News & Views

Research Highlights

Highlights from the latest articles in interventional cardiology

PROTECT AF trial: left atrial appendage closure device (Watchman®) for stroke prevention in atrial fibrillation

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Evaluation of: Holmes DR, Reddy VY, Turi ZG *et al.*; PROTECT AF investigators: Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised noninferiority trial. *Lancet* 374, 534–542 (2009).

Embolic stroke resulting from thrombus development in the left atrial appendage (LAA) is a major complication associated with atrial fibrillation. For patients at risk, long-term warfarin anticoagulation is recommended for stroke prevention.

"...closure of the LAA might provide an alternative strategy to chronic warfarin therapy for stroke prophylaxis in patients with nonvalvular AF."

Holmes and the investigators of the PROTECT AF trial present the results of a randomized multicenter study assessing the noninferiority of the Watchman® (Atritech, MN, USA) LAA occlusion device versus chronic warfarin therapy. The Watchman device is a percutaneously and trans-septally delivered, self-expanding device to seal the LAA ostium. A total of 707 patients were randomized in a 2:1 fashion to the device or control (warfarin) arm in 59 enrolling centers. Device patients stopped oral anticoagulation at day 45 and continued with dual antiplatelet inhibition with clopidogrel (75 mg) and aspirin (81–325 mg) until 6 months. Thereafter, aspirin alone was continued. The device was successfully implanted in 88% of patients. The primary efficacy event rate per 100 patient-years was 3.0 in the device group versus 4.9 in controls. No differences were observed regarding stroke or all-cause mortality, proving noninferiority. However, the rate of adverse events was significantly higher in the device group, particularly early after/during treatment. These consist of serious pericardial effusion (requiring percutaneous or surgical drainage) in almost 5%, major bleeding in 3.5% and device embolization in 0.6% of patients. The authors conclude that closure of the LAA might provide an alternative strategy to chronic warfarin therapy for stroke prophylaxis in patients with nonvalvular AF.

"...the routine use of the Watchman device does not appear to be recommended."

Although the PROTECT AF trial provides important data on the feasibility and efficacy of an interventionally implanted mechanical protection device for stroke prevention, the routine use of the Watchman device does not appear to be recommended. Further developments of the implantation techniques to reduce complications associated with the intervention itself and long-term data in large patient populations with long-term patient follow-up are desired to evaluate the eligibility of the device for a routine application.

future medicine part of fsg

EVEREST trial: interventional mitral valve repair with the MitraClip® system

Evaluation of: Feldman T, Kar S, Rinaldi M *et al.*; EVEREST investigators: Percutaneous mitral valve repair with the MitraClip® system. Safety and midterm durability in the initial EVEREST (Endovascular Valve Edge-to-Edge Repair Study) cohort. *J. Am. Coll. Cardiol.* 54, 686–694 (2009).

Percutaneous treatment of valvular heart diseases generally requiring open heart surgery is a rapidly evolving field in interventional cardiology.

The Endovascular Valve Edge-to-Edge Repair Study (EVEREST), a prospective multicenter, single-arm study, investigated the feasibility, safety and efficacy of a new device-based interventional technique for the treatment of mitral regurgitation (MR). This trial comprised 107 patients with moderate-to-severe MR enrolled in 31 centers and treated with the MitraClip® system. The technique is based on the surgical approach to create a double-orificed mitral valve with the middle scallops of the anterior and posterior leaflets sutured together. The MitraClip system involves a clip that is inserted into the left ventricle via a transfemoral, trans-septal access. The clip grasps both mitral leaflets by retracting the device from the left ventricle below the leaflets. Acute procedural success was achieved in 74% of patients, and 64% were discharged with a MR of 1+ or less. Among the patients treated successfully, 66% were free from death, mitral valve surgery and MR of more than 2+ at 1-year follow-up. By contrast, 30% of patients underwent mitral valve surgery during 3.2 years after clip procedures. Of note, a major adverse event occurred in 9% of patients, consisting of transient ischemic attack, major bleeding, surgical intervention and one intraprocedural death in a high-risk patient. The authors conclude that percutaneous repair using the MitraClip system can be accomplished with low rates of morbitity and mortality with acute MR reduction of more than 2+ in the majority of patients.

> *"...percutaneous repair using the MitraClip system can be accomplished with low rates of morbitity and mortality."*

Even though the presented data are encouraging, a prospective randomized study to investigate surgical mitral valve repair is required to reveal the true advantages of interventional mitral valve treatment in a head-to-head comparison. Furthermore, a study in patients not eligible for cardiac surgery is desired to demonstrate the feasibility of the MitraClip system in a population in whom an effective and safe alternative therapeutic option is desired.

Intended cardiac interventions under therapeutic anticoagulation

Evaluation of: Hussein AA, Martin DO, Patel D *et al.*: Radiofrequency ablation of atrial fibrillation under therapeutic international normalized ratio: a safe and efficacious periprocedural anticoagulation strategy. *Heart Rhythm.* DOI: 10.1016/j.hrthm.2009.07.007 (2009) (Epub ahead of print).

Patients with a chronic coumadin therapy who are scheduled for percutaneous cardiac interventions are usually advised to discontinue oral anticoagulation combined with a bridging low-molecular-weight heparin therapy. However, discontinuation of coumadin may increase the risk for thrombus formation in the heart.

A recent study, comprising more than 3000 patients, investigated the efficacy and safety of continuation of oral anticoagulation with an international normalized ratio in a therapeutic range in patients undergoing catheter ablation for atrial fibrillation. For this purpose, the investigators use venous accesses with two 8 French (F), one 10.5 F and one 8 F sheath inserted through the right femoral

vein, left femoral vein and right internal jugular vein, respectively. Two catheters were advanced into the left atrium after trans-septal puncture and the activated clotting time was maintained for 350 and 450 s throughout the procedure. Bleeding complications occurred in 34 patients (1.1%), of whom ten (0.33%) were major bleeders. Nine patients (0.29%) had pericardial effusion with five of them requiring percutaneous or surgical (n = 1) intervention and reversal of anticoagulation. In 20 patients (0.66%), hematomas of the groin occurred and three patients required blood transfusions. Ischemic stroke occurred in three patients (0.098%) and a cerebrovascular hemorrhagic event in one patient (0.03%). The authors conclude that continuation of coumadin at a therapeutic international normalized ratio at the time of catheter ablation for atrial fibrillation is a safe and efficacious periprocedural anticoagulation strategy and, therefore, potentially provides a better alternative to strategies using bridging with heparin or enoxaparin.

"...interventional cardiac procedures performed via a venous access can be safely performed under anticoagulation in a therapeutic range."

The data from the presented study suggest that interventional cardiac procedures performed via a venous access can be safely performed under anticoagulation in a therapeutic range, even in procedures requiring trans-septal intervention. However, a large-scale, randomized, multicenter study comparing both strategies, continuation of anticoagulation versus discontinuation and heparin-bridging, is desired before the described approach can be deployed widely.