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MitraClip® and Amplatzer® cardiac plug implantation in a single procedure: A reasonable approach?

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ABSTRACT

Background: Percutaneous mitral valve repair using MitraClip® (MC) is a well-established method for a subset of patients with severe mitral regurgitation (MR) and high risk for surgical intervention. Amplatzer® Cardiac Plug (ACP) occludes left atrial appendage and allows the discontinuation of oral anticoagulation and prevention of thromboembolic stroke. Due to the need for femoral and transseptal access in both procedures, a single approach could lead to minor risk of further complications and shorter cumulative intervention time.
Methods: We systematically analysed all four patients who underwent a combined procedure with MC and ACP in our heart-centre. All procedures were performed under fluoroscopic as well as echocardiographic guidance, and follow-up controls in a midterm period were carried out.
Results: In all patients (2 male/female; age 73–88 years), MC (1–2 Clips) and ACP (size 18-28 mm) were successfully implanted in one procedure (mean total time: 114 ± 17 min). At least moderate MR was achieved and two patients had no complications and therefore were discharged early. In a third patient, a dislocation of ACP occurred 2 h after the implantation. The oldest patient developed a respiratory insufficiency due to cardiac decompensation and further complications.
Conclusion: A combination of MC and ACP in a single procedure was feasible in this first case series of patients without a significant extension of procedure time. However, it might be important to select patients carefully. The location of optimal transseptal puncture may be challenging in regard to ACP placement, even in experienced hands and subsequent complications can occur.

1. Introduction

Percutaneous mitral valve repair (MVR) using the MitraClip® system (MC, Abbott, Chicago, IL) is a well-established therapeutic alternative for patients at high risk for surgical MVR [1], [2]. Atrial fibrillation (AF) is a frequent comorbidity in this heart failure patient cohort. Due to additional co-factors such as advanced age, renal insufficiency/failure and the need for dual anti-platelet therapy after MC implantation, increased bleeding complications in the short- and long-term post-interventional period should be presumed. Patients with AF who exhibit a high risk for thromboembolic as well as bleeding events seem to benefit from percutaneous occlusion of the left atrial appendage (LAA) using Amplatzer Cardiac Plug system (ACP, St. Jude Medical Inc.) which abstains them from long-term oral anticoagulation and nevertheless achieves prevention of thromboembolic stroke. The feasibility of LAA closure with ACP has been recently evaluated and has proven to be safe [3], [4]. Likewise to the MC system, the ACP is designed for transfemoral, transvenous access and implantation via a transseptal route. To date, in existing randomised studies with LAA occlusion systems, e.g. Protect-AF [5] and Prevail trail [6] with the Watchman device, only a single cardiac device implantation was performed. There is only one case report describing a percutaneous procedure of MC implantation and LAA occlusion with a Watchman device in a single procedure [7]. It should be emphasised that it is still unclear if the combination of percutaneous MVR using MC and LAA occlusion with the ACP device in patients with severe MR declined for surgical MVR is feasible and safe. From an interventional cardiologist's perspective, it seems to be reasonable to combine these procedures because both procedures have the same access route and require transseptal puncture. In fact, it could be beneficial for the patient in order to prevent two separate procedures. It appears consistent comparable to cumulative time or vascular and transseptal access complications of two separate interventions, a single approach could lead to minor risk of further complications and shorter cumulative intervention time.

We screened our database of patients undergoing such a combined approach at our heart centre and could identify four cases. To our

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knowledge, this is the first report of a case series combining MitraClip implantation with LAA occlusion by ACP device.

2. Methods

We analysed all four patients who underwent a combined procedure with the MC and ACP between 06/2012 and 04/2013. Written informed consent was obtained from all patients. Our study was approved by local ethics committee and therefore was done in accordance with Good clinical practice and the declaration of Helsinki.

All patients underwent general anaesthesia with endotracheal intubation and ventilation by an anaesthesiologist for the time of procedure. First, MC was implanted with transseptal puncture site typically used for MC procedure. Subsequently, ACP implantation was performed via the existing transseptal access. All procedures were done by an experienced investigator under fluoroscopic and echocardiographic guidance. In all cases the 'Proglide Suture-mediated Closure System' (Abbott vascular, Chicago, IL) was used at the site of transvenous access, and transseptal puncture was performed using a standard SL0 sheath with a BRK1 transseptal needle (St. Jude Medical Inc.). Therapeutic heparin doses were given after successful transseptal puncture. For the implantation of ACP, an Amplatzer® TorqVue® Delivery System 45°×45° or 45° (St. Jude Medical Inc.) was used. Additionally, ACP device stability was tested by a modified 'Minnesota wiggle manoeuvre' (i.e. very gently pulling and releasing the delivery cable). Post-interventional controls were done by fluoroscopy as well as echocardiography, and follow-up controls were documented up to 18 months after procedures.

3. Results

Case 1. A 73-year-old woman was admitted to our clinic with severe symptoms of global heart failure. In a chest x-ray, we could find signs of hypostatic pneumonia due to a dilative cardiomyopathy with a severely reduced left ventricular ejection fraction and a severe MR. Furthermore, the patient was suffering from permanent AF with need for oral anticoagulation, from recurrent episodes of epistaxis, chronic obstructive pulmonic disease and mild chronic kidney disease. Due to episodes of angina pectoris on admission and elevated cardiac troponin serum levels, a coronary angiography was performed and a three vessel coronary disease with significant stenosis of the right coronary artery was diagnosed. The case was discussed in our 'heart team', and an interventional strategy was recommended due to the patient's surgical high-risk status (Logistic EuroScore I 39.5%). First, percutaneous coronary intervention (PCI) was performed and the right coronary artery was treated with two drug-eluting stents. Subsequently, a percutaneous MVR with MC was planned to reduce severe MR. Due to recurrent pulmonary oedema with orthopnoea, the patient was treated with intravenous diuretics (i.e. furosemide) and inotropes (i.e. levosimendan) in order to achieve cardiopulmonary recompensation before further interventions. Due to increased risk of thromboembolic stroke and bleeding (CHA_2DS_2-VASc-Score: 4/ HAS-BLED-Score: 4) and in order to avoid triple anticoagulation after PCI [8] it was also decided to perform LAA occlusion. MC was implanted (Fig. 1a + b), and a significant MR reduction could be confirmed by echocardiography (mild MR, mean transmitral gradient of 4 mm Hg) during intervention. After

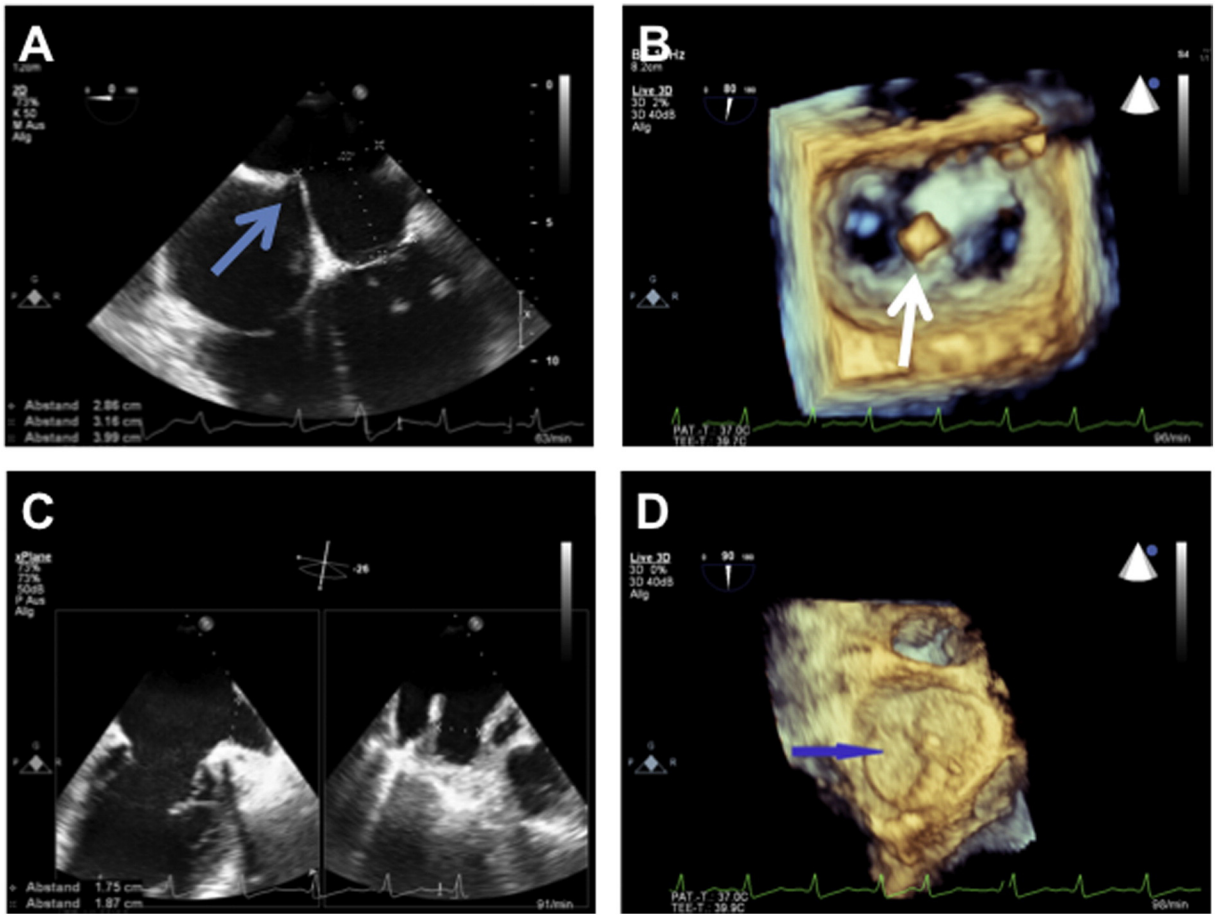

Fig. 1. A) Intraprocedurally performed transoesophageal echocardiography (TEE, four chamber view, 0° position) indicated the optimal position of transseptal puncture for MitraClip (MC) implantation. *Arrow* is pointing on the so-called 'tenting' of the atrial septum by the transseptal needle. **B)** Using 3D TEE the optimal view for MC implantation was achieved. *Arrow* indicates the MC and native valve material creating the typical 'double-orifice'. **C)** Intraprocedural sizing of the left atrial appendage (LAA) for subsequent ACP implantation (TEE, 90° position). **D)** 3D TEE could illustrate LAA occlusion after implantation, *arrow*: ACP device, completely sealing the LAA.