An Experimental Case-Based Role Model Study of Mitral NeoChord Implantation with New Tools via Transapical Approach

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ARTICLE INFO

Article history:
Submitted: 1. 3. 2023
Revised: 20. 4. 2023
Accepted: 9. 5. 2023
Available online: 6. 12. 2023

Klíčová slova:
Chlopenní vada
Mitrální chlopeň
Zvířecí modely

Keywords:
Animal role models
Mitral valve
Valve disease

SÚHRN

Rostoucí seniorská křehkost stárnoucí populace vyžaduje stále méně invazivní výkony. I když se invazivita kardiochirurgických výkonů díky novým postupům a technickým prostředkům stále snižuje, je řada kandidátů operace na chlopních považována za nevhodné k výkonu z důvodu seniorské křehkosti, nestabilního oběhového systému, případně proto, že prodělali infarkt myokardu, a jejich život je tak ohrožen každý den, kdy nejsou operováni. Hlavním smyslem této experimentální modelové studie bylo ověřit nový způsob implantace umělých šlašinek mitrální chlopně apikální cestou s použitím nových nástrojů.

ABSTRACT

Increasing fragility with the aging population compels less invasive procedures. Even if cardiac surgeries are getting minimally invasive with new techniques and technological development in the field, many valve surgery candidates suffer from being qualified as inoperable due to fragility, unstable circulatory system, and to be post-myocardial infarction and their life is in danger every day that they are not operated. The main purpose of this case-based role model study is to invent a new technique for implanting a transapical mitral valve NeoChord implantation with new tools.

Introduction

In parallel with the ongoing technological developments in cardiology and cardiovascular surgery, minimally invasive approaches and percutaneous intervention methods in heart valve surgery have increased in recent years.[1] The increasing number of fragile patients in our ageing society urges us to invent less invasive new technologies to reduce the high mortality rates of major surgical operations. (High mortality rates of major surgeries and increased fragile patients with an ageing population force us to invent new techniques which are less invasive and have less mortality than major surgeries.) Mitral regurgitation has been treated by open surgical approaches for decades.[2] In 2008, a minimally invasive approach was defined called "transapical endovascular implantation of NeoChord" which we think is not appropriate for the physiology of the mitral valve.[3] We present a role model study of an alternative technique to NeoChord implantation with new tools which are developed by us.

Case report

The study was designed as a role model study with a domestic pig. The pig was operated upon at the Experimentaanimalss' production and research center in the Veterinarian Faculty of Baskent University. This study was approved by University Institutional Review Board and Ethics Committee (Project no: KA14/287) and supported by University Research Fund. The animal was treated by policies and principles of good laboratory practice for animal care and with the European Union guidelines (86/609/EEC). The pig was 3 years old and weighed 350 kilograms.

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DOI: 10.33678/cor.2023.044

Please cite this article as: Doganozu E, Doganozu AC, Beyazpınar DS, et al. An Experimental Case-Based Role Model Study of Mitral NeoChord Implantation with New Tools via Transapical Approach. Cor Vasa 2023;65:870–873.

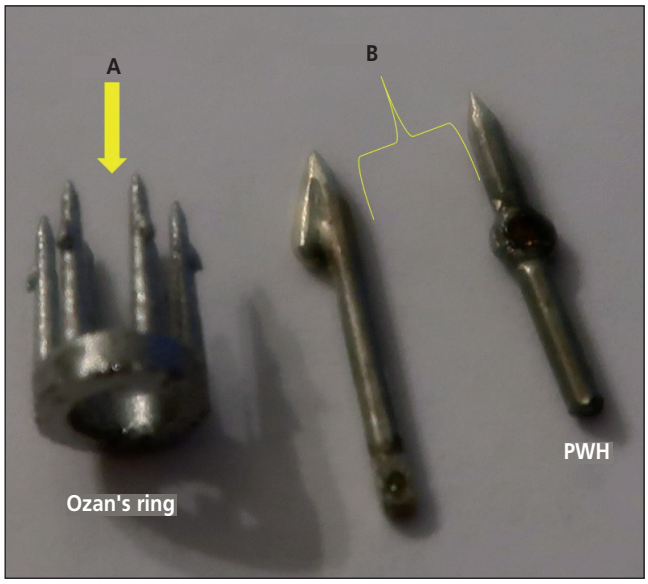

Fig. 1 – (A) Ozan's ring: Contents of it: A ring-based six arrows with notches. The purpose of the apparatus is to stabilize the myocardium and to resist the widening of the hole that is made by the Seldinger needle. (B) Picket with the hole: The purpose of the apparatus is to pierce the mitral valve. It is placed on the dilatator of the sheath. After piercing the mitral valve is pushed by a Teflon wire to the atrial face of the mitral valve. Two types of PWH were designed but middle-hole PWH was used for the experiment.

The domestic pigs which are candidates for cardiac studies weigh generally 40–70 kilograms.[3] Two kinds of new apparatus that are patented by the Turkish Patent Institute (patent no: 2021/019396) were used in the experimental study.

Equipment

Figure 1A presents Ozan's Ring: The purpose of the apparatus is to stabilize the myocardium and to resist the widening of the hole that is made by the seldinger needle.

Figure 1B shows picket with the hole: The purpose of the apparatus is to pierce the mitral valve. It is placed on the dilatator of the sheath. After piercing the mitral valve it is pushed by a Teflon wire to the atrial face of the mitral valve.

The step-by-step description of the procedure

a. Left ventricle is punctured by a seldinger needle and a J guide wire is advanced to the left ventricle.
b. The apparatus which has a diameter as the distal part of an 8 F sheath is loaded **(Ozan's ring)** on the 8 F sheath, it is advanced to the apical of the left ventricle till it penetrates the myocardium, and the sheath is removed except J wire.
c. The 7 F sheath is advanced on the guide wire into the left ventricle.
d. With TEE guidance, the sheath is manipulated under the posterior leaflet of the mitral valve.
e. The NeoChord is attached to the part of the second apparatus **(picket with the hole-PWH)**, the chord is placed on the top of the dilator, and when the heart rate is paced at 200 beats/min, the second apparatus is pushed with TEE guidance to pierce the posterior leaflet. With a J-tipped Teflon wire, the second apparatus is pushed from the dilator tip to the atrial surface of the mitral valve, and the dilator is removed.
f. Three pro-glides are placed on the apical left ventricle at 10-14-18 o'clock.
g. A sheath will be removed and bleeding control is achieved by making an apical knot with pro-glides.
h. Then the processing is terminated.
i. The subject will be allowed to remain alive for about an hour, after which it will be sacrificed and the entrance and placement of the NeoChord will be observed.

Pilot pig procedure

Anesthesia and monitoring

The domestic pig was premedicated with ksilazine 10 mg/kg and keteamine 20 mg/kg. Atropin was administrated at 1 mg intramuscular followed by orotracheal intubation under general anesthesia with the infusion of ksilazin and keteamine. General anesthesia was maintained intravenously via peripheral venous access. The domestic pig laid on the operating table in a supine position and the superficial femoral artery was cannulated via the seldinger technique and a 6 F sheath was introduced. Hemodynamic follow-up was going on via the femoral artery. Electrocardiography monitorization and saturation were monitored by GE GA18911793818 The CARESCAPE* VC150.

The procedure

Midline sternotomy was performed and the pericardium was opened because the pig heart was out of reach of the seldinger needle. Although the procedure was planned to be performed under transesophageal echocardiography (TEE) the heart could not be visualized most probably due to pneumothorax that developed during sternotomy and the overweight of the domestic pig. We decided to continue the procedure by attaching the TEE probe over to the heart. The seldinger needle was advanced into the left ventricle from the side of the left anterior

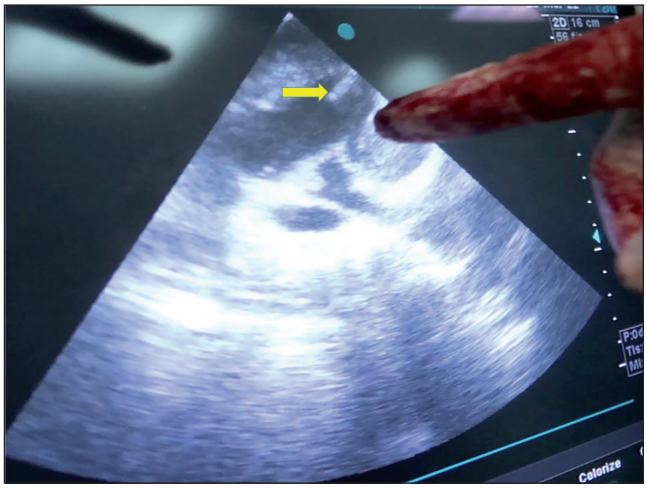

Fig. 2 – 7F sheath was visualized in the left ventricle with insufficient imaging in transapical echocardiography that was administered in one-to-one contact with the apex.

descending artery. The J guide wire was advanced to the left ventricle and the needle was removed. An 8 F sheath and **PWH** apparatus over the sheath was advanced into the wall of the left ventricle till the apparatus was implanted in the myocardium. Hereupon, an 8 F sheath was extracted while the J wire was inside and a 7F sheath was advanced over the J wire and the PWH apparatus is advanced through the valve. The sheath was visualized inside of the left ventricle (Fig. 2). The hemodynamics of the pig deteriorated due to pneumothorax and the echocardiographic images were insufficient to manipulate the sheath under the posterior leaflet of the mitral valve. The cardiovascular team decided to terminate the procedure. Intracardiac propofol was used for sacrification. The heart was displaced and the desired experimental study was performed in a disconnected heart.

Discussion

The novel-developed apparatus called **Ozan's ring** is going to be expected to be helpful to stop bleeding into the pericardium by fixing the parietal and visceral pericardium percutaneously. The apparatus was produced by a 3D printer. The PWH apparatus was made with silver by a goldsmith. The apparatuses produced by a professional manufacturer would be serviceable. Although the current pilot role model study is unsuccessful, it can be considered an initial step for future percutaneous or laparoscopic apical intracardiac interventions.

Although surgical treatments are the gold standard of heart valve surgery, recent developments in the field demonstrate that endovascular procedures may provide an alternative to open-heart operations for heart valve interventions.[4–7] Transcatheter aortic valve implantation is one of the leading operations in this field, tricuspid and pulmonary interventions have become popular recently.[8–10] Furthermore, recent percutaneous approaches to mitral valve repair include the Carillion device[11] and Mitra-clip[12] also for NeoChord implantation[3] an off-pump minimal invasive surgical technique has been developed in recent years.

Technological developments in the field pave the way for practitioners to perform minimal surgical procedures. New techniques and novel systems are required for development in the field. The present role model study is planned for the first step of apical laparoscopic and percutaneous procedures. The structure of the myocardium consists of longitudinal transverse and circumferential muscle fibers and the myocardium works in torsion detorsion mechanics. In light of this information and clinical experience, it is obvious that the hole created by an apical intervention will expand with the movement of the working heart and myofibrils. The expansion of an apical 6 F size intervention to 8–9 F after half an hour of operation is of high possibility. The Ozan's ring aims to prevent this enlargement at the heart apex and to help control bleeding by keeping the heart muscle together during the procedure. As long as there is no total rupture of the chordae tendineae, we consider that the newly developed system will be effective in the treatment of the posterior mitral valve and its parts, however, the probability of success in total ruptures will decrease. Therewithal the P1-2 mitral valve parts might be the most suitable parts for this system. Although considering the possibility of treating the anterior leaflet with this newly developed system is lower than the posterior leaflet, it is obvious that this idea should be supported by current experiments. To focus on the reasons for the failure of the role model study, despite the apparatus being successful to stop the enlargement of the entrance hall and controlling bleeding, technological inadequacies were made challenging the procedures. The inadequacy of echocardiographic images seriously affected the feasibility of the procedure. An animal laboratory with C-arm fluoroscopy and intravascular echocardiography would be suitable for studies like the present study.

The **Ozan's Ring** apparatus was designed primitively with 6 notched arrows on a round base and produced by a 3D printer. If it would be designed as a gun that penetrates and fixes all of the endocardium, pericardium, and myocardium, the procedure could be performed with less risk of bleeding and much more safety. Also, the apparatus could be designed notchless with a condom that has twisted tips that are straightened while connected with arrows. This design may help to drain blood to the outside of the human body.

Conclusion

We concluded that this role model study is significant in that it has the potential to be a precursor to laparoscopic or percutaneous intracardiac procedures. The method that we administered in the current study is innovative and groundbreaking if it would be performed. Future role model studies must be designed with materials that would have a better technological design in equipped animal laboratories.

Authors' contribution

The authors state that the article is original, has not been submitted for publication in other journals and has not yet been published either wholly or in part. All authors read and approved the final version of the manuscript.

Ersin Doganozu: Idea, design, writer, literature review.
Ayşe Ceren Doganozu: Resources, materials.
Deniz Sarp Beyazpınar: Resources, materials, literature review.
Atilla Sezgin: Audit/Consulting.
Ibrahim Haldun Muderrisoglu: Audit/Consulting, design.
Alp Aydınalp: Analyses and/or comments, critical review, design.

Acknowledgements

We would like to thank the nurse Levent Ulutaş and the nurse Kevser Ileri for their voluntary support and employees of the Animal Experiments Laboratories of Başkent University for their dedicated work.

Conflict of interest

The authors don't have any conflict of interest.

Ethical statements

This study was approved by Baskent University Institutional Review Board and Ethics Committee (Project no:

KA14/287) at 16. 3. 2020 and supported by Baskent University Research Fund.

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