

# Percutaneous valve repair for mitral regurgitation using the Carillon™ Mitral Contour System™. Description of the method and case report

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## Abstract

Mitral regurgitation may result from left ventricular dilatation and cause progression of heart failure. Percutaneous techniques for mitral valve repair are under development. Techniques utilizing a trans-coronary venous approach exploit the anatomical relationship between the mitral annulus and the venous system of the heart. The coronary sinus, great cardiac vein and the origin of the anterior interventricular vein surround the posterior mitral annulus. This enables percutaneous approaches to annuloplasty for mitral regurgitation. Devices can be implanted into the coronary veins that modify the shape and size of the mitral annulus. We present a case of ischaemic mitral regurgitation successfully treated by use of a percutaneous approach, the Carillon™ Mitral Contour System™. Significant reduction of the mitral regurgitation jet was observed. The patient was discharged 4 days after the procedure.

During the follow-up visits, the patient showed an improved general condition and increased exercise capacity. Procedural steps are shown in detail and the current status of the coronary sinus based technique is discussed. Percutaneous techniques for mitral valve repair may be an attractive alternative to cardiac surgery in heart failure patients with secondary mitral regurgitation. The Carillon™ Mitral Contour System™ is under ongoing clinical evaluation in the AMADEUS trial.

**Key words:** mitral regurgitation, percutaneous techniques, ischaemic heart disease, coronary veins

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## Introduction

Mitral valve regurgitation (MR) may be a result of changes in leaflet structure and/or function as well as left ventricular dilatation. Increased left ventricular diameters and volume lead to the elongation of the mitral valve annulus and subsequent secondary or functional MR. The severity of MR is an independent predictor of outcome in patients with post-infarction heart failure [1, 2].

The application of interventional cardiology techniques resulted in several approaches to mitral valve repair in patients with secondary MR. Currently, several concepts for valvuloplasty for MR are in various

stages of development from bench testing to early clinical trials. Techniques utilizing a trans-coronary venous approach are considered promising in patients with a dilated mitral annulus. These techniques exploit the anatomic relationship between the mitral annulus and the venous system of the heart. The coronary sinus, great cardiac vein and the origin of the anterior interventricular vein, surround the posterior mitral annulus. This enables percutaneous approaches to annuloplasty for mitral regurgitation. Devices can be implanted into the coronary veins that modify the shape and reduce the diameter of the annulus to allow proper coaptation of the leaflets.

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One of the most advanced designs for trans-coronary venous mitral annuloplasty, the Carillon™ Mitral Contour System™ (Cardiac Dimensions Inc., Kirkland, WA, USA), is currently undergoing clinical testing. The device is introduced into the coronary venous system by a proprietary delivery system. The implant is composed of two nitinol anchors (Figure 1) to be fixed within the lumen of coronary veins and connected by a curved nitinol bridge. After deployment of the distal anchor in the great cardiac vein, tension is applied by gently pulling on the delivery system and then the proximal anchor is deployed within the coronary sinus. Following extensive pre-clinical testing [3, 4], the Carillon™ Mitral Contour System™ is currently under evaluation in a multicenter European clinical trial (AMADEUS). We present the first case in Poland of the successful percutaneous treatment of mitral regurgitation with the Carillon™ system.

### Case report

A 63-year-old male with diagnosed chronic ischemic heart disease, concomitant mitral regurgitation, congestive heart failure (NYHA class III), and type II diabetes was referred to our center for diagnostic coronary angiography. The coronary arteriography showed progression of atherosclerotic changes compared to a year earlier. Occlusion of the left anterior descending artery was confirmed and new significant changes in the circumflex and right coronary arteries were found. Due to unstable myocardial ischaemia, the right coronary artery was treated with implantation of two coronary stents. During a subsequent hospitalization, the patient underwent successful stent implantation into the circumflex artery.

Four months after the second angioplasty and despite treatment with aspirin, carvedilol, ramipril, spironol, indapamide as well as potassium supplementation, the patient still suffered from fatigue and shortness of breath after even minimal physical effort. Electrocardiography showed QS complexes in leads V<sub>1</sub>-V<sub>3</sub> and negative T waves in leads I, aVL. Echocardiography showed left ventricular dilatation (7.08 cm) and increased left atrial diameter (4.85 cm), akinesia of apex and apical segments of the anterior wall and septum, ejection fraction below 40%, and mitral regurgitation (grade III) without presence of any organic changes on the mitral leaflets. The patient met the inclusion criteria for the AMADEUS trial and after giving informed consent he was enrolled in the study. The patient underwent baseline examination, including multi-slice computed tomography that enabled evaluation of the anatomical relationship between the circumflex artery and coronary veins.

According to the protocol, real time transesophageal echocardiography (ALOKA 5500) was performed during

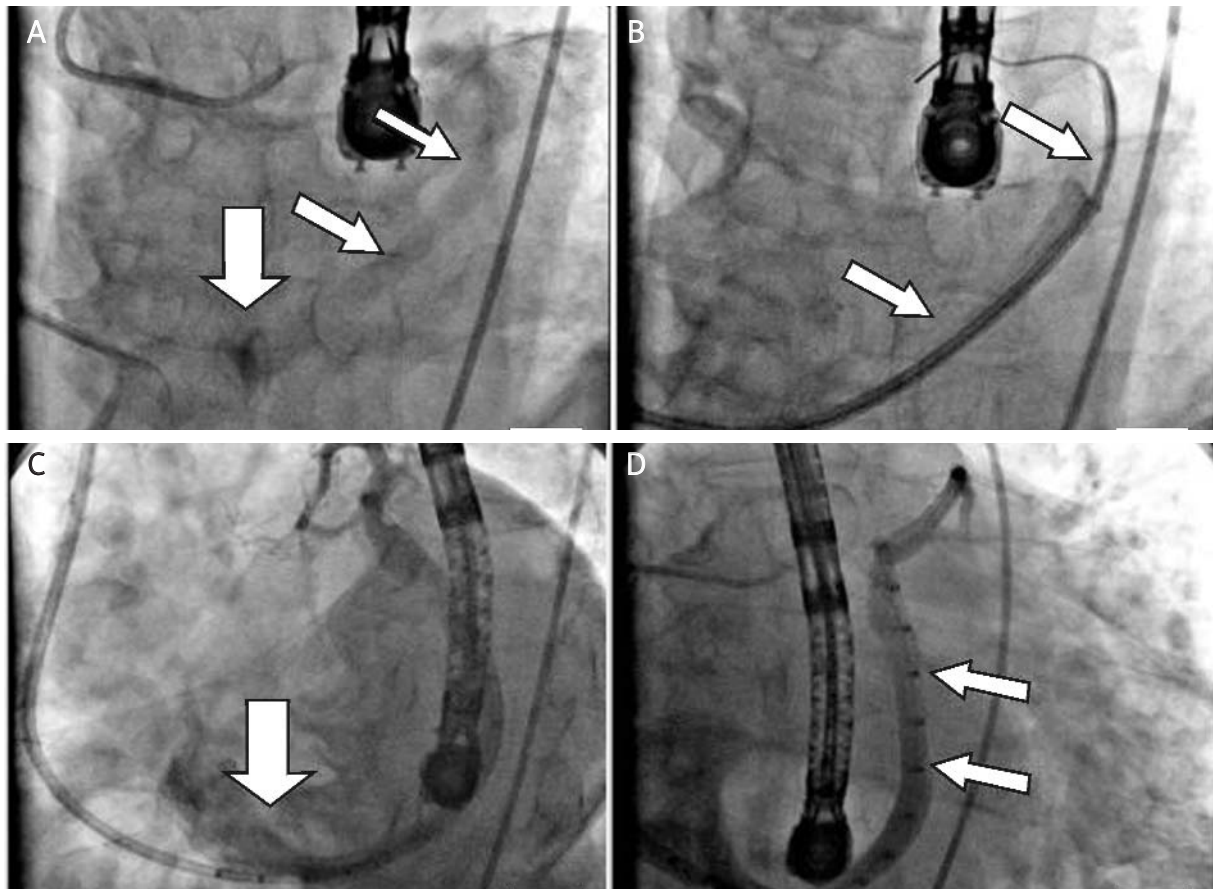


**Figure 1.** The design of Carillon™ XE device. Note the distal (small, left) and proximal (big, right) nitinol anchors

the implantation procedure. Solely due to this fact, the procedure was performed under general anesthesia. Initially, left main coronary arteriography was performed, which allowed for the visualization of the coronary venous efflux (Figure 2A) and coronary sinus ostium. Using the right internal jugular venous approach, a 9F delivery catheter was introduced into the coronary sinus and great cardiac vein over a 7F multipurpose diagnostic catheter (MPA-2, Cordis) and 0.035" guide wire (Glide Wire, Terumo). Coronary venography was performed through the 9F delivery catheter (Figures 2B and 2C). Then, a dedicated calibration catheter was introduced into the guiding catheter (Figures 2C and 2D) enabling precise measurement of the length and diameters of great cardiac vein and the coronary sinus. After selection of the appropriate size Carillon™ XE device, it was introduced into the coronary venous system (Figure 3A) and the distal anchor was deployed in the great cardiac vein. After verification that the deployed distal anchor did not compromise the circumflex coronary artery, tension was applied to the implant by gently pulling on the delivery system in order to plicate the mitral annulus tissue (Figure 3B). Coronary flow was checked again. Then, transesophageal echocardiography was checked and showed a marked reduction in mitral regurgitation. Next, the proximal anchor was deployed in the coronary sinus (Figure 3C). The effect of the implant on the degree of mitral regurgitation was verified again (Figure 4) and finally the Carillon™ XE implant was decoupled from the delivery system (Figure 3B).

After the procedure, the patient was monitored in the coronary care unit. Because neither cardiac enzymes nor troponin levels were increased, the patient was moved to the floor the following morning. Transthoracic echocardiography performed in the following days confirmed significantly decreased mitral regurgitation and showed no signs of pericardial exudate. The patient was discharged home on day 4 after the procedure.

During the follow-up visits, the patient continues to present with improved general condition and increased exercise capacity. The patient is currently classified as



**Figure 2.** Preparation steps for the implantation of Carillon™ XE device: **A** – coronary arteriography with visualization of the venous outflow (small arrows) and coronary sinus ostium (big arrow); **B** – insertion of the 9F delivery catheter (lower arrow) over the guiding wire and over 7F multipurpose catheter (upper arrow); **C** – coronary venography via the delivery catheter; **D** – recording of the calibration catheter within the delivery catheter (arrows indicate 1 cm markers on the calibration catheter)

NYHA class one. Transthoracic echocardiography continues to show markedly decreased mitral regurgitation.

## Discussion

Mitral regurgitation remains a common complication in survivors of acute myocardial infarction (MI). It can be diagnosed in 20% of post-infarct patients by angiography [5, 6] and up to 40% of patients with modern echocardiography techniques [7, 8]. The development of MR results in cardiac overload, progression of left ventricular remodeling [9], neurohormonal activation and increased frequency of heart failure symptoms [10, 11].

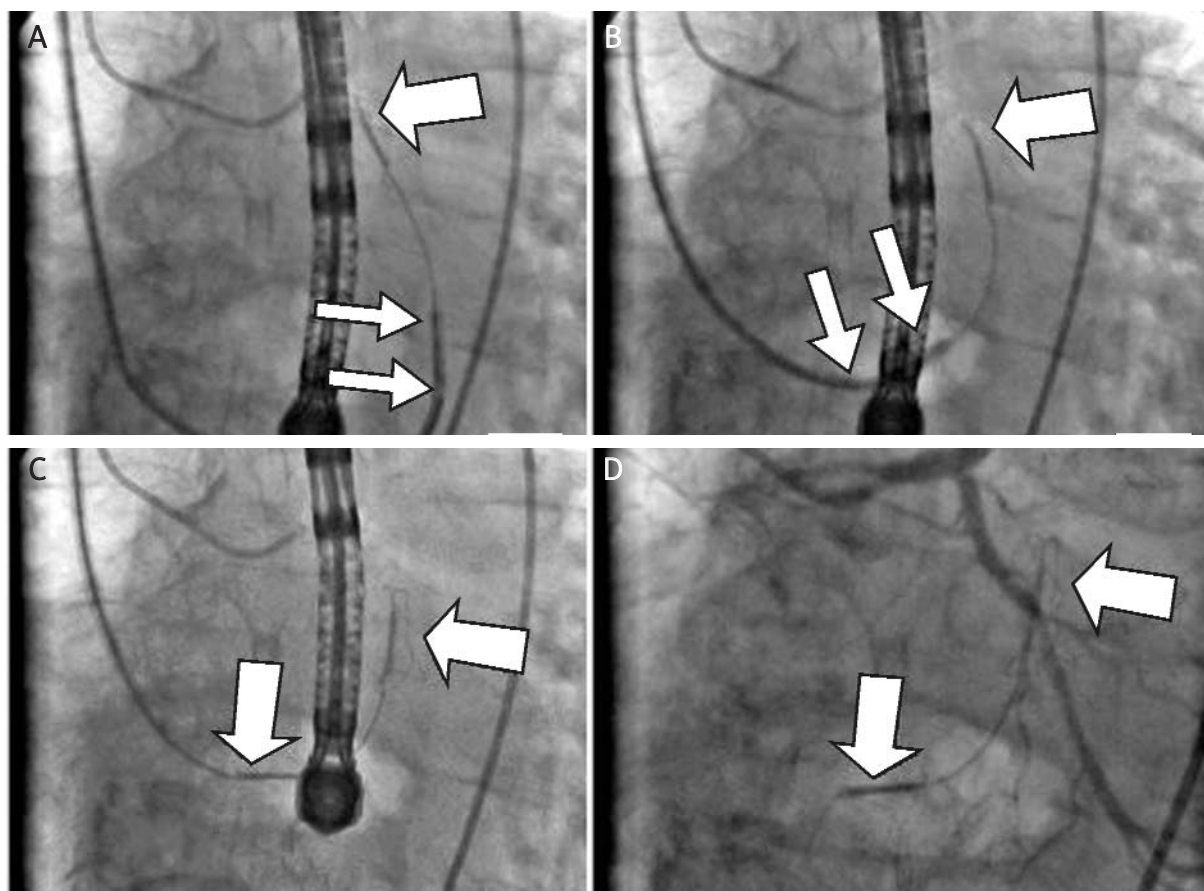
Ischemic mitral regurgitation (IMR) is defined as insufficiency of the mitral valve subsequent to ischaemic heart disease, with no concomitant organic changes in the valve leaflets or chordae.

Despite a clear definition, the mechanisms of the development of IMR are complex and not completely understood. Left ventricular remodeling and dysfunction,

enlargement of the mitral annulus, dislocation or malfunction of papillary muscles, decreased leaflet mobility all may influence the development of IMR [12, 13]. Mitral regurgitation, even if asymptomatic, contributes to a poor prognosis in patients with postinfarction heart failure, independent of age, sex, ejection fraction and Killip class in the acute phase of the MI [1, 2]. This indicates a need for more aggressive treatment of patients with IMR.

Currently, surgical approaches to mitral regurgitation include valve replacement or repair. Recent clinical data favor early valvuloplasty in patients with IMR. However, despite increased experience in surgical techniques, morbidity, mortality and late recurrent mitral regurgitation limit widespread application of surgical repair in secondary MR [14].

Techniques for percutaneous interventions in patients with structural heart disease, including mitral regurgitation are under development. In contrast to surgery, currently available percutaneous techniques aim at repair

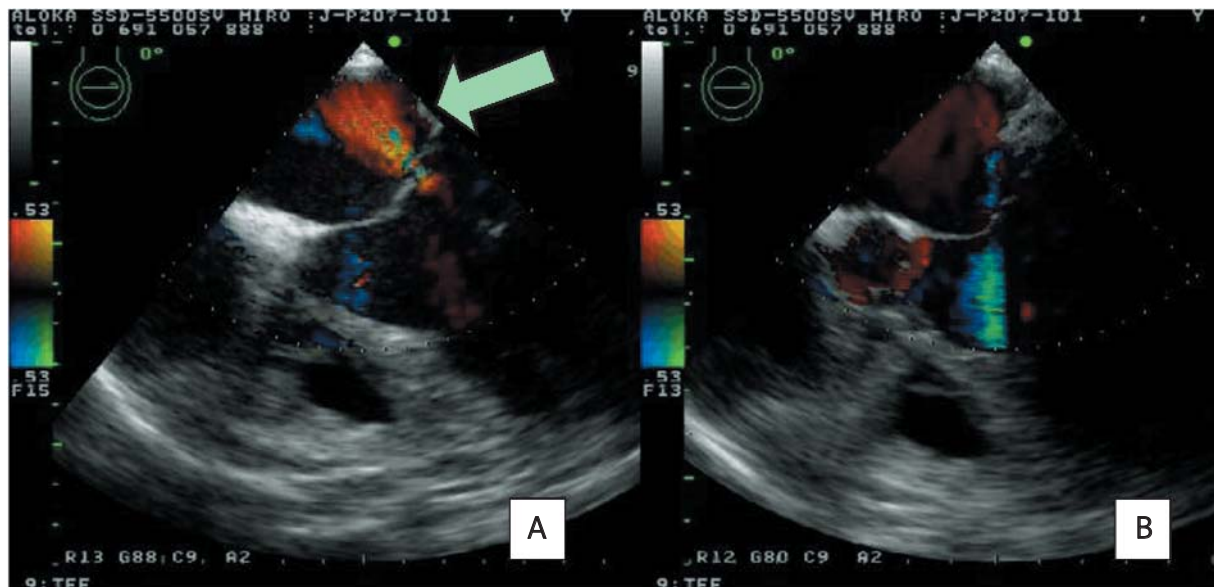


**Figure 3.** Procedural steps of the implantation of Carillon™ XE device: **A** – deployment of the distal anchor (big arrow) within the coronary venous system; **B** – application of tension (arrows indicate modified position of guiding catheter tip vs. A); **C** – deployment of the proximal anchor (left arrow); **D** – the circumflex artery following device implantation (arrows indicate both anchors)

of native valves only. There is no clinical experience with percutaneous mitral valve replacement so far. This is a result of several factors, including expected difficulties in appropriate placement of a new valve within the mitral annulus as well as the expected large size of the delivery catheter, which would have to be advanced transseptally or retrograde via the left ventricle. Therefore much effort has been spent on the development of percutaneous techniques for mitral valve repair, including those aimed at modification of the mitral annulus by devices implanted into the coronary venous system. The most advanced of such approaches is the Carillon™ Mitral Contour System™ (Cardiac Dimensions Inc., Kirkland, WA, USA). A unique advantage of the Carillon™ system is the ability to recapture the implant at any time prior to final release from the delivery system. This may be useful in case of inappropriate position of the device within the venous system, compression of the circumflex artery or insufficient effect on mitral regurgitation. Thus, the ope-

rator may decide after angiographic and echocardiographic evaluation whether or not to leave the device in place.

The main limitations of percutaneous techniques for mitral valve repair using the trans-coronary venous approach are related to variability in coronary venous anatomy, presence of venous valves within the coronary veins as well as variability of the crossing point of the great cardiac vein and the circumflex artery. Advancement of the device deeply into the coronary veins requires movement against the direction of the blood and across the venous valves. On the other hand, our own experience with trans-coronary venous procedures indicate, that despite the anatomical variability of coronary veins, in majority of cases the advancement of devices into the coronary venous tree is possible. Only in a single patient enrolled in our POZNAN trial evaluating trans-coronary venous cell transplantation [15], we found anatomical difficulties (a large venous valve at the beginning of anterior



**Figure 4.** Transesophageal echocardiography (ALOKA 5500) before the procedure (A) and after the procedure (B). Note the mitral regurgitation jet (arrow) seen at Figure A and its reduction on Figure B

interventricular vein) that made the advancement of the device impossible.

The efficacy of devices designed to modify the shape of mitral annulus may be dependent on the anatomic relationship of coronary veins to the annulus. In some cases, the distance of coronary sinus to the annulus may increase as the vein courses over the myocardium. In other cases the coronary sinus may run above the level of the annulus [16, 17]. In addition, some percutaneous trans-venous mitral annuloplasty techniques, in principle, use the venous system between the coronary sinus ostium and the point where the vein intersects with the circumflex artery to avoid artery impingement. Such strategy allows safe application of tension on the annulus, but may limit the candidates for the procedure to those with a favorable anatomic relationship [17, 18].

In our patient, after implantation of the Carillon™ XE, a significant reduction in mitral regurgitation was observed. However, only controlled clinical trials enable appropriate evaluation of the efficacy and potential risks of the procedure. This is the aim of the ongoing AMADEUS trial.

The above shown technique consists one of few approaches to percutaneous repair of mitral valve in patients with secondary MR, currently undergoing clinical evaluation. The proximity of the coronary sinus to the mitral annulus has been the basis for several techniques of percutaneous transvenous mitral valve annuloplasty, including Percutaneous Mitral Annuloplasty System Viking™ (Edwards Lifesciences Inc.) [18]. The implant itself is made up of 3 sections: a distal self-expanding stent-like

anchor, a springlike “bridge”, and a proximal stent anchor. The bridge has shape-memory properties that result in shortening forces at body temperature. Unlike the Carillon™ system, once deployed the device can not be recaptured. Since the shortening of the bridge of the Viking™ system applies tension on the mitral annulus during prolonged time, certain risk of uncontrolled compression of the circumflex artery has to be considered. Initial clinical experience with the Viking™ system provided the proof-of-concept for trans-coronary-venous mitral annuloplasty [18]. Five patients with chronic ischemic MR underwent percutaneous transvenous implantation of the annuloplasty device in the coronary sinus. Implantation was successful in 4 patients. Baseline MR in the entire group was significantly reduced at the last postimplantation visit when the device was intact. However, separation of the bridge section of the device occurred in 3 of 4 implanted devices and was detected at 28 to 81 days after implantation [18]. The device was modified and currently undergoes further clinical evaluation.

A completely different approach to percutaneous treatment of MR has been evaluated in the Endovascular Valve Edge-to-Edge Repair Studies (EVEREST) introducing MitraClip™ device [9, 20]. This method mimics surgical technique involving the suture approximation of the anterior and posterior leaflets creating an edge-to-edge repair for MR (double-orifice mitral valve) initially described by Alfieri. The percutaneous method of creating a double-orifice repair was developed using a transseptal approach. After positioning of the delivery

catheter tip in the left atrium, the MitraClip™ device is used to approximate the leaflets in a similar manner as the suture-based edge-to-edge repair. Initial clinical results show expected decrease in mitral valve area and only slight postprocedural increase in mean mitral valve gradient [20]. Long-term observations are needed to evaluate whether fibrosis at the site of clip implantation on the leaflets could lead to a slowly progressive loss of mitral valve area over time.

Because secondary mitral regurgitation develops as a result of left ventricular dilatation and impaired ventricular function, the risk of cardiac surgery procedures in this subgroup of patients remains high. Development of percutaneous techniques for mitral valve repair may constitute an attractive alternative to surgery, especially considering that aggressive antithrombotic treatment after percutaneous repair procedures is not required.

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# Przezskórna walwuloplastyka niedomykalności mitralnej systemem Carillon™. Prezentacja metody i opis przypadku

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## Streszczenie

Niedomykalność zastawki mitralnej jest częstym powikłaniem rozstrzeni lewej komory (LV) i może prowadzić do nasilenia objawów niewydolności krążenia. Ryzyko zabiegowe operacji kardiologicznych u pacjentów z wtórną niedomykalnością zastawki mitralnej, a więc ze znacznym uszkodzeniem LV, jest nadal wysokie. W ostatnich latach opracowywane są przezskórne techniki naprawcze niewydolnej zastawki mitralnej. Rozwój technik zabiegowych w kardiologii interwencyjnej doprowadził do podjęcia prób przezskórnych zabiegów naprawczych u pacjentów z wtórną niedomykalnością mitralną. Największe nadzieje wiąże się z technikami wykorzystującymi dostęp przez żyły serca. Techniki te wykorzystują to, że zatoka wieńcowa, żyła wielka serca oraz początkowy odcinek żyły międzykomorowej przedniej przebiegają wzdłuż pierścienia mitralnego, obejmując go niemal na całej długości przyczepu tylnego płotka mitralnego. Taka topografia głównych żył serca umożliwia podjęcie prób anuloplastyki mitralnej poprzez przezskórne wprowadzenie do żył urządzeń zaciskających pierścień mitralny i zmniejszających jego światło.

Jednym z pierwszych urządzeń wykorzystujących dostęp zabiegowy przez żyły serca, testowanym obecnie w warunkach klinicznych, jest system Carillon™ (Cardiac Dimensions, Inc.). Urządzenie, wprowadzane przez światło cewnika prowadzącego do żyły wielkiej serca, zbudowane jest z dwóch podwójnych pętli wykonanych z nitinolu, stanowiących „kotwice” do unieruchomienia urządzenia w systemie żylnym, połączonych zakrzywionym metalowym korpusem.

Przedstawiono przypadek niedokrwiennej niedomykalności mitralnej leczony z powodzeniem za pomocą nowej techniki zabiegowej polegającej na implantacji urządzenia Carillon™ do układu żył wieńcowych. Opisano kolejne etapy zabiegu. Po zabiegu zaobserwowano istotne zmniejszenie niedomykalności mitralnej. W przekłatkowym badaniu echokardiograficznym wykonanym w kolejnych dobach po zabiegu potwierdzono utrzymywanie się istotnego zmniejszenia niedomykalności mitralnej oraz brak płynu w worku osierdziowym. W 4. dobie po zabiegu chorego wypisano w stanie ogólnym dobrym do domu.

W pracy omówiono spodziewane korzyści i ewentualne ograniczenia nowej metody zabiegowej oraz stan jej rozwoju. Prezentowana technika zabiegowa oraz urządzenie Carillon™ jest przedmiotem oceny klinicznej w ramach trwającego badania wieloośrodkowego AMADEUS. Technikę omówiono na tle innych przezskórnych zabiegów na niedomykalnej zastawce mitralnej. Ponieważ wtórna niedomykalność mitralna dotyczy pacjentów z rozstrzenią i uszkodzeniem LV, ryzyko zabiegów kardiologicznych w tej grupie jest wysokie. Należy mieć nadzieję, że rozwój przezskórnych technik naprawczych zastawek stworzy alternatywę dla tych chorych, szczególnie że po tego typu zabiegach nie jest wymagane leczenie przeciwwkrzepliwie.

**Słowa kluczowe:** niedomykalność mitralna, techniki przezskórne, choroba niedokrwienności serca, żyły serca

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