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Original Article

Unconventional uses of septal occluder devices: Our experience reviewed

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ABSTRACT

Device closure is now an accepted modality of treatment for cardiac septal defects such as fossa ovalis Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) and Patent Ductus Arteriosus (PDA) and have well-accepted indication and long term results. Devices used for these defects have been specifically designed for use in closing these defects. In this manuscript, we are reporting the efficacy of closure of nonseptal defects with devices conventionally used for septal cardiac defects although they have not been prototyped for use in such conditions.

Aim: To study use of occluder devices in nonseptal defects/malformation.

Material & methods: 39 patients, in the age group 2–67 yrs, were treated percutaneously with occluder devices for various conditions. These included: coronary arteriovenous (CAV) fistula ($n = 6$), pulmonary AV fistula ($n = 4$), systemic AV fistula (vascular plug; $n = 1$), closure of AP window (duct occluder; $n = 3$), closure of ascending aorta perforation (septal occluder; $n = 2$), ruptured sinus of Valsalva (RSOV) (duct occluder; $n = 13$), Fontan fenestration closure (ASD septal occluder, patent foramen ovale device, vascular plug $n = 3,1$ each), splenic artery (duct occluder; $n = 1$), Balock Taussig shunt (duct occlude; $n = 1$)and closure of mitral paravalvular leak ($n = 3$; duct occlude devices = 2, VSD device: $n = 1$) and aortic paravalvular leak $n = 2$ (duct occluder; $n = 2$ additional vascular plug = 2).

Results: Procedural success: Successful closure as signified by no residual shunt was achieved in all coronary AV fistula (immediately $n = 2$, at 3 months in all), ruptured sinus of Valsalva (immediate in all), fenestrated Fontan (immediately in all), and ascending aorta perforations (immediate), mitral paravalvular leak (immediate in none, and late in 2/3). The aortic paravalvular leak closed at 3 months follow-up in one and small residual persisted after 1 month in another. Complications: Local site Hematoma was observed in 4 patients. 2 of them required post procedure transfusion for the same. Hematuria was observed in 2 of the 4 patients of mitral paravalvular leak and 2 patients of RSOV device closure. Hematuria subsided with conservative management before discharge from hospital in all the

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4 cases. One patient with residual mitral regurgitation required surgical management for continuing hematuria, anemia and hyperbilirubenemia. There was one mortality observed on table during the attempted closure of a very large RSOV who presented to us in severe congestive heart failure and shock. On follow up ranging from 2 months to 6 years, all the patients are asymptomatic. There was no late complication related to device in any patient. *Conclusion:* It is feasible in selected nonseptal defects, which traditionally have been subjected to surgical interventions, to treat successfully, non surgically with the use of non prototype occluder devices without significant complications. Conventionally these devices have not been recommended for closure of nonseptal defects but show good early outcome. Adequate sample size with good follow up data is necessary before concluding that it can be safe alternative to surgery on long term.

1. Introduction

Transcatheter closure of septal defects (fossa ovalis ASD, VSD, PDA) is a recognized modality for treatment of cardiac defects. With increasing experience, unconventional use of these devices in defects other than septal defects is now increasing. Here we are reporting our experience of these devices in cardiac and extracardiac defects/malformation and review the available literature for their usage in the current era.

2. Methods

2.1. Patient population

From June 2001 to April 2013 39 patients were included.

2.2. Exclusions

Unconventional methods of device deployment at conventional sites like hybrid approaches for VSD devices have been excluded from the manuscript. Excluded from the study were venous channels closed with vascular plugs, major aorto-pulmonary collaterals (MAPCA), PDA who underwent coil or vascular plug closures have also been excluded. An informed written consent was taken from all the patients or their parents.

2.3. The device

The devices used included, Amplatzer Septal Occluder and delivery system (AGA Medical, Golden Valley, Minnesota), Lifetech (Heart R) device systems and delivery system (ASD, VSD, PDA). Amplatzer vascular plug (generation 1,2 and 4). All the devices have been described in detail in other reports (2,6). There are well documented standardized protocol for the deployment of the respective devices with multiple series describing the efficacy and safety of the device at conventional sites.

2.4. Patient's selection for transcatheter closure

Selection of patients suitable for device closure was based on measurement of maximal defect diameter done using various investigational modalities like echocardiography, Computerized Tomography (CT) angiography, Magnetic resonance imaging (MRI) and angiography. It was also based on morphological characteristics like location and size of the defect, relationship with the adjoining structures and rims of the defect.

2.5. Protocol for all patients

Detailed clinical and physical examinations, a standard 12-lead electrocardiogram (ECG), chest radiograph, transthoracic echocardiography (TTE) were performed in all patients. In patients with poor echo windows (adolescents and adults) or whenever it was needed to define the morphological characteristics of the defect, transesophageal echocardiography (TEE), CT angiography or MRI and angiography was also done if necessary for anatomical definition.

2.6. Implantation procedure

The procedure was done in catheterization laboratory under general anesthesia/local anesthesia in most of the patients with or without echocardiography and fluoroscopy guidance (Table 1). After obtaining the venous and arterial access, 100 units/kg of unfractionated Heparin is given to all the patients. Right heart hemodynamic data is obtained in all the patients prior to the procedure.

2.7. Follow up protocol

Detailed echocardiography examination was performed immediately after device closure in all patients to check for device position, stability, encroachment of device on adjoining structures. Flow through device fabrics was common at the time of device deployment and was not taken as residual shunt while any additional jet of shunt was taken as residual shunt. At 24 h Chest X-ray (Deep penetrating, frontal and lateral views), and transthoracic echocardiography were performed. On TTE, device position, stability, any evidence of encroachment over adjoining structures was checked. Bacterial endocarditis prophylaxis was advised for 6 months post procedure. Thereafter, follow up was done at 1 month, 3 months, 1 year and then annually with clinical evaluation,