

Chapter 2: Standard Wires and Balloons Used in TAVR.

Manoj Thangam MD¹, Prakash Balan MD, FACC²

¹ McGovern Medical School, Internal Medicine Department, Houston, TX

² McGovern Medical School, Cardiovascular Medicine Department, Houston, TX

The selection of guide wires and balloon catheters is largely determined by each operator's familiarity and training with available options. The following chapter intends to offer an overview of commonly utilized guide wires and balloon catheters during TAVR.

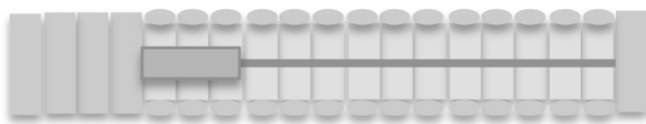
Guide Wires

In the setting of TAVR, guide wires are used for the introduction of sheaths, crossing the stenotic valve, guiding balloons for aortic valvuloplasty, and valve deployment across the aortic annulus. Each wire possesses different characteristics regarding stiffness and shape that must be considered during the wire selection process.

Guide Wire Basics

Guide wires are made of stainless steel, nitinol, platinum, and/or alloy metals. Although the composition of each part of the wire tends to vary, the structure of a wire is comprised of a central safety ribbon covered by a core that is then wrapped by a braid (Figure 1). The shaft of wires can have different degrees of stiffness and facilitates structural integrity during wire use. The stiffness of the shaft is primarily attributed to the metal type and thickness of the core. A tapering core generates the distal end of the wire forming a spring-tip. This area is composed of a thinner core that allows for increased flexibility and moldability.

Figure 1: Wire structure



The central safety band flows the entire length of the wire with a surrounding core that tapers at the distal end to allow increased flexibility with the aid of the surrounding braid.

Guide Wire Related Complications

Guide wire use in the setting of TAVR has several possible complications. The introduction of the wire into a vascular structure creates the potential for vessel dissection, which may then require endovascular or open repair. Once the wire is placed into the left ventricle it may irritate the myocardium resulting in ventricular arrhythmias. Additionally, ventricular wire placement may result in wire entanglement in choral structures. Although wire selection may minimize this risk, careful manipulation is usually sufficient to safely retract the wire. The most deleterious wire related complication in TAVR is ventricular perforation. Due primarily to straight wire use, folding of a wire loop, or deep apical placement of the wire, perforation is associated with a high risk of mortality and morbidity.^{1,2}

Available Guide Wires

There are six commonly used guide wires in the TAVR procedures. They have a diameter of 0.035 inches, with length ranging from 260 – 300 cm for wires used for device implantation; wires used for intravascular access and sheath placement may be shorter.

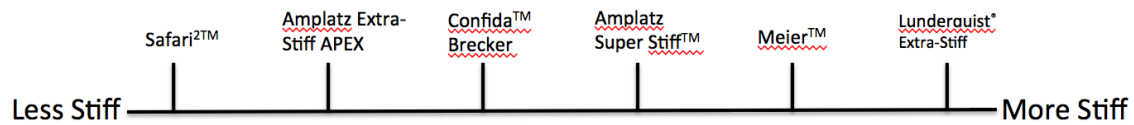
The shaping of a wire refers to the distal portion of the wire. Due to the risk of ventricular perforation, the distal end is best shaped into a loop. This facilitates the anchoring of the wire into the ventricle without creating a ventricular pressure point for the wire during rapid ventricular pacing. The anchoring effect of the wire serves to add stability while crossing the aortic valve with a balloon or TAVR device. Some wires are available pre-formed with the loop engineered into the product while others require manual shaping of the distal loop (Table 1).

Table 1:

Pre-Formed	Not Pre-Formed
Confida™ Brecker wire (Medtronic, Inc., Minneapolis, MN)	Amplatz Super Stiff™ wire (Boston Scientific, Malborough, MA)
Amplatz Extra- Stiff APEX wire (Cook Medical, Inc., Bloomington, IN)	Meier™ wire (Boston Scientific, Malborough, MA)
Safari²™ Pre-Shaped wire (Boston Scientific, Malborough, MA)	Lunderquist® Extra-Stiff wire (Cook Medical, Inc., Bloomington, IN)

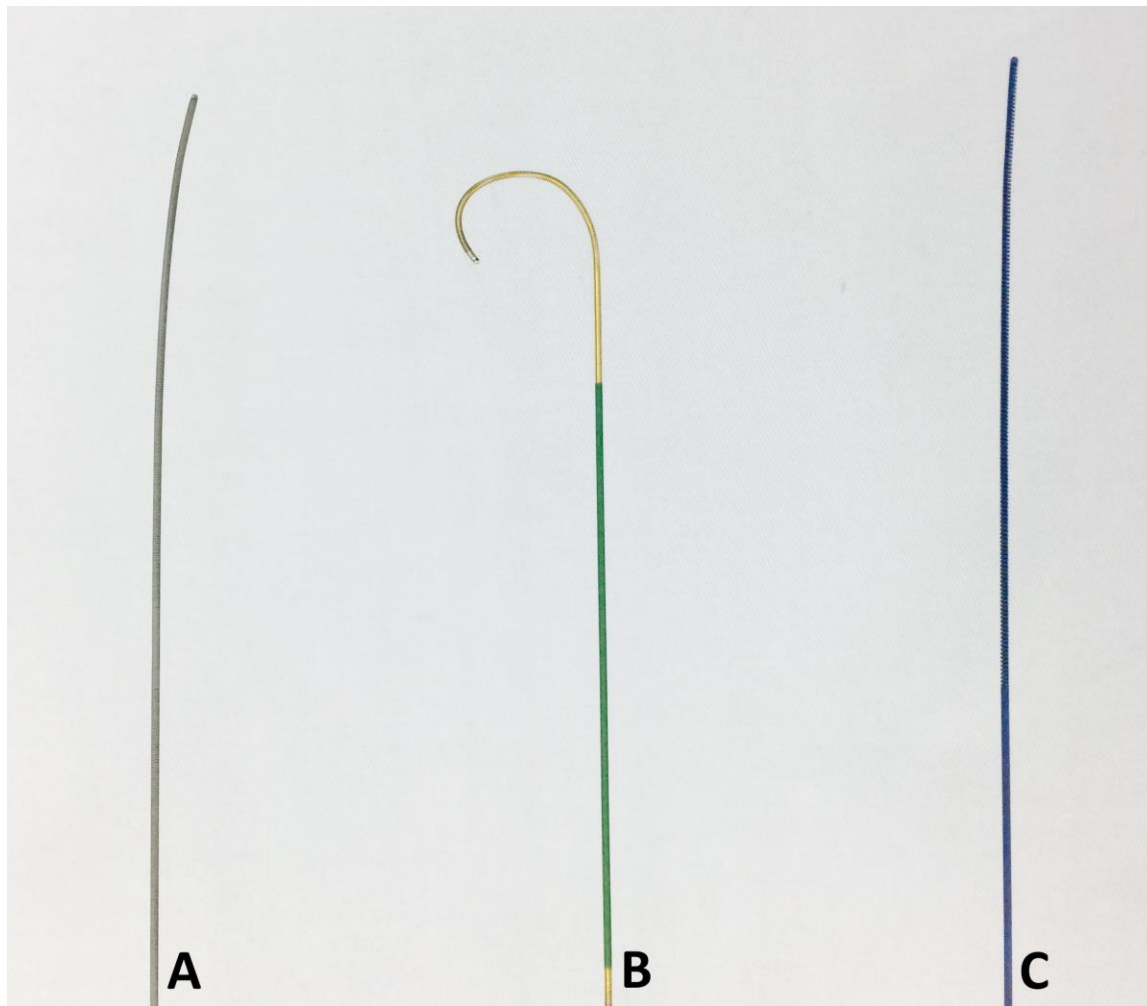
The stiffness of the wire is an important consideration during the wire selection process (Figure 2). Stiffer wires offer more stability while less stiff wires are associated with a lower risk of vascular damage and ventricular perforation.

Figure 2: Relative stiffness of wires



Generally, operators choose a stiffer wire to gain intravascular access and introduce large diameter sheaths required for TAVR. The most frequently used wires for this purpose include the Lunderquist® Extra-Stiff wire (Cook Medical, Inc., Bloomington, IN), Meier™ wire (Boston Scientific, Marlborough, MA), and Amplatz Super Stiff™ wire (Boston Scientific, Marlborough, MA) (Figure 3).

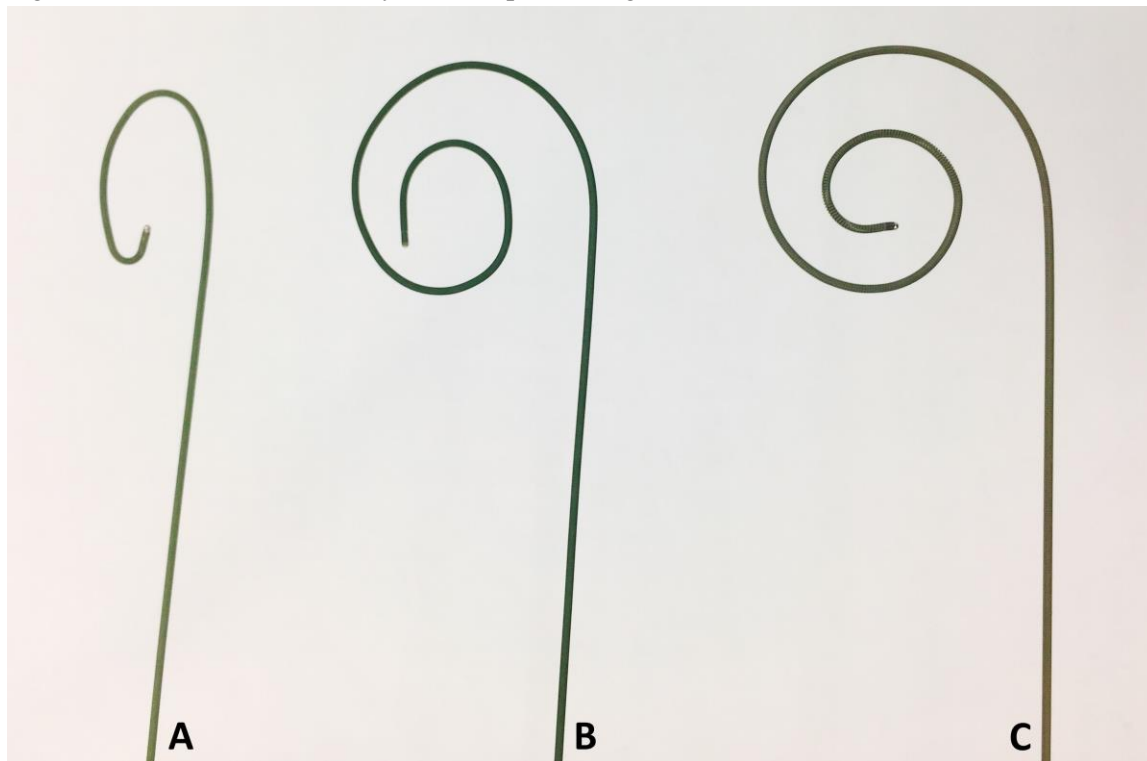
Figure 3: Guide wires commonly used for access.



(A) Lunderquist® Extra-Stiff guide wire, (B) Meier™ guide wire, (C) Amplatz Super Stiff™ guide wire.

Less stiff wires are often selected for guiding balloon catheters during aortic valvuloplasty and the percutaneous valve apparatus itself. These wires generally have a pre-formed loop at the distal end in order to reduce the risk of ventricular perforation and to be anchored safely into the ventricle. The geometry of the left ventricle and the plane of the aorta and aortic annulus should also be considered when choosing a wire. The Amplatz Extra-Stiff APEX wire (Cook Medical, Inc., Bloomington, IN), Confida™ Brecker wire (Medtronic, Inc., Minneapolis, MN), and Safari²™ wire (Boston Scientific, Marlborough, MA) are commonly used for this portion of the procedure (Figure 4). The Confida™ Brecker wire was specifically designed for use with the CoreValve Evolut R® system (Medtronic, Inc., Minneapolis, MN) and is included in the valve package, though it may be used with other TAVR systems. The Amplatz Extra-Stiff APEX wire has a double curve design composed of a larger curve with the distal tip of the wire forming a 2mm J bend; it can easily maneuver in smaller ventricles and is the most commonly used guide wire for TAVR. The Safari²™ wire is available in three different loop sizes. In the setting of very large ventricles, the 50 mm diameter wire may be more suitable. Rarely, the Amplatz Super Stiff™ wire has been used in the setting of a very horizontal aorta and aortic annulus; its stiffness does increase the risk of ventricular perforation when used for valve deployment. Ultimately, operators consider the characteristics of each case when determining wire choice.

Figure 4: Guide wires commonly used for positioning in the left ventricle.



(A) Amplatz Extra- Stiff APEX guidewire, (B) Confida™ Brecker guidewire, (C) Safari²™ guidewire.

Balloons

In TAVR, balloon catheters are used to perform aortic valvuloplasty, valve deployment, and post-dilation of implanted valves.

Balloon Catheter Basics

Percutaneous balloon catheters are composed of a central sheath that can be advanced over a guide wire, with the distal end containing a pneumatically inflated balloon. Two radiopaque indicators positioned on the catheter display the length of the inflated balloon to the operator under fluoroscopy. Balloons are made from various plastics, polymer fibers, and even Kevlar® coating (Dupont®, Wilmington, DE). Variable lengths (3-6 cm) and diameters (20-30 mm) are available in order to accommodate specific aortic architecture and valve types.

Prior to use, a syringe with contrast dye (usually a diluted mix with heparinized saline) is used to “prepare” the balloon, which means to apply negative pressure to the distal port to empty the balloon of air, in order to have the smallest possible profile during insertion in the catheter and sheath, and to avoid embolization of air in the aorta in the event of a balloon rupture (which can be caused by aortic valve calcification or inflation above the burst pressure of the balloon). The central wire port should be flushed with heparinized saline. An insufflator is then connected to the distal end of the balloon port, and is used to manually inflate the balloon at specific operating pressures. After inflation, negative pressure is again applied to deflate the balloon completely.

Aortic Valvuloplasty

The size of the aortic valve orifice determines the need for valvuloplasty prior to valve deployment. Although TAVR can be successfully performed without prior valvuloplasty, it may be necessary if the aortic orifice is too narrow for the device to be successfully maneuvered into the aortic annulus. In this situation, operators may choose to perform a valvuloplasty to dilate the stenosed valve and facilitate passage of the valve delivery system. Commonly, a 20mm diameter balloon catheter is used for valvuloplasty although operator preference and aortic architecture may influence balloon selection.

A wide array of balloon valvuloplasty catheters are available on the market. The most frequently used include the Z-MED™ balloons (B. Braun Interventional Systems Inc., Bethlehem, PA), True Dilation® balloons (Bard Peripheral Vascular, Inc., Temple, AZ), and True™ Flow balloons (Bard Peripheral Vascular Inc., Temple, AZ). Z-MED™ catheters are advertised to have rapid inflation and deflation times (Figure 5). True Dilation® balloons are far more rigid due to their Kevlar® coating (Figure 6). True™ Flow balloons have a unique design featuring a central canal surrounded by eight smaller balloons all housed within a larger fiber sheath that facilitates blood flow during balloon insufflation (Figure 7).

Figure 5: Z-MED II™ balloon

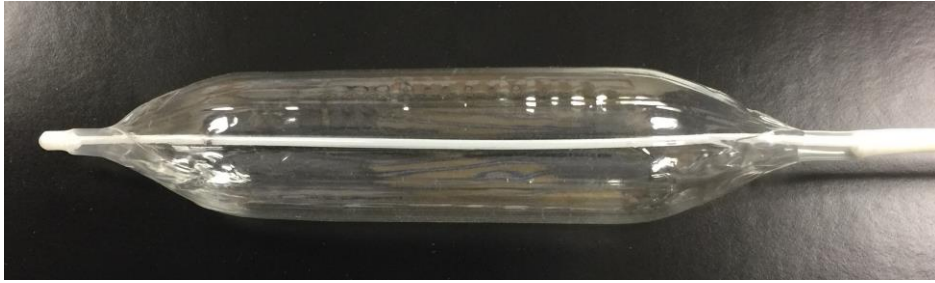


Figure 6: True Dilation® balloon.

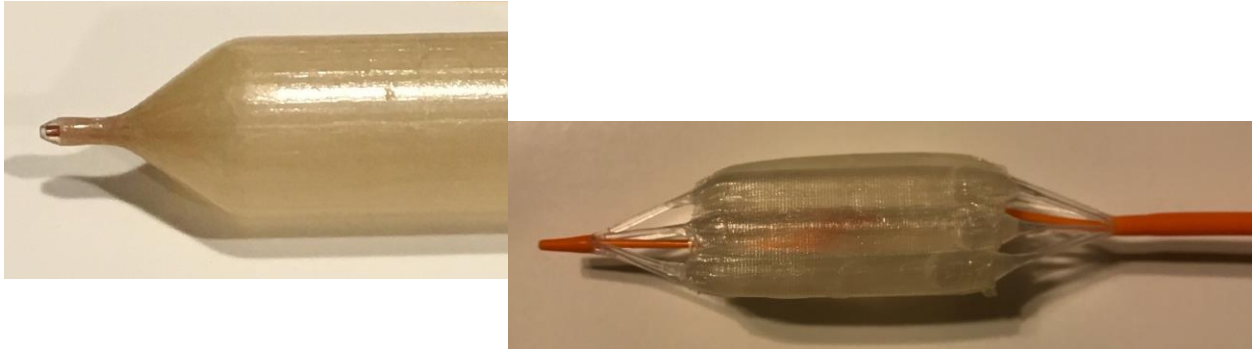
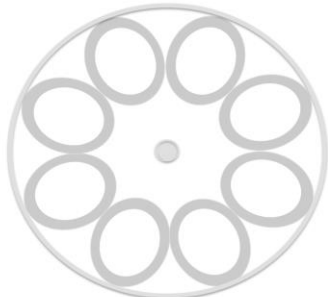


Figure 7: True™ Flow Balloon

- A. 
- B. True® Flow balloon catheter.
- A. Diagram of the True® Flow balloon depicting the organization of eight small balloons to produce a central tunnel for blood flow during inflation.
- B. True® Flow balloon catheter.

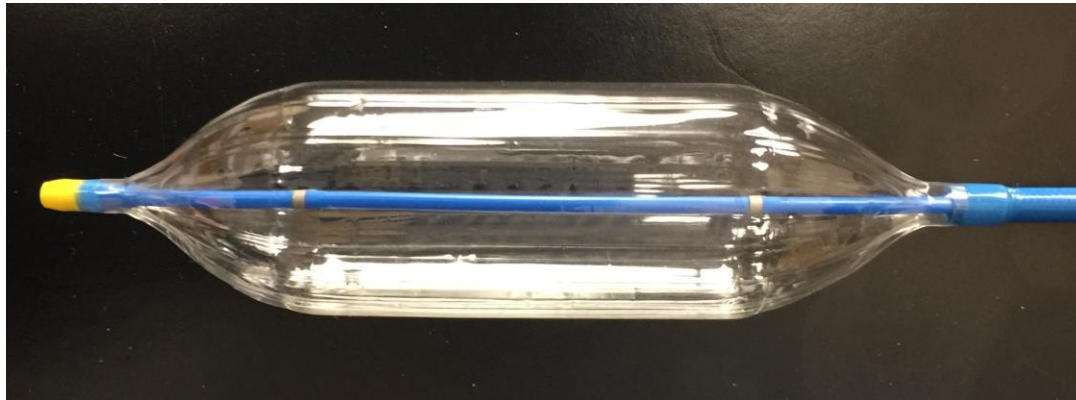
Difficult Valve Sizing

Balloon catheters can also be used to confirm aortic annular size when pre- or intra-procedural imaging is inconclusive in determining appropriate bioprosthetic valve size. This most commonly occurs when considering the implantation of a 23 mm or 26 mm valve. The operator may place the balloon in the aortic annulus and dilate to a diameter consistent with the smaller valve size while concurrently injecting radiopaque dye in the proximal aorta. Visualization of the dye passage into the left ventricle during balloon inflation indicates that a larger valve size would be appropriate.

Valve Deployment

Valve deployment is performed with the aid of balloon insufflation for balloon expandable systems. Note that the CoreValve Evolut R[®] system is a self-expanding valve that does not require use of an additional balloon for valve deployment. Commonly used balloon expandable valves (Sapien 3, Edwards Life Sciences, Irvine, Ca), are packaged with a delivery balloon catheter specifically engineered for the housing and deployment of these valves.

Figure 8: Edwards balloon catheter.



Post-Dilation

After a bioprosthetic valve is implanted in the aortic annulus, the operator may note paravalvular regurgitation. Often times, balloon post-dilation is used in this setting to minimize the amount of regurgitation. With the Sapien valve systems, post-dilation is typically performed with the same balloon that was used as part of the valve delivery system (Figure 8). An addition of 1 or more ml of contrast to the balloon volume used during valve deployment may be performed incrementally to mitigate paravalvular regurgitation. For the CoreValve Evolut R[®], a new balloon must be used. Most commonly, the Z-MED[™] or True Dilation[®] balloon catheters are selected for this purpose.

Compliance amongst balloons varies. Moderately compliant balloons are commonly utilized for valvuloplasty. In rare instances, less compliant balloons may be necessary. However, operators must exercise caution since less compliant balloons may be more prone to cause structural damage including annular rupture. Regardless of balloon choice, balloon sizing is based on native aortic annulus size and may not necessarily correspond to the valve size. Post-dilation is accomplished with the aid of angiographic landmarks and/or intra-procedural echocardiography. Operators who choose to employ post-dilation strategies must weigh the risk of intra-operative complications against the risks associated with persistent para-valvular regurgitation.^{3,4}

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