Research Highlights

Highlights from the latest articles in the percutaneous treatment of structural heart disease

PC trial: percutaneous closure of patent foramen ovale in cryptogenic embolism

Diego Fernández-Rodríguez[1] & Salvatore Brugaletta*[1]

[1]Department of Cardiology, Thorax Institute, Hospital Clínic, Villarroel 170, 08036 Barcelona, Spain
**Author for correspondence: sabrugal@clinic.ub.es*

Evaluation of: Meier B, Kalesan B, Mattle HP *et al.* Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N. Engl. J. Med.* 368(12), 1083–1091 (2013).

The presence of a patent foramen ovale (PFO) allowing paradoxical embolisms has been postulated as one of the main mechanisms in cryptogenetic embolism. The Amplatzer® PFO Occluder (St Jude Medical, MN, USA) is a self-expanding double-disc device, made of nitinol with a polyester fabric patch sewn into both discs, with a flexible and stretchable connector between the discs.

In patients with a PFO who presented with a cryptogenetic embolism, causing ischemic stroke, transient ischemic attack (TIA) or a peripheral thromboembolic event, Meier and colleagues conducted a multicenter, randomized, superiority trial comparing percutaneous PFO closure with the Amplatzer PFO Occluder versus medical therapy with oral anticoagulation or antiplatelet therapy, at the discretion of the treating physician [1].

Between 2000 and 2009, a total of 414 patients were randomized 1:1 to device or medical therapy in 29 enrolling centers. The device was successfully implanted into 95.9% of patients. No major complications, defined as cardiac death, major bleeding or device embolization, were described. The mean follow-up was 4.1 years in the device group and 4.0 years in the medical therapy group, and the data were analyzed with intention-to-treat. The primary end point, which was a composite end point of death, nonfatal stroke, TIA or peripheral embolism, occurred in 3.4% in the device group and in 5.2% in the medical therapy group (hazard ratio: 0.63; 95% CI: 0.24–1.62; p = 0.34). No significant differences were observed in nonfatal stroke (0.5 vs 2.4%; p = 0.14), TIA (2.5 vs 3.3%; p = 0.56) and noncardiovascular death (1.0 vs 0.0%; p = 0.24) between the device group and medical therapy group, respectively. There were no cardiovascular deaths or peripheral embolisms. The authors concluded that percutaneous closure of PFO for secondary prevention of cryptogenetic embolisms did not significantly reduce the risk of recurrent embolic events or death compared with medical therapy.

Based on the results of this trial, the routine use of the Amplatzer PFO Occluder does not appear to be recommended. Nevertheless, its use in a more selected population with PFO and right-to-left shunt should be tested. Moreover, owing to its safety and efficacy, the Amplatzer PFO Occluder could represent an interesting therapeutic option for secondary prevention in patients with PFO, cryptogenic embolisms and contraindication for anti-thrombotic therapy.

Reference

1 Meier B, Kalesan B, Mattle HP *et al.* Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N. Engl. J. Med.* 368(12), 1083–1091 (2013).

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

Outcomes of MitraClip® therapy in elderly patients

Evaluation of: Schillinger W, Hünlich M, Baldus S *et al.* Acute outcomes after MitraClip® therapy in highly aged patients: results from the German TRAnscatheter Mitral valve Interventions (TRAMI) Registry. *EuroIntervention* 9(1), 84–90 (2013).

Mitral regurgitation (MR) is the second leading cause of heart valve disease worldwide and its prevalence increases with age, affecting more than one in ten people over the age of 75 years. In patients who are not candidates for surgical treatment of severe symptomatic MR, percutaneous mitral valve repair with the MitraClip® system (Abbott Vascular, IL, USA) has emerged as a new therapeutic strategy for selected patients.

The German TRAMI Registry is the largest real-world registry of patients treated with MitraClip. The aim of this observational study is to evaluate the influence of age on the selection and acute outcomes in the MitraClip population [1].

Between August 2010 and March 2013, 1064 patients were included. Patients were classified according to age into two groups: the elderly group (EG; ≥76 years; n = 525) and nonelderly group (NEG; <76 years; n = 539). The EG had a higher proportion of women (47.2 vs 29.3%; p < 0.0001), preserved left ventricular ejection fraction (40.1 vs 21.8%; p < 0.0001), degenerative MR (35.3 vs 25.6%; p < 0.01) and higher logistic EuroSCORE (25 vs 18%; p < 0.0001) in comparison with the NEG. At discharge, the rate of the composite end point of intrahospital death, myocardial infarction and stroke (3.5% in the EG vs 3.4% in the NEG; p = 0.93) and the proportion of nonsevere MR (95.8% in the EG vs 96.4% in the NEG; p = 0.73) were low and similar between groups. A higher rate in major bleeding was observed in the EG (14.5 vs 8.2%; p < 0.01) compared with the NEG. The most frequent reason for rejecting surgical treatment in the EG, was advanced age (69.4%). The multivariate analysis did not show any impact of advanced age on the efficacy and safety of MitraClip therapy. The authors concluded that elderly patients have similar benefits with MitraClip implantation in severe MR compared with relatively younger patients.

The EVEREST II trial showed that surgical treatment remains to be the treatment of choice for severe MR, MitraClip being an attractive option in those patients not suitable for surgical treatment. According to the German TRAMI Registry, where advanced age was the leading cause for rejecting patients for surgical treatment, MitraClip implantation is safe and effective for elderly patients.

Reference

1 Schillinger W, Hünlich M, Baldus S *et al.* Acute outcomes after MitraClip® therapy in highly aged patients: results from the German TRAnscatheter Mitral valve Interventions (TRAMI) Registry. *EuroIntervention* 9(1), 84–90 (2013).

Utility of cross-sectional 3D transesophageal echocardiography in transcatheter aortic valve replacement therapy

Evaluation of: Jilaihawi H, Doctor N, Kashif M *et al.* Aortic annular sizing for transcatheter aortic valve replacement using cross-sectional 3-dimensional transesophageal echocardiography. *J. Am. Coll. Cardiol.* 61(9), 908–916 (2013).

Transcatheter aortic valve implantation (TAVI) is becoming the standard of care for inoperable patients with severe symptomatic aortic stenosis and a valid alternative for patients with severe symptomatic aortic stenosis at high surgical risk.

Paravalvular aortic regurgitation (PVAR) is one of the most important prognostic factors after TAVI and methods, such as 2D transesophageal echocardiography (TEE) or cross-sectional contrast computed tomography (CT), are usually used to evaluate the size of the aortic annulus in order to estimate accurately the prosthesis diameter and reduce the incidence of PVAR.

The aim of this prospective observational study was to evaluate the cross-sectional 3D TEE as a method for predicting PVAR after transcatheter aortic valve replacement with balloon-expandable prostheses [1].

A total of 256 patients were evaluated by 2D TEE, 3D TEE and CT scan for measuring aortic annulus. The primary end point, which was the presence of at least moderate PVAR after TAVI, occurred in 26 out of 256 patients (10.2%). Receiver-operating characteristic curves indicated that 2D TEE measurements offered a low degree of discrimination (area under the curve [AUC]: 0.52; 95% CI: 0.40–0.63; p = 0.75). The average cross-sectional diameter measured by CT had a high

discriminatory value (AUC: 0.82; 95% CI: 0.73–0.90; p < 0.0001) and eventually the mean cross-sectional diameter measured by 3D TEE presented an intermediate value (AUC: 0.68; 95% CI: 0.54–0.81; p = 0.036). Sizing of the aortic annulus by cross-sectional 3D TEE was significantly superior to that of 2D TEE (AUC: 0.68 vs 0.52; p = 0.031). Of note, was that assessment of the aortic annulus measurements by cross-sectional CT and 3D TEE measurements showed excellent reproducibility. The authors concluded that evaluation of the aortic annulus by cross-sectional 3D TEE is more accurate than by 2D TEE and should be used if data from cross-sectional CT are unavailable.

Correct estimation of the aortic annulus size is one of the key points in transcatheter aortic valve replacement, allowing for the selection of the appropriate prosthesis size for each patient, thus, reducing the incidence of paravalvular leaks, which have an important impact on long-term prognosis after TAVI. This work shows that 3D TEE is a more useful tool to accurately evaluate the aortic annulus for transcatheter aortic valve replacement sizing and optimize prosthesis implantation, as compared with 2D TEE.

Reference

1 Jilaihawi H, Doctor N, Kashif M *et al.* Aortic annular sizing for transcatheter aortic valve replacement using cross-sectional 3-dimensional transesophageal echocardiography. *J. Am. Coll. Cardiol.* 61(9), 908–916 (2013).