Research Highlights

Highlights from the latest articles in device implantation and in coronary, valvular and lifestyle intervention

Pacemaker and defibrillator surgery: keep them anticoagulated

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Evaluation of: Birnie DH, Healey JS, Wells GA *et al.* Pacemaker or defibrillator surgery without interruption of anticoagulation. *N. Engl. J. Med.* 368(22), 2084–2093 (2013).

In patients who are anticiagulated perioperatively anticoagulation is stopped and bridged with heparin, but the benefit of this strategy is unproven. In an attempt to verify whether it is safe to perform pacemaker or implantable cardioverter defibrillator surgery without interruption of anticoagulation therapy, a study group from the University of Ottawa Heart Institute, Ottawa, Canada, randomly assigned 681 patients with an annual risk of thromboembolic events of 5% or more to continued warfarin treatment (343 patients) or bridging therapy with heparin (338 patients). The primary outcome was defined as clinically significant device-pocket hematoma necessitating prolonged hospitalization, interruption of anticoagulation therapy or further surgery. The results showed that the incidence of clinically significant device-pocket hematoma was considerably less in the group receiving continued warfarin treatment (12 out of 343 patients; 3.5%) compared with the group with heparin-bridging (54 out of 338 patients; 16%; relative risk: 0.19; 95% CI: 0.10–0.36; $p < 0.001$). There was no significant difference between the two groups with regard to major surgical and thromboembolic complications which, in the present study, consisted of one case of cardiac tamponade and one myocardial infarction in the heparin-bridging group, and one stroke and one transient ischemic attack in the warfarin group. The authors concluded that warfarin continuation yielded better results than heparin bridging at the time of pacemaker or implantable cardioverter defibrillator surgery as it significantly decreased the incidence of device-pocket hematoma. This important information adds simplification and safety to our practice.

Attractive news for diabetic Epicureans

Evaluation of: Look AHEAD Research Group. Cardiovascular effects of intensive lifestyle intervention in Type 2 diabetes. *N. Engl. J. Med.* 369(2), 145–154 (2013).

Current guidelines strongly recommend obese diabetic patients adjust their lifestyle, a task that is not only difficult but also requires considerable energy both from patients and their physicians. An extensive multicenter study carried out in the USA by the Look AHEAD (Action for Health in Diabetes) Research Group revealed that an intensive lifestyle intervention in obese patients with Type 2 diabetes could achieve weight loss, but could not reduce the risk of cardiovascular morbidity and mortality.

The study included 5145 overweight or obese patients with Type 2 diabetes who were randomized to participate in an intensive lifestyle intervention aimed at weight loss (intervention group), or to receive

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diabetes support and counseling (control group). The primary outcome was a composite of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke or hospitalization for angina. The study was initially planned to be carried out to a maximum follow-up of 13.5 years; however, based on a futility analysis, it was stopped prematurely after a median follow-up of 9.6 years. While more patients in the intervention group achieved a significant weight loss compared with those in the control group (8.6 vs 0.7% at 1 year and 6 vs 3.5% at the end of the study), there was almost no difference between the two groups with regard to cardiovascular events. Although a reduction in glycated hemoglobin and all cardiovascular risk factors, except for LDL cholesterol levels, could be noted in the the intervention group. The primary outcome occurred in 403 patients in the intervention group and in 418 patients in the control group (1.83 and 1.92 events per 100 person-years, respectively; p = 0.51).

Its quite frustrating to learn that the huge effort and pressure we were investing into optimal nonmedical treatment since decades is not granted by a better outcome.

New alternative to transfemoral transcatheter aortic valve replacement

Evaluation of: Lardizabal JA, O'Neill BP, Desai HV *et al.* The transaortic approach for transcatheter aortic valve replacement: initial clinical experience in the United States. *J. Am. Coll. Cardiol.* 61(23), 2341–2345 (2013).

Up to now, for patients with an inoperable aortic stenosis who require transcatheter aortic valve replacement (TAVR) but are not eligible for the transfemoral approach, the most popular alternative has been the transapical (TAP) approach, which does not provide completely satisfactory outcomes. In an attempt to investigate whether the transaortic (TAO) approach for TAVR (TAO TAVR) in these patients is also feasible, the Lardizabal study group performed TAO TAVR in 44 consecutive patients. A total of 76 consecutive patients subjected to TAVR via the TAP route (TAP TAVR) served as a control group. The outcomes of the first 20 cases and the subsequent patients who underwent each procedure were compared in order to assess the learning curves. The safety end point was a composite of all-cause mortality, myocardial infarction, major stroke, disabling bleeding, severe acute kidney injury, and valve re-intervention. The results revealed that both the TAO and TAP TAVR groups were similar with respect to the Valve Academic Research Consortium criteria defining the device success (89 vs 84%; p = 0.59) and to the 30-day safety end point (20 vs 33%; p = 0.21) [1]. However, regarding the combined bleeding and vascular event rate and the median stay at the ICU, TAO TAVR showed more favorable results when compared with TAP TAVR (27 vs 46%; p = 0.05 and 3 vs 6 days; p = 0.01, respectively). The TAO approach also showed a more favorable learning curve. The authors therefore conclude that the TAO approach represents a good alternative to the TAP approach. We agree that this is an interesting approach, but the numbers are far too small to draw any conclusion and TAO should be further evaluated before the approach gets promoted.

Reference

1 Leon MB, Piazza N, Nikolsky E *et al.* Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium. *Eur. Heart. J.* 32(2), 205–217 (2011).

Primary percutaneous coronary intervention in ST-segment elevation myocardial infarction: keep it simple

Evaluation of: Fröbert O, Lagerqvist B, Olivecrona GK *et al.* Thrombus aspiration during ST-segment elevation myocardial infarction. *N. Engl. J. Med.* 369(17), 1587–1597 (2013).

Thrombus aspiration received a IIa recommendation in the current European Society of Cardiology guidelines, mainly because of the favorable results of the single-center TAPAS trial. This is now challenged by a Scandinavian team of cardiologists that conducted a multicenter, prospective, randomized, controlled, open-label study in order to assess whether routine intracoronary thrombus aspiration before primary percutaneous coronary intervention (PCI) in patients with ST-segment elevation myocardial infarction reduces mortality. The study carried

out at various hospitals in Sweden, Iceland and Denmark included 7244 patients with ST-segment elevation myocardial infarction who were registered in the national comprehensive Swedish Coronary Angiography and Angioplasty Registry. The patients were randomly assigned to either manual thrombus aspiration prior to PCI (n = 3.126) or PCI alone (n = 3.623). The primary end point was all-cause mortality at 30 days. The results showed that there was no significant difference between the two groups with respect to death from any cause (2.8 vs 3.0%; p = 0.63), hospitalization for recurrent myocardial infarction at 30 days (0.5 vs 0.9%; p = 0.09) and stent thrombosis (0.2 vs 0.5%; p = 0.06). As for the incidence of stroke or neurologic complications at the time of discharge, no significant difference between the two groups could be noted (p = 0.87). Thus, the results clearly showed that routine thrombus aspiration before PCI was not superior to PCI alone with regard to a possible reduction of the 30-day mortality rate in patients with ST-segment elevation myocardial infarction. This does not, however, allow to conclude that thrombaspiration for large thrombi is also ineffective and we do strongly recommend to still apply it in this subgroup of patients.