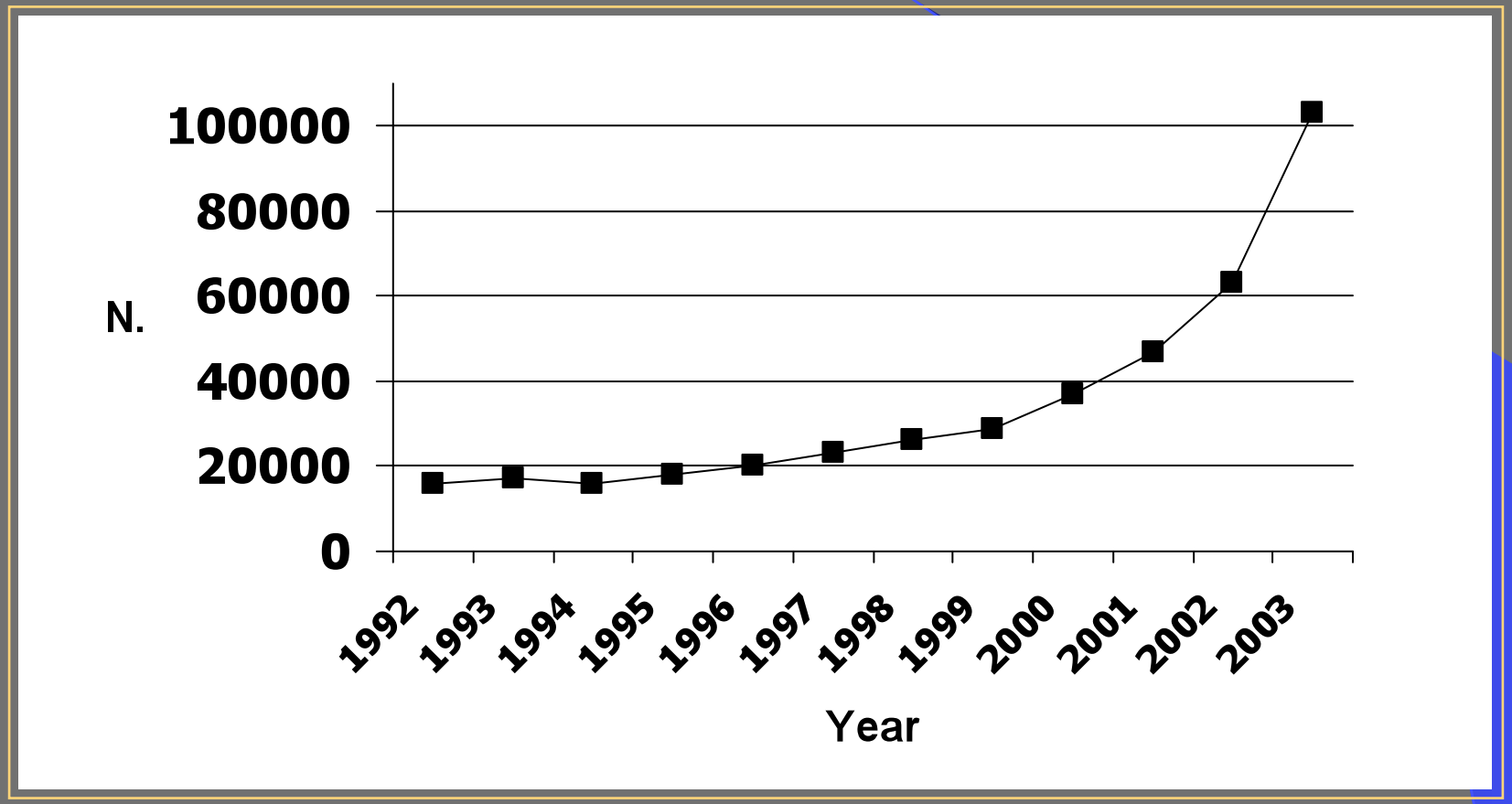
# IL RAZIONALE IN CHIRURGIA BARIATRICA: EBM e linee guida

Luca Busetto
Dipartimento di Scienze Mediche e Chirurgiche
Università degli Studi di Padova

**2° CORSO RESIDENZIALE TEORICO-PRATICO**
**"La gestione integrata del paziente bariatrico"**
**Sezione Triveneto Società Italiana dell'Obesità**
Trieste, 21-22 maggio 2010

## Estimated Number of Bariatric Operations performed in the United States, 1992-2003 (data from ASBS).




Steinbrook R. NEJM 2004;350:1075.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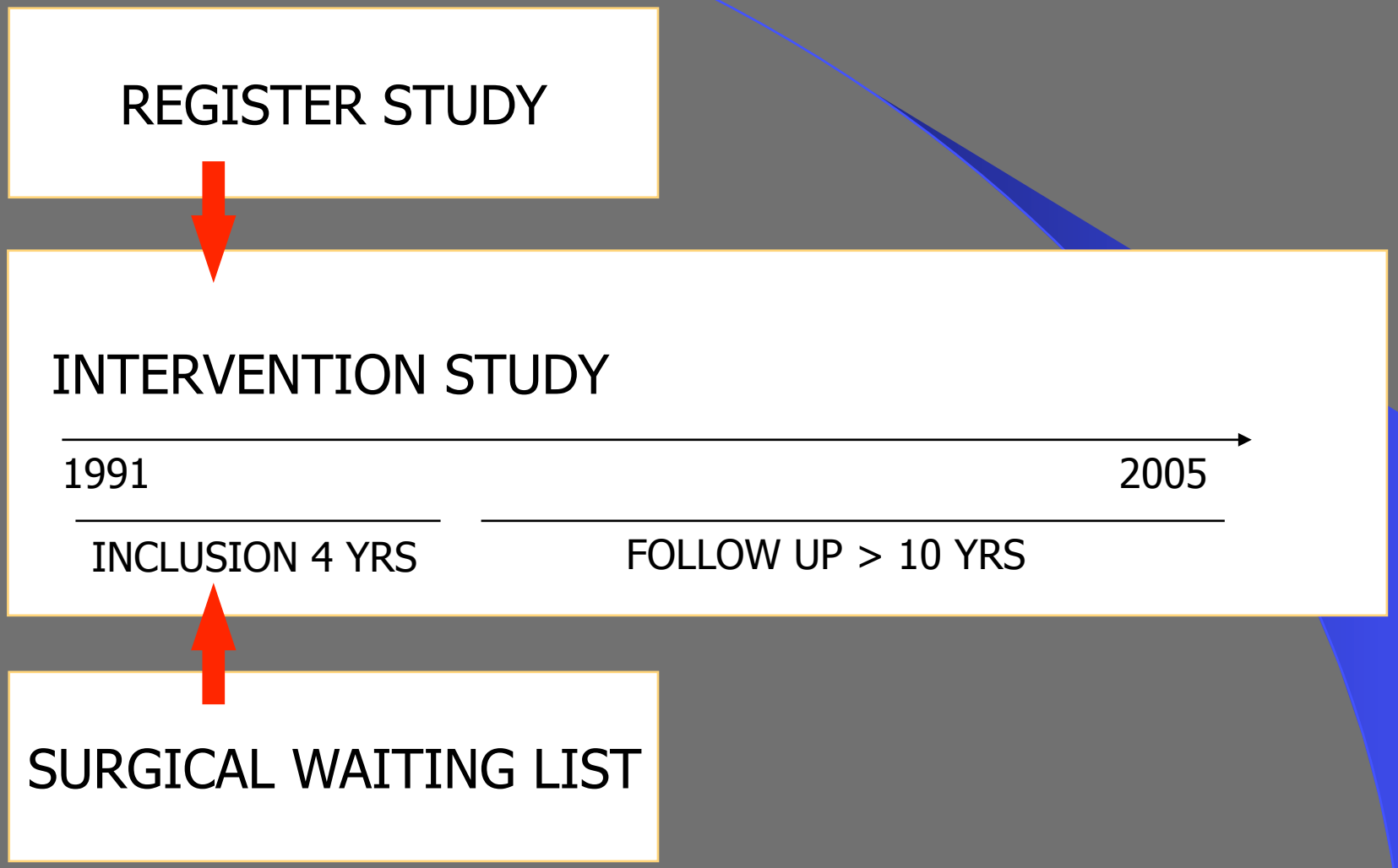
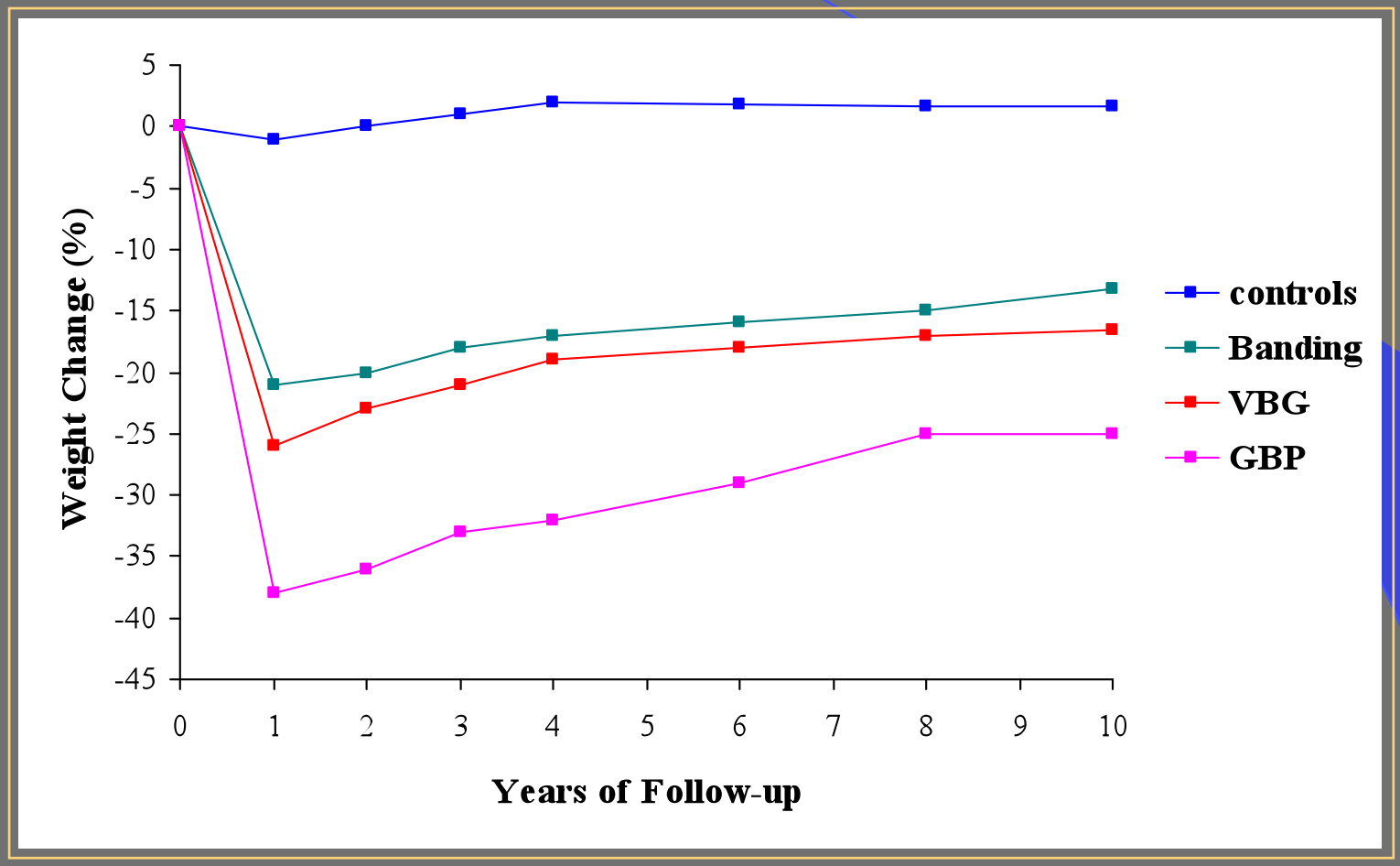
# Swedish Obese Subjects (SOS) Study




Sjostrom et al. Int J Obes 1992;16:465

# Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years after Bariatric Surgery




Sjostrom et al. NEJM 2004*; 351*:2683

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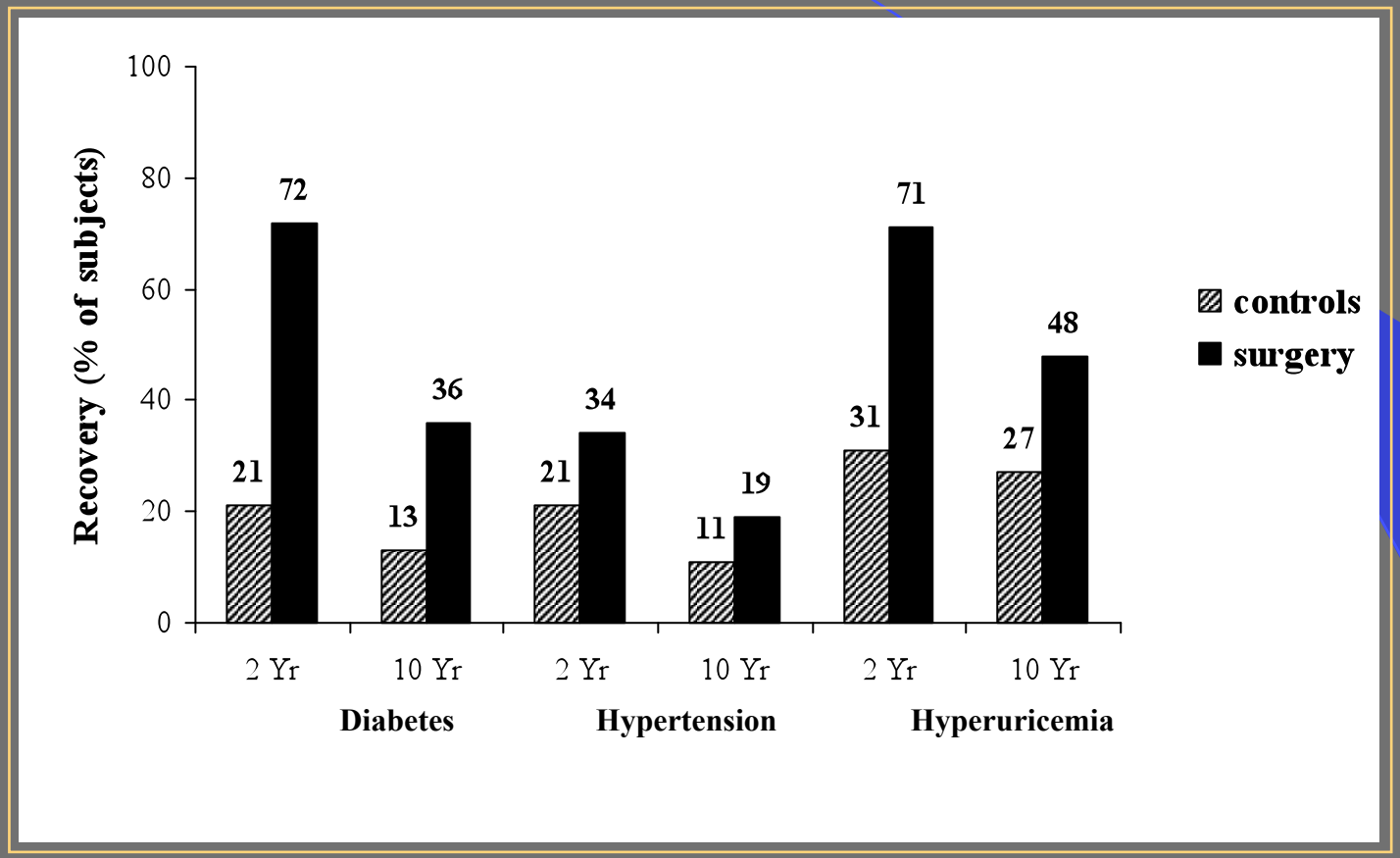
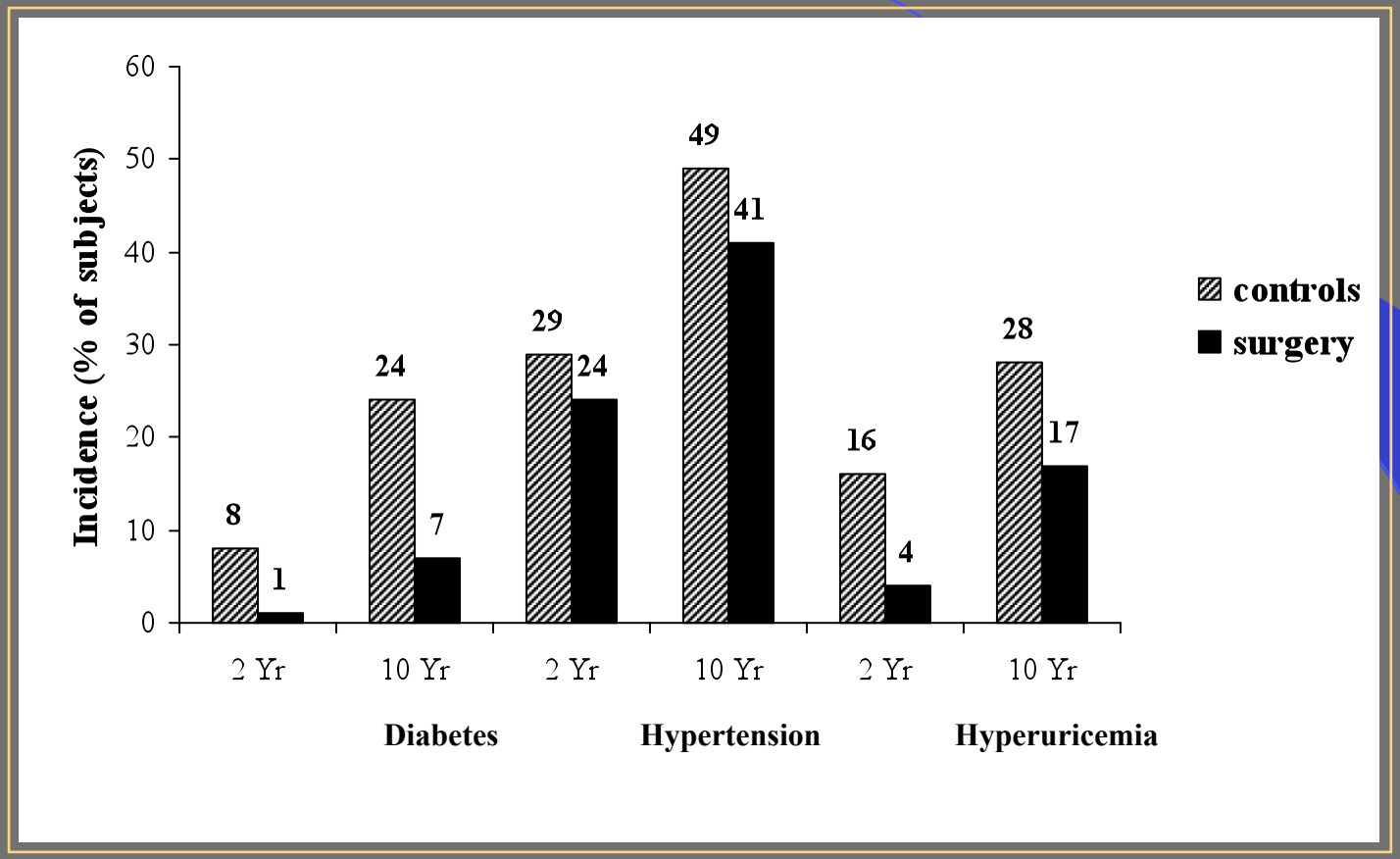



Sjostrom et al. NEJM 2004*; 351*:2683

# Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years after Bariatric Surgery




Sjostrom et al. NEJM 2004;*351*:2683

# Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial.

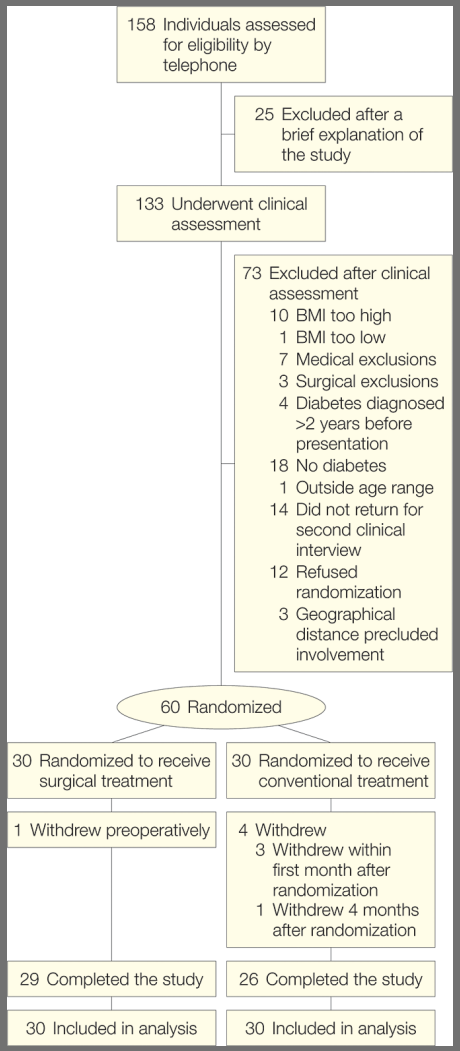



**Table 1.** Baseline Characteristics of Participants[a]

| Characteristic | Surgery (n = 30) | Conventional Therapy (n = 30) |
|---|---|---|
| Age, mean (SD), y | 46.6 (7.4) | 47.1 (8.7) |
| Men, No. (%) | 15 (50) | 13 (43) |
| Hypertension, No. (%) | 28 (93) | 27 (90) |
| Metabolic syndrome, No. (%) | 29 (97) | 29 (97) |
| Coronary artery disease, No. (%) | 0 | 1 (3) |
| BMI, mean (SD)[b] | 37.0 (2.7) | 37.2 (2.5) |
| Weight, mean (SD), kg | 105.6 (13.8) | 105.9 (14.2) |
| Waist circumference, mean (SD), cm | 114.1 (10.2) | 116.0 (10.0) |
| Waist to hip ratio, mean (SD) | 0.96 (0.09) | 0.96 (0.10) |
| Neck circumference, mean (SD), cm | 41.8 (4.0) | 42.4 (4.5) |
| Blood pressure, mean (SD), mm Hg | | |
| Systolic | 136.4 (15.6) | 135.3 (14.4) |
| Diastolic | 86.6 (9.4) | 84.5 (9.8) |
| $HbA_{1c}$, mean (SD), % | 7.8 (1.2) | 7.6 (1.4) |
| Plasma glucose, mean (SD), mg/dL | 156.7 (38.5) | 158.0 (48.7) |
| Plasma insulin, median (IQR), μIU/mL | 19.7 (16.5-27.5) | 18.7 (13.7-30.7) |
| Lipids, mean (SD), mg/dL | | |
| Total cholesterol | 201.8 (32.7) | 198.2 (56.7) |
| Triglycerides | 190.6 (106.6) | 188.7 (111.8) |
| HDL-C | 47.1 (10.1) | 48.1 (11.1) |
| Total cholesterol to HDL-C ratio | 4.41 (0.87) | 4.23 (1.11) |

Abbreviations: BMI, body mass index; $HbA_{1c}$, glycated hemoglobin; HDL-C, high-density lipoprotein cholesterol; IQR, interquartile range.
SI conversion factors: To convert glucose values to mmol/L, multiply by 0.0555; insulin to pmol/L, by 6.945; total cholesterol and HDL-C to mmol/L, by 0.0259; and triglycerides to mmol/L, by 0.0113.
[a] There were no statistically significant differences between the groups.
[b] Calculated as weight in kilograms divided by height in meters squared.

Dixon et al. JAMA 2008;299:316.

# Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial.

**Table 2.** Primary and Secondary Outcomes at 2 Years[a]

| Variable | Mean (SD) Surgery (n = 30) | Mean (SD) Conventional Therapy (n = 30) | Between-Group Difference, Mean (95% CI) | *P* Value |
|---|---|---|---|---|
| **Primary Outcome, No. (%)** | | | | |
| Remission of diabetes, No. (%) | 22 (73) | 4 (13) | RR for surgical remission, 5.5 (2.2 to 14.0) | <.001 |
| **Secondary Outcomes** | | | | |
| Weight, kg | 84.6 (15.8) | 104.8 (15.3) | | |
| Change, kg | −21.1 (10.5) | −1.5 (5.4) | −19.6 (−23.8 to −15.2) | <.001 |
| Waist circumference, cm | 95.8 (10.3) | 112.7 (10.3) | | |
| Change, cm | −17.9 (10.8) | −4.0 (9.1) | −13.9 (−19.0 to −8.7) | <.001 |
| Waist to hip ratio | 0.90 (0.06) | 0.95 (0.08) | | |
| Change | −0.06 (0.06) | −0.01 (0.06) | −0.05 (−0.07 to −0.007) | .02 |
| Blood pressure, mm Hg | | | | |
| Systolic | 130.4 (19.0) | 132.6 (17.7) | | |
| Change | −6.0 (17.9) | −1.7 (14.2) | −4.3 (−13.6 to 5.1) | .37 |
| Diastolic | 85.4 (7.0) | 83.1 (8.5) | | |
| Change | −0.7 (11.1) | −0.9 (11.1) | 0.2 (−5.4 to 6.0) | .92 |
| $HbA_{1c}$, % | 6.00 (0.82) | 7.21 (1.39) | | |
| Change | −1.81 (1.24) | −0.38 (1.26) | −1.43 (−2.1 to −0.80) | <.001 |
| Plasma glucose, mg/dL | 105.6 (30.3) | 139.6 (38.1) | | |
| Change | −51.2 (37.6) | −18.4 (41.2) | −32.8 (−53.1 to −12.3) | .002 |
| Plasma insulin, μIU/mL | 9.8 (4.7) | 24.1 (13.6) | | |
| Change | −12.4 (8.4) | 1.0 (14.8) | −13.4 (−19.6 to −7.3) | <.001 |
| HOMA IR[b] | 1.90 (0.73) | 3.50 (0.97) | | |
| Change, % | −45.5 (19.0) | −3.3 (35.4) | −42.2 (−57 to −26.8)[c] | <.001 |
| Total cholesterol, mg/dL | 205.4 (46.6) | 197.8 (59.3) | | |
| Change | 3.6 (51.6) | −0.4 (31.4) | 4.0 (−18.8 to 26.0) | .72 |
| Triglycerides, mg/dL | 118.9 (79.7) | 186.7 (127.2) | | |
| Change | −71.7 (92.9) | −2.1 (120.6) | −69.6 (−125.3 to −13.6) | .02 |
| HDL-C, mg/dL | 59.7 (13.6) | 50.7 (12.1) | | |
| Change | 12.6 (9.8) | 2.6 (6.1) | 10.0 (5.8 to 14.2) | <.001 |
| Total cholesterol to HDL-C ratio | 3.58 (1.00) | 4.1 (1.4) | | |
| Change | −0.82 (1.9) | −0.14 (1.04) | −0.68 (−1.24 to −0.14) | .02 |

Abbreviations: CI, confidence interval; $HbA_{1c}$, glycated hemoglobin; HDL-C, high-density lipoprotein cholesterol; HOMA IR, insulin resistance by homeostatic model assessment; LDL-C, low-density lipoprotein cholesterol; RR, relative risk.
SI conversion factors: see Table 1 footnote.
[a] Mean (SD) percentage change for participants with baseline values carried forward for those who dropped out of the study. A comparison of the actual change from baseline is also presented. Data include all 60 participants with baseline data carried forward for missing data.
[b] An indirect measure of insulin resistance calculated from levels of fasting plasma glucose and fasting C-peptide.[28]
[c] $P < .05$ calculated using independent *t* test.

Dixon et al. JAMA 2008;299:316.

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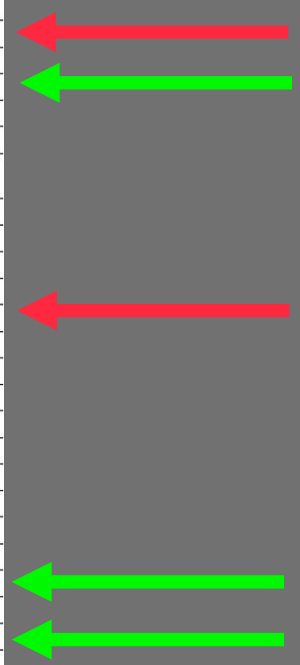

Dixon et al. JAMA 2008;299:316.

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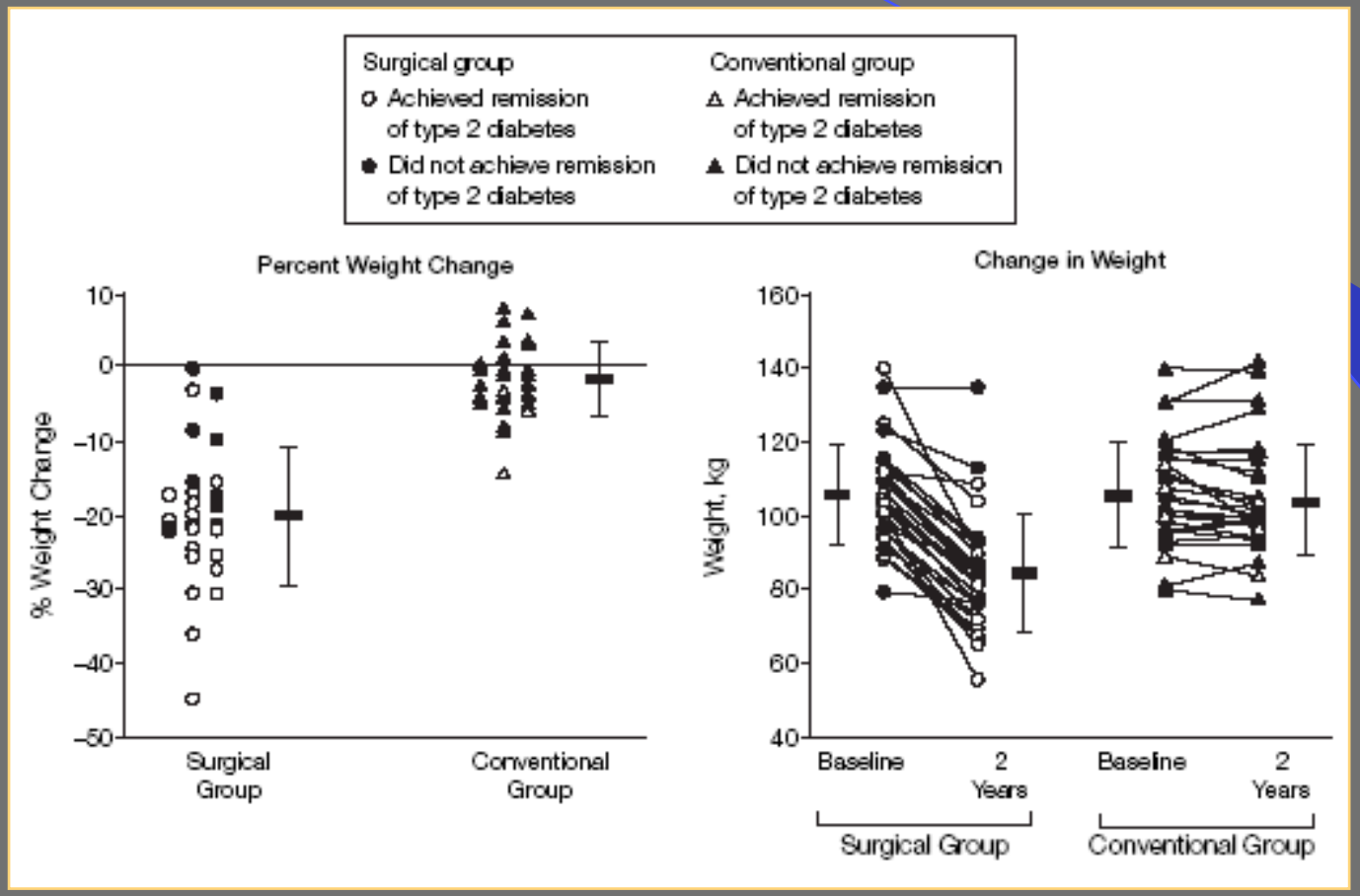
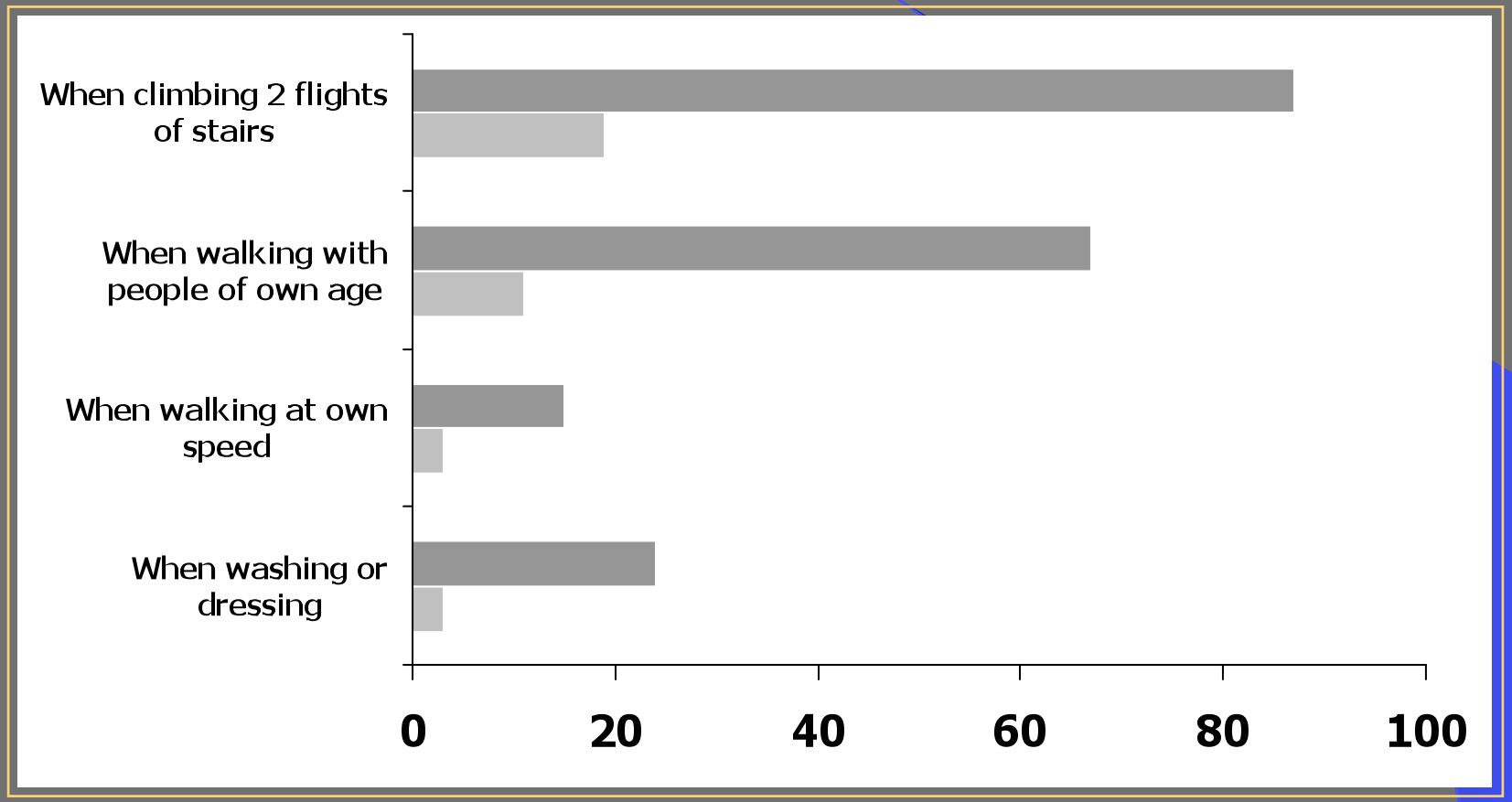



**RR of remission: 5.5 (95%CI 2.2-14.0) in surgical group**

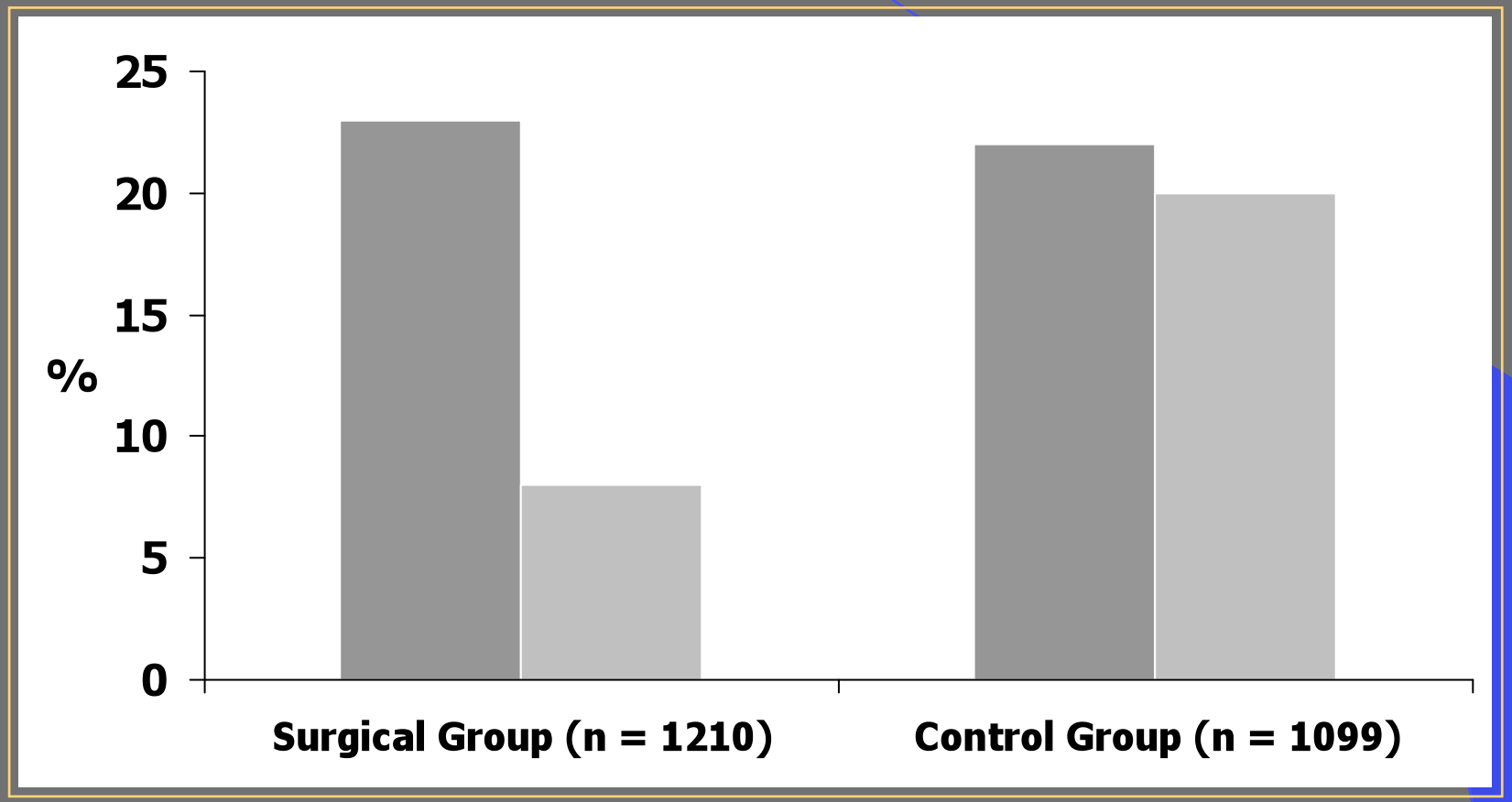
Dixon et al. JAMA 2008;299:316.

## Dyspnea at baseline and 2-year follow-up in 1210 surgically treated morbid obese patients.



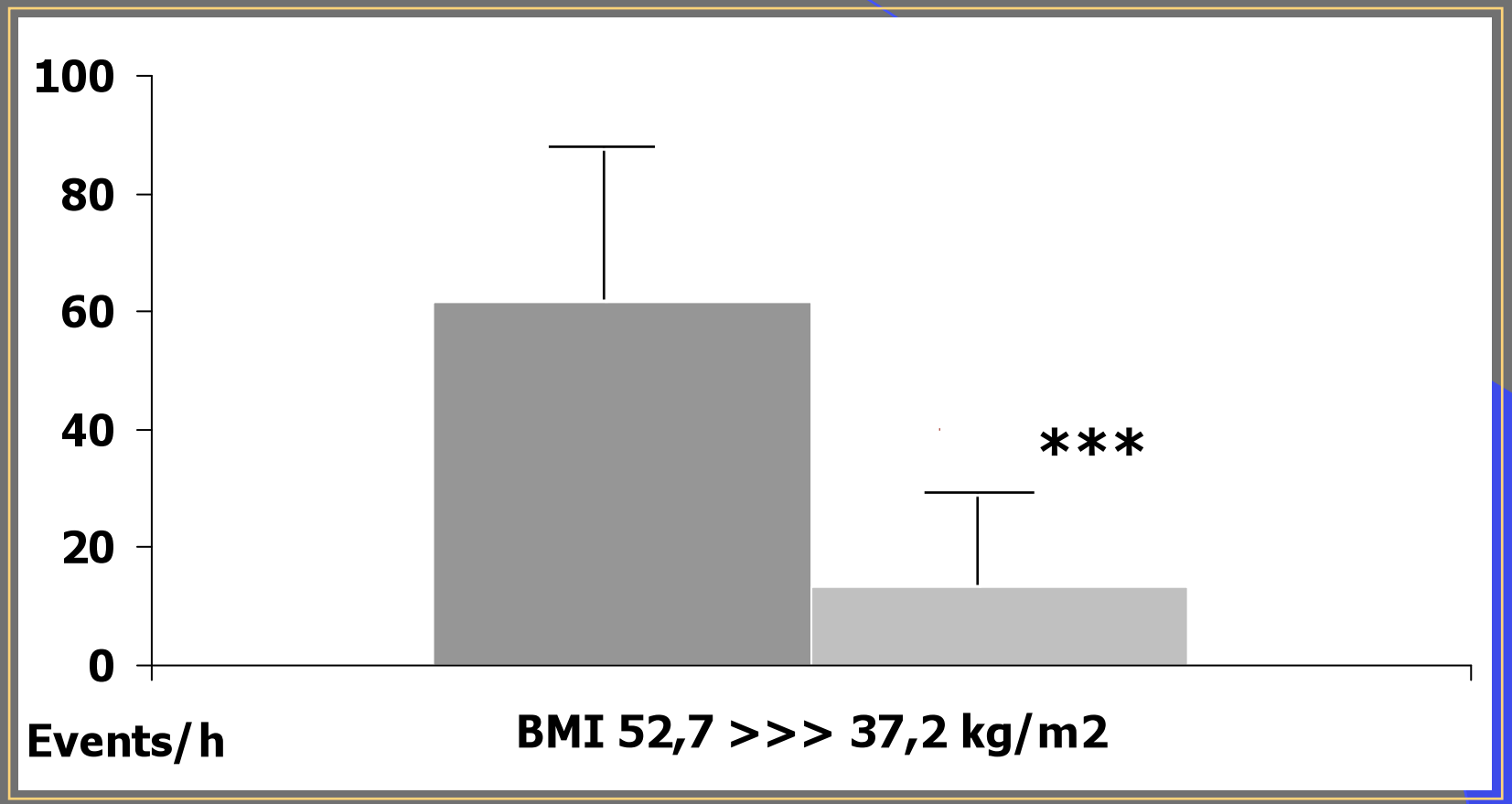

Karason et al. Arch Int Med 2000;160:1797

## Symptoms of Sleep Apnea at baseline and 2-year follow-up in surgical and control group.



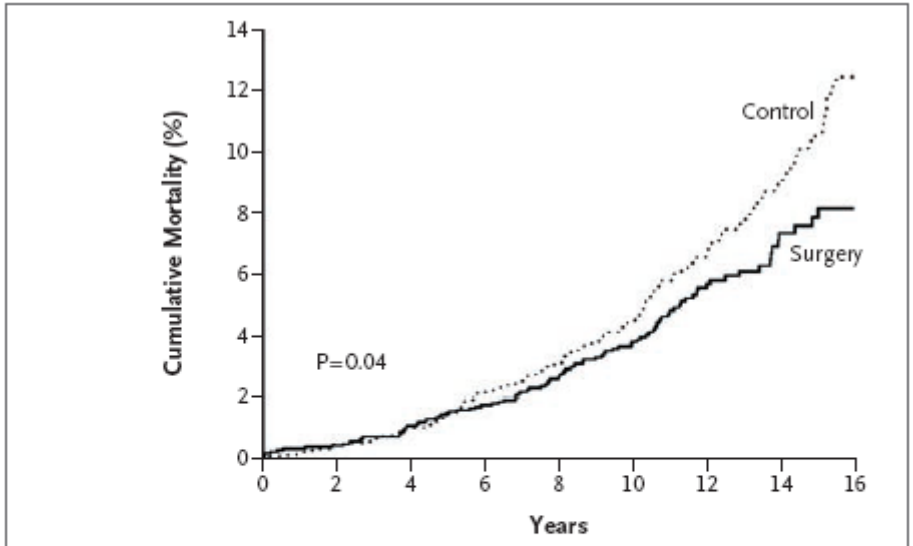

Karason et al. Arch Int Med 2000;160:1797

## AHI in 25 morbid obese patients with OSA before and after gastric banding.




Dixon et al. Int J Obes 2005;29:1048

# Effects of bariatric surgery on mortality in Swedish Obese Subjects.




**No. at Risk**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Surgery | 2010 | 2001 | 1987 | 1821 | 1590 | 1260 | 760 | 422 | 169 |
| Control | 2037 | 2027 | 2016 | 1842 | 1455 | 1174 | 749 | 422 | 156 |

**Figure 2. Unadjusted Cumulative Mortality.**

The hazard ratio for subjects who underwent bariatric surgery, as compared with control subjects, was 0.76 (95% confidence interval, 0.59 to 0.99; P=0.04), with 129 deaths in the control group and 101 in the surgery group.

**Table 2. Cause of Death.***

| Variable | Surgery Group (N=2010) | Control Group (N=2037) |
|---|---|---|
| | *no. of subjects* | |
| **Cardiovascular condition** | | |
| Any event | 43 | 53 |
| Cardiac | 35 | 44 |
| Myocardial infarction | 13 | 25 |
| Heart failure | 2 | 5 |
| Sudden death | 20 | 14 |
| Stroke | 6 | 6 |
| Intracerebral hemorrhage | 2 | 4 |
| Infarction | 1 | 2 |
| Subarachnoid bleeding | 3 | 0 |
| Other | 2 | 3 |
| Aortic aneurysm | 1 | 2 |
| Aortic thrombosis | 0 | 1 |
| Diabetic gangrene | 1 | 0 |
| **Noncardiovascular condition** | | |
| Any event | 58 | 76 |
| Tumor | 29 | 48 |
| Cancer | 29 | 47 |
| Meningioma | 0 | 1 |
| Infection | 12 | 3 |
| Thromboembolic disease | 5 | 7 |
| Pulmonary embolism | 4 | 7 |
| Vena caval thrombosis | 1 | 0 |
| Other | 12 | 18 |
| **Total no. of deaths** | 101 | 129 |

* During the first 90 days after study initiation, there were five deaths in the surgery group (four from peritonitis with organ failure and one sudden death) and two deaths in the control group (one from cancer of the pancreas and one from alcohol-related causes).

**Sjostrom et al. NEJM 2007; 357:741**

# Effects of bariatric surgery on cancer incidence in obese patients in Sweden (Swedish Obese Subjects Study): a prospective, controlled intervention trial.

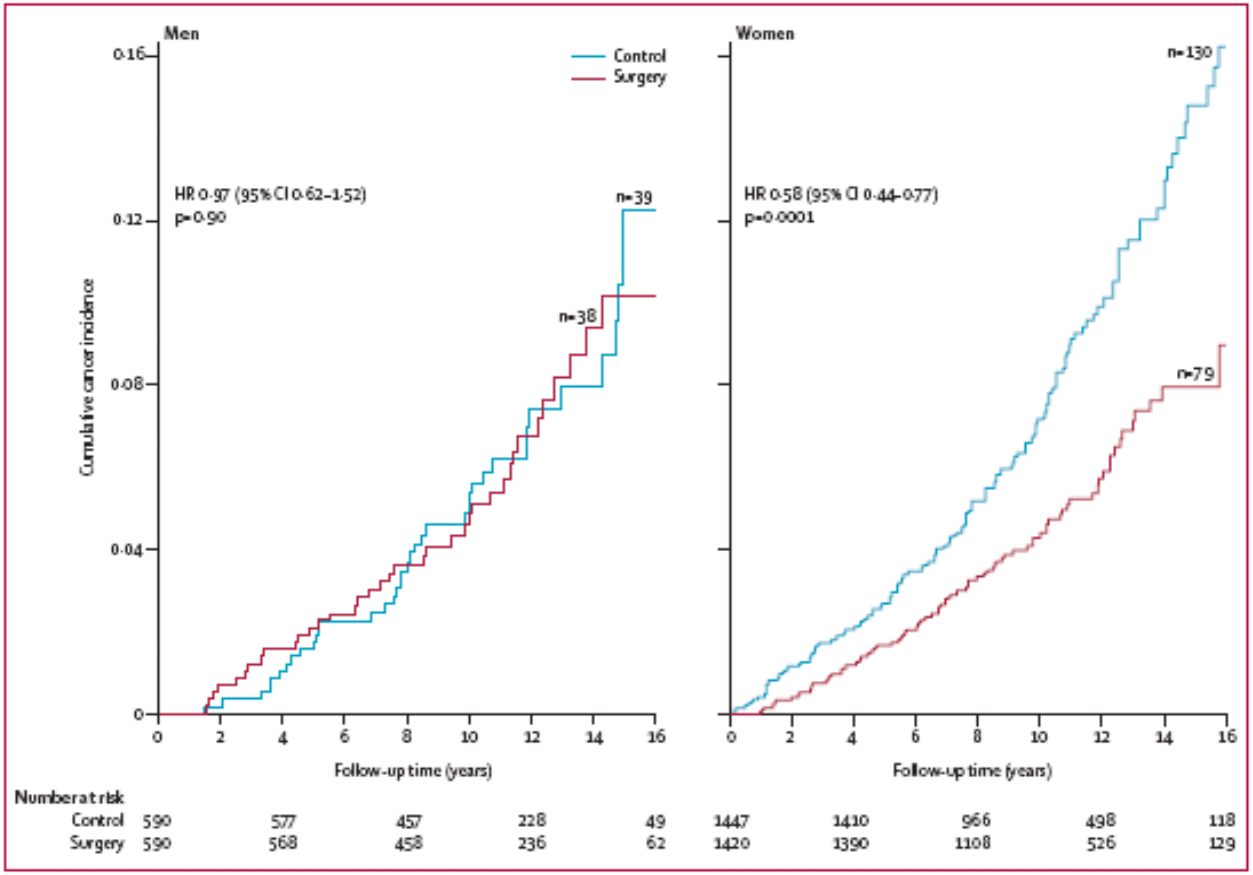
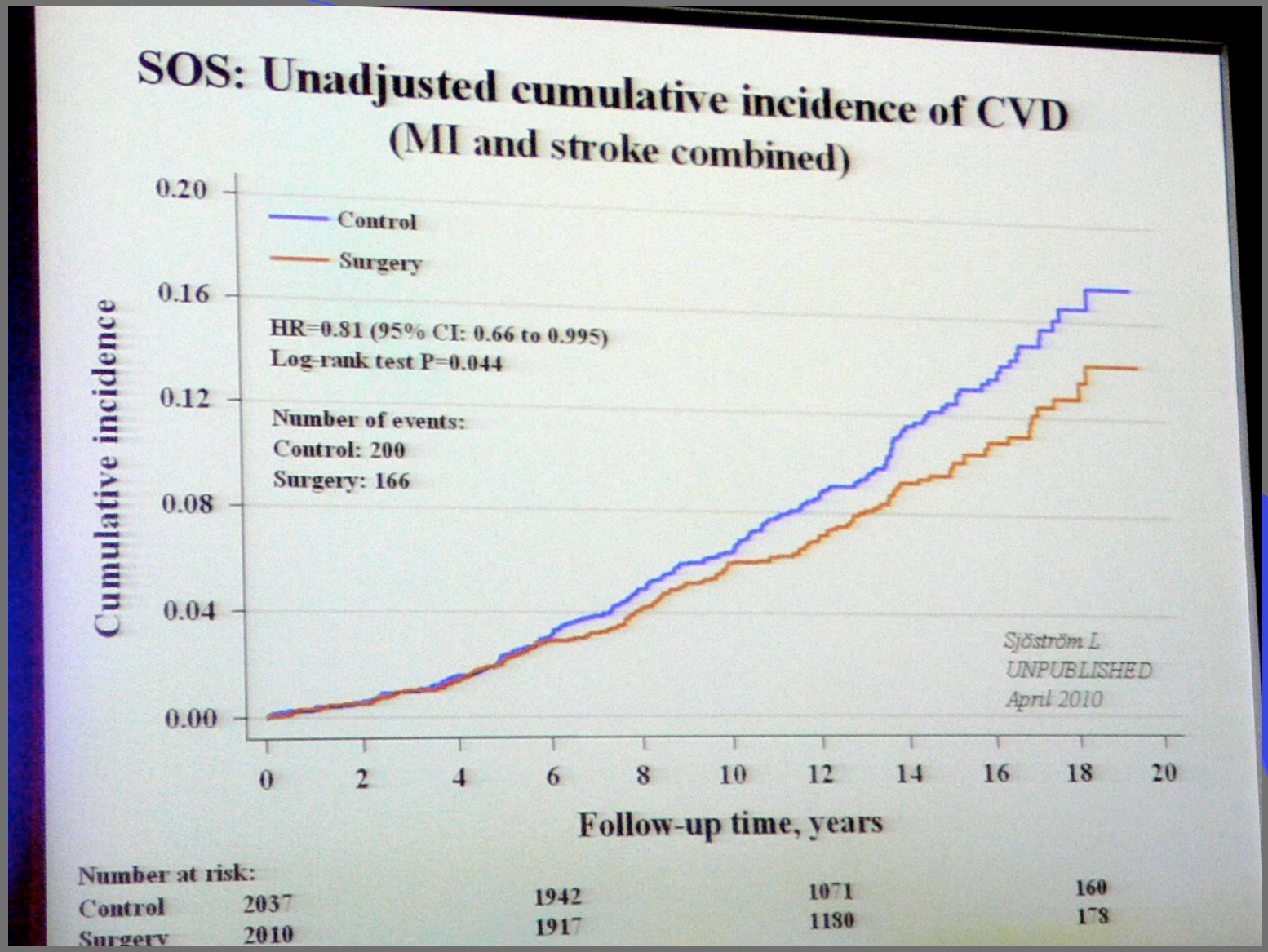



*Figure 3:* The unadjusted cumulative fatal plus non-fatal cancer incidence from the start of the intervention by sex in surgically treated obese individuals and in obese control individuals

**Sjostrom et al. Lancet Oncol 2009; 357:741**




**Sjostrom. 5° Congresso Nazionale SIO 15-17 aprile 2010**

# BARIATRIC SURGERY
# Retrospective mortality studies

| | FU | case and controls deaths | | ADJ- HR |
|---|---|---|---|---|
| Christou 2004 | 5 yrs | 7/1118 | 354/6210 | 0.11 (0.04–0.27) |
| Adams 2007 | 7 yrs | 213/7925 | 321/7925 | 0.60 (0.45–0.67) |
| Busetto 2007 | 6 yrs | 8/821 | 36/821 | 0.36 (0.16-0.79) |
| Peeters 2007 | 4 yrs | 5/1015 | 225/2119 | 0.27 (0.09-0.81) |

## Comparative long-term mortality after LAGB versus non surgical controls.

Bariatric surgery cohort:
Padova series 1994-2001: 1015 LAGB pts.
821 patients with BMI>40

OUTCOME STUDY (total and cause-specific mortality)

Death determined by direct or administrative searching

FOLLOW UP rate >97%; mean follow-up 5.6 / 7.2 yrs

Matched Controls:
4732 patients with BMI>40 from GISGO cohort
821 sex, age and bmi matched obese subjects

**Busetto et al. SOARD 2007; 3:496**

## Comparative long-term mortality after LAGB versus non surgical controls.

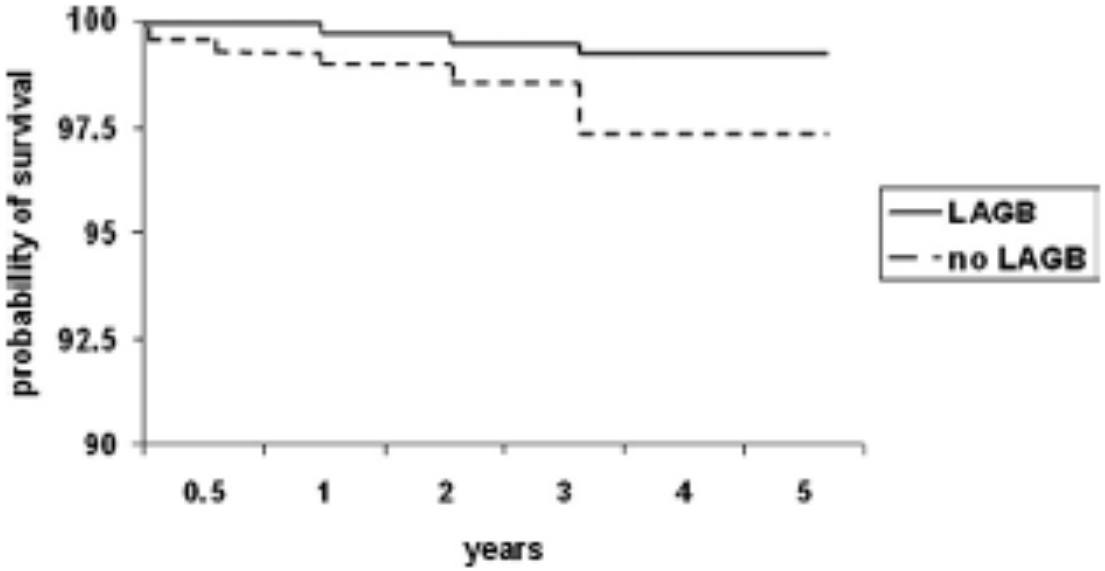



Fig. 2. Kaplan-Meier estimates of survival in 821 obese patients with BMI >40 kg/m$^2$ consecutively treated with LAGB at University of Padova and 821 morbidly obese patients observed at 6 tertiary obesity care Italian centers not using bariatric surgery (no LAGB).

**Adj. HR of death in LAGB group: 0.36 (95%CI: 0.16-0.79)**

**Busetto et al. SOARD 2007; 3:496**

# NIH Consensus Development Conference Statement Bethesda, March 25-27, 1991.

## INDICATIONS

- BMI > 40 kg/m$^2$ (BMI > 35 kg/m$^2$ if complicated obesity).
- Age : 18-60 years.
- Longstanding obesity (> 5 years).
- Previous failure of medical therapy.
- Able to participate to long-term follow-up.

## CONTRAINDICATIONS

- Treatable secondary obesity.
- Very high anaesthesiological risk.
- General conditions reducing life-expectancy.
- Severe psychiatric illnesses.
- Alcohol or drug abuse.
- Bulimia Nervosa.

Am J Clin Nutr 1992;55:615S

# Inter-disciplinary European guidelines on surgery of severe obesity (IFSO-EC, EASO, IOTF, ECOG)

## Indications for bariatric surgery

Patients in age groups from 18 to 60 years.

1. With BMI $\geqslant 40\,kg/m^2$
2. With BMI 35–40 $kg/m^2$ with co-morbidity in which surgically induced weight loss is expected to improve the disorder (such as metabolic disorders, cardio-respiratory disease, severe joint disease, obesity related severe psychological problems) etc. EL A, B, D[19–37]
3. BMI criterion may be the current BMI or a documented previous BMI of this severity. Note that
   (a) Weight loss as a result of intensified treatment before surgery (patients who reach a body weight below the required BMI for surgery) is not a contraindication for the planned bariatric surgery.
   (b) Bariatric surgery is indicated in patients who exhibited a substantial weight loss in a conservative treatment program but started to gain weight again.

To be considered for surgery, patients must have failed to lose weight or to maintain long-term weight loss, despite appropriate non-surgical medical care. EL B, D.[20,37]

Patients must have shown their compliance with medical appointments.

## Contraindications specific for bariatric surgery

1. Absence of a period of identifiable medical management
2. Patient who is unable to participate in prolonged medical follow-up
3. Non-stabilized psychotic disorders, severe depression and personality disorders, unless specifically advised by a psychiatrist experienced in obesity
4. Alcohol abuse and/or drug dependencies
5. Diseases threatening life in the short term
6. Patients who are unable to care for themselves and have no long-term family or social support that will warrant such care

**Int J Obesity 2007;31:569-77**


Società Italiana di
Chirurgia dell'Obesità
e delle malattie metaboliche

# LINEE GUIDA E STATO DELL'ARTE DELLA CHIRURGIA BARIATRICA E METABOLICA IN ITALIA

www.sicob.org

# American Diabetes Association Clinical Practice Recommendations 2009.

The new "Bariatric surgery" section contains the following recommendations.

- Bariatric surgery should be considered for adults with BMI>35 kg/m2 and type 2 diabetes, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy. (B)

- Patients with type 2 diabetes who have undergone bariatric surgery need life-long lifestyle support and medical monitoring. (E)

- Although small trials have shown glycemic benefit of bariatric surgery in patients with type 2 diabetes and BMI 30–35 kg/m2, there is currently insufficient evidence to generally recommend surgery in patients with BMI<35 kg/m2 outside of a research protocol. (E)

- The long-term benefits, cost effectiveness, and risks of bariatric surgery in individuals with type 2 diabetes should be studied in well designed randomized controlled trials with optimal medical and lifestyle therapy as the comparator. (E)

**Diabetes Care 2009;32:S3.**

# STANDARD ITALIANI PER LA CURA DEL DIABETE MELLITO

## 2009-2010

www.siditalia.it

Issue date: December 2006

# Obesity

NHS
National Institute for Health and Clinical Excellence

Bariatric surgery is recommended as a treatment option for people with obesity if all of the following criteria are fulfilled:

- they have a BMI of 40 kg/m$^2$ or more, or between 35 kg/m$^2$ and 40 kg/m$^2$ and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months
- the person has been receiving or will receive intensive management in a specialist obesity service
- the person is generally fit for anaesthesia and surgery
- the person commits to the need for long-term follow-up.

www.nice.org.uk

Issue date: December 2006

# Obesity

NHS
National Institute for Health and Clinical Excellence

Surgery for obesity should be undertaken only by a multidisciplinary team that can provide:

- preoperative assessment, including a risk–benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)
- information on the different procedures, including potential weight loss and associated risks
- regular postoperative assessment, including specialist dietetic and surgical follow-up
- management of comorbidities
- psychological support before and after surgery
- information on, or access to, plastic surgery (such as apronectomy) where appropriate

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