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Review

New devices and technology in interventional cardiology

Jonathan Marvin Tobis (MD)[a,*], Islam Abudayyeh (MD, MPH)[b]

[a] UCLA David Geffen School of Medicine, Division of Cardiology, Los Angeles, CA, USA
[b] Division of Cardiology, Interventional Cardiology, Loma Linda University Health, Loma Linda, CA, USA

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ABSTRACT

There have been substantial improvements made in the tools and techniques used since the advent of percutaneous coronary intervention. What was primarily developed as a treatment of coronary artery disease is now used to address a variety of structural heart disease problems. The outcomes have been remarkably successful with relatively low complication rates that rival the results of open-heart surgery.

This article will review some of the new devices available for management of structural cardiac conditions including congenital defects and acquired valvular abnormalities. Transcatheter treatment offers advantages over surgical intervention in recovery time, improved patient satisfaction, lower procedural risk, and avoidance of cardio-pulmonary bypass especially in high-risk patients. We will discuss different medical conditions and introduce the devices used to treat these conditions. Each device or technique has benefits and risks, and familiarity with the devices along with patient selection will best optimize the outcome.

Contents

Introduction

Significant improvements have been made in the tools and techniques used since the advent of percutaneous coronary intervention. What was primarily developed as a treatment of coronary artery disease has become adapted to address the problems associated with structural heart disease. The outcomes have been remarkably successful with relatively low complication rates that rival the results of open-heart surgery [1]. There has been a continuous trend to use endovascular techniques for management of most cardiac conditions while simultaneously minimizing open surgical interventions.

This article will review some of the new devices available for management of a variety of structural cardiac conditions such as

* Corresponding author at: 10833 Le Conte Avenue, Factor Building, Room B-976, Los Angeles, CA 90095, USA. Tel.: +1 310 794 4797; fax: +1 310 267 0384.
E-mail address: jtobis@mednet.ucla.edu (J.M. Tobis).

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adults with congenital defects as well as acquired valvular abnormalities. Transcatheter treatment offers advantages over surgical intervention in recovery time, improved patient satisfaction, lower procedural risk, and avoidance of cardio-pulmonary bypass especially in high-risk patients.

Atrial septal defects

An atrial septal defect (ASD) is the second most common congenital heart defect occurring in 8 of 1000 live births. Small defects less than 1 cm may be discovered without any clinical symptoms since they do not produce significant shunting of blood and thus do not require closure. Larger defects with a Qp:Qs ratio greater than 1:1.4 may produce hemodynamic consequences consisting of atrial arrhythmias or right heart failure and should be closed. Only a secundum ASD may be closed by transcatheter devices rather than open-chest surgery, provided the anatomy is amenable with sufficient rims to hold a device. The most common device is the Amplatzer septal occluder (ASO, St. Jude Medical, St. Paul, MN, USA) (Fig. 1). The device is composed of a self-expanding double disk with a short connecting waist that acts to center the device within the defect. The device is made from 0.004 to 0.008-inch nitinol wire mesh that covers a polyester material to reduce blood flow through the device. Fibrous tissue ingrowth occurs in a few months to provide a biologic seal. The size of the device is selected by measuring the diameter of the septal defect, usually with an inflated sizing balloon. The Amplatzer device is available in sizes of 4 mm to 38 mm in the USA and up to 40 mm in the rest of the world. Depending on the size of the device chosen, the overhang for the atrial disks ranges from 6 to 8 mm. The device is easy to deploy except for large ASDs and has proven to be reliable with a low risk of complications or failure of implantation [2]. It is estimated that there have been over 200,000 percutaneous ASD implants worldwide. An ASD may also exhibit multiple fenestrations in the inter-atrial septum, which are too small to accommodate an ASO waist. These may require the use of the Amplatzer Multi-Fenestrated Septal Occluder or cribriform device (Fig. 2). Unlike the ASO, this device has matched atrial disk sizes to ensure maximal coverage of surrounding fenestrations, and a narrow waist to pass through the smaller defects. Two or three devices can be implanted close to each other to cover a wider area or an aneurysmal fenestrated septum. Long-term outcomes and facility of deployment is similar to the ASO. Complications related to the ASO range from 0.6 to 1%, with the worst complication, erosion, occurring in approximately 0.1% [3]. Although rare, allergy to nickel may cause complications including chest pain due to inflammation that requires surgical extraction of the device in about 0.2% [4].

A second device commonly used to close ASDs is the Gore-Helex septal occluder (Gore & Associates, Inc., Flagstaff, AZ, USA) (Fig. 3). The device is composed of a nitinol wire on an ePTFE (expanded polytetrafluoroethylene) patch creating a helix with 1.5 turns in the left atrium and 1.5 turns on the right side. The device is not self-centering so a device to defect diameter size of 2:1 is required so that an edge cannot prolapse through the ASD. The Gore-Helex occluder is a good option for smaller defects less than 13 mm in diameter. No erosions or allergic reactions to nickel have been documented with this device. There is a higher likelihood of wire fracture but this has not translated to an adverse clinical outcome or displacement. The CardioSeal and STARflex devices (NMT Medical, Inc., Boston, MA, USA) were previously available for ASD closures. Due to a high frequency of residual shunts, and lower procedural success rates of 85%, the devices are no longer available on the market worldwide [5].

Gore & Associates is currently evaluating a new septal occluder (Fig. 4). This device is composed of a 5-wire support frame covered with ePTFE. The device is intended to conform better to septal anatomy while maintaining stronger radial compression and reduced shunting compared with their previous design. All of the ASD devices are retrievable before release.

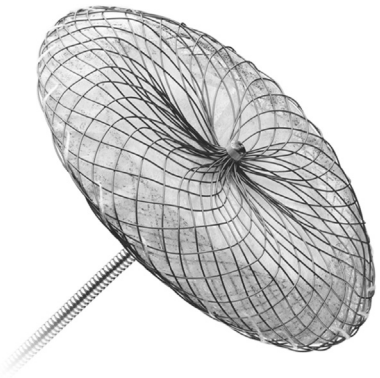

Fig. 1. Amplatzer septal occluder and delivery cable.

Fig. 2. Amplatzer cribriform device.

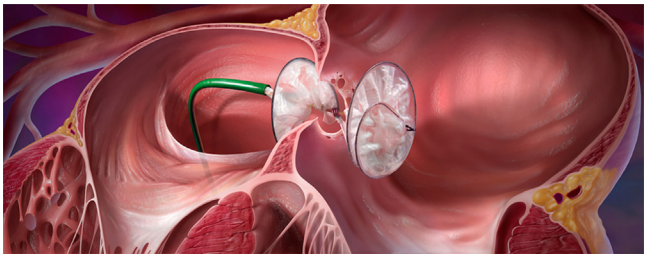

Fig. 3. Gore-Helex device.

Patent foramen ovale

A patent foramen ovale (PFO) is a congenital inter-atrial pathway that persists in 20–30% of the population. In utero, the foramen ovale permits shunting of oxygenated placental blood to

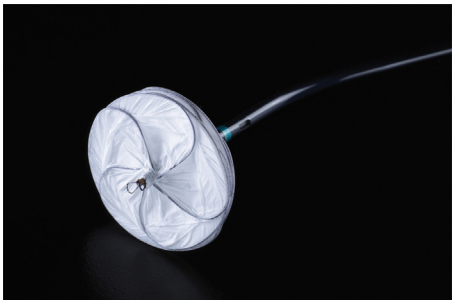

Fig. 4. Gore septal occluder (not yet approved).