ABSTRACTS

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Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery

Sjöström L, Lindroos A-K, Peltonen M, and The Swedish Obese Subjects Study Scientific Group. N Engl J Med 2004;351:2683-93.

Conclusion: Bariatric surgery, when compared with conventional obesity therapy, provides better long-term weight loss, improved lifestyle, and amelioration of cardiovascular risk factors, with the exception of hypercholesterolemia.

Summary: The Swedish Obese Subjects Study is a prospective investigation involving obese subjects who underwent bariatric surgery or conventional treatment for obesity. This report documents follow-up data for subjects (mean age, 48 years; mean body mass index, 41 kg/m^2) who were enrolled in the study for at least 2 years (4047 subjects) or 10 years (1703 subjects). The follow-up rate for laboratory examinations was 86.6% at 2 years and 74.5% at 10 years.

After 2 years of follow-up, weight increased 0.1% in the control group and decreased 23.4% in the surgery group ($P < .001$). After 10 years, weight had increased by 1.6% in the control group and had decreased by 16.1% in the surgery group ($P < .001$). There were proportionally more physically active subjects in the surgery group than in the control group throughout the observation period. Two- to 10-year recovery rates from hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, diabetes, hypertension, and hyperuricemia were more favorable in the surgery than the control group. There were no differences in recovery from hypercholesterolemia in the control and surgery groups. The surgery group had lower 2- and 10-year incidence rates of diabetes, hypertriglyceridemia, and hyperuricemia than the control group. There were no differences between the groups in the incidence of hypercholesterolemia and hypertension.

Comment: This was not a randomized study. The data, however, strongly implicate bariatric surgery as an effective means of improving cardiovascular risk factors in the morbidly obese. The study does not tell us whether progression of established vascular disease in the morbidly obese can be slowed by bariatric surgery. We are not currently at the point where we can recommend bariatric surgery as a treatment to slow progression of peripheral vascular disease. However, in patients with established cardiovascular risk factors who are morbidly obese, bariatric surgery can be recommended to diminish these risk factors and improve lifestyle.

Subintimal angioplasty in the treatment of patients with intermittent claudication: Long-term results

Florenes T, Bay D, Sandbaek G, et al. Eur J Vasc Endovasc Surg 2004;28: 645-50.

Conclusion: Subintimal angioplasty should be the primary treatment for patients with intermittent claudication when medical treatment alone has been unsatisfactory.

Summary: The authors report the results of subintimal angioplasty used for treatment of patients with intermittent claudication. The authors performed 116 subintimal angioplasties in 104 patients from February 1997 to January 2000. The authors calculated primary assisted patency rates for successful angioplasties, as well as calculated primary assisted patency rates, on an intention-to-treat basis. Univariant and multivariant Cox regression analysis was used to evaluate correlations of patency with comorbidities, occlusion length, and runoff.

Technical success was achieved in 87% (n = 101) of cases. There was no early mortality. On an attention-to-treat basis (116 cases), primary assisted patency at 6, 12, 36, and 60 months was 69%, 62%, 57%, and 54%, respectively. In successfully recanalized cases (101 cases), primary assisted patency at 6, 12, 36, and 60 months was 79%, 70%, 66%, and 64%. The risk of reocclusion was related to length of occlusion, age, and male sex. Periprocedural complications included seven hematomas, one requiring surgical evacuation, and six perforations that did not require intervention.

Comment: The patency results in this study are reasonable, but overall the paper is not all that helpful. We already know that subintimal angioplasty can be successful. The goal of treatment in patients with intermittent claudication, however, is improvement in walking and quality of life. The authors do not even present hemodynamic data, much less data regarding walking and quality of life. In a prospective study of treatment for intermittent claudication, more functional data, and not just simple patency analysis, should be included.

Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal inflammatory drugs: Nested case-control study

Graham DJ, Campen D, Hui R, et al. Lancet Online Publication, January 25, 2005

Conclusion: Compared with celecoxib, rofecoxib increases the risk of serious coronary heart disease. Naproxen does not offer a protective effect against coronary heart disease.

Summary: The Vioxx Gastrointestinal Outcomes Research Trial (VIGOR) raised questions about the cardiovascular risk of COX-2–selective drugs. In this trial, there was a fivefold difference in the incidence of acute myocardial infarction in patients treated with rofecoxib 50 mg/d and naproxen 1000 mg/d. There was no placebo group in this trial; therefore, findings could suggest adverse effects of coxibs in general, an adverse effect of rofecoxib, or a previously unrecognized protective effect of naproxen. The authors sought to establish whether cardiovascular risk was increased with rofecoxib at standard or high doses in comparison to remote nonsteroidal anti-inflammatory drug (NSAID) use or celecoxib. Celecoxib was chosen as a comparison drug to rofecoxib because celecoxib was the most common alternative to rofecoxib.

This was a nested case-control study. Data were derived from Kaiser Permanente in California. The authors assembled a cohort of all patients aged 18 to 84 years treated with NSAIDs between January 1, 1999, and December 31, 2001. Cases of serious coronary heart disease (defined as acute myocardial infarction and cardiac death) were risk-set–matched for age, sex, and health plan region. There were four controls for each case. The authors compared current exposure to COX-2–selective and –nonselective NSAIDS and to remote exposure to any NSAID. Rofecoxib was also compared with celecoxib.

There were 2,302,029 person-years of follow-up. There were 8143 cases of serious coronary heart disease, 27.1% (n = 2210) of which were fatal. Multivariant adjusted odds ratios vs celecoxib were as follows: for rofecoxib (any dose), 1.59 (95% CI, 1.1-2.32; $P = .015$); for rofecoxib 25 mg/d or less, 1.47 (95% CI, 0.99-2.17; $P = .054$); and for rofecoxib greater than 25 mg/d, 3.58 (95% CI, 1.27-10.11; $P = .016$). For naproxen vs past NSAID use, the adjusted odds ratio was 1.14 (95% CI, 1.00-1.30; $P = .05$).

Comment: Parts of this article were first posted on the US Food and Drug Administration (FDA) Web site on November 2, 2004. At that point, the document was considered preliminary and was a source of great controversy within the FDA. It is important to recognize that the current document represents the opinion of the authors and not necessarily that of the FDA and that the FDA did not participate in the study design, data collection, analysis, or writing of this report. This study, however, obviously has enormous implications for the entire class of COX-2 inhibitors and the mechanisms of oversight used by the FDA.

Randomized clinical trial of intraoperative autotransfusion in surgery for abdominal aortic aneurysm

Mercer KG, Spark JI, Berridge DC, et al. Br J Surg 2004;91:1443-8.

Conclusion: Autotransfusion effectively reduces the need for homologous blood transfusion (HBT) during repair of abdominal aortic aneurysm (AAA). Use of autotransfusion was associated with a reduced incidence of both the systemic inflammatory response syndrome (SIRS) and postoperative infectious complications.

Summary: This was a randomized, single-center clinical trial of intraoperative autotransfusion in patients undergoing repair of AAA. There were 40 patients randomized to intraoperative autotransfusion and 41 patients who underwent surgery for AAA with homologous blood transfusion alone. Patients in both groups received, when necessary, HBT to maintain hemoglobin levels >8 g/dL. Comparisons were made among transfusion requirements, the incidence of infection, and the incidence of SIRS between the two groups.

Fewer patients in the intraoperative autotransfusion group required HBT (21 vs 31; $P = .038$). The median blood requirement per patient was two units lower in the patients undergoing intraoperative autotransfusion vs those treated with HBT alone ($P = .012$). There was a higher incidence of SIRS (20 vs 9 patients; $P = .020$) and a higher incidence of chest infection (12 vs 4 patients; $P = .049$) in the HBT-alone group. The risk of SIRS was related to aortic cross-clamp time in the intraoperative autotransfusion group only.

Comment: The author's finding that intraoperative autotransfusion is associated with reduced postoperative infection is consistent with observational studies linking a diminished immunologic response to HBT. The