

Endoscopic access closure for direct implantation of valved stents

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Summary

Objectives: The off-pump trans left ventricular approach provides an alternative option for insertion of stented aortic valves of any size for endovascular replacement. One of the key steps in this procedure is the repair of the ventricle after catheter withdrawal. This study evaluates the reliability of a new device for sutureless and quick repair of the left ventricle access.

Methods: The Amplatz-nitinol occluder consists of two square heads that squeeze the ventricle wall between them thus sealing the ventricular defect. In four adult pigs weighing 55 kg, left thoracoscopy was performed to open the pericardium and visualise the cardiac apex. Following a heparin injection (100 U/kg) under ICUS and fluoroscopic control, we inserted a 30 F sheath into the epigastric area through the cardiac apex up into the left ventricle thus simulating the approach for an off-pump aortic valve replacement. The sheath was then removed and the ventricle closed with the oc-

cluder. Animals were followed-up for three hours; the haemodynamics and pericardial bleeding were recorded. The animals were then sacrificed and the gross anatomy of the heart was examined.

Results: The device was successfully deployed in four animals in less than one minute. ACT was above 200 seconds in all cases. All animals survived the procedure with a mean arterial pressure of 50±15 mm Hg. Bleeding during deployment was 80±20 ml and over a 3 hour period was 800±20 ml. Examination of the gross anatomy examination demonstrated the correct positioning of the device.

Conclusions: The occluder is easy to use and the procedure is feasible and reproducible. However, the occluder design requires technical improvements in order to reduce bleeding before it can be used clinically.

Key words: aortic valve replacement; stented aortic valve; sutureless closure cardiac defects

Introduction

Off pump aortic valve replacement cannot be considered a new approach since Davies deployed a catheter-mounted unicuspid valve above the aortic valve for the temporary relief of aortic insufficiency in 1965 [1]. Many other authors have modified and improved the endovascular approach for aortic valve replacement using stented valves [2–4]. However, the endovascular approach still has several limitations: the size of the valve is limited by the delivery sheath diameter therefore only small stented valves can be implanted; the precise positioning of the stented valve onto the aortic annulus or supra-annular position is cumbersome because it is very difficult to properly drive long and stiff catheters into the arterial tree. The off pump trans-left ventricle approach overcomes all these limitations. It allows more precise deployment of stented aortic valves of any size with respect to the

endovascular replacement as has been demonstrated in our previous studies [5, 6]. One of the key steps in this procedure is the ventricle repair after catheter withdrawing. The closure of the left ventricle access is a challenging procedure even when the open chest approach supported with extracorporeal circulation is used. Moreover, there is a consistent risk of air embolism.

Recent developments in sutureless devices for septal defect repairs appear to provide a tool allowing easy and safe closure of the ventricle access. However, these devices have been designed to deal with low-pressure systems and it would be helpful to assess if current design shape, number of wires, dimensions, etc provide a sealing effect comparable to the open surgical technique when applied to high-pressure systems.

We designed an animal study to assess the re-

liability of a new device for sutureless and quick repair of the left ventricle access. The endpoint of the study is to assess the feasibility of the deploy-

ment procedure and to its effect on haemodynamic stability.

Materials and methods

The occluder

The occluder 12 mm Amplatz (AGA, Golden Valley, MN) is made of a nickel – titanium alloy with a pre-determined thermal memory shape. It consists of two square heads that squeeze the ventricle wall between them sealing the ventricular defect (figure 1). A third element, a semi rigid guide wire, is secured to the device to aid insertion. This element is unscrewed once insertion is completed. The device is mounted in a 30 F sheath to simulate the use of a 25 mm stented valve. The insertion begins in the left ventricle with release of the endocardial square head. The guide wire is gently pulled back until the square head is in contact with the ventricle wall. The second head is then released pulling back the sheath and the guide wire is unscrewed.

Study design

An acute in vivo evaluation was performed in four adult pigs, weighing 55 ± 4.3 kg (range 43–56 kg), equipped with an arterial pressure line in the right carotid artery and ECG. Under general anaesthesia, left thoracoscopy was used to open the pericardium. One 12 mm port was inserted into the 7th intercostal space for the camera and two 5 mm ports were inserted into the 11th and 5th spaces respectively. A pericardial window 4×3 cm was then created in order to visualise the cardiac apex clearly. After injection of heparin (100 U/kg), under Intra Cardiac Ultra-

Sound (ICUS Sequoia Inc.) inserted into the right femoral vein (figure 2) and fluoroscopic control, we inserted the 30 F sheath into the epigastric area through the cardiac apex and up into the left ventricle, simulating the approach for an off-pump aortic valve replacement. The thickness of the ventricular wall at the insertion site was measured. The sheath was then removed and the ventricle closed with the occluder. Animals were followed up for three hours, haemodynamic data (heart rate, ECG, blood pressure, pO_2 , pCO_2) was collected every 15 minutes. Pericardial bleeding was assessed using the Smart Suction (Cardio Smart LLC, Fribourg, Switzerland) [7] and the blood lost during the procedure was transfused back to the animal. Animals were then sacrificed and an examination of the gross anatomy of the heart was carried out.

All the pigs received care in compliance with the “Principles of Laboratory Animals” formulated by the National Society of Medical Research and “the Guide for the Care and Use of Laboratory Animals” prepared by the Institute of Laboratory Animal Resources and published by the National Institute of Health (NIH publication 85–23, revised 1985). The protocol was approved by the Institutional Committee on Animal Research.

Data were analyzed with SPSS software (Statistical Package for the Social Sciences). Paired t tests were used. Values were reported as mean \pm SD.

Results

The device was successfully used in four animals in less than a minute. Mean ventricular wall thickness at the insertion site was 9 ± 2 mm. Activating Clotting Time was above 200 seconds in all cases during the procedure. No major arrhythmias were detected. All animals survived the procedure

with a mean arterial pressure of 50 ± 15 mm Hg. Bleeding during deployment was 80 ± 20 ml and over 3 hour period was 800 ± 20 ml. Gross anatomy examination demonstrated the correct positioning of the device. Detailed results are reported in table 1.

Figure 1

Front view of 12 mm Amplatz occluder. It is made of a nickel – titanium alloy with a pre determined thermal memory shape, which allows the device to be crimped into the delivery sheath. The device is mounted into a 30 F sheath to simulate the deployment of a 25 mm stented valve and its insertion is aided by a semi rigid wire.



Figure 2

ICUS image. The probe is in the inferior vena cava – right atrium. Left ventricle free wall (bottom) and mitral valve (top) are identified to select the appropriate point to insert the catheter for the trans-apical aortic valve replacement.



Table 1

Cumulative results.

	Baseline	During deployment	After deployment
Mean Arterial Pressure	56 ± 5 mm Hg	48 ± 5 mm Hg	55 ± 5 mm Hg
ECG	Sinus rhythm	Ventricular extrasystole	Sinus rhythm
Bleeding	–	80 ± 20 ml	800 ± 20 ml/3 h
			P <0.001

Discussion

The transventricular approach for off-pump aortic valve replacement with stented valves is considered to be the next revolution in cardiac surgery and its impact on aortic valve disease treatment will be as important if not more so, than that of angioplasty in coronary diseases.

One of the key steps in the transventricular approach is the closure of the ventricular defect. Every experimental cardiac surgeon knows that safe closure of a 30 F hole in the free wall of the left ventricle is a challenging procedure if extracorporeal circulation is not used. Moreover, since the procedure is performed percutaneously closure of the left ventricle defect seems almost impossible.

The aim of this study was to assess if it is possible to do the seemingly impossible simply by applying advanced material technology.

The concept of using a two square head nitinol device to close cardiac wall defects has been extensively investigated [8] and nowadays the endovascular closure of a patent foramen ovale is considered a routine procedure. The 12 mm Am-

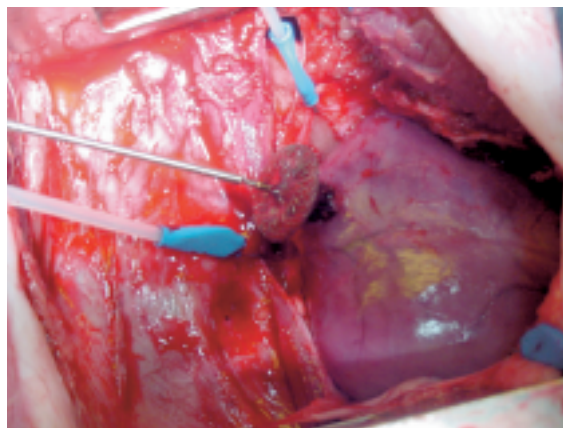
plaz occluder has the same geometry as that used for interatrial septal defect closure but the distance between the two heads is increased to 7 mm on account of the thickness of the ventricle wall. Figure 3 shows the occluder on the left ventricle surface.

Despite several limitations, this study has demonstrated that the Nitinol device described could be the solution that permits a transventricular approach to off-pump aortic valve replacement. The occluder is easy to use and the procedure is feasible and reproducible.

However, 800 cc bleeding over three hours makes this device unsuitable for clinical use. Therefore, the occluder requires technical improvement in order to dramatically reduce the bleeding. It seems that bleeding occurs within the Nitinol wires before thrombus formation. We are now studying the addition of a pericardial cuff on the endocardial head to prevent the bleeding. Another further concern is ventricle thickness. The present configuration can not be deployed in cases of left ventricle hypertrophy as the epicardial head would not pass through the ventricle wall. The third problem to solve before clinical application of the occluder is to define a back up strategy in case the device is lost during insertion as sometimes happens during the endovascular closure of a patent foramen ovale.

Figure 3

Intraoperative view of pig's heart. The 30 F defect of the free wall of the left ventricle has been repaired using a Nitinol occluder. After sacrifice of the animal, the delivery guide wire is re screwed in the occluder and slightly pulled back for demonstration purposes.



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