Evaluation of Current Eligibility Criteria for Bariatric Surgery

Diabetes prevention and risk factor changes in the Swedish Obese Subjects (SOS) study

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OBJECTIVE—Patients with a BMI <35 kg/m² and patients with a BMI between 35 and 40 kg/m² without comorbidities are noneligible by current eligibility criteria for bariatric surgery. We used Swedish obese subjects (SOS) to explore long-term outcomes in noneligible versus eligible patients.

RESEARCH DESIGN AND METHODS—The SOS study involved 2,010 obese patients who underwent bariatric surgery (68% vertical-banded gastroplasty, 19% banding, and 13% gastric bypass) and 2,037 contemporaneously matched obese controls receiving usual care. At inclusion, the participant age was 37–60 years and BMI was ≥34 kg/m² in men and ≥38 kg/m² in women. The effect of surgery was assessed in patients that do (n = 3,814) and do not (n = 233) meet current eligibility criteria. The date of analysis was 1 January 2012. The follow-up time was up to 20 years, with a median of 10 years.

RESULTS—Cardiovascular risk factors were significantly improved both in noneligible and eligible individuals after 10 years of follow-up. Surgery reduced the diabetes incidence in both the noneligible (adjusted hazard ratio 0.33 [95% CI 0.13–0.82], P = 0.017) and eligible (0.27 [0.22–0.33], P < 0.001) groups. We could not detect a difference in the effect of surgery between the groups (adjusted interaction P value = 0.713).

CONCLUSIONS—Bariatric surgery drastically reduced the incidence of type 2 diabetes both in noneligible and eligible patients and improved cardiovascular risk factors in both groups. Our results show that strict BMI cutoffs are of limited use for bariatric surgery prioritization if the aim is to prevent diabetes and improve cardiovascular risk factors.
bariatric surgery and 2,037 contemporaneously matched obese controls received conventional care. The selection of these individuals has previously been described in detail (3–5). The inclusion criteria were 37–60 years of age and BMI ≥34 kg/m² for men and ≥38 kg/m² for women before or at a matching examination. Thus, individuals that were noneligible by current eligibility criteria for bariatric surgery could be included in the study.

The BMI inclusion criteria in SOS were based on a 100% increase in mortality as compared with BMI 20–25 kg/m² in men and women of a Norwegian population study (20), representing the most valid Nordic data available at the start of the SOS study. The exclusion criteria were minimal and were aimed at obtaining operable individuals (21).

In the surgery group, 376 individuals underwent nonadjustable or adjustable banding, 1,369 underwent vertical banded gastroplasty, and 265 underwent gastric bypass. Control individuals were given the customary treatment for obesity at their primary healthcare centers, i.e., essentially the standard nonsurgical obesity treatment in Sweden.

Physical examinations were performed at matching and baseline and repeated after 0.5, 1, 2, 3, 4, 6, 8, 10, 15, and 20 years. Biochemical analyses were performed at matching and baseline examinations and after 2, 10, 15, and 20 years.

The cutoff date for the current analysis was 1 January 2012. Seven regional ethics review boards approved the study protocol, and informed consent was obtained from all participants.

Criteria for comorbidities
In this report, selected comorbidities based on laboratory and physical examinations and also on self-reported medications at the time of the matching examination were examined. These comorbidities included hypertension, type 2 diabetes, and dyslipidemia and were diagnosed based on cutoff values from international expert reports (22–24) or the use of medication for the specific condition. Patients were given the diagnosis of type 2 diabetes when having a fasting venous whole blood glucose of ≥6.1 mmol/L (corresponding to fasting plasma glucose ≥7.0 mmol/L) (22) and/or self-reported treatment with antidiabetic drugs, including insulin. The study was started before repeated measurements were routinely used for the diagnosis of type 2 diabetes, and blood glucose was therefore measured only once per study occasion. The criteria for hypertension were systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg (23) and/or presence of antihypertensive treatment. Dyslipidemia was defined as having serum cholesterol ≥5.2 mmol/L and/or serum triglycerides ≥1.7 mmol/L (24) and/or using lipid-lowering medication regularly.

Patient groups in SOS divided by surgery eligibility criteria
Based on current eligibility criteria, patients were divided into eligible and noneligible individuals using data from the matching examination: eligible, BMI ≥40 kg/m² or BMI 35 to <40 kg/m² and at least one of the comorbidities defined above; noneligible, BMI 35 to <40 kg/m² with no comorbidities or BMI <35 kg/m².

Statistics
To describe group characteristics at matching, mean values and SDs were used.

A general linear model was used to assess differences in the effect of treatment on outcome variables in criteria groups by inclusion of an interaction term (i.e., product of type of treatment [surgery or control] and criteria group [noneligible or eligible]). Δ values from baseline to 10 years were used, and the model was adjusted for sex and age.

Time to diagnosis of type 2 diabetes was calculated from the study inclusion date. Study patients with a type 2 diabetes diagnosis at the matching examination or at baseline were excluded from the incidence analysis. Study patients that were not diagnosed with type 2 diabetes during the study were treated as censored observations at the time of dropout from the study or at the end of follow-up. Time to diabetes in the two treatment groups was analyzed using Kaplan-Meier estimates of cumulative incidence rates. A Cox proportional hazards model was used to evaluate the effect of surgery on diabetes incidence in the different selection criteria groups, unadjusted or adjusting for sex and age at baseline.

The expected number of surgeries needed to prevent one diabetes event over 15 years (numbers needed to treat) was calculated in different groups as the reciprocal of the absolute risk difference.

| Variable | Noneligible | Surgery | Control |
|----------|-------------|---------|---------|
| n        | 104         | 129     |         |
| Age (years) | 44.6 ± 5.8 | 44.6 ± 5.8 |         |
| Sex (M/F) (%) | 53/47       | 43/57   |         |
| Weight (kg) | 108.6 ± 11.7 | 106.3 ± 11.2 | 119.8 ± 16.1 |
| Height (m) | 1.74 ± 0.11 | 1.73 ± 0.10 | 1.69 ± 0.09 |
| BMI (kg/m²) | 36.0 ± 2.5 | 35.5 ± 2.3 | 42.1 ± 4.2 |
| Waist (cm) | 116 ± 7 | 115 ± 8 | 125 ± 11 |
| Hip (cm) | 116 ± 7 | 117 ± 7 | 126 ± 10 |
| WHR | 0.994 ± 0.068 | 0.986 ± 0.080 | 0.987 ± 0.074 |
| Sagittal diameter (cm) | 25.8 ± 2.9 | 25.4 ± 2.8 | 28.6 ± 3.6 |
| SBP (mmHg) | 130 ± 16 | 129 ± 15 | 141 ± 19 |
| DBP (mmHg) | 83 ± 12 | 80 ± 10 | 88 ± 11 |
| B-glucose (mmol/L) | 6.1 ± 1.1 | 5.1 ± 2.5 | 5.1 ± 1.9 |
| S-insulin (pmol/L) | 123.6 ± 80.7 | 115.7 ± 90.0 | 149.7 ± 100.7 |
| s-TG (mmol/L) | 1.97 ± 1.36 | 1.97 ± 1.73 | 2.24 ± 1.44 |
| s-Chol (mmol/L) | 5.3 ± 1.1 | 5.4 ± 1.1 | 5.9 ± 1.1 |
| s-HDL (mmol/L) | 1.32 ± 0.31 | 1.30 ± 0.35 | 1.36 ± 0.32 |
| s-AST (units/L) | 23.0 ± 9.7 | 23.7 ± 14.4 | 25.0 ± 14.9 |
| s-ALT (units/L) | 36.0 ± 23.1 | 34.0 ± 21.2 | 35.9 ± 21.7 |
| Comorbidity, n (%) | 53 (51.5) | 72 (55.8) | 1,850 (97.1) |
| Type 2 diabetes, n (%) | 9 (8.7) | 15 (11.6) | 278 (14.6) |
| Hypertension, n (%) | 35 (34.0) | 38 (29.5) | 1,361 (71.4) |
| Dyslipidemia, n (%) | 46 (44.2) | 68 (52.7) | 1,609 (84.5) |

ALT, alanine aminotransferase; AST, aspartate aminotransferase; Chol, cholesterol; DBP, diastolic blood pressure; SBP, systolic blood pressure; TG, triglyceride; WHR, waist-to-hip ratio.
(obtained from Kaplan-Meier estimates over 15 years) between surgery and control individuals.

All P values are two-sided, and \( P < 0.05 \) was considered as statistically significant. In all calculations, the intention-to-treat principle was applied in that each participant remained in the original treatment group. Statistical analyses were carried out using the Stata statistical package 10.1 (Stata Statistical Software: Release 10.1, StataCorp LP, College Station, TX).

**RESULTS**

**Characteristics of the patients in the noneligible and eligible groups**

When the 4,047 SOS patients were divided by whether they fulfilled the current selection criteria for bariatric surgery, 233 patients were noneligible (Table 1). As expected, the noneligible group had lower rates of diabetes, hypertension, and/or dyslipidemia (Table 1). The noneligible patients had a median BMI of 35.7 (IQR 34.1–38.2) kg/m\(^2\), whereas the eligible group had a median BMI of 41.0 (IQR 38.5–44.0) kg/m\(^2\). Out of the 4,047 patients, 3,335 patients without diabetes at both matching and baseline were included in the analysis on diabetes incidence (Table 2). On the date of analysis (1 January 2012), the median follow-up time was 10 (range 0–20) years. The follow-up rates, after accounting for mortality, were 89% at 2 years, 73% at 10 years, and 53% at 15 years. In addition to dropout and mortality, the low number of participants at year 15 is explained by the fact that not all study participants had reached that follow-up point at the time of data analysis (7).

**Effect of bariatric surgery on risk factors in noneligible and eligible patients**

Body weight and cardiovascular risk factors, such as insulin, lipids, and blood pressure, were significantly improved in both noneligible and eligible patients after 10 years of follow-up (Table 3). Furthermore, using the analysis of the eligibility treatment interaction, we could not detect a difference in treatment effect between noneligible and eligible patients with respect to most cardiovascular risk factors and BMI. The exceptions were slightly smaller effects on blood glucose and hip circumference and a greater effect on waist-to-hip ratio and alanine aminotransferase (ALT) in the noneligible group (Table 3).

**Diabetes incidence in the noneligible and eligible groups**

The effect of bariatric surgery on diabetes incidence was similar in noneligible and eligible patients. Out of the 3,335 patients without type 2 diabetes at study start, 204 were noneligible (Table 2). After 15 years of follow-up, bariatric surgery reduced the cumulative incidence of diabetes in both the noneligible (adjusted hazard ratio 0.33 [95% CI 0.13–0.82], \( P = 0.017 \)) and eligible groups (0.27 [0.22–0.33], \( P < 0.001 \)), and the treatment effect on diabetes incidence was not significantly different between the groups (adjusted interaction \( P = 0.713 \)) (Fig. 1). Of the nondiabetic participants in the noneligible group, 12% of surgery patients and 13% of controls had impaired fasting glucose at study start (7). In the eligible group, the percentages were 17 and 18, for surgery and control patients, respectively. The number needed to treat to prevent one case of type 2 diabetes over 15 years was not significantly different between noneligible (6.9 [3.5–296]) and eligible (4.1 [3.5–5.1]) groups.

**CONCLUSIONS**—In this explorative analysis, we investigated whether the long-term effects of bariatric surgery on the incidence of type 2 diabetes and changes in cardiovascular risk factors differ between patients that do or do not meet current eligibility criteria. Our results show that bariatric surgery reduces diabetes incidence by 73% in eligible SOS individuals after 15 years of follow-up. However, bariatric surgery reduced diabetes incidence by 67% in noneligible patients, and the number needed to treat to prevent one diabetes event over 15 years was low in both groups, reflecting the strong effect of surgical treatment. Improvements in body weight, lipids, blood pressure, glucose, and insulin were significant not only in the eligible group but also in the noneligible group after 10 years of follow-up. Hence, our results clearly show that nondiabetic patients may also benefit from bariatric surgery.

In this report, there was a marked reduction of diabetes incidence 15 years after the surgical intervention, both in...

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**Table 2—Characteristics and comorbidities in noneligible and eligible SOS study participants without type 2 diabetes at study start**

| Variable          | Noneligible | Control | Eligible | Control |
|-------------------|-------------|---------|----------|---------|
| n                 | 91          | 113     | 1,540    | 1,591   |
| Age (years)       | 44.1 ± 5.8  | 44.2 ± 5.7 | 45.8 ± 5.7 | 47.3 ± 6.0 |
| Sex (M/F, %)      | 49/51       | 41/59   | 25/75    | 26/74   |
| Weight (kg)       | 108.4 ± 11.7 | 106.5 ± 11.4 | 119.0 ± 15.4 | 117.4 ± 15.4 |
| Height (m)        | 173 ± 0.11  | 173 ± 0.10 | 168 ± 0.09 | 169 ± 0.09 |
| BMI (kg/m\(^2\))  | 36.2 ± 2.5  | 35.8 ± 2.4 | 42.0 ± 4.2 | 41.3 ± 4.1 |
| Waist (cm)        | 115 ± 8     | 115 ± 8  | 124 ± 10 | 122 ± 10 |
| Hip (cm)          | 117 ± 7     | 117 ± 7  | 126 ± 9 | 125 ± 9 |
| WHR               | 0.090 ± 0.070 | 0.080 ± 0.081 | 0.981 ± 0.074 | 0.979 ± 0.074 |
| Sagittal diameter (cm) | 25.7 ± 2.9 | 25.2 ± 2.7 | 28.3 ± 3.5 | 27.9 ± 3.4 |
| SBP (mmHg)        | 128 ± 15    | 128 ± 15 | 140 ± 18 | 140 ± 18 |
| DBP (mmHg)        | 82 ± 13     | 80 ± 10  | 87 ± 11 | 87 ± 11 |
| B-glucose (mmol/L) | 4.2 ± 0.6   | 4.3 ± 0.6 | 4.4 ± 0.6 | 4.5 ± 0.6 |
| s-insulin (pmol/L) | 115.2 ± 61.8 | 103.2 ± 71.9 | 138.2 ± 75.9 | 131.4 ± 75.8 |
| s-TG (mmol/L)     | 1.95 ± 1.39 | 1.67 ± 1.35 | 2.09 ± 1.15 | 2.01 ± 1.27 |
| s-Chol (mmol/L)   | 5.2 ± 1.2   | 5.2 ± 1.0 | 5.9 ± 1.1 | 5.8 ± 1.1 |
| s-HDL (mmol/L)    | 1.35 ± 0.31 | 1.32 ± 0.36 | 1.38 ± 0.33 | 1.37 ± 0.34 |
| s-AST (units/L)   | 22.1 ± 9.5  | 23.0 ± 11.7 | 23.6 ± 11.4 | 23.6 ± 11.8 |
| s-ALT (units/L)   | 34.2 ± 21.3 | 32.7 ± 18.8 | 34.0 ± 19.2 | 34.0 ± 21.8 |
| Comorbidity, n (%)| 41 (45.6)   | 57 (50.4) | 1,487 (96.6) | 1,502 (94.4) |
| Hypertension, n (%)| 25 (27.8)  | 28 (24.8) | 1,059 (68.8) | 1,107 (69.6) |
| Dyslipidemia, n (%)| 38 (41.8)  | 54 (47.8) | 1,290 (83.8) | 1,281 (80.5) |

ALT, alanine aminotransferase; AST, aspartate aminotранferase; Chol, cholesterol; DBP, diastolic blood pressure; SBP, systolic blood pressure; TG, triglyceride; WHR, waist-to-hip ratio. *In total, 29 noneligible participants were excluded from the analysis on diabetes incidence. At matching, 24 noneligible participants had type 2 diabetes. At baseline, there were five additional noneligible participants who had developed type 2 diabetes.*
Table 3—Mean change in clinical and biochemical measurements over 10 years in the SOS study#

| Variable          | Noneligible participants | Eligible participants | P value for interaction |
|-------------------|--------------------------|-----------------------|-------------------------|
|                   | Surgery                  | Control               | Difference in change Δ (95% CI) | Surgery                  | Control               | Difference in change Δ (95% CI) |
| n                 | 80                       | 86                    |                          | 1,391                    | 1,181                 |                          |
| ΔWeight (kg)      | -14.3 ± 12.3             | 15.7 ± 14.0           | -18.0 (-22.0 to -14.0)*  | -21.2 ± 15.5             | 0.6 ± 14.2            | -21.8 (-22.9 to -20.6)*  | 0.089                   |
| ΔBMI (kg/m²)      | -4.6 ± 4.4               | 1.5 ± 4.6             | -6.1 (-7.5 to -4.8)*     | -7.2 ± 5.4               | 0.4 ± 5.0             | -7.7 (-8.1 to -7.3)*     | 0.060                   |
| ΔWaist (cm)       | -9.5 ± 11.6              | 5.5 ± 11.2            | -15.0 (-18.5 to -11.5)*  | -14.3 ± 13.6             | 2.2 ± 11.6            | -16.6 (-17.5 to -15.6)*  | 0.500                   |
| ΔHip (cm)         | -6.5 ± 9.4               | 2.6 ± 9.3             | -9.1 (-11.9 to -6.2)*    | -11.2 ± 11.6             | 2.0 ± 10.3            | -13.1 (-14.0 to -12.3)*  | 0.014                   |
| ΔWHR              | -0.028 ± 0.057           | 0.024 ± 0.060         | -0.052 (-0.070 to -0.034)* | -0.030 ± 0.075           | 0.003 ± 0.063         | -0.033 (-0.039 to -0.028)* | 0.044                   |
| ΔSagittal diameter (cm) | -4.2 ± 4.2               | 1.3 ± 5.0             | -5.5 (-6.9 to -4.1)*     | -4.6 ± 4.3               | 0.9 ± 4.2             | -5.5 (-5.8 to -5.1)*     | 0.963                   |
| ΔSBP (mmHg)       | -1.6 ± 19.9              | 5.3 ± 20.0            | -6.9 (-13.0 to -0.8)*    | -4.8 ± 21.3              | 2.8 ± 19.0            | -7.5 (-9.1 to -6.0)*     | 0.709                   |
| ΔDBP (mmHg)       | -4.1 ± 12.6              | 0.5 ± 11.8            | -4.6 (-8.3 to -0.8)*     | -4.9 ± 13.3              | -2.3 ± 12.1           | -2.6 (-3.6 to -1.6)*     | 0.480                   |
| ΔB-glucose (mmol/L) | -0.25 ± 0.85             | 0.47 ± 1.15           | -0.72 (-1.03 to -0.41)*  | -0.44 ± 1.91             | 0.77 ± 2.12           | -1.22 (-1.37 to -1.06)*  | 0.010                   |
| Δ-insulin (pmol/L) | -48.9 ± 68.5             | -6.9 ± 77.3           | -41.9 (-64.3 to -19.6)*  | -57.4 ± 108.6            | -0.9 ± 90.9           | -56.5 (-64.3 to -48.6)*  | 0.247                   |
| Δ-TG (mmol/L)     | -0.67 ± 1.06             | 0.06 ± 1.41           | -0.72 (-1.10 to -0.34)*  | -0.56 ± 1.23             | -0.16 ± 0.96          | -0.40 (-0.49 to -0.32)*  | 0.148                   |
| Δ-Chol (mmol/L)   | -0.38 ± 0.92             | -0.41 ± 1.19          | 0.02 (-0.30 to 0.35)     | -0.39 ± 1.09             | -0.35 ± 1.04          | -0.04 (-0.12 to 0.04)    | 0.320                   |
| Δ-HDL (mmol/L)    | 0.21 ± 0.36              | -0.02 ± 0.23          | 0.22 (0.13 to 0.31)*     | 0.24 ± 0.36              | 0.03 ± 0.28           | 0.20 (0.18 to 0.23)*     | 0.520                   |
| Δ-AST (units/L)   | 1.88 ± 13.22             | 6.29 ± 10.43          | -4.41 (-8.02 to -0.80)*  | 1.30 ± 15.66             | 3.53 ± 13.96          | -2.23 (-3.39 to -1.07)*  | 0.335                   |
| Δ-ALT (units/L)   | -14.21 ± 23.17           | 2.74 ± 15.67          | -16.95 (-22.93 to -10.96)* | -10.94 ± 23.19           | -1.59 ± 23.65         | -9.34 (-11.16 to -7.53)*  | 0.038                   |

Δ, difference in mean change between surgery and control groups; ALT, alanine aminotransferase; AST, aspartate aminotransferase; DBP, diastolic blood pressure; SBP, systolic blood pressure; TG, triglyceride; WHR, waist-to-hip ratio. #Mean change was calculated using the baseline value for each variable. *Significant differences in mean change between surgery and control groups, P < 0.05. ¶P value for interaction term eligibility × treatment group, from linear regression, adjusted for sex and age.

In this study, surgery improved cardiovascular risk factors and prevented type 2 diabetes in nondiabetic patients. Eighteen studies have demonstrated that bariatric surgery has a favorable effect on established type 2 diabetes (20,33). In this study, surgery improved cardiovascular risk factors and prevented type 2 diabetes in nondiabetic patients. Eighteen studies have demonstrated that bariatric surgery has a favorable effect on established type 2 diabetes (20,33).
findings, together with the results from this report, suggest that guidelines for bariatric surgery eligibility should be refined and complemented with metabolic assessment in obese patients.

The main limitation of the SOS study is that participants could not be randomized due to the high mortality rates after bariatric surgery in the 1970s and 1980s (35). In addition, the number of patients in the noneligible subgroup in the SOS study is low, especially affecting the power of the treatment interaction analyses.

In conclusion, this report clearly shows that bariatric surgery can prevent the development of type 2 diabetes both in noneligible and eligible patients. Furthermore, cardiovascular risk factors are significantly improved in both noneligible and eligible patients. Our data indicate that, among obese individuals, strict BMI cutoffs are of limited use for bariatric surgery prioritization. Thus, as long as current eligibility criteria are used, some patients with high risk for future metabolic disease may not qualify for bariatric surgery.

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K.S. and Å.A. designed the analyses, interpreted the data, and wrote the manuscript. M.P. designed and conducted the analyses, interpreted the data, contributed to discussion, and edited the manuscript. P.J., S.R., and P.-A.S. contributed to discussion and reviewed the manuscript. L.S. and L.M.S.C. interpreted the data, contributed to discussion, and edited the manuscript. All the authors read and approved the final version of the manuscript. M.P., L.S., and L.M.S.C. are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Eligibility and effects of bariatric surgery

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