

Percutaneous direct mitral annuloplasty using the Mitralign Bident™ system: description of the method and a case report

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Abstract

Background: Functional mitral regurgitation (FMR) is known to contribute to a poor prognosis in patients with heart failure (HF). Current guidelines do not recommend cardiac surgery in patients with FMR and impaired ejection fraction due to the high procedural risk. Percutaneous techniques aimed at mitral valve repair may constitute an alternative to currently used routine medical treatment.

Aim: To provide a description of a novel percutaneous suture-based technique of direct mitral annuloplasty using the Mitralign Bident™ system, as well as report our first case successfully treated with this method.

Methods: A deflectable guiding catheter is advanced via the femoral route across the aortic valve to the posterior wall of the ventricle. A nested deflectable catheter is advanced through the guide toward the mitral annulus that allows the advancement of an insulated radiofrequency wire to cross the annulus. The wire is directed across the annulus in a target area that is 2–5 mm from the base of the leaflet into the annulus, as assessed by real-time 3D transoesophageal echocardiography. After placement of the first wire, another wire is positioned using a dual lumen bident delivery catheter, which provides a predetermined separation between wires (i.e. 14, 17 or 21 mm). Each wire provides a guide rail for implantation of sutured pledget implants within the annulus. Two pairs of pledgets are implanted, one pair in each of the P1 and P3 scallop regions of the posterior mitral annulus. A dedicated plication lock device is used to provide a means for plication of the annulus within each pair of the pledgets, and to retain the plication by delivering a suture locking implant. The plications result in improved leaflet coaptation and a reduction of the regurgitant orifice area.

Results: A 60-year-old female with diagnosed dilated cardiomyopathy, concomitant FMR class III and congestive HF was successfully treated with the Mitralign Bident™ system. Two pairs of pledgets were implanted resulting in an improvement of transoesophageal echocardiographic parameters, including proximal isovelocity surface area radius (0.7 cm to 0.4 cm), effective regurgitant orifice area (0.3 cm² to 0.1 cm²) and mitral regurgitant volume (49 mL to 10 mL).

Conclusions: Percutaneous mitral annuloplasty with the Mitralign Bident™ system is feasible. Future clinical trials are needed to assess its safety and efficacy.

Key words: functional mitral regurgitation, new techniques, mitral annulus, annuloplasty

Kardiol Pol 2013; 71, 12: 1287–1292

INTRODUCTION

In patients with a dilated cardiomyopathy, one of the consequences of chronic cardiac deterioration is progressive ventricular dilation. This progressive dilation also compromises the efficiency of the ventricle by contributing to the develop-

ment of functional mitral regurgitation (FMR). FMR refers to leakage of the mitral valve due to dilation of the left ventricle (LV) and the mitral annulus as well as subsequent changes in subvalvular structures. In patients with severe heart failure (HF), FMR increases the haemodynamic stress on the failing

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Received: 18.10.2013

Accepted: 23.10.2013

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LV, resulting in higher filling pressures, progressive LV dilation, progressive systolic dysfunction, and lower cardiac output. From 54% to 60% of patients with dilated cardiomyopathy have been reported as having FMR. FMR is known to increase both the morbidity and mortality of patients with HF [1–4]. A positive correlation between mitral regurgitation (MR) and increased mortality has in fact been confirmed in a variety of recent studies. Blondheim et al. [5] followed 91 patients with dilated cardiomyopathy longitudinally and found a markedly decreased survival in the group with MR (i.e. 22% vs. 60% at 32 months). In addition, the trend held true for mild MR.

Heart failure patients are routinely managed with a combination of four types of drugs: an angiotensin converting enzyme inhibitor (or angiotensin receptor blocker), a beta-adrenergic blocker, a diuretic and digitalis, if not contraindicated [6]. According to current guidelines [7], patients with FMR who are candidates for coronary artery bypass grafting should undergo surgical mitral repair, if feasible. In patients with FMR and low ejection fraction, who are not candidates for surgical revascularisation, current guidelines do not recommend surgical mitral repair [7], due to the high procedural risk. As a result, percutaneous techniques for mitral repair may be the preferred treatment option.

The two techniques, which after evaluation in clinical trials have been commercialised in Europe include an edge-to-edge procedure with the MitraClip™ device, and an indirect approach utilising the coronary sinus with the Carillon™ device. The surgical edge-to-edge approach to mitral valve repair was developed by Alfieri; it involves the anterior and posterior leaflets of the mitral valve being stitched together to reduce the degree of MR [8]. A percutaneous alternative form of this procedure has been developed: a mitral valve ‘grasper’ that is directly placed through a transeptal approach and incorporates a clip, percutaneously placed [9, 10]. A percutaneous indirect approach using the Carillon™ system is based on the anatomical proximity of the coronary sinus to the mitral annulus [11]. The device is placed in the coronary sinus and great cardiac vein, and tension is applied to obtain pressure on the posterior part of the mitral annulus resulting in improved mitral leaflet coaptation. The AMADEUS and TITAN clinical trials have addressed the safety and efficacy of this approach [12, 13] and the technique has been employed in commercial use. Both percutaneous techniques require long-term clinical observations to fully assess their clinical value.

In this paper, we describe a novel percutaneous direct mitral annuloplasty, and report our first case of its use in our centre in a patient with FMR.

METHODS

Description of the technique

The Mitralign Percutaneous Annuloplasty System emulates a surgical suture-based annuloplasty, which was introduced as an early surgical technique for mitral repair [14, 15]. Later, Burr

et al. [16] published a technique based on the posterior plication suture which involved a double, semicircular, buttressed annuloplasty suture that constricts the enlarged mitral annulus to correct MR, while maintaining the flexibility and integrity of the mitral annulus and the subvalvular apparatus. With the development of the Carpentier ring, mitral ring annuloplasty has provided a template for suture-based annuloplasty to become more repeatable with consistent long-term results, although in some countries the method is still performed with long-term efficacy. Comparative studies in centres performing both ring and suture annuloplasty found no differences in one-year death, morbidity, or New York Heart Association (NYHA) score in patients with an MR grade of greater than 3+ [17, 18]. Similarly to ring based annuloplasty, there have been no randomised trials of this technique with either a ring approach or of mitral valve replacement.

Mitralign has developed a percutaneous procedure utilising a known surgical treatment for MR. The procedure consists of three main steps that can be repeated: wire placement, pledget delivery, and plication and lock (Fig. 1). These steps result in the placement of implants in the posterior mitral annulus, consisting of two pledget pairs with each pair separately pliated and secured with a Mitralign lock. Specifically, the P1 and P3 regions of the posterior mitral annulus are targeted in order to decrease the anterior-posterior (AP) dimension. This results in increased coaptation of the mitral leaflets and therefore decreases MR. The procedure is performed under general anaesthesia to enable the use of transoesophageal (TEE) imaging for continuous monitoring and visualisation of mitral apparatus.

Wire delivery is the first main step in delivering the Mitralign implants. All components of the Mitralign system are delivered through a dedicated 13.5 F deflectable guide catheter via the femoral artery. The guide catheter is designed to direct other catheters towards the posterior mitral annulus. A soft tip obturator is used to facilitate crossing the aortic valve and placement of the guide in the cordal free zone between the papillary muscles of the LV. During the initial guide placement, simultaneous deflection and catheter rotation is applied to position the guiding catheter along the posterior ventricle wall. Subsequent clockwise or counterclockwise rotation of the guiding catheter allows for repositioning at the P1 or P3 region of the mitral annulus, respectively. A deflectable wire delivery catheter is advanced through the guide catheter and positioned at either the P1 or P3 region of the mitral annulus. Real time 3D and 2D TEE echo imaging (Philips) is used to confirm the position of the tip of the wire delivery catheter at the target points of the annulus. A PTFE insulated 0.019 inch, 330 cm, crossing wire is used to cross the annulus from the ventricular to the atrial side. The crossing wire is connected to a radiofrequency (RF) energy source that allows passage of the wire across the mitral annulus at low power levels up to 30 W. Each crossing wire is used to

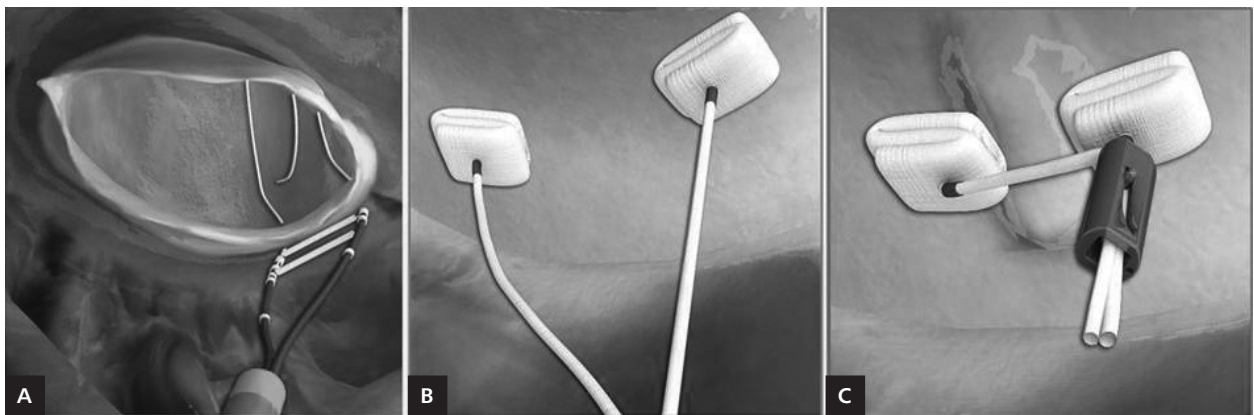


Figure 1. Schematic representation of the Mitralign Bident™ system technique; **A.** Wire delivery; **B.** Pledget delivery; **C.** Plication and lock. See text for details

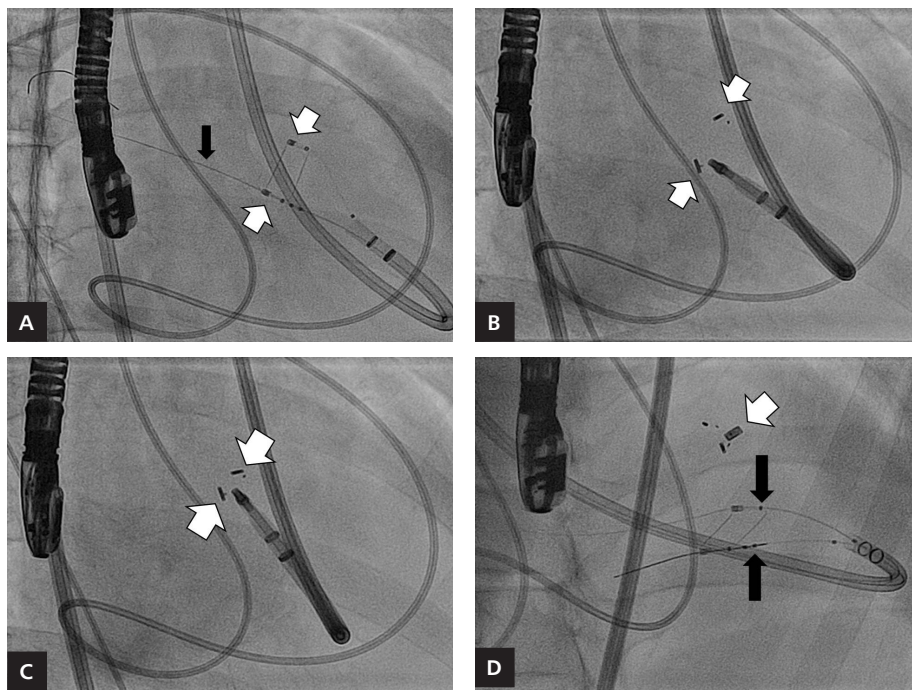


Figure 2. Angiographic images of the procedure; **A.** Advancement of the Bident device (white arrows) over a guiding wire (black arrow) placed across the mitral annulus from ventricular into atrial side; **B.** Pledgets before; **C.** After, application of tension: note the decreased distance between the pledgets indicated by white arrows; **D.** Complete implant of a pair of pledgets with sutures locked in P1 (white arrow) and advancement of the Bident device (black arrows) over the guiding wires placed across the annulus in P3

provide a path for the advancement of one pledget delivery catheter across the annulus (Fig. 2).

After placement of the first wire across the annulus, its position and depth is verified by TEE to ensure that it is located 2–4 mm into the posterior annulus of either the P1 or P3 region. The second wire is placed using a dual lumen catheter (Bident Translational Catheter) that is advanced over the first crossing wire. Once advanced to the annulus, the translation catheter is expanded to a predefined distance in order to guide the placement of the second crossing wire. The second wire

is advanced through the second lumen thereby positioning it 14 mm, 17 mm or 21 mm from the first wire. The steps described above comprise the first main step ('Wire Delivery').

The second main step is 'Pledget Delivery'. A delivery catheter is provided that contains a foldable polyester pledget with an integrated suture. One of these catheters is delivered over each wire and the tip advanced across the annulus. The distal portion of the pledget is deployed and folded onto the catheter in the atrium and the wire is removed. When the catheter tip is withdrawn from the atrium, the pledget is

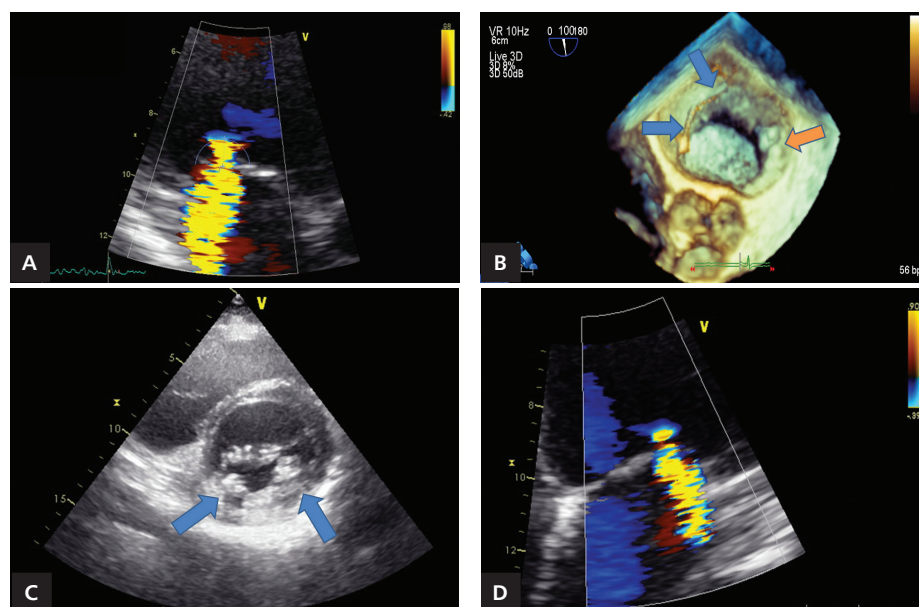


Figure 3. Echocardiographic images of the procedure; **A.** Mitral regurgitation before the procedure; **B.** 3D image of implanted pledget (orange arrow) and guiding wires positioned across the annulus (blue arrows) before placement of the second implant; **C.** Short axis view, two pledgets implanted (arrows); **D.** Reduced mitral regurgitation after the procedure

seated on the atrial side of the annulus. The remaining portion of the pledget is deployed and folded against the ventricular side of the annulus. Thus, the pledget apposes both the atrial and ventricular surfaces of the annulus anchoring the suture which is externalised through the guide catheter. After two pledgets are implanted, a plication lock catheter pre-loaded with a lock implant is tracked along the pledget sutures to the annulus. The plication lock catheter provides a means for plication and, once the lock is deployed, secures the plicated pledgets. The stainless steel lock implant measures approximately $3.8 \text{ mm} \times 2.4 \text{ mm} \times 2.0 \text{ mm}$ (18.7 mm^3). The proximal portions of both sutures are cut with a cutter catheter containing a fully enclosed blade. This marks the end of the third and final main step, 'Plication and Lock'.

Once the implant system is deployed at either P1 or P3 of the posterior mitral leaflet, wire delivery, pledget delivery, and plication and lock are repeated for the other annulus segment. The procedure is performed under general anaesthesia allowing TEE monitoring and assessment of the results (Fig. 3).

RESULTS

Case report

The approval of both the appropriate ethics committee and the national competent authority were obtained. The patient gave a written, extensively informed consent before the procedure.

A 60 year-old female with diagnosed dilated cardiomyopathy, concomitant functional MR and signs of congestive HF NYHA class II was referred to our centre due to progression of symptoms of HF as well as recurrent tachyarrhythmic episodes. The coronary angiography showed no significant

coronary stenosis. Despite treatment with beta-blockers and diuretics as well as amiodarone, the patient suffered from fatigue and shortness of breath after even minimal physical effort. The patient had also been treated for 12 years for *lupus erythematosus*, recently not using steroids. Echocardiography showed atrial fibrillation with mean heart rate 100/min.

Baseline transthoracic echocardiography (TTE) showed signs of LV dilatation (LV end diastolic diameter = 60 mm), and impaired systolic performance (ejection fraction = 35%), MR III° with no significant changes within the mitral leaflet apparatus and good leaflet mobility. The patient was referred to percutaneous mitral annuloplasty using the Mitralign Bident™ system.

The procedure was performed under general anaesthesia. As described above in detail, a deflectable guiding catheter was advanced to the mitral annulus from the ventricular side, allowing further advancement of the wire delivery catheter and subsequent crossing of the annulus with a RF crossing wire. Two pairs of pledgets were successfully implanted in the P1 and P3 regions of the posterior mitral annulus. Immediately post procedure, an improvement in MR parameters was noted via TEE, including proximal isovelocity surface area (PISA) radius (0.7 cm to 0.4 cm), effective regurgitant orifice area (EROA) (0.3 cm^2 to 0.1 cm^2) and mitral regurgitant volume (49 mL to 10 mL).

After the procedure, the patient was monitored for several hours in the intensive care unit. Neither cardiac enzymes nor troponin levels were increased, and the patient was mobilised the following morning. TTE performed at discharge confirmed a significantly decreased MR and showed no signs of pericardial exudate.

During follow-up visits, the patient continues to present an improved general condition and increased exercise capability, currently being at NYHA class I. TTE continues to show a markedly decreased degree of MR — the MR parameters one month post procedure were: PISA radius (0.6 cm), EROA (0.1 cm²), mitral regurgitant volume (22 mL).

DISCUSSION

The contribution of ventricular dilatation and subsequent functional MR to the morbidity and mortality of patients suffering from HF has been well documented. Routine medical management continues to inadequately address the problem of FMR [1–7]. The high post-operative morbidity and mortality associated with surgery in this patient population has resulted in the development of percutaneous techniques aimed at FMR repair with a decreased procedural risk.

The Mitralign Percutaneous Annuloplasty System allows the performance of a direct mitral annuloplasty by emulating a known surgical suture-based technique. The Mitralign system is currently under clinical investigation to treat subjects with chronic FMR by performing mitral annulus plication. Each pledget pair is drawn together (plicated) and locked in place. The plication is intended to shorten the spacing between each pledget pair by $50 \pm 15\%$, to produce up to a 20 ± 3 mm total reduction in the posterior annulus of the mitral valve. These geometric reductions of the posterior annulus result in subsequent decrease of the AP diameter, which may provide a clinical benefit by improving coaptation of the mitral valve leaflets and symptoms associated with MR.

The Mitralign system has gone through two major design iterations. Where the first iteration utilised a Trident configuration delivering three pledgets centered around the P2 region, the Trident approach utilised the same implant and percutaneous techniques. The Bident approach simplified the procedure and when implanted in the P1 and P3 regions of the annulus more closely mimicked the original surgical approach. In addition, several components of the system, including delivery catheters, have been modified to provide greater safety and ease of use for the clinician implanting the device.

The goal of the Mitralign annuloplasty system is to provide benefit with reduced risk, trauma, cost and recovery time as compared to cardiac surgery. Our case confirms the feasibility of the technique. However, large clinical trials with long term follow-up are needed to assess its safety as well as its clinical benefit in patients with FMR and HF.

CONCLUSIONS

Since FMR develops as a result of LV dilatation and impaired ventricular function, the risk of cardiac surgery procedures in this subgroup of patients remains high. Future development of percutaneous techniques for mitral valve repair may constitute an attractive alternative.

Acknowledgements

This work was sponsored by Mitralign Inc. The authors would like to thank Mike Sutherland for his contribution. The authors thank ProfiMedical s.j. for providing state-of-the-art real time 3D TEE equipment (Philips).

Conflict of interest: CL, LF and AG are employees of Mitralign Inc, Tewksbury, MA, USA. TS is a principal investigator in a clinical trial supported by Mitralign Inc, Tewksbury, MA, USA and is receiving investigator honoraria.

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Przezskórna bezpośrednia annuloplastyka mitralna za pomocą systemu Mitralign Bident™: prezentacja metody i opis przypadku

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Streszczenie

Wstęp: Czynnościowa niedomykalność mitralna (FMR), powstała w wyniku rozstrzeni lewej komory, istotnie pogarsza rokowanie u pacjentów z niewydolnością serca. U osób z chorobą niedokrwienną i wskazaniami do chirurgicznej rewaskularyzacji leczeniem z wyboru jest chirurgiczna korekta FRM wykonana łącznie z zabiegiem pomostowania aortalno-wieńcowego. Obecne standardy postępowania nie zalecają naprawy chirurgicznej FMR u pacjentów z obniżoną frakcją wyrzutową bez opcji rewaskularyzacji, z powodu znacznego ryzyka związanego z zabiegiem. Nowe przezskórne techniki zabiegowe naprawy zastawki mitralnej mogą stanowić atrakcyjną alternatywę dla rutynowo stosowanej farmakoterapii.

Cel: Celem pracy było opisanie nowej metody przezskórnej bezpośredniej annuloplastyki mitralnej z użyciem szwów połączonych z implantami umiejscowionymi w pierścieniu mitralnym za pomocą systemu Mitralign Bident™, a także przedstawienie opisu przypadku pacjentki z FMR skutecznie leczonej tą metodą.

Metody: Z dostępu przez tętnicę udową wprowadzono sterowalny cewnik prowadzący zakończony miękkim obturatorem do światła lewej komory, a następnie między mięśniami brodawkowatymi w pobliżu komorowej powierzchni pierścienia mitralnego. Po usunięciu obturatora wprowadzono kolejny sterowalny cewnik, którego koniec zbliżono do pierścienia mitralnego u nasady płotka tylnego. Pod kontrolą przezprzełykowej trójwymiarowej echokardiografii w czasie rzeczywistym poprzez światło cewnika wprowadzono metalowy przewodnik, który podłączono do generatora prądu o wysokiej częstotliwości (RF) i przeprowadzono przez pierścień mitralny do lewego przedsionka w odległości 2–5 mm od nasady płotka tylnego. Po przewodniku wprowadzono cewnik Bident, który po wysunięciu z cewnika prowadzącego otwiera się, umożliwiając precyzyjne umiejscowienie kolejnego przewodnika, którym również wykonano nakłucie pierścienia mitralnego podczas generowania prądu RF. Następnie, po przewodnikach, wprowadzono kolejno poliesterowe implanty (Mitralign Pledget), połączone z odpowiednio mocnymi szwami, o długości umożliwiającej wymianę cewników za pomocą techniki „over the wire”. Za pomocą urządzenia Mitralign Plication Assist Device, wprowadzonego po odpowiednich parach szwów, pary implantów zbliżano do siebie, powodując zmniejszenie obwodu pierścienia mitralnego. Urządzenie to umożliwia również zespolenie napiętych szwów tuż przy powierzchni pierścienia za pomocą metalowego zatrzasku. Szwy obcinano bezpośrednio przy klipsie przy użyciu specjalnego cewnika posiadającego na dystalnym końcu ostrze wysuwane przez pociągnięcie cyngla w ręczce. Umieściono dwie pary implantów w pierścieniu mitralnym na wysokości segmentów P1 i P3 tylnego płotka mitralnego.

Wyniki: Pacjentka w wieku 60 lat, z czynnościową niedomykalnością zastawki mitralnej III° i niewydolnością serca została poddana zabiegowi przezskórnej annuloplastyki mitralnej systemem Mitralign Bident™. Zabieg wykonano w znieczuleniu ogólnym, ze względu na konieczność stałego monitorowania za pomocą echokardiografii przezprzełykowej. Wszczepiono dwie pary implantów w obrębie pierścienia mitralnego na poziomie odpowiednio segmentów P1 i P3 tylnego płotka. Po naprężeniu szwów i wykonaniu pozostałych etapów zabiegu stwierdzono poprawę w zakresie echokardiograficznych parametrów FRM: promienia PISA (z 0,7 cm do 0,4 cm), efektywnego pola ujścia fali zwrotnej (z 0,3 cm² do 0,1 cm²) i objętości fali zwrotnej mitralnej (z 49 ml do 10 ml).

Wnioski: Przezskórna annuloplastyka mitralna systemem Mitralign Bident™ jest wykonalna. Dalsze badania kliniczne pozwolą na ocenę bezpieczeństwa i skuteczności tej metody.

Słowa kluczowe: czynnościowa niedomykalność mitralna, nowe techniki, pierścień mitralny, annuloplastyka

Kardiologia 2013; 71, 12: 1287–1292

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Praca wpłynęła: 18.10.2013 r. Zaakceptowana do druku: 23.10.2013 r.