Asian Journal of Research in Surgery

5(1): 8-12, 2021; Article no.AJRS.63890

In vitro Behavior of an Intra and Postoperative Adjustable Mitral Ring for Mitral Valve Repair

Leandro Cura[1*], Victor Dayan[2] and Krupskaya Mejia[3]

[1]Department of Cardiac Surgery, Cardiocentro - Asociación Española, Uruguay.
[2]Department of Cardiac Surgery, Instituto Nacional de Cirugía Cardíaca, Uruguay.
[3]Independent Consultant Engineer, Uruguay.

Authors' contributions

This work was carried out in collaboration among all authors. Author LC designed the adjustable ring, designed the study, wrote the protocol and wrote the first draft of the manuscript. Author VD collaborated and translated. Author KM collaborated and participated in the manufacturing and test of the prosthesis. All authors read and approved the final manuscript.

Article Information

Editor(s):
(1) Dr. Wagih Mommtaz Ghannam, Mansoura University, Egypt.
Reviewers:
(1) Joaquim Barreto, University of Campinas (UNICAMP), Brazil.
(2) G. Yoganandan, Periyar University, India.
(3) Osman Yilmaz, University of Health Sciences, Turkey.
Complete Peer review History: http://www.sdiarticle4.com/review-history/63890

Original Research Article

Received 01 November 2020
Accepted 06 January 2021
Published 30 January 2021

ABSTRACT

The adjustable mitral ring reported was developed to be used in mitral regurgitation, during "mitral ring downsizing" surgery, and permits modification of it's dimensions during surgery and forever on afterwards. We evaluated its functioning in an *in vitro* porcine model.

Keywords: Mitral ring; valve; postoperation; coaptation.

1. INTRODUCTION

Mitral ring downsizing is one of the techniques used in ischemic mitral regurgitation (MR) and MR due to dilated cardiopathy. In this technique, a prosthetic ring smaller than the native is implanted in order to achieve mitral leaflet coaptation, known as restrictive mitral annuloplasty and popularized by Bolling [1].

The new adjustable mitral ring we report, was developed to be used in MR during mitral ring downsizing surgery and permits modification of it's dimensions during surgery and afterwards.

**Corresponding author: E-mail: leandrocurahochbaum@gmail.com, leandrocura@cardiocentro.uy;*

Mitral ring prosthesis available or reported up to date have fixed sizes or it's size can only be modified before the surgery ends [2].

When a fixed sized ring is to be implanted, its dimensions are previously determined by measuring the native mitral annulus and by means of inexact estimations the surgeon must decide a size. Therefore, there is a risk that the chosen size turns out to be inadequate at echocardiographic evaluation after it's placement. This situation can only be resolved by changing the prosthetic ring and increasing extracorporeal circulation time and postoperative morbidity and mortality.

After mitral downsizing annuloplasty, some patients show echocardiographic evidence of reverse remodeling, whereas in others a progressive remodeling ensues. In these patients the initial annular compensation for ventricular dilatation, provided by the undersized annuloplasty, may not be durable and recurrence of MR may occur as a result of retethering of the leaflets [3].

2. TECHNOLOGY

The adjustable mitral ring is biocompatible and its implantation technique is similar as conventional mitral rings with minor modifications.

This synthetic ring is entirely semi-rigid, it's size can always be subject to modification after surgery from an extra-cardiac located device, which does not require an energy source and can be easily accessed percutaneously or by means of a minimal incision using local anesthetics.

The prosthetic ring has a "D" shape which resembles the mitral valve ring and this shape with its proportions are maintained even when its dimensions are being modified for each patient.

3. MATERIALS AND METHODS

An isolated heart from a 80 kg pig was used. The aortic valve was removed in order to obtain aortic regurgitation. Water was infused in the left ventricle using a canula inserted in the ascending aorta. In this way intraventricular pressure could be controlled by regulating water flow from its source. Ventricular pressure was monitored using an intraventricular canula placed through the left ventricular apex. Another intraventricular canula placed through the lateral wall of the left ventricle permitted to drain it. In this way we obtained a pressure waveform similar to systolic and diastolic cardiac cycle.

The mitral valve was approached through a left atriotomy parallel to the interatrial groove. Mitral valve coaptation was visually confirmed by means of filling and emptying the left ventricle. Regurgitation of the mitral valve was obtained by progressive annular dilatation maneuvers.

The prosthetic mitral ring was implanted using 11 Ethibond 2-0 (Ethicon, Inc. Somerville, NJ, USA) interrupted stitches (Fig. 1). The control device was fixed at its extra-cardiac location.

Multiple maneuvers of dilatation and reduction of the prosthetic mitral ring with the extra-cardiac device were done and its functioning was assessed with changing intraventricular volumes.

No live animals were used.

4. RESULTS

After filling the left ventricle, mitral regurgitation was visually observed when intraventricular pressure reached 50 mmHg.

Using the extra-cardiac device the mitral annulus could be reduced and dilated obtaining annular diameters of 20 mm to 31 mm. Proportional modification of annulus dimensions were observed, maintaining the characteristic shape of the mitral ring and its proportions (Fig. 2).

Mitral regurgitation was corrected and the optimal annulus dimension was determined after various dilatation and reduction maneuvers. In the range of pressure obtained from 50 mmHg to 250 mmHg leaflet coaptation was confirmed and absence of regurgitation was visually verified.

5. DISCUSSION

Through this isolated porcine heart model of MR, we could evidence that this prosthetic ring can reduce and dilate the mitral annulus proportionately without changing the native mitral annulus shape. Annulus dimension could be modified using an extra-pericardial device.

A limitation of our heart model is that it does not reproduce the physiological conditions of the beating heart. Nonetheless, the filling and emptying maneuvers made in our model are similar to those done by the surgeon when exploring and testing the mitral valve during surgery.

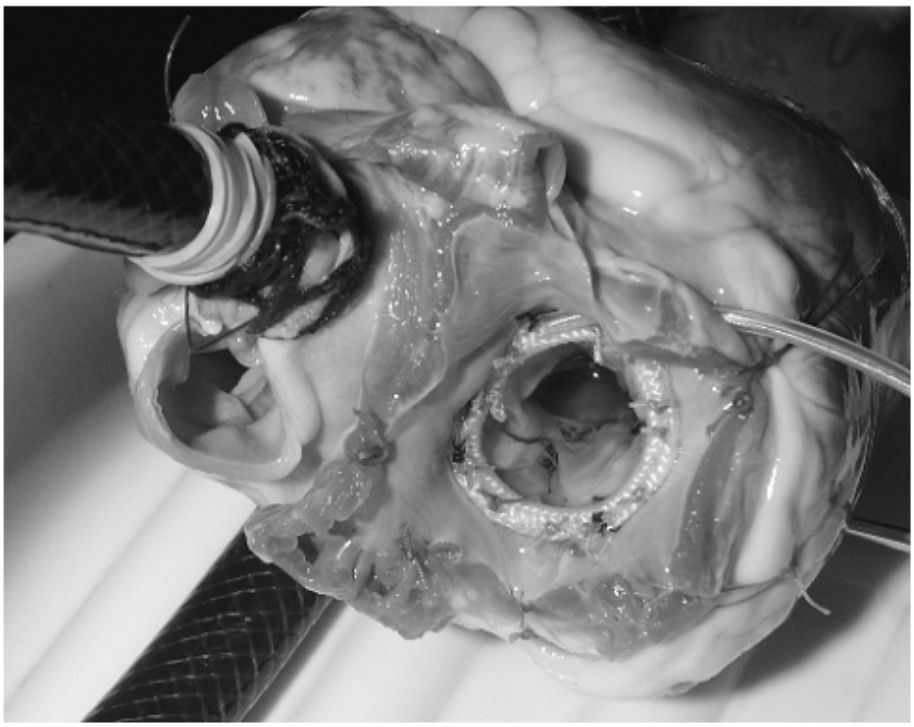

Fig. 1. The porcine heart is seen from its base. A canula was placed through the ascending aorta after the valve was removed. The left was approched through a left atriotomy. The ring was implanted at the mitral annulus

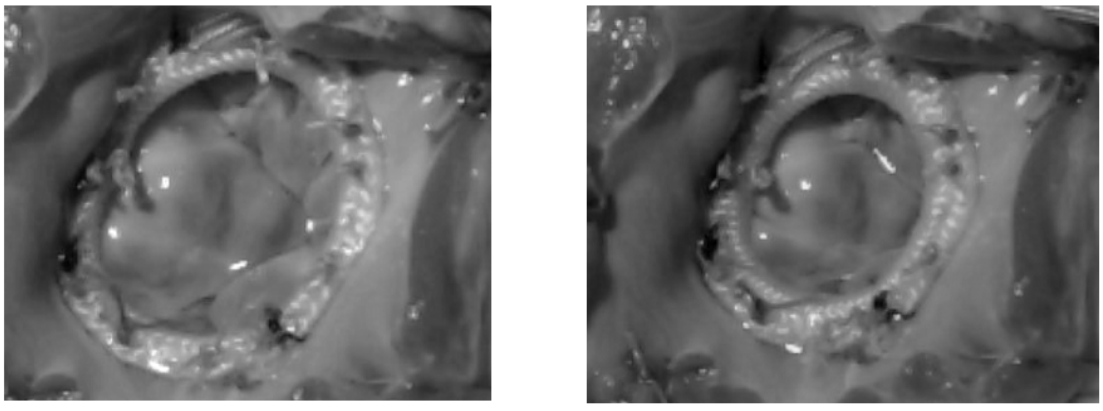

Fig. 2. These photographs show the closed mitral valve and the implanted ring as seen from the left atrium. Left, the mitral rinf with 31 mm diameter. Right, after reducing the mitral ring to 20 mm diameter with extra-cardiac located device

The distinctive characteristic of this ring, allows a surgeon to perform a mitral downsizing surgery without the need of an exact determination of the ring size previous to its placement, since this size is established and set during the testing maneuvers. After surgery, through a non-invasive or minimally invasive procedure, the mitral annulus can be modified using the extra-cardiac device to optimize leaflet coaptation or reproduce some degree of regurgitation if it requires. This is the case of patients with severe ventricular dysfunction, with immediate postoperative ventricular claudication due to an increase in afterload after the sudden correction of MR. In these patients, reproducing some degree of MR may be useful after surgery. Perhaps by reducing the mitral ring progressively guided by the patients tolerance, and not suddenly as nowadays, along with an optimal medical treatment, represents a new strategic approach for reducing morbi-mortality in these high-risk group of patients.

We consider that these adjustable ring characteristics, are a great advance in cardiac surgery and could widen the surgical indications for MR including some patients with very low ventricular function and functional MR. Nowadays, these patients are subject of discussion and are frequently rejected for surgery by fear of ventricular claudication due to the sudden correction of the MR and therefore an abrupt increase in afterload [4].

Another advantage of this prosthesis is that it could probably adapt the annulus to the ventricular evolution after a successful mitral repair. It is well known that after two years of mitral repair with a downsizing surgery, in 30-40% [5] of patients, MR recurs. In some of the patients in whom MR recurs, this could be explained by the progress of left ventricular remodeling with papillary muscle displacement and leaflet retethering [3]. In these cases, by a minimal invasive approach of the device, the mitral annulus could be adjusted to the new condition and restore its function. This represents our current line of investigation.

Aiming to reduce the recurrence rates of MR, new annuloplasty rings were developed [2] and its association with the edge-to-edge technique have been advocated [4]. None of these newly developed rings have the ability neither to modify its dimensions after its placement nor to prevent the “afterload mismatch” produced by the newly competent repaired mitral valve.

The adjustable mitral ring, represents a singular therapeutic approach for functional MR and bares the basis for future experimental and clinical trials that would permit a better knowledge of its therapeutic potential and evolution of functional MR.

Although through our model, we could demonstrate the optimal functioning *in vitro* of this prosthetic ring, it is not possible to extend our results to the beating heart. Therefore, future investigations are required using in vivo animal models of functional MR, which represents our current status.

6. CONCLUSION

We consider that this prosthetic ring could be an excellent option for selected patients, which at present time have no surgical indication or are at very high risk, since it aims at the physiopathological function of the left ventricle and therefore, will reduce the morbi-mortality, hospitalization and costs.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

As per international standard or university standard guideline participant consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Bolling SF, Pagani FD, Deeb GM, Bach DS. Intermediate-term outcome of mitral reconstruction in cardiomyopathy. J Thorac Surg. 1998;115:381-385.

2. Fedak WM, McCarthy PM, Bonow RO. Evolving concepts and technologies in mitral valve repair. Circulation. 2008;117: 963-974.
3. Hung J, Papakostas L, Tahta SA, et al. Mechanism of recurrent ischemic mitral regurgitation after anuloplasty: Continued LV remodeling as a main target. Circulation. 2004;110:II-85-9.
4. De Bonis M, Lapenna E, La Canna G, Ficarra E, Pagliaro M, Torraca L, Maisano F, Alfieri O. Circulation 2005;1121:I-402:I-408.
5. Braun J, Van De Veire NR, Klautz RJM, Versteegh MIM, Holman ER, Westenberg JJM, Boersma E, Van De Wall EE, Bax JJ, Dion RAE. Ann Thorac Surg. 2008;85: 430-437.

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/63890