

There's an App for That!

An overview of the Valve in Valve app for TAVR and how it was developed.

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With the booming popularity of handheld technology, smartphones and tablets have become an integral part of daily life for on-the-go, instant communication as well as access to information. Applications (or apps) are computer programs designed to run on smartphones or tablets and were originally designed for general productivity and information, such as weather reports, emails, stock prices, etc. Software tools have rapidly expanded, leading to the development of a vast variety of apps, including those for medical use for patients as well as physicians.

The Apple App Store and Google Play are home to more than a million apps each and, between them, have more than a billion downloads. Within these services, there are over 100,000 medical apps currently available, and trends seem to suggest an increase in use of these apps in the medical field, in particular by the younger generation of physicians. It is estimated that by 2015, more than 500 million smartphone users worldwide will use some sort of medical app and that the global market for health apps may reach £16 billion by 2016.¹ The most popular physician-targeted apps include those that help find drug information, make clinical calculations, and take notes.² Apps that provide a quick-reference guide to medical procedures or conditions can be extremely advantageous, as they can aid physicians in their daily clinical practice.

Transcatheter aortic valve replacement (TAVR) has emerged as a suitable alternative for traditional surgical aortic valve replacement in high-risk patients, in whom open surgery may be considered too hazardous. An ongoing clinical need has led to the expansion of this procedure for degenerated surgical heart valve disease (ie, the valve-in-valve [VIV] procedure).^{3,4}

In a VIV procedure, a transcatheter heart valve (THV) is placed within a degenerated surgical heart valve (SHV) by a percutaneous method.⁵ The VIV procedure is a more technically straightforward procedure compared to native TAVR, as the THV is implanted within the existing scaffold

of the SHV. Nonetheless, the design differences between the implanted SHVs can vastly influence the outcome. For this reason, it is important for all operators to be familiar with the morphological details of SHVs, as well as available THVs.

Each SHV has a distinct appearance under fluoroscopy, which will not only help with identifying the type of SHV but also helps in correct placement of THVs. Dimensions of various stented aortic valves (16 types) and stentless SHVs (eight types) vary and are model and label size specific. Hence, it is sometimes impossible to obtain information about various combinations of SHVs and THVs for a VIV procedure in a given patient. For this reason, a smart phone app was developed (the Aortic Valve in Valve app, Dr. Bapat and UBQO Ltd.) with the aim of providing essential information in a succinct, freely available, and easily accessible manner. Figure 1 shows the workflow containing information that led to the development of the app.

DEVELOPMENT OF THE VIV AORTIC APP

There are four main objectives that need to be considered to ensure the success of a VIV procedure. These objectives are (1) understanding the design or anatomy, in particular, fluoroscopic appearances of the failing SHV; (2) understanding THV design; (3) choosing the correct size of the THV prosthesis for the existing SHV; and (4) the ideal implantation position of the THV within the existing SHV.

The aortic app was developed with these features in mind, addressing each in detail to ensure that operators were provided with all relevant information to enable a successful procedure. Within the app, a workflow could be provided such that information specific to a clinical scenario could be easily obtained in a stepwise fashion (Figure 2). Each step takes the user from important generic information about a particular SHV to very detailed information about a particular combination of SHV and THV, including the end result. This reduces the need to search through vast amounts of literature to find relevant information to help plan and perform a VIV procedure.

SURGICAL HEART VALVE DESIGN

One of the key features of the VIV aortic app is that it provides the TAVR team with a quick and easy reference guide to the anatomy, dimensions, and design features of available SHVs and THVs, including their fluoroscopic appearances. To achieve this, major heart valve manufacturers were contacted, and all sizes of the commercially available 16 stented aortic valves and eight stentless valves

were obtained. Important valve-related details were also obtained. For stented valves, these include leaflet type, position of the leaflet relevant to the stent frame (inside or outside), stent inner diameter (ID) from manufacturer charts, and stent height. For stentless SHVs, the type (root of valve) and tissue annulus diameter information were obtained (Figure 3). Each SHV design characteristic was documented with high-quality photographs and fluoroscopic imaging.

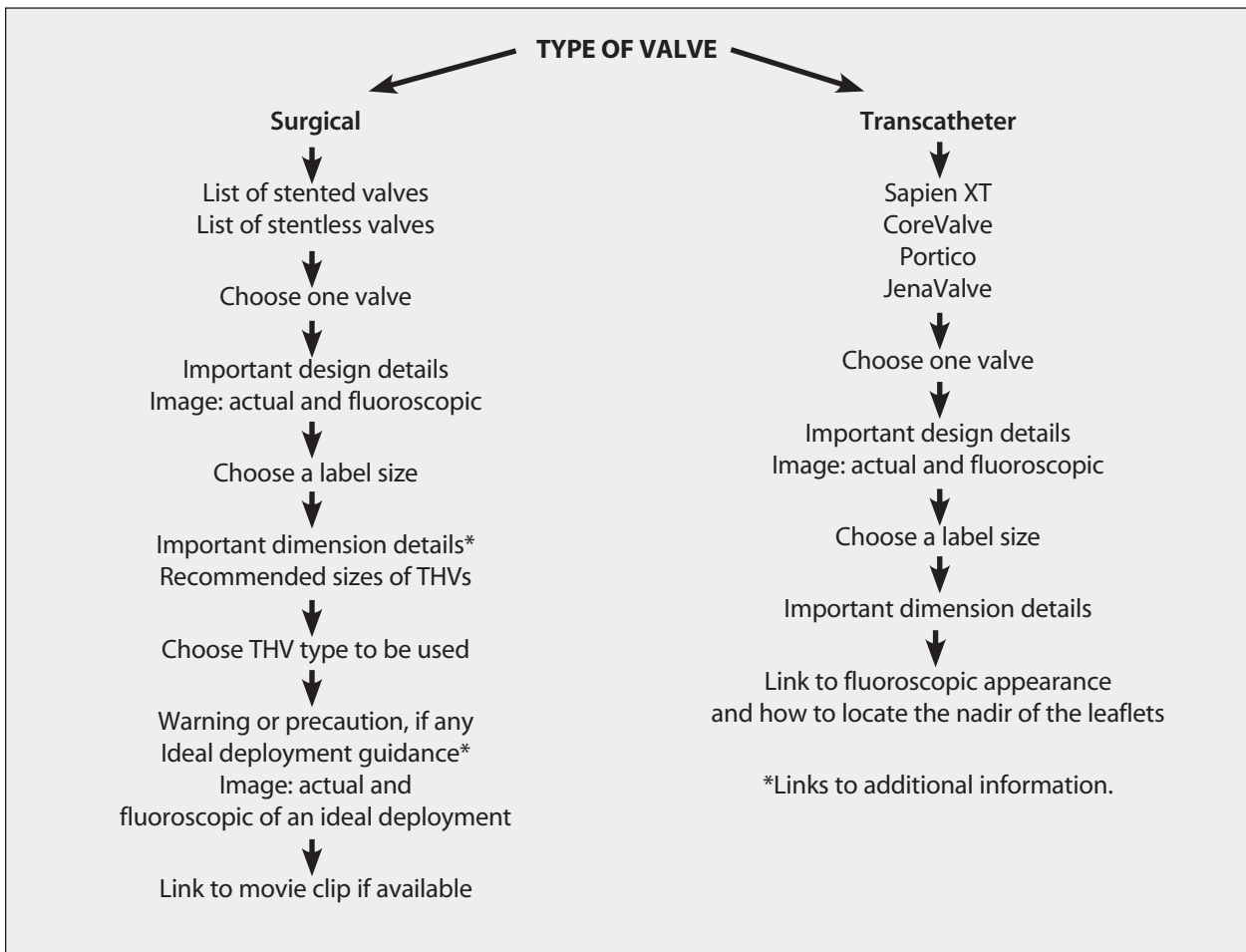


Figure 1. Workflow for the development of the VIV app.

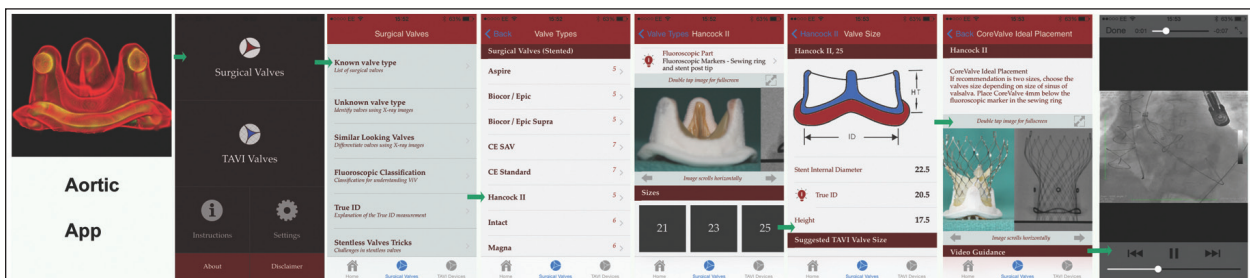


Figure 2. The aortic VIV app. A stepwise approach from a list of available SHVs to the anatomy and fluoroscopic appearances of a SHV and a guide to suitable THV implantation are shown in the app.

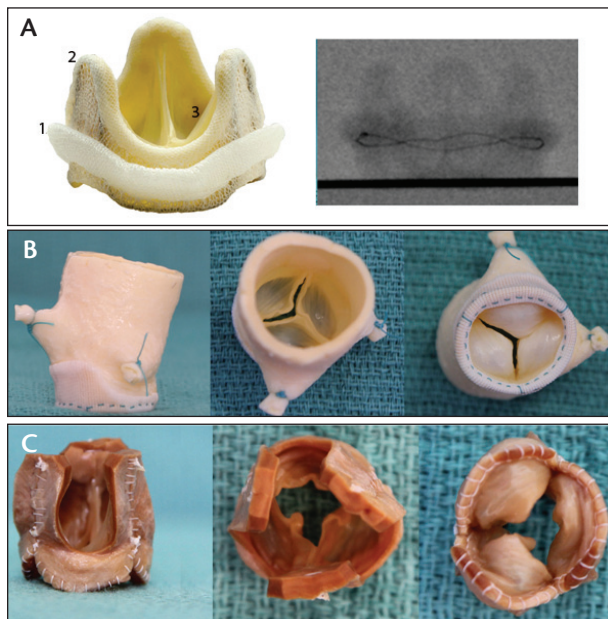


Figure 3. Stented versus stentless surgical valves. An example of a stented SHV, Carpentier-Edwards Porcine valve (Edwards Lifesciences) and its corresponding fluoroscopic appearance showing a visible sewing ring (1 = sewing ring, 2 = stent posts, 3 = leaflets) (A). Almost all stented valves have a radiopaque marker, either within the sewing ring, the frame, or the posts. The Toronto SPV root (St. Jude Medical) (B) and Cryolife O'Brien (Cryolife, Inc.) stentless (C) valves have no radiopaque markers.

THV DESIGN

All sizes of the four THVs in clinical use for VIV procedures (Sapien, Edwards Lifesciences; CoreValve, Medtronic, Inc.; Portico, St. Jude Medical; and JenaValve, JenaValve Technology, Inc.) were obtained from their manufacturers (Figure 4). These were then photographed, and their fluoroscopic images were obtained. Because VIV is a fluoroscopically directed procedure, it is vital to be familiar with the most important fluoroscopic landmark (ie, the nadir of the leaflets), which allows for correct placement of the THV within the SHV (Figure 5).

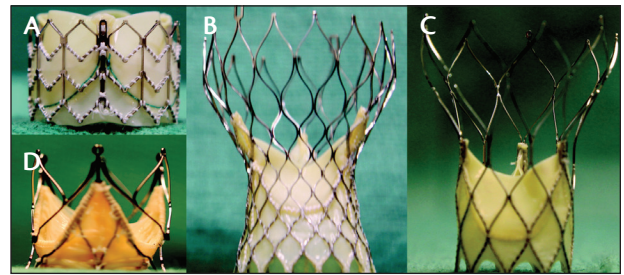


Figure 4. Details of the four THVs in use for VIV are given in the TAVR section of the VIV app: Sapien XT (A), CoreValve (B), Portico (C), and JenaValve (D).

CORRECT SIZING OF THVs AND THE CONCEPT OF TRUE ID

The true ID of an SHV is different from the stent ID. The stent ID is based on the stent diameter of the valve without leaflets, and the true ID of a SHV is the ID of the valve with the presence of the valve leaflets. This diameter varies (as shown in Figure 6) with the type and placement of leaflets.

Essentially, when compared to the stent ID, the true ID is smaller by 2 mm in all porcine valves, smaller by 1 mm in all pericardial valves with leaflets mounted inside the stent, and equal to the true ID when pericardial leaflets are mounted outside the stent.⁶ The size of THV should be chosen according to the true ID because it is the most relevant measurement during a VIV procedure.

IDEAL IMPLANT POSITION OF A THV WITHIN A GIVEN SHV

To avoid malposition (ie, too low placement leading to interference with mitral function or too high placement leading to embolization), the THV must be optimally placed within the SHV. Because the sewing ring of the SHV is its narrowest diameter, it can provide a good anchor for a THV. The sewing ring, however, is not radiopaque in all SHVs. In fact, valves may have either a visible sewing ring or visible stent frame or no radiopaque features at all (Figure 7). It is easy to obtain an ideal implantation position when using valves with a visible sewing ring,

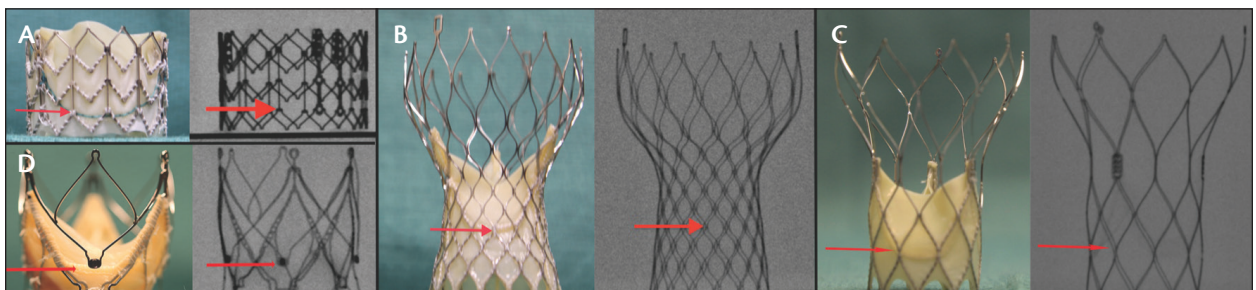


Figure 5. Fluoroscopic anatomy of the THVs: Sapien XT (A), CoreValve (B), Portico (C), and JenaValve (D). The red arrows point to the nadirs of the leaflets.

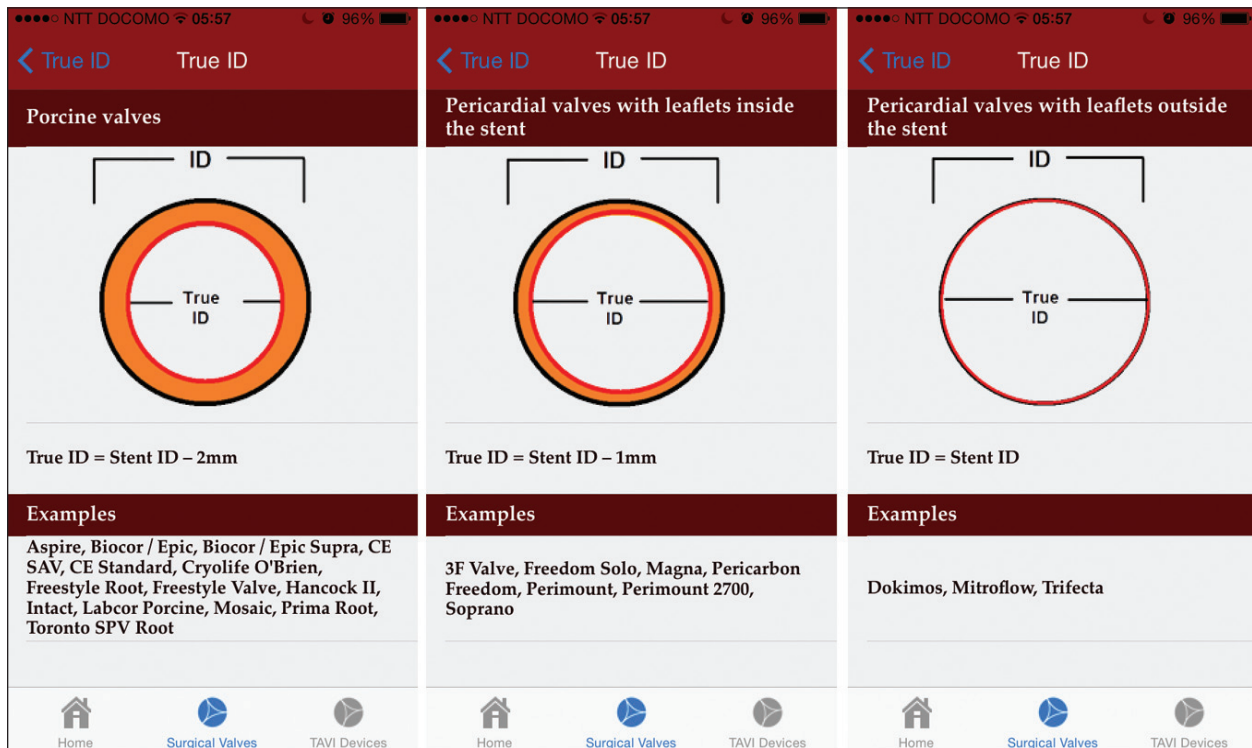


Figure 6. The concept of true ID, as shown in the app. The true ID of a SHV is dependent on the type of leaflets (porcine or bovine) and their configuration relative to the stent.

regardless of the supra- or intra-annular design, whereas in valves with a visible stent frame, this design feature requires more consideration.

To help visualize this for each of these valve types, a suitable THV was implanted in the optimal implant position and photographed, in addition to taking fluoroscopic images. This represents the ideal or optimal end result for every VIV combination (Figure 8). Finally, short movie clips showing real-life cases have also been included to make this app as clinically relevant and useful as possible.

STENTLESS VALVES

Stentless valves can be implanted either as a root replacement or in a subcoronary fashion. The former includes reimplantation of the coronary buttons and hence is at lower risk for coronary obstruction after a VIV procedure. On the other hand, the suture line is in close proximity to the coronary ostia in a subcoronary implantation technique, and there is a higher risk of coronary obstruction after a VIV procedure. Stentless valves lack a stent frame and therefore are not visible under fluoroscopy (Figure 3). These two features make VIV procedures in a stentless valve challenging. Tips and tricks used during a VIV implantation within stentless valves have been included in the app as a separate section to help users ensure a successful outcome.

ADDITIONAL APPS

The VIV aortic app focuses on information relevant to the VIV procedure within a failing aortic SHV. There are

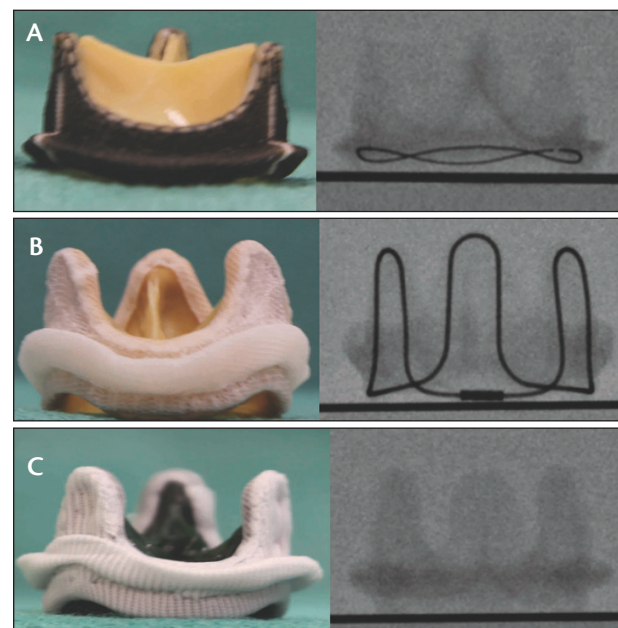


Figure 7. Fluoroscopic appearances of SHVs. Valves with a visible sewing ring (A), valves with a visible stent frame (B), and valves with no fluoroscopic markers (C).

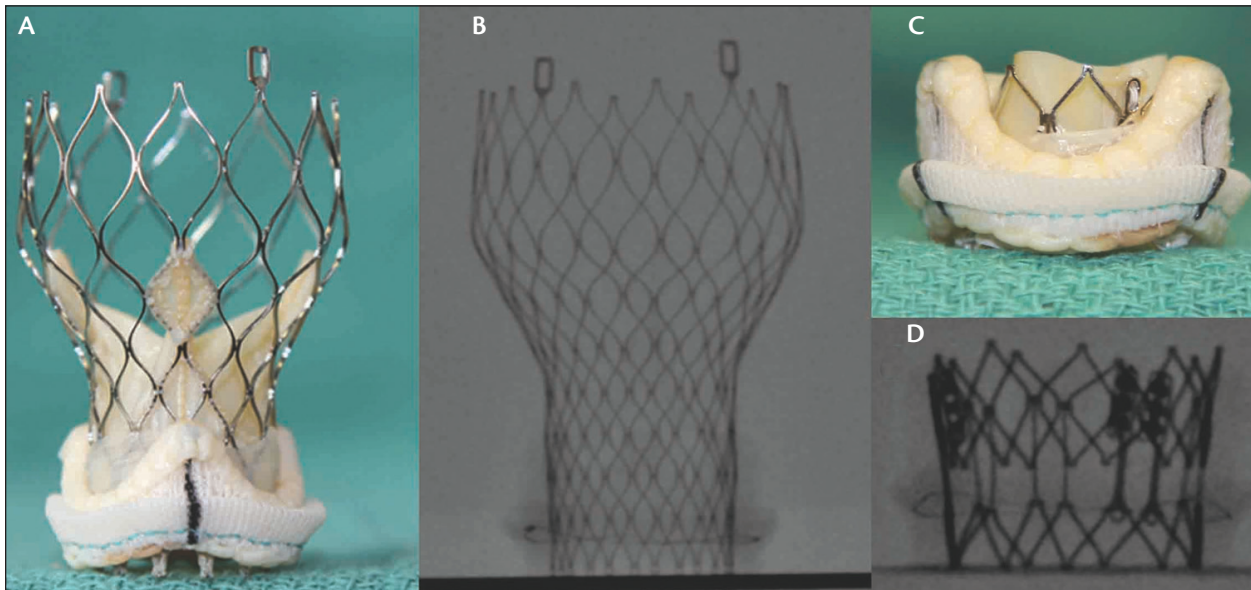


Figure 8. An example from the VIV app. Ideal placement of THVs within the Epic Supra SHV (St. Jude Medical). CoreValve implantation (A), fluoroscopic appearances of an ideally implanted CoreValve (B), Sapien implantation (C), and fluoroscopic appearances of an ideally implanted Sapien valve (D).

considerable differences between SHVs for aortic use and those for mitral use. Additionally, various rings are used for mitral valve repair procedures. For this reason, a separate app, the Mitral Valve in Valve app (Dr. Bapat and UBQO Ltd.) was developed, focusing on the VIV procedure within failing mitral valves and rings. The workflow from the aortic app has been maintained, and it is easy for the user to familiarize themselves with the contents. An additional information section has useful links, including differences to be considered between aortic and mitral VIV procedures.

BENEFITS OF THE APP PLATFORM

Ease of Access

The VIV aortic app is free to download and once downloaded, does not require an Internet connection for access and use. Because of the nature of the smartphone platform, all information (including images, movies, and text) has been kept to a very small size (< 50 MB) and can be easily downloaded on any device. Users can therefore use the app in real time, before and during a case.

Additional Information

Finding specific information relevant to a user's clinical case can be tedious, with searches involving a detailed review of published articles and presentations. The app contains all relevant information in one place, as well as details on similar-looking valves, fluoroscopic classification, true ID, and unknown valve types, which will help the users fine tune the concept of VIV.

Future Proof

The app platform allows us to include information on new THV devices with ease. This aspect of its functionality is unique.

CONCLUSION

VIV procedures are a new and exciting development within the rapidly expanding TAVR arena. To ensure a good clinical outcome, the app provides an excellent visual guide, which collates a vast amount of information in an easy-to-navigate platform and provides patient-specific answers. ■

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