Assessment of annular distensibility in the aortic valve

John O’Dea* and David J. Nolan

School of Engineering and Informatics, National University of Ireland, Galway, Ireland

* Corresponding author: School of Engineering and Informatics, National University of Ireland Galway, University Rd., Newcastle, Galway, Ireland. Tel: +353-91-519882; fax: +353-91-519873; e-mail: j.odea1@nuigalway.ie (J. O’Dea).

Received 29 March 2012; received in revised form 10 May 2012; accepted 16 May 2012

Abstract

OBJECTIVES: The recent introduction of transcatheter aortic heart valves into clinical practice has driven the need to develop methodologies to size such valves without access to the annulus in the manner hitherto possible with open heart surgery. To date, sizing has largely been done according to manufacturer-supplied guidelines based on transoesophageal echocardiography or multidetector computed tomography. We sought to examine how the diameter of the aortic valve annulus stretches under typical pressures encountered in normal and diseased states. In particular, we sought to measure how the area-derived diameter, Dcsa, i.e. the diameter derived from a cross-sectional area, varies with distending pressure.

METHODS: We conducted testing on 14 explanted pig hearts. Placing each heart in a 37°C bath, an EndoFLIP EF-325 catheter (Crospon, Galway, Ireland) was introduced into the aortic valve transapically. The catheter allows intra-balloon pressure and up to 16 area-derived diameters to be measured simultaneously, thus permitting the shape of a lumen to be observed. By dividing the minimum area-derived diameter by distending pressure, a measure of distensibility (mm/mmHg) could be determined. Once the balloon was centred, balloon pressure was ramped between 100 and 200 mmHg, and the area-derived diameter was calculated at each pressure.

RESULTS: Between 100 and 200 mmHg, the mean (SD) increase in diameter was found to be 3.0 (1.5) mm. Distensibility in the different hearts ranged from 0 to 0.05 mm/mmHg. In some cases, the diameter change over the pressure range was negligible, whereas in one case, the diameter change over the range was 5 mm. Whereas different nominal values of diameter are to be expected, a significant variation in the degree of distensibility was observed.

CONCLUSIONS: Distensibility of the aortic valve annulus is highly variable. Measurement of this parameter in addition to nominal annulus diameter may suggest occasions where a larger transcatheter aortic-valve implantation valve than would be suggested by annulus diameter measurement alone, could be deployed safely with an objective of reducing regurgitation where the annulus is sufficiently distensible.

Keywords: TAVI • Aortic valve sizing • Heart valves

INTRODUCTION

The recent introduction of transcatheter aortic heart valves into clinical practice has driven the need to develop methodologies to size such valves without access to the annulus in the manner hitherto possible with open heart surgery. To date, sizing has largely been done according to manufacturer-supplied guidelines based on transoesophageal echocardiography. More recently, attempts have been made to use sizing techniques based on annulus diameter measurements derived from multidetector computed tomography (MDCT). Whereas the annulus is elliptical in shape, recent papers have suggested that an optimum ‘diameter’ to use for sizing percutaneous heart valves is the area-derived diameter, Dcsa [1–3]. Dcsa, i.e. the diameter derived from a cross-sectional area (CSA) measurement, is calculated as follows. The area, A, circumscribed by the annulus is measured. Dcsa represents the diameter of a circle having the equivalent CSA to A, and is calculated as follows:

$$D_{csa} = \sqrt{\frac{4A}{\pi}}$$

We have previously reported [4] a method, based on impedance planimetry with electrodes mounted within a balloon catheter, which permits the valve area-derived diameter to be measured at different balloon distending pressures, and we found that the measurement obtained at a balloon-distending pressure of 120 mmHg most closely matched that which would be obtained using a mechanical sizer. Once the diameter is determined, the interventional cardiologist has to decide which valve to select from a relatively limited number of options. If too small a valve...
is selected, there is the risk of paravalvular leakage and/or embolization. If too large a valve size is selected, there is a risk of annular rupture. Given the choice, the smaller size valve will therefore be chosen. It would be desirable to know the degree to which the annulus distends under pressure. Were the annulus suitably distensible, the interventional cardiologist would be in a better position to select a larger valve size in order to reduce paravalvular leakage, while at the same time being better able to assess the risk of annular rupture given this added knowledge of distensibility. It has been recently suggested [5] that imaging alone may thus need to be enhanced to elicit the mechanical response of the native tissue to the stress of the valve deployment. Such valves sit within a stent, the final diameter of which will be a function of the point where equilibrium exists between the distending force of the stent and the recoil force related to the distensibility of the annular ring within which it is sitting [6]. Previous attempts have been made to assess annular distensibility using magnetic resonance imaging [7] or CT [8]. However, neither method provides simultaneous measurements of distending pressure and annulus diameter, two parameters that are logically required to calculate valve distensibility. We sought to examine how the diameter of the aortic valve annulus stretches under typical pressures encountered in normal and diseased states. In particular, we sought to measure how the area-derived diameter varies with distending pressure.

MATERIALS AND METHODS

For this pilot study, we conducted testing on 14 explanted pig hearts. Placing each heart in a 37°C bath, an EndoFLIP EF-325 catheter (Crospon, Galway, Ireland) was introduced into the aortic valve transapically (Fig. 1). The catheter allows the intraballoon pressure and up to 16 area-derived diameters to be measured simultaneously, thus permitting the shape of a lumen to be observed. By dividing the minimum area-derived diameter by distending pressure, a measure of distensibility (mm/mmHg) could be determined. The balloon was centred on the aortic annulus. Once the balloon was centred, the balloon pressure was ramped between 100 and 200 mmHg, and the area-derived diameter was calculated at each pressure.

RESULTS

Figure 2 shows the regression lines of the valve area-derived diameter vs pressure relationship in this range for the 14 pig hearts. In this pressure range, all the valves were observed to distend in a linear fashion. Between 100 and 200 mmHg, the mean (SD) increase in valve diameter was found to be 3.0 (1.5) mm. Distensibility in the different hearts ranged from 0 to 0.05 mm/mmHg. In some cases, the diameter change over the pressure range was negligible, whereas in one case, the diameter change over the range was 5 mm. Whereas different nominal values of diameter are to be expected, a significant variation in the degree of distensibility was observed.

DISCUSSION

We have demonstrated a method for measuring the distensibility of the annulus of the aortic valve using a measurement catheter designed to assess distensibility in a physiological range of pressures, and using a low-pressure balloon. In testing with explanted pig hearts, we observed considerable variability in the degree to which the annulus of the aortic valve stretches over a pressure range of 100–200 mmHg. It is to be noted that on dissection, these hearts did not appear to have calcification. Previous work using an alternative measurement methodology [8] has, however, demonstrated that the normal and diseased annulus have a similar degree of variability in stretch. A challenge in this field is that there is no availability of a standard diseased heart model that can be tested. We have established that there is a high degree of variability in distensibility between different aortic valves. We have not sought to establish normative values for the diseased valve per se. To the contrary, we believe that in clinical practice, the distensibility of the annulus needs to be assessed on a case-by-case basis because of this very high degree of variability, in order that a decision can be taken for a
given patient as to whether or not to deploy a larger valve safely with an objective of reducing paravalvular regurgitation.

To assess the degree of distensibility at the higher distending pressures encountered during valvuloplasty or stent deployment, a similar methodology could be employed using a catheter with the electrodes located within the dilation balloon. In this study, the valve diameter extended in a linear fashion with respect to pressure. At higher pressures, a limit will be reached where this relationship will become non-linear. The inflexion point of the distensibility curve could thus serve as the maximum safe diameter permitted for the valve. We believe that an algorithm employing area-derived diameter and distensibility may thus begin to address the sizing problem brought about by the limited range of transcatheter aortic heart valves currently available and may suggest occasions where a larger transcatheter aortic-valve implantation valve, than would be suggested by annulus diameter measurement alone, could be deployed safely with an objective of reducing regurgitation where the annulus is sufficiently distensible.

**FUNDING**

This work was supported by Crospon Ltd.

**Conflict of interest:** John O’Dea is an employee and stockholder in Crospon Ltd.

**REFERENCES**


