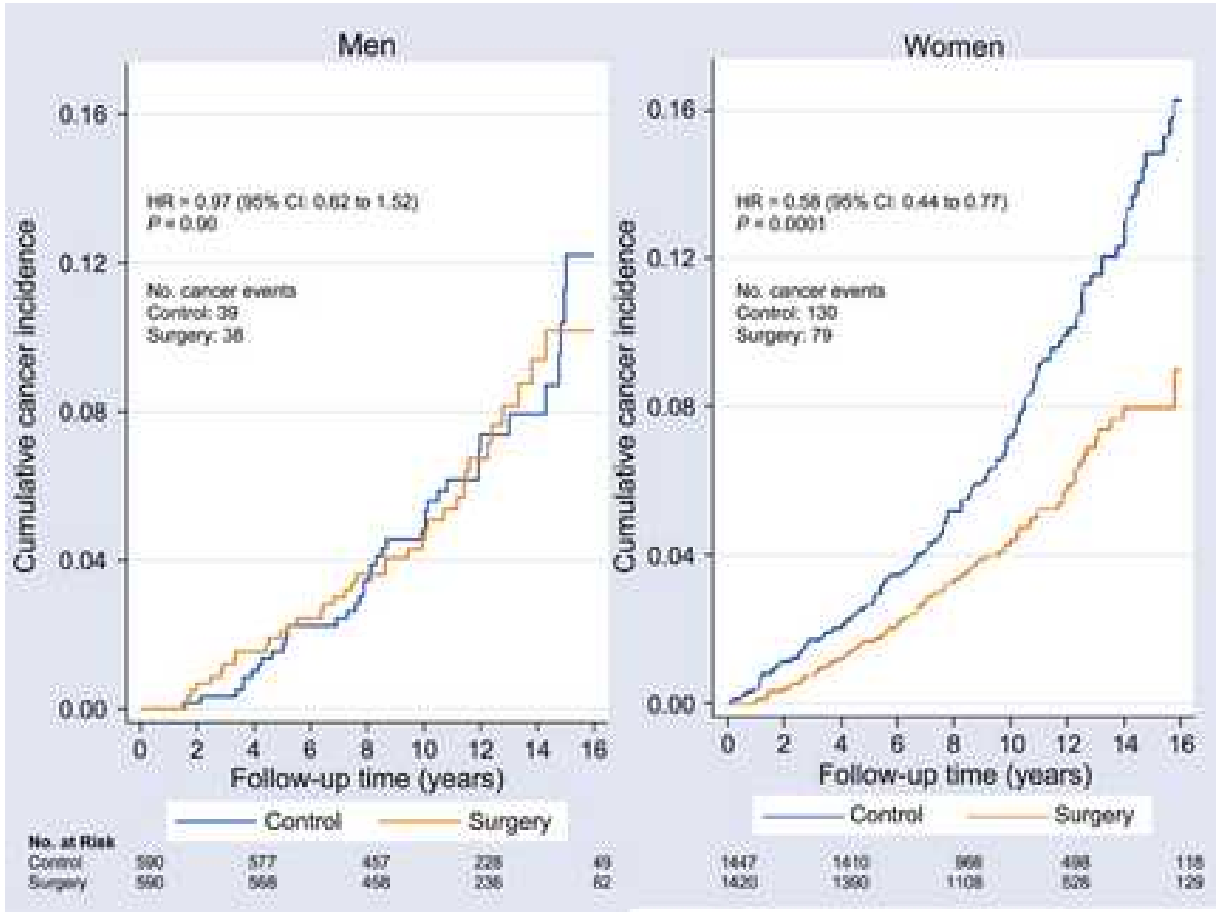
Cancer incidence in the Swedish Obese Subjects (SOS) trial



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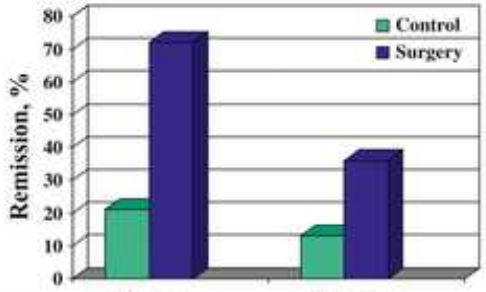
http://onlinelibrary.wiley.com/doi/10.1111/joim.12012/full#joim12012-fig-0006

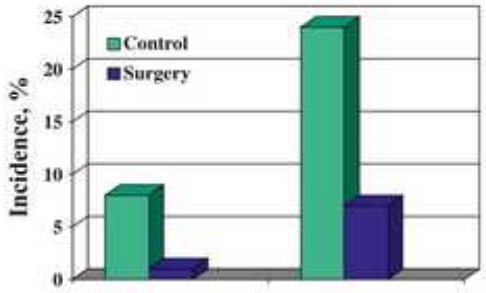
Diabetes Remission/Incidence in the Swedish Obese Subjects (SOS) trial

(a) SOS. Remission from diabetes over 2 and 10 years



Number of subjects:	2 year	10 year
Control	248	84
Surgery	342	118
Adjusted Odds ratio	8.42	3.45
95% CI	5.68 - 12.5	1.64 - 7.28
P value	<0.001	<0.001

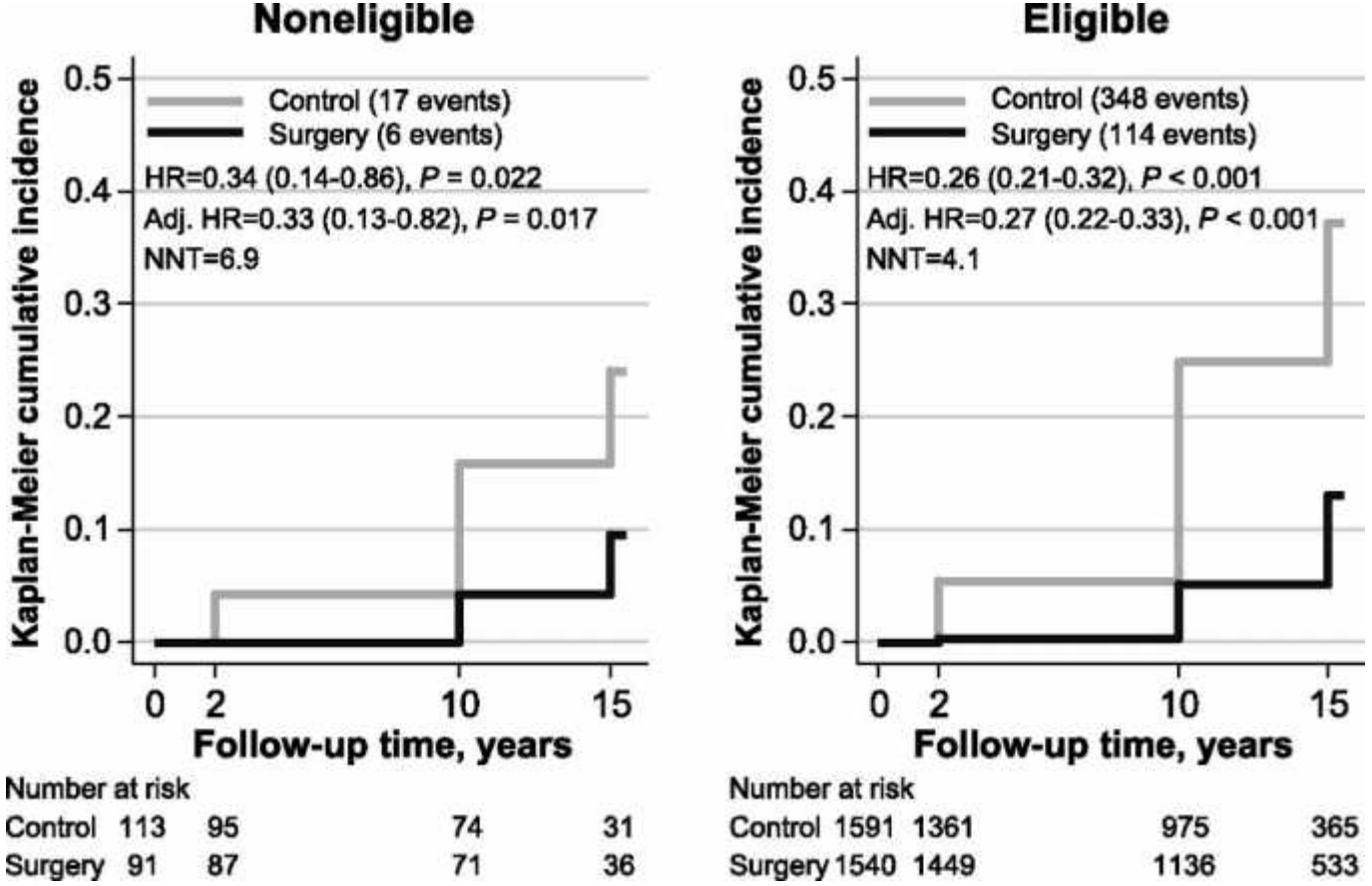
(b) SOS. Incidence of diabetes over 2 and 10 years



Number of subjects:	2 year	10 year
Control	1402	539
Surgery	1489	517
Adjusted Odds ratio	0.14	0.25
95% CI	0.08 - 0.24	0.17 - 0.38
P value	<0.001	<0.001

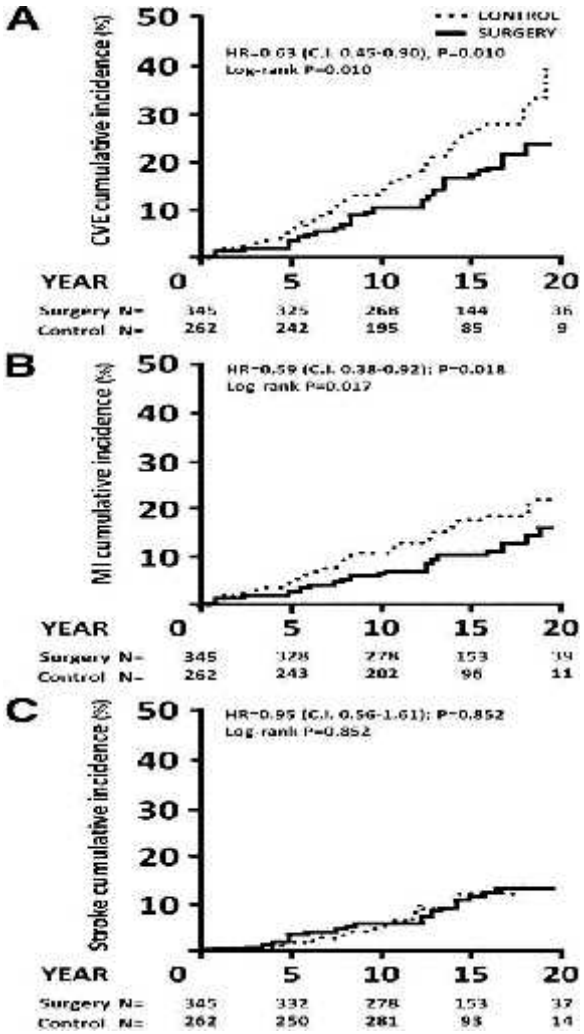
Journal of Internal Medicine
Volume 273, Issue 3, pages 219-234, 8 FEB 2013 DOI: 10.1111/joim.12012
http://onlinelibrary.wiley.com/doi/10.1111/joim.12012/full#joim12012-fig-0003

Cumulative incidence of type 2 diabetes over 15 years by treatment in noneligible and eligible groups (SOS study).



Sjöholm K et al. Diabetes Care 2013;36:1335-1340

Incidence of cardiovascular events in SOS subjects with diabetes at baseline.



Romeo S et al. Diabetes Care 2012;35:2613-2617

Percentage Change in Risk Factors at 2 and 10 Years in the SOS Study

Variable	Changes at 2 Years			Changes at 10 Years		
	Control n=1660	Surgery n=1845	Δ (95%CI)	Control n=627	Surgery n=641	Δ (95%CI)
SBP	0.5	-4.4	2.8 (2.1 to 3.6)§	4.4	0.5	1.1 (-0.3 to 2.6)
DBP	0.3	-5.2	3.2 (2.4 to 3.9)§	-2.0	-2.6	-2.3 (-3.5 to -1.0)§
Chol	0.1	-2.9	1.0 (0.1 to 1.9)*	-6.0	-5.4	-2.0 (-0.2 to -3.8)*

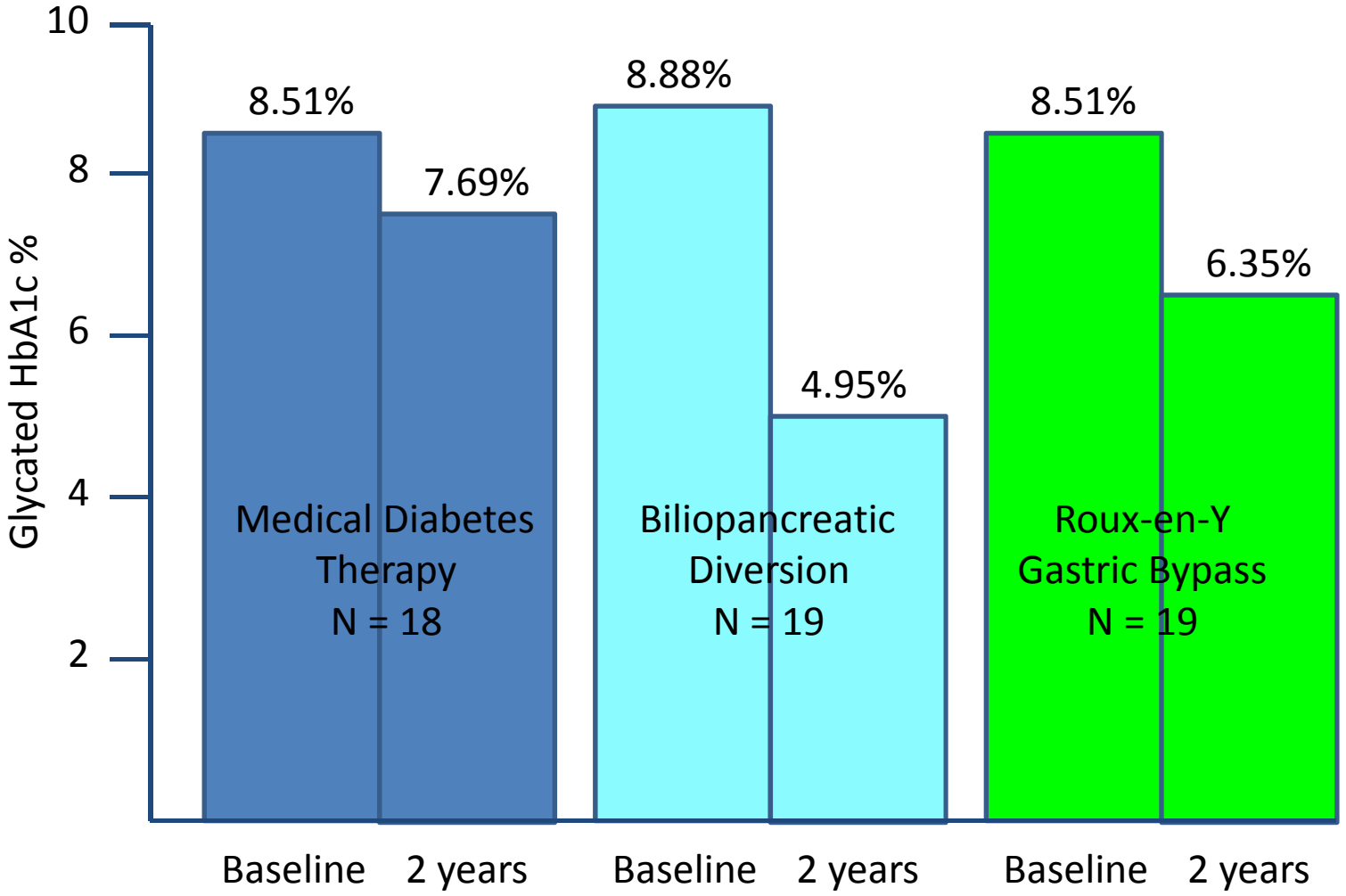
SBP: systolic blood pressure. DBP: diastolic blood pressure. Chol: cholesterol.
§*P*<0.001 **P*<0.05

Variable	Changes at 10 Years in Surgery Subgroups		
	Banding n=156	VBG n=451	Gastric Bypass n=34
SBP	2.1	0.4	-4.7
DBP	-1.4	-2.5	-10.4†
Chol	-5.0	-5.0	-12.6‡

VBG: vertical banded gastroplasty
† *P*<0.10 ‡*P*<0.05

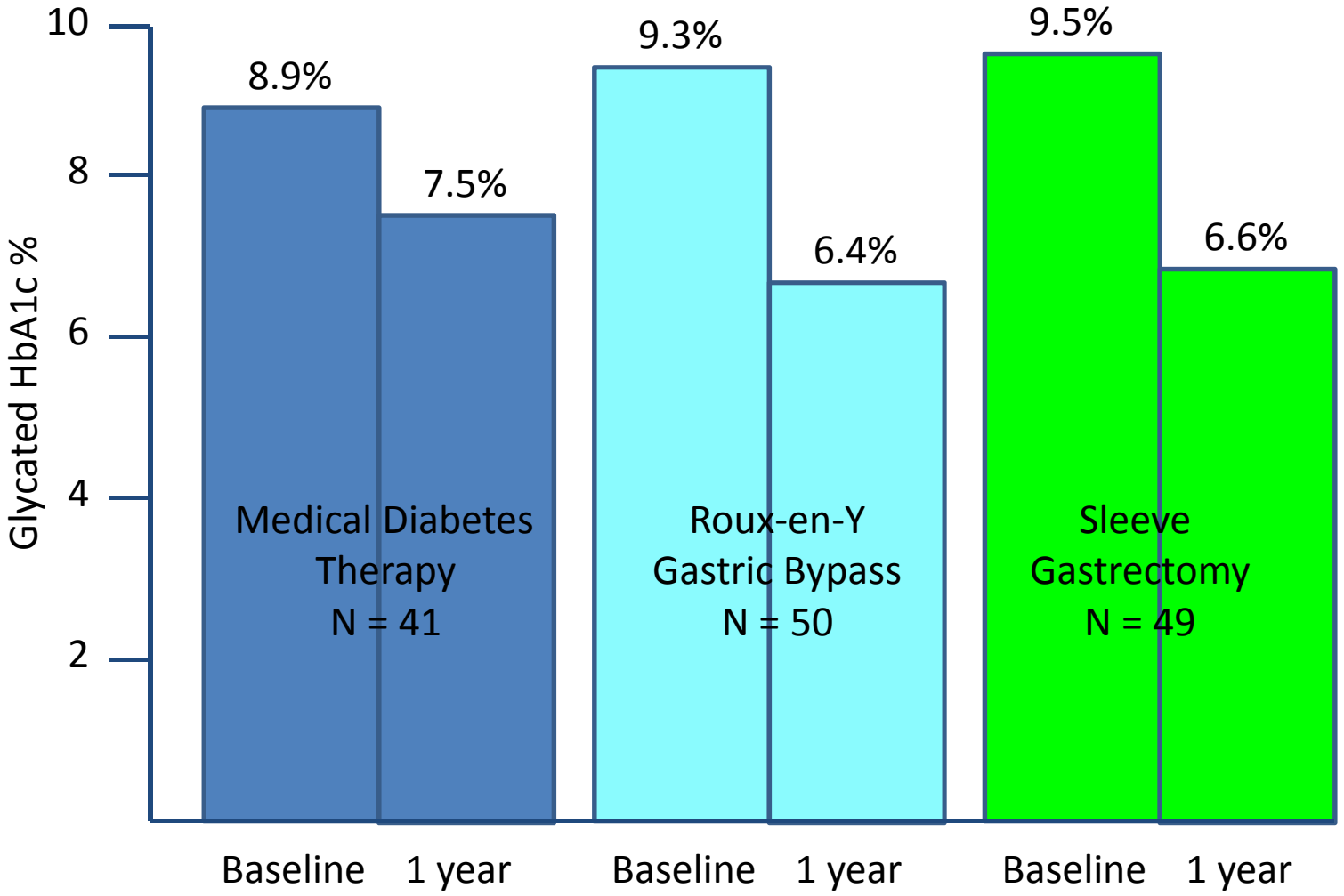
Sjostrom L, et al. *N Engl J Med.* 2004;351(26):2683-2693.

Bariatric Surgery versus conventional Medical Therapy for Type 2 Diabetes



Mingrone G et al. NEJM 2012; 366:1577-1585.

Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes



Schauer P, et al. NEJM 2012; 366:1567-1576.

Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes (STAMPEDE)

Change from baseline to 12 months		Medical Therapy	Gastric Bypass	Sleeve Gastrectomy
HbA1c<6% (PEP)	n (%)	5 (12)	21 (42)	18 (37)
No diabetes drugs	n (%)	0	21 (42)	13 (27)
Δ Insulin use	%	51 to 38	46 to 4	45 to 8
Δ weight	Kg	-5.4 ± 8.0	-29.4 ± 8.9	-21.5 ± 8.5
Δ BMI	Kg/m^2	36.3 to 34.4	37.0 to 26.8	36.1 to 27.2
Δ HDL	%	+11.3±25.7	+28.5±22.7	+28.4±21.9
Δ Triglycerides	%	−14 (−40 to 3)	−44 (−65 to −16)	−42 (−56 to 0)
ΔCRP	%	−33.2 (−71 to 0)	−84 (−91 to −59)	−80 (−90 to −63)

Data are mean ± SD or median (IQR).
150 randomised. 41 (MT) 50 (GB) and 49 (SG) completed follow-up.

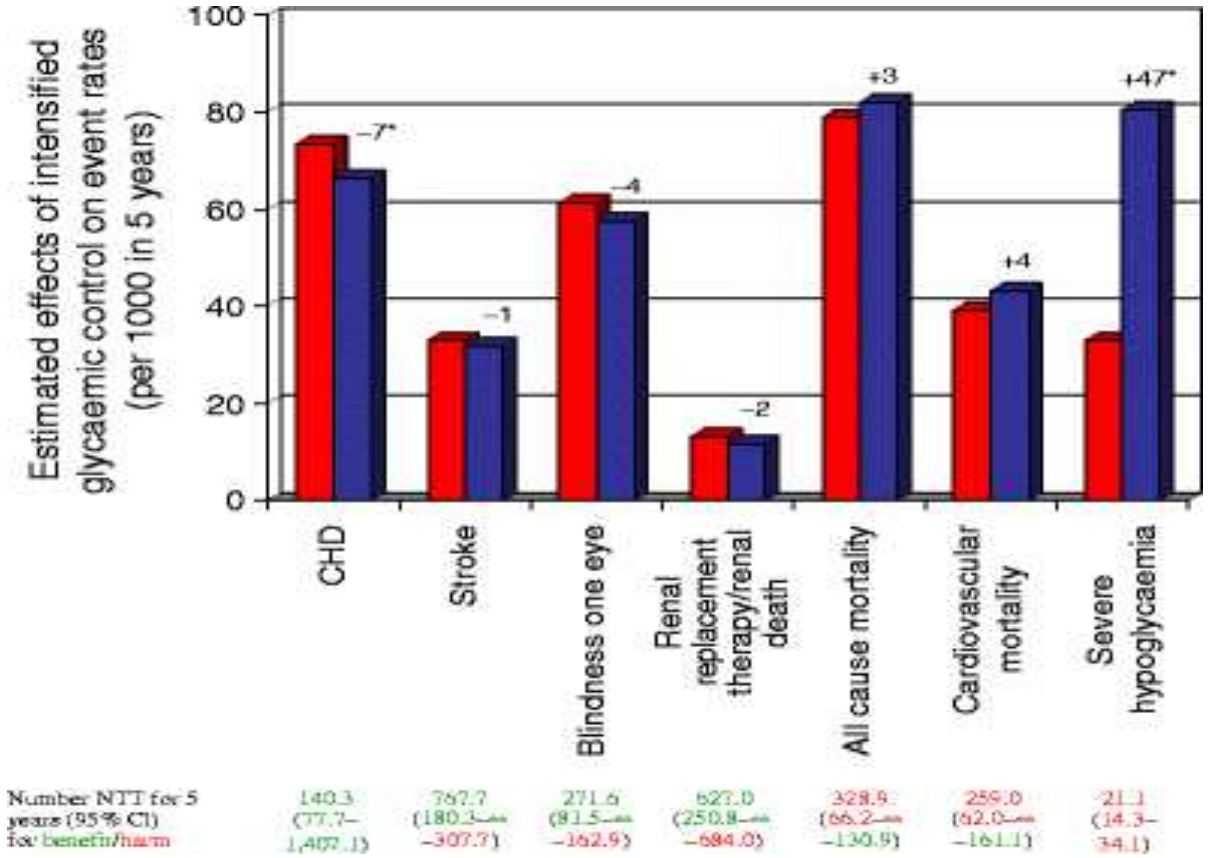
Schauer P, et al. NEJM 2012; 366:1567-1576.

Sleeve gastrectomy and type 2 diabetes mellitus: a systematic review.

27 studies
673 patients
Baseline mean BMI 47.4 kg/m(2)
Mean % EWL 47.3% (range 6.3-74.6%)
Mean follow-up 13.1 months (range 3-36).
DM “resolved” in 66.2%, improved in 26.9%, stable in 13.1%.
Mean decrease in HbA1c -1.7%

Gill RS, Birch DW, Shi X, Sharma AM, Karmali S.
World J Surg 2010.

Effect of intensive glycaemic control on macrovascular and microvascular events, mortality and serious hypoglycaemia in type 2 diabetes



% incidence rates are indicated in red over 5 years. The calculated effects of glucose lowering (from metaanalysis) are shown in blue, and absolute risk reductions /increases are shown at the top of the bars per 1,000 patients / 5 years. NNT for benefit or harm for 5 years is shown in green and red, respectively.
*Statistically significant treatment effects (CHD $p = 0.03$; severe hypoglycaemia $p < 0.00001$)

Gale E et al. Diabetologia 2010;53:2079

Diabetes relapse after RYGB

- 42 RYGB >3 yrs follow-up
- 64% initial remission + 36% improved
- At follow-up 24% (10) recurred or worsened
- Associated with: Lower preoperative BMI (47.9 versus 52.9 kg/m2; P=0.05)
  Regain of greater % of lost weight (37.7% vs 15.4%; =0.002)
  Greater weight loss failure rate (63% vs 14%; P=0.03)
  Higher postoperative glucose levels (P= 0.0002)
- Use of insulin or oral medication before RYGB were more likely to experience improvement rather than resolution (92% versus 8%, P <or=0.0001; and 85% versus 15%; P 0.0006, respectively).

DiGiorgi M, Rosen DJ, Choi JJ, Milone L, Schrope B, Olivero-Rivera L, Restuccia N, Yuen S, Fisk M, Inabnet WB, Bessler M. Surg Obes Relat Dis. 2010 May-Jun;6(3):249-53. Epub 2009 Oct

Diabetes relapse after RYGB

- N=177 RYGB. Follow-up 5 to 16 years.
- 157 (89%) initial “remission” of T2DM
- Decrease mean BMI (50.2 +/- 8.2 kg/m(2)) to 31.3 +/- 7.2 kg/m(2) postoperatively
- 20 patients (11.3%) did not have T2DM remission despite substantial weight loss
- Of 157 patients with initial remission, 68 (43%) subsequently developed T2DM recurrence.
- Remission of T2DM was durable in 56.9%.
- Durable (>5-year) resolution of T2DM was greatest in the patients who originally controlled their T2DM with diet (76%) or oral agents (66%). Relapse more likely in men, and those who regained weight.

Chikunguwo SM, Wolfe LG, Dodson P, Meador JG, Baugh N, Clore JN, Kellum JM, Maher JW. Surg Obes Relat Dis. 2010 May-Jun;6(3):254-9. Epub 2009 Nov 10

Principal outcome measures for bariatric surgery

Weight loss

Impact on comorbidity

Quality of life

Safety

Cost

Effects of bariatric surgery on quality of life

Quality of life studies:

Substantial short-medium term improvements for all common procedures in most Studies (eg using tools such as BAROS, HRQoL, SF36).

487 surgical and matched controls (SOS): Improved HRQL, peak at 6-12 months, reduced but maintained at 2 years (Karlsson et al IJO 1998).

Sick leave and disability pension:
369 surgical versus 371 control patients (SOS): Surgery – 35% more sickness in year 1, 10-14% less in year 2, and fewer thereafter (Narbro et al. IJO 1999).

156 surgical versus control Patients (SOS): Males – Marginal effect for up to 19 years. Females – no effect (Gripiteg et al IJO 2012).

Return to work:
Increased return to paid work after bariatric surgery (Hawkins et al Obes Surg 2007)

Effects of bariatric surgery on quality of life in people with diabetes

What are the benefits?

Treatment simplification?

Insulin withdrawal

Eating restrictions

Reduce health resource use?

Reduce long term complications?

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Weight loss
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13871 bariatric procedures in Italy,1996-2006

	AGB	VBG	RYGB	BPD
Number	612	4215	1106	1988
Mortality	0.1%	0.15%	0.54%	0.8%

Causes of death		
	Pulmonary embolism	38.2%
	Cardiac failure	17.6%
	Leaks	17.6%
	Respiratory failure	11.8%
	Pancreatitis	
	Cerebral ischaemia	
	Intestinal ischaemia	
	Bleeding gastric ulcer	
	Internal hernia	

Factors associated with mortality

Type of surgery ($p<0.001$), open surgery, long operating time, case load, preoperative diabetes, preoperative hypertension.

Morino M et al., Mortality after bariatric surgery: analysis of 13,871 morbidly obese patients from a national registry. Ann Surg. 2007 Dec;246(6):1002-7; 2007

Adverse Outcomes Within 30 Days After Surgery

Outcome	LAGB n=1198	Laparoscopic RYGB n=2975	Open RYGB n=437	*P* value
Death	0 (0%)	6 (0.2%)	9 (2.1%)	<0.001
DVT or VTE	3 (0.3%)	12 (0.4%)	5 (1.1%)	0.05
Tracheal reintubation	2 (0.2%)	12 (0.4%)	6 (1.4%)	0.004
Endoscopy	1 (0.1%)	45 (1.5%)	5 (1.1%)	<0.001
Operations				
Tracheostomy	0 (0%)	6 (0.2%)	5 (1.1%)	0.001
Percutaneous drain	0 (0%)	13 (0.4%)	3 (0.7%)	0.48
Abdominal surgery	9 (0.8%)	94 (3.2%)	15 (3.4%)	<0.001
Failure to discharge at 30 days	0 (0%)	13 (0.4%)	4 (0.9%)	0.02
Composite endpoint	12 (1.0%)	143 (4.8%)	34 (7.8%)	<0.0001

Composite endpoint: death; deep-vein thrombosis (DVT) or venous thromboembolism (VTE); reintervention with the use of a percutaneous, endoscopic, or operative technique; or failure to be discharged from the hospital within 30 days after surgery

Flum DR, et al. *N Engl J Med.* 2009;361(5):445-454.

Nutritional Deficiencies Reported After Malabsorptive Bariatric Surgery

Problem	**Mechanisms**
Anemia	Poor diet; malabsorption of iron, folic acid, vitamin B12, and ascorbate; non-adherence and lost to follow-up
Neurological syndromes	
Neuropathy	Deficiencies of thiamin, B12, copper and zinc; Guillain-Barre syndrome
Wernicke encephalopathy	
Osteomalacia	Vitamin D deficiency
Visual problems	Vitamin A deficiency
Pellagra	Niacin deficiency
Cardiomyopathy	Selenium deficiency
Acrodermatitis	Zinc deficiency
Neural tube defects	Maternal deficiencies of folic acid and vitamins
Fetal brain hemorrhage	

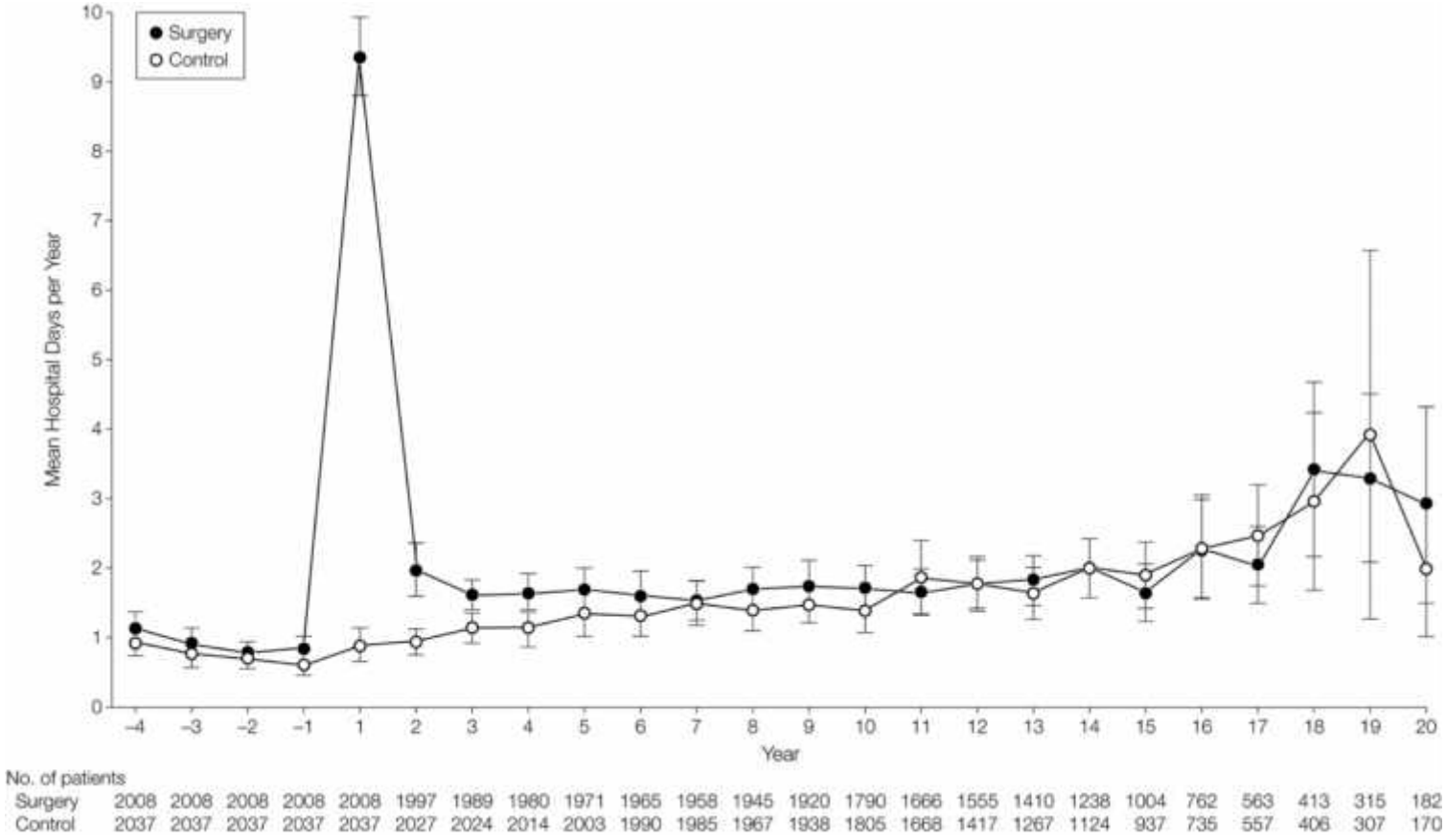
Long-term nutritional, medical and psychological complications of bariatric surgery

Complication	Main causal factors	Frequency [Ref.]
More common nutritional problems		
Anaemia	Iron deficiency	52% [51]
	Vitamin B_{12} deficiency	64% [51]
	Folic acid deficiency	38% [51]
	Vitamin C deficiency	34.6% [52]
	Bleeding	
Secondary hyperparathyroidism and metabolic bone disease	Vitamin D deficiency	51% [51]
	Hypocalcaemia	10% [51]
Peripheral neuropathy	Vitamin B_{12} deficiency	
	Thiamin deficiency	18.3% [52]
Unusual or rare nutritional problems		
Wernicke–Korsakoff syndrome	Thiamin deficiency	
Mixed sensorimotor disturbance	Copper deficiency	
Night blindness	Vitamin A deficiency	
Coagulopathy	Vitamin K deficiency	
Fetal coagulopathy	Maternal vitamin K deficiency	
Fetal neural tube defects	Maternal folate deficiency	
Rash, neurological	Vitamin E deficiency	
Oedema	Protein malnutrition	
Pellagra	Niacin deficiency	
Acrodermatitis	Zinc deficiency	
Cardiomyopathy	Selenium and thiamin deficiencies	
Other medical complications		
Hypoglycaemia	Hyperinsulinism	0.2% [59]
Hair loss	Multiple deficiencies?	
Renal stones	Oxalosis	
Liver failure	Steatohepatitis?	
Drug malabsorption	Intestinal bypass	
Psychological complications		
Persistent binge and night eating	Unmet expectations?	51% [61]
Depression	Unmet expectations?	23.4% [50]
Suicide and accidental death	Unmet expectations?	1.58 relative risk [62]

Micronutrient deficiencies and medical problems are procedure-specific and are principally complications of malabsorptive gastric and intestinal bypass surgery

Pinkney et al. Diabetologia 2010; 53: 1815-1822.

Hospital admissions after Bariatric Surgery in SOS trial



Neovius et al. 2012

Health Care Use During 20 Years after Bariatric Surgery in SOS trial

Outcome	Adjusted mean difference (95%CI)	P for difference
Hospital days year 1		
Surgery	7.8 (8.4-9.1)	**<0.001**
Control		
Hospital days years 2-6		
Surgery	0.5 (0.2-0.7)	**<0.001**
Control		
Hospital days years 7-20		
Surgery	0 (-0.3-0.3)	0.95
Control		
Non-Primary care outpatient visits years 2-6		
Surgery	0.3 (0.1-0.4)	**0.003**
Control		
Non-Primary care outpatient visits years 7-20		
Surgery	-0.2 (-0.4-1.0)	0.12
Control		
Drug costs years 7-20		
Surgery	-228 (-335 to -121)	**<0.001**
Control		

Neovius et al. JAMA 2012

Too lean a service?

A review of the care of patients who underwent bariatric surgery

NCEPOD 2012

Who assesses patients before bariatric surgery?

Table 4.7 Who assessed the patient prior to surgery?

Assessed by prior to surgery	Number of patients	%
Bariatric surgeon	384	96.5
Dietitian	326	81.9
Anaesthetist	268	67.3
Specialist nurse	248	62.3
Bariatric physician	89	22.4
Psychologist/Psychiatrist	70	17.6
Other	40	10.1
Respiratory physician	34	8.5

Table 4.3 Professionals attending the MDT

MDT attendees	Number of patients	%
Bariatric surgeon	236	93
Dietitian	230	91
Specialist nurse	207	81
Anaesthetist	114	45
Administrator	90	35
Bariatric physician	87	34
Psychologist/Psychiatrist	82	32
Other	18	7
Respiratory physician	14	6

*Answers may be multiple n/251

Adequacy of follow-up

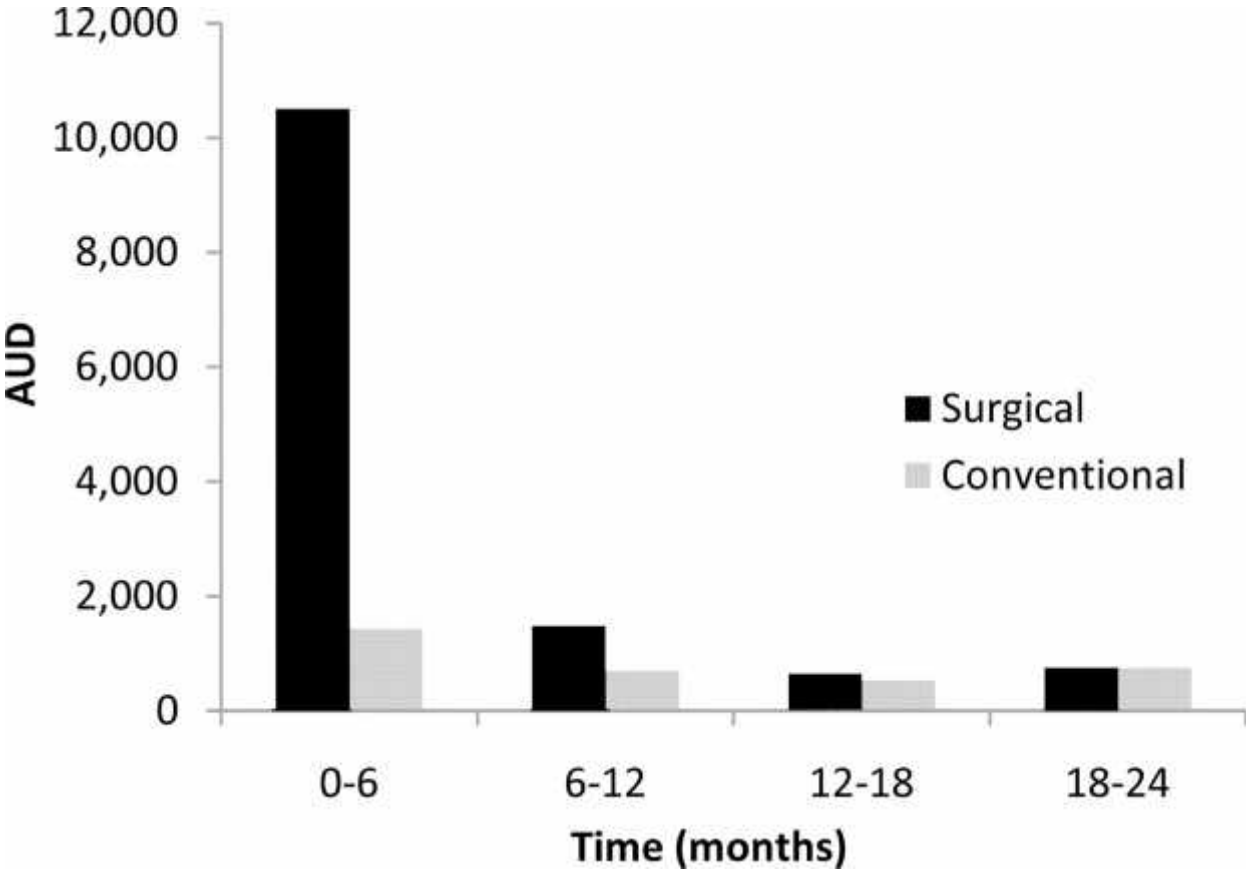
Table 6.5 Advisors' opinion on the adequacy of patient follow-up

Adequate follow-up	Number of patients	%
Yes	215	67.8
No	102	32.2
Subtotal	**317**	
Unknown	64	
Total	**381**	

Principal outcome measures for bariatric surgery

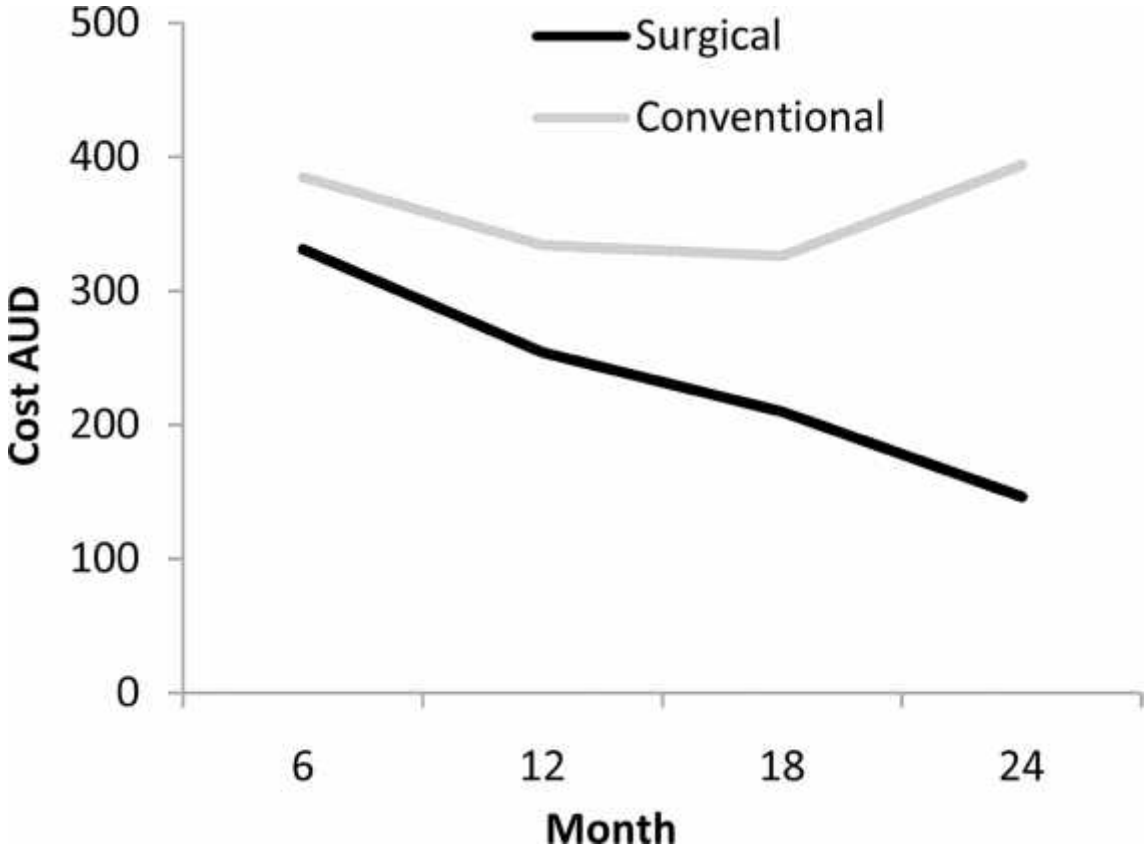
Weight loss
Impact on comorbidity
Quality of life
Safety
Cost

Mean total intervention cost over time by intervention group



Keating C L et al. Dia Care 2009;32:580-584

Mean medication cost per patient over time by intervention group.



Keating C L et al. Dia Care 2009;32:580-584

Cost-Effectiveness of Surgically Induced Weight Loss for the Management of Type 2 Diabetes: Modeled Lifetime Analysis

Years in diabetes remission over a lifetime 11.4 for surgery and 2.1 for conventional therapy.

Over the remainder of their lifetime, surgical and conventional therapy patients lived 15.7 and 14.5 discounted QALYs, respectively.

The mean discounted lifetime costs were 98,900 AUD per surgical and 101,400 AUD per conventional therapy patient.

Relative to conventional therapy, surgically induced weight loss was associated with a mean health care saving of 2,400 AUD and 1.2 additional QALYs per patient.

Keating D et al. Diabetes Care 2009

Uncertainties in economic analyses

Costs of training and configuring services for long term bariatric aftercare

Drug treatment costs

Frequencies and costs of side effects

Diabetes relapse incidence

Costs and frequency of late cosmetic procedures

IDF position statement 2012

- “Bariatric surgery is an appropriate treatment for people with type 2 diabetes and obesity (BMI>35) not achieving recommended treatment targets with medical therapies, especially where there are obesity-related comorbidities. Under some circumstances people with a BMI 30-35 should be eligible for surgery”
- Complementary to other medical therapies
- Importance of MDT approach
- Optimise perioperative medical management
- Long term nutritional support
- Importance of risk/benefit assessment
- Evidence based approach to the introduction of new techniques

BUT

- Many remaining research needs

Main gaps in the evidence base

Prediction of likely impact on diabetes
Prediction of diabetes relapse
Long term outcomes from different procedures
Mechanisms of diabetes improvement
Impact on natural history of complications
Optimum concomitant medical therapy
Effects on diabetes at lower BMI
Long term controlled studies
Health economics
Diabetes-specific outcome studies

A critical review of outcomes of bariatric surgery

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