Interventional treatments of structural heart disease are evolving at a rapid pace and are now established routine in many centres worldwide. Some have even left the traditional interventional field of cardiology behind and have emerged from coronary catheterisation labs into specialised units for catheter-based therapy of structural heart diseases. The term “structural heart disease interventions” was primarily established by Dr. Martin Leon at the Transcatheter Cardiovascular Therapeutics Conference (TCT) in 1999, when he was looking for an overarching category to describe catheter-based treatment modalities of various types of non-vascular heart diseases at a time when many of these concepts were just on the horizon. Over the last ten years, this term has been generally accepted as a category of disease by the medical community. The following overview highlights the newest commercially available devices, as well as developing strategies to treat structural heart diseases percutaneously.

Catheter Closure of Congenital and Acquired Shunts

PFO closure

A wide variety of percutaneous devices targeting congenital and acquired heart defects have recently become commercially available or are currently evaluated in clinical trials. In transcatheter closure of patent foramen ovales (PFO) for example, a trend can be seen towards defect-tailored devices and new designs or techniques which minimise the amount of foreign material left in the atria after implantation. Promising new concepts of PFO closure include the SeptRx™ device (Stout Medical Group, U.S.), which is positioned into the PFO pocket and is stabilised by two left atrial anchors that adapt to the tunnel length without significant alteration of the configuration of the septum primum (Majunke N et al. 2008) or the Coherex FlatStent™ PFO closure system (Coherex Medical, Inc., Salt Lake City, UT, U.S.) which consists of a lightweight, self-expanding, flat “stentlike” Nitinol lattice with integrated polyurethane foam designed to stimulate tissue growth inside the PFO tunnel.

The BioTREK™ (NMT Medical, Boston, MA, U.S.) is a fully bioabsorbable device. Its main component is a novel biosynthetic polymer named poly-4-hydroxybutyrate (P4HB) (Tepha, Inc., Lexington, MA, U.S.). As this device, which is currently in pre-clinical studies, is eventually replaced with native tissue, late device-related complications may be avoided. Another concept is the HeartStitch™ (Sutura Inc., Fountain Valley, CA, U.S.) strategy, which is based on the SuperStitch vascular suturing system designed for vascular stitching in general surgery (Ruiz CE et al. 2008).

One of the most recent techniques for PFO closure under clinical investigation is the Nit-Occlud® PFO umbrella (Pfm medical mepro, Nonnweiler-Otzenhausen, Germany) which is a double-disc Nitinol device with integrated polyurethane foam designed to stimulate tissue growth inside the PFO tunnel.

As the discussion on the potential pathological importance of PFO and the best possible therapy for secondary stroke prevention is still on, these new concepts for PFO closure will hopefully lead to further decrease of acute and late device-related complications. Safety and long-term reliability novel devices are especially important when PFO closure is discussed in migraine patients or divers.

ASD Closure

Percutaneous techniques for most secundum atrial septal defects (ASD) have largely replaced surgical closure. New devices commercially available are the partially bioabsorbable BioSTAR® occluder (NMT Medical Inc. Boston, MA, U.S.) and the Occlutech® ASD device (Occlutech, Jena, Germany). Despite this era of new technologies, conventional surgery currently remains the primary treatment modality for large defects (> 40mm), non-secundum defects and for those atrial septal defects in which the septal rim is insufficient.

VSD Closure

Ever since the very first interventional approach to ventricular septal defect (VSD) closure described in 1988 (Lock et al. 1988), various catheter-based techniques have been proposed for this purpose such as the Sideris buttoned device, the Rashkind device, Gianturco coils, the Clamshell device, the CardioSEAL and CardioSEAL/STARflex device, the Amplatzer occluder family and Nit-Occlud coils. Compared to transcatheter atrial septal defect or patent foramen ovale closure, intervention closure of ventricular septal defect is considered rather complex while it requires
both venous and arterial access to establish an arteriovenous wire loop. Efficacy of percutaneous closure of muscular ventricular septal defects has been reported for over a decade. Moreover, since the introduction of the Amplatzer Membranous ventricular septal defect occluder (AGA Medical, Golden Valley, MN, U.S.), perimembranous defects which have a higher incidence, have become more amenable to transcatheter closure techniques (Hijazi ZM 2003). However, there is an ongoing discussion as to whether coils may be an advantage due to the presumably reduced risk of AV block.

In post-myocardial infarction VSDs, interventional closure has shown to be feasible as well. However, despite gaining expertise and novel devices, due to the often atypical location of the defect, deficient and irregular rims and the presence of multiple defects, transcatheter treatment remains a major challenge for today’s interventionalists.

Closure of Patent Ductus Arteriosus

The ductal anatomy is known to be quite variable with the most common phenotype being a conical duct with a large aortic ampulla which narrows as it approaches the pulmonary artery at the ductus. Due to the variability, a number of different concepts of closure have been developed, e.g. Cook PDA coils (Cook Inc., Bloomington, IN, U.S.) for small PDA or a specific Nitinol duct occlusion devices like the Amplatzer® Duct Occluder (AGA Medical, Golden Valley, MN, U.S.) for larger PDAs.

Occlusion of the left atrial appendage in patients with non-rheumatic atrial fibrillation was first attempted by cardiac surgeons during open heart surgery (Blackshear JL et al. 1996; Johnson WD et al. 2000). The first two interventional approaches specifically developed for occlusion of the left atrial appendage were the PLAAATO™ device (eV3, Inc., Plymouth, MA, U.S. - not available anymore) and the Watchman® implant (Atritech, Inc., Minneapolis, MN, U.S.).

Data from the PROTECT-AF randomised trial have just been published which showed non-inferiority of the Watchman® implant compared to warfarin therapy for stroke prophylaxis (Holmes DR et al. 2009) and therefore pointing out the great potential of percutaneous occlusion of the left atrial appendage as an alternative to long-term anticoagulation. Next to the Amplatzer® septal occluder (AGA Medical Corporation, Golden Valley, MN, U.S.) which was not originally intended for occlusion of the left atrial appendage but has been reported with acceptable results (Meier B et al. 2003), the Amplatzer® cardiac plug (AGA Medical, Golden Valley, MN, U.S.), specifically developed for atrial appendage occlusion, is now available within a European registry.

Endless List of Techniques

The list of developing techniques seems endless and demonstrates that this medical field is expanding at a stunning pace. Some interventional techniques like closure of atrial septal defect and patent foramen ovale have already proven to be effective. Low complication rates of many catheter-based therapies of congenital shunts and satisfactory results in long-term follow-up have led to a higher acceptance from physicians and patients alike, and consequently have led to the replacement of surgery as the standard therapeutic approach.

One must acknowledge that the prevalence of most structural heart diseases is comparably low. Therefore, a major growth in numbers of interventional procedures as with interventional therapy of coronary heart disease cannot be expected. Critics may as well claim that some novel percutaneous approaches may potentially be less efficacious than present surgical standards.

Need for Less Invasive Solutions

However, it is unquestionable that there is an enormous need for less invasive catheter based solutions as alternative strategy, particularly in the...
treatment of patients at high surgical risk. Moreover, due to the complex anatomy and broad pathophysiological spectrum of some structural heart diseases, it will likely be necessary to combine different therapeutic strategies in order to achieve satisfactory results - as is still the case with conventional surgery today. Discussions concerning the balance between advances in catheter-based technology and the cost-effectiveness of patient treatment have concurrently arisen. Percutaneous aortic valve replacement for example, raises the costs of treatment compared to traditional surgical valve replacement. Looking at the present target patient cohort, who perhaps wouldn’t have been considered for surgery and therefore would have been treated by medical therapy alone, the costs are increased significantly.

Glancing beyond this discussion, more dedicated fellowship programmes need to be developed to provide hands-on training as well as accessible research platforms for those interested in turning empirical clinical know-how of structural heart diseases into pre-clinical research and subsequently transforming successful technologies into feasible interventional solutions of the near future.

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