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Review Article

Structural heart disease interventions

B.G.K.Sudhakar*, B.Sai Rahul
Consultant cardiologist, KIMS, Secunderabad
Kamineni Institute of Medical Sciences, LB Nagar, Hyderabad
***Corresponding Author:** B.G.K.Sudhakar, Consultant cardiologist, KIMS, Secunderabad

Received date: May 03, 2021; **Accepted date:** May 18, 2021; **Published date:** May 29, 2021

Citation: B.G.K.Sudhakar, B.Sai Rahul. (2021) Structural heart disease interventions. Clinical Research and Clinical Trials. 3(5); DOI: 10.31579/2693-4779/042

Abstract

Seed for invasive cardiology was sown in early part of nineties. Cardiac catheterization was actually pioneered by Werner Forssmann in 1929. However, credit for therapeutic interventional cardiology should go to US vascular radiologist, Charles Theodore Dotter for performing first peripheral arterial angioplasty [PTA] in 1964. Subsequently, a German cardiologist by name Andreas Gruentzig adapted the technique in 1974 to suit coronary artery disease and performed the first human coronary balloon angioplasty to treat blockage in coronary artery in 1977.

Key words: Structural heart disease; percutaneous procedures; heart team; surgery; imageology

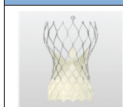
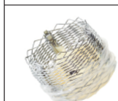
Introduction

Seed for invasive cardiology was sown in early part of nineties. Cardiac catheterization was actually pioneered by Werner Forssmann in 1929. However, credit for therapeutic interventional cardiology should go to US vascular radiologist, Charles Theodore Dotter for performing first peripheral arterial angioplasty [PTA] in 1964. Subsequently, a German cardiologist by name Andreas Gruentzig adapted the technique in 1974 to suit coronary artery disease and performed the first human coronary balloon angioplasty to treat blockage in coronary artery in 1977. The term Structural heart disease [SHD] was first introduced by Martin Leon in 1999, to separate non-coronary cardiovascular disorders like valvular heart disease [VHD], hypertrophic obstructive cardiomyopathy [HOCM], congenital heart disease [CHD] and vascular disorders from coronary heart disease **[Table.1]**. Aim was to develop and promote interventional techniques dedicated to management of these non-coronary disorders. Earlier, surgery used to be the only option for majority of these conditions. However, introduction of transcatheter techniques lead to paradigm shift in the way SHDs are treated consequently. Many of the percutaneous procedures are adopted from various surgical procedures and modified to suit the percutaneous route. Majority of patients are happy because of reduced discomfort, shorter hospital stay, and improved morbidity and mortality. Nevertheless, durability and cost are a cause for concern for doctors as well as patients. Major hurdle of the percutaneous procedures is limited number of cases, learning curve, and limited number of specialists, diversity of cases, end result and lack of structured training programs for many interventions. The success of the procedure rests on appropriate case selection, detailed pre and intra procedural imaging and knowledge and expertise of various techniques of device deployment, familiarity with the equipment, anticipation of complications and ways to deal with them.

Condition
Congenital Heart Disease
Ostium Secundum Atrial Septal defect [ASD]
Ventricular septal Defect [VSD]
Patent Ductus arteriosus [PDA]
Ruptured Sinus of Valsalava aneurysm [RSOV]
Coarctation of Aorta
Pulmonary valvular stenosis
Arterio-Venous [A-V] fistulas
Valvular Heart Disease
Mitral stenosis [MS]
Mitral regurgitation [MR]
Aortic Stenosis [AS]
Tricuspid valve regurgitation [TR]
Degenerated Tissue heart valve [THV]
Coronary Artery Disease
Post myocardial infarction [MI] VSD

Left Ventricular [LV] apical aneurysm
Miscellaneous Left Atrial Appendage occlusion [LAAO] Hypertrophic Obstructive Cardiomyopathy [HOCM] Patent Foramen Ovale [PFO] Para-valvular leak [PVL] Takayasu Aortoarteritis Iatrogenic ASDs consequent to some interventions

Table 1. *Overview of SHD*

Device Image*	Device Name	Device Characteristics	Regulatory Approval Status by Region
	Evolut family	• Self-expanding, supra-annular valve • Wide range of annular sizes • Ability to recapture and reposition when < 80% deployed • Good durability data; extensive evidence base	• FDA approved • CE Mark approved
	Sapien family	• Balloon-expandable, intra-annular valve • Low frame height and outer skirt to limit paravalvular leak • No ability to recapture • Good durability data; extensive evidence base	• FDA approved • CE Mark approved
	Acurate neo	• Self-expanding, supra-annular valve • Top-down deployment provides hemodynamic stability • Upper crown that caps native leaflets below coronary ostia • Low pacemaker rates • Flexible delivery system • Moderate evidence base	• CE Mark approved
	Allegra (NVT AG)	• Self-expanding, supra-annular valve • Early valve functionality minimizes outflow obstruction during deployment • Leaflet stress reduction through flexible commissures • Flexible delivery system • Limited evidence base	• CE Mark approved
	Centera	• Self-expanding, intra-annular valve • Low frame height • Motorized delivery system enables stable valve deployment by a single operator • Low rates of paravalvular leak and pacemaker • Ability to recapture and reposition when < 80% deployed • Limited evidence base	• CE Mark approved
	JenaValve	• Self-expanding, intra-annular valve (porcine pericardial tissue; size range: 65–92 mm) • Calcium-independent anchoring • Attaches to native leaflets, moving them away from coronary ostia • Transfemoral delivery • Limited evidence base	• Currently in trial in the United States and Europe
	Lotus Edge	• Mechanically expandable, intra-annular valve • Lowest rates of paravalvular leak • Fully repositionable, even after deployment • Moderate evidence base	• FDA approval anticipated Q2 2019 • CE Mark approved
	Portico	• Self-expanding, intra-annular valve • Ability to recapture and reposition when ≤ 80% deployed • Flexible delivery system • Moderate evidence base	• Approved for investigational use only in the United States • CE Mark approved

*All product images provided courtesy of their respective manufacturers.

Table.2. *Contemporary transcatheter aortic valve types and design features*

Noman Ali, PhD, andDaniel J Blackman, MD. TAVI: which valve foe which patient. Cardiac interventions today, vol.1, 2, March/April 2019

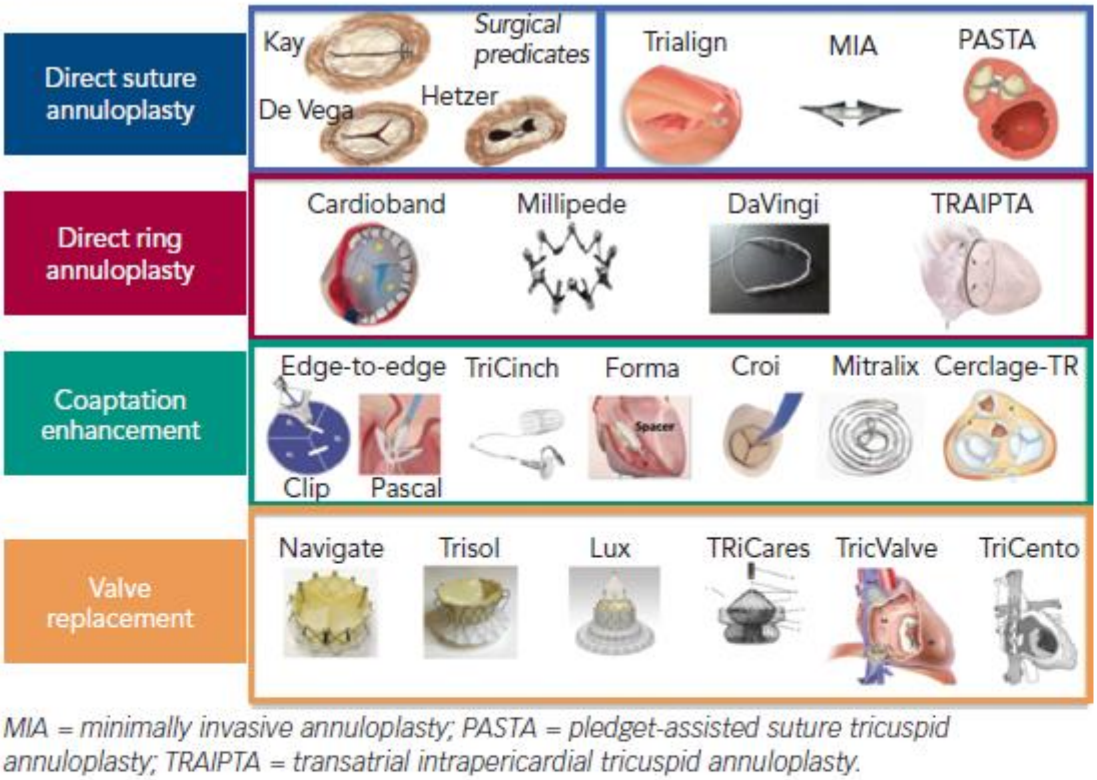


Figure 1: *Transcatheter tricuspid valve interventions*

Jonathan Curio, Ozan M Demur, Matteo Pagnesi, Antonio Mangieri, Francesco Giannini, Giora Weisz, Azeem Latib. Update on the current Landscape of Transcatheter option for TR treatment. International Cardiology Review. 2019; 14[2]:54-61

	Surgical	**Transcatheter interventions**
Duration of hospitalization	Long	Usually short
Morbidity/mortality	High in sick patients	Less compared to surgery
Cost	Expensive	Expensive
Imageology specialist	Not mandatory	Essential
Anesthesia and Cardio-Pulmonary support	Required	Local anesthesia, mild sedation
Durability	Good	TAVI, 5 yrs to 10 yrs results are satisfactory
Expertise, training	Well established	Adequate for CHD,HOCM, PVL, TAVI
Cosmetic	Risk of keloid formation is real	No scar
Redo surgery	Higher risk	Valve in Valve is feasible and safe
Complications	Relatively easy to manage	Some are difficult to manage

Table 3: *Comparison of Surgical vs Transcatheter therapy*

Requirement:

Well-structured dedicated training program

A well-equipped catheterization laboratory or a hybrid laboratory

In-house Cardio-Thoracic [CT] surgery team

Heart team- clinical cardiologist, interventional cardiologist, anesthesiologist, imaging specialist, cardiothoracic surgeon

Availability of Hard ware and familiarity with its usage

Well trained cardiac catheterization laboratory staff

Support from Industry

Imageology:

Imageology plays a central role in planning, execution and follow-up of percutaneous interventions for SHD. Imaging modalities like Two Dimensional Echocardiography [2D Echo], three-dimensional Transesophageal echocardiography [3D TOE], and Multi-Detector Computed Tomography [MDCT] are indispensable as they provide crucial information about anatomy of the lesion as well as surrounding structures beforehand which facilitates planning. Fluoroscopy, cine angiography, Intra Cardiac Echocardiography [ICE], and 3 D TOE are of immense value in guiding the procedure [1, 2]. There is limited experience with cardiac magnetic resonance [CMR]; however, it is an attractive alternative imaging modality in pre and post procedural evaluation of SHD, particularly in patients with renal impairment and in patient with suboptimal echocardiographic window [3].

More recently, advances in software and hardware have enabled the integration of various imaging modalities into a single data set, this resulting in real-time fusion imaging after the separate acquisition of two image data sets from two different sources [4]. Patient specific computer simulation in preparation for SHD intervention would help better planning and execution of procedures.

Challenges unique to SHD interventions

Interventions involving ASD, VSD, PDA, MS and HOCM are less complex whereas TAVI, Mitra Clip, PVL occlusion and LAAO implantation are relatively complex procedures. There are a number of issues unique to SHD interventions that pose inherent challenges to training and implementation [5, 6].

The first issue is the role of imaging before, during and after the procedure. So, imaging specialist has a very special role in the planning and success of the procedure.

A second issue relates to patient and procedural volume. Compared to coronary interventions per year, SHD interventions volume is considerably less.

A third issue relates to the wide spectrum of SHD and variability within each disease category. Therefore comprehensive training is not an easy task. Further subspecialization may be required.

Fourth issue is patient's acceptability and affordability.

Fifth issue is availability of multiple devices for each defect manufactured by different companies to suit subtle variability in the anatomy. Each device has advantages and disadvantages. Learning and mastering usage of each device is not an easy task.

Sixth issue is interventions involving tricuspid valve. Tricuspid valve is anatomically a complex valve and interventions are in nascent stage. The safety, feasibility and durability of Transcatheter tricuspid valve interventions are still being investigated.

Seventh issue is steep learning curve

Outcomes:

As majority of patients are elderly, better understanding and knowledge of diverse prognostic factors that influence the outcomes of transcatheter techniques are necessary. These factors include Left ventricular function, Right ventricular function, Previous valve surgery, Atrial Fibrillation, Renal function, Pulmonary arterial pressure, Tricuspid regurgitation, Residual defects after repair, Para Valvular Leak, Device failure, Severe LVOT calcification and frailty index of the patient.

Over the past decade, there has been a paradigm shift in the management of severe symptomatic AS with the development of TAVR therapies **[Table.2].** Based on available data, TAVR has now been approved as a therapy for patients with severe symptomatic AS, regardless of their surgical risk profile. An updated meta-analysis of seven Randomized Controlled Trials [RCTs] comparing TAVI and Surgical Aortic Valve Replacement [SAVR] among 8,020 patients with severe, symptomatic AS reported a lower risk of all-cause mortality [12% relative risk reduction] and stroke [19% relative risk reduction]. Faster recovery, less morbidity, less mortality, and durability of the valves used in TAVR compare favorably with surgically implanted valves **[Table 3].** Compared to redo surgery, valve in valve TAVR is safer in majority [7, 8].

Short term data of PFO closure demonstrated feasibility, ease of doing, and safety of the procedure. The long-term results of RESPECT [Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care] trial, Close Patent Foramen Ovale Closure or Anticoagulants Versus Anti-platelet Therapy to prevent Stroke Recurrence], and Reduce [Gore Septal occluder Device for PFO closure in stroke patients] trials confirmed lower stroke rates with PFO closure compared with medical therapy in apparently selected cases.

Mitral clip is another procedure which revealed promising results in selected group of patients. The results of COAPT [Cardiovascular Outcomes Assessment of the Mitra Clip Percutaneous Therapy for Heart Failure patients with functional mitral regurgitation] trial demonstrated that reducing functional MR in patients with left ventricular systolic dysfunction can improve Heart Failure symptoms and mortality; something surgical Mitral Valve repair in this cohort failed to demonstrate [9].

Tricuspid valve was ignored for many years because tricuspid regurgitation was always considered a benign condition. However, realization came when various studies clearly revealed any TR higher than mild progresses and leads to higher mortality and morbidity. Surgical repair of TV carries highest mortality compared to other valve surgeries due to inordinate delay in referral. Therefore, Tricuspid valve interventions are considered final frontiers to conquer for interventional cardiologist **[Figure. 1]**. The Trivalent [Transcatheter Tricuspid Valve Therapies] Registry included 312 high-risk patients with severe TR [76.4 ± 8.5 yrs; 56% females; mean Euroscore II: 9 ± 8%] at 18 centers. Interventions included repair at the level of the leaflet [Mitra clip, Abbott vascular], Annuloplasty [cardioband, TriCinch, Trialign], or Coaptation [FORMA] and Replacement. A total of 108 patients [34.6%] had prior left heart valve intervention (84 surgical and 24 transcath, respectively]. TR etiology was functional in 92%. Implanted devices included Mitra clip in 210 cases, Navigate in 6 cases, and PASCAL in 1, Trialign in 18 cases, Tricinch [first generation] in 14 cases, Caval valve in 30 cases, cardioband in 13 cases, forma in 24 caese and pascalin one case. Procedural success [defined as the device successfully implanted and residual TR ≤ 2+] was 72.8%. Thirty day mortality was 3.6% and was significantly lower among patients with procedural success [1.9 vs 6.9%; P=0.04]; Actuarial survival at 1.5 yrs was 82.8 % ± 4% and was significantly higher among patients who had procedural success achieved.

Discussion:

Transcatheter management of SHD is a rapidly growing and highly challenging field. Heart team approach ensured success in majority of cases of SHD interventions. Variety of cardiovascular disorders with diverse etiology are included under the heading of SHD requiring different training protocols with long learning curves. Currently, interventional procedures are well established for treatment of SHDs like ASD, VSD, PDA, AS, MS and PVL. Indeed, the pioneering work by Rubio-Alvares and Limon in 1952 to relieve critical pulmonic valve stenosis heralded a new era in transcatheter therapy for SHD [10]. Turning point in the history of interventional cardiology came with peripheral arterial angioplasty by Charles Theodore Dotter in 1964 and coronary angioplasty in late 1970s by Andreas Gruentzig. Transcatheter device closure of ASD has come a long way since the first experimental closure in dogs by Kings and Mills 1992. The Mitra clip is the major breakthrough in the journey of interventional cardiology. It is a transcatheter technology closely mimicking the double-orifice surgical techniques to MR repair pioneered by Alfieri et al [11]. Success of this technique enhanced the confidence and invigorated cardiologist to explore similar option for other SHDs. Next milestone was discovery of TAVI. Almost 4% of all adults beyond 75 years of age or older have moderate or severe AS. Balloon Aortic Valvotomy [BAV] remains an option for children or in adults for temporary palliation and symptomatic relief in patients who are not candidates for surgical valve replacement. BAV also continues to serve an important role as a bridge to either surgical or transcatheter aortic valve replacement in certain patients with AS requiring temporary hemodynamic stabilization. In 1989, Andersen and colleagues developed a bioprosthetic heart valve designed for transcatheter deployment. The assembly was carefully compressed onto a balloon catheter and deployed in various positions via endovascular insertion in several pigs. Laurels go to Cribier and colleagues for performing the first human implantation of Transcatheter Heart Valve implantation [THV] for the treatment of severe inoperable aortic stenosis on April 16, 2002 [12]. TAVR has now been approved as a therapy for patients with severe symptomatic AS, regardless of their surgical risk profile.

After the success of percutaneous aortic and mitral valve repair, focus has shifted to Tricuspid Valve. Till a couple of decades ago, many cardiologists considered TR a benign condition and conservative management is adequate, consequently, many patients were referred late for surgery with highest mortality among all valve surgeries. Now, there is enough evidence to show that more than mild TR progresses relentlessly and causes RV dysfunction and right heart failure.

Non-valvular Atrial fibrillation is relatively frequent in elderly and is responsible for increased incidence of stroke. Atrial fibrillation promotes stagnation of blood and Left atrial clots. In 90% of patients, clot forms within the left atrial appendage [LAA] [13]. These clots are responsible for peripheral embolism. Patients who have increased risk of bleeding or who are ineligible for oral anticoagulants can be offered LAA occluder implantation to prevent peripheral embolism. Right now, four devices are available- WATCHMAN device [Boston scientific], Amplatzer Cardiac Plug [St.Judes], WaveCrest device [Coherex medical], and LARIAT system [SentreHeart.incl]

New technologies for the treatment of SHD are proliferating like never before; consequently, the number of interventions for SHD is increasing exponentially and the procedures are becoming more complex [14]. The development and utility of advanced cardiac imaging constitutes one of the key factors in the success of SHD interventions. Every potential patient should be thoroughly evaluated utilising clinical examination and imageology techniques like MDCT, TTE, 3D TOE, and MRI [15]. Interventional cardiologists are best suited to deal with SHD. Dedicated fellowship programs have recently been developed such as the program in the Massachusetts general hospital [16, 17].

Conclusions:

Studies have demonstrated SHD interventions are non-inferior to surgical procedures in selected group of patients. Acceptance among patients is increasing as more data confirming their durability and safety are pouring in. Thanks to the foresight and perseverance of pioneers, percutaneous procedures have evolved and matured very rapidly in the last 2-3 decades. With durability not being a major issue, low risk cases are being considered for transcatheter techniques. Imageology plays a vital role in the planning and accomplishment of the procedures. Patient specific computer simulation in preparation for SHD intervention would help better planning and execution of procedures. In future, cases which are not suitable for nonsurgical intervention may be referred to surgeon for correction. As of now, lack of insurance coverage, adequate training and expertise and of course cost are major impediments for rapid growth of SHD interventions at least in developing countries.

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