News & Views

Research Highlights

Highlights from the latest research in interventional cardiology

STOP-AF trial: sustained treatment of paroxysmal atrial fibrillation

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Evaluation of: Packer D (Mayo Clinic, Rochester, MN, USA); for the STOP-AF trial investigators. Presented at the American College of Cardiology 2010 Scientific Sessions/i2 Summit (late-breaking clinical trial session).

The interventional treatment of atrial fibrillation (AF) using catheter-based techniques has evolved to a routine procedure with a favorable safety and efficacy profile. Electrical isolation of the pulmonary veins is the cornerstone of all AF ablation procedures and is a widely accepted fundamental end point.

"The STOP-AF trial is important because it highlights the superiority of an interventional atrial fibrillation treatment over antiarrhythmic therapy."

Recently, different randomized studies have demonstrated superiority of catheter ablation in the treatment of paroxysmal AF in comparison with a pharmacological antiarrhythmic therapy (e.g., first line Radiofrequency Ablation Versus Antiarrhythmic Drugs for Atrial Fibrillation Treatment [RAAFT] [1] and A4 study [2]). At the American College of Cardiology 2010 summit in Atlanta, USA, Packer presented the preliminary data of the Sustained Treatment Of Paroxysmal Atrial Fibrillation (STOP-AF) trial. In this study, a total of 245 patients with paroxysmal AF were enrolled at 26 centers. These patients were randomized in a 2:1 fashion to receive either ablation or antiarrhythmic drug treatment. Catheter ablation was performed using the Cryoballoon technology (Arctic Front, Medtronic, MN, USA). All patients had failure of at least one antiarrhythmic drug. As a result, on the basis of an intention-to-treat analysis, the 12-months efficacy (no detectable AF) was significantly higher in the ablation arm (69.9 vs 7.3%). Notably, complications related to catheter ablation occurred in both study arms (owing to crossover from antiarrhythmic to ablation treatment). These include stroke (2.5%), pulmonary vein stenosis (3.1%) and phrenic nerve palsy (13.5%).

"...more experience with the Cryoballoon may result in a lower complication rate."

Catheter ablation for AF is a more effective treatment with higher success rates than conventional drug treatment. The STOP-AF trial is important because it highlights the superiority of an interventional AF treatment over antiarrhythmic therapy. However, the promising results of ablation therapy, with the majority of patients in sustained sinus rhythm after 1 year, are clouded by a relatively high amount of side effects. This is particularly surprising since the Cryoballoon ablation was supposed to have a lower adverse event profile compared with ablation techniques using radiofrequency current. Packer concluded that more experience with the Cryoballoon may result in a lower complication rate.

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Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

future medicine part of fsg

EVEREST II trial: Endovascular Valve Edge-to-Edge Repair study

Evaluation of: Feldman T (Evanston Hospital, IL, USA); for the EVEREST II trial investigators. Presented at the American College of Cardiology 2010 Scientific Sessions/i2 Summit (late-breaking clinical trial session).

Percutaneous treatment of mitral regurgitation is developing rapidly with the evolution of different devices using different approaches and techniques, one of which is the MitraClip (Abbott, UK) device, which is a transvenous, trans-septal and transmitral applied edge-to-edge mitral valve repair emulating the surgical technique pioneered by Alfieri *et al.* [1]. Recently, three different single-arm studies designed to investigate the feasibility, safety and efficacy of the MitraClip device have reported favorable results, even in a population with a high risk for periprocedural complications [2–4].

At the American College of Cardiology 2010 summit in Atlanta, USA, Ted Feldman presented the data of the prospective, randomized Endovascular Valve Edge-to-Edge Repair Study (EVEREST II) trial. In this study, 279 patients with significant mitral regurgitation were included at 37 centers and were randomized in a 2:1 ratio to the MitraClip treatment or surgical repair or replacement at the surgeon's discretion. The predefined hypothesis was to test noninferiority of MitraClip treatment. Primary end points were major adverse events (e.g., death, major stroke, emergent surgery and blood transfusions), clinical success and improvement of at least two grades of mitral regurgitation at 12 months. The safety and efficacy profile of both treatment options were similar in an intention-to-treat analysis, demonstrating noninferiority of the MitraClip. However, MitraClip treatment was less effective in terms of reduction in mitral regurgitation grade compared with the surgically treated patient group.

Data from the EVEREST II trial are encouraging and support previous reports. Combining these data with the other single-arm trials on MitraClip therapy, particularly a study by Franzen *et al.* [3], this new therapeutic option offers an alternative to the surgical treatment of mitral valve repair. This is particularly true for patients not eligible or considered to be at a high risk for surgery, mandating sternotomy and extracorporeal circulation. A potential concern of the MitraClip therapy may be that patients requiring surgical mitral valve treatment years later are ruled out for mitral valve reconstruction, and consequently, are relegated to valve replacement owing to leaflet scar formation and deterioration over time. However, no prospective data are currently available and, thus, further investigations have to clarify this potentially critical disadvantage.

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