

Echocardiographic evaluation of percutaneous valve repair in patients with mitral regurgitation using the CARILLON™ system

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Abstract

Background: Dilated cardiomyopathy is characterised by significant enlargement of cardiac chambers, which can lead to functional mitral regurgitation. Surgery is a widely accepted treatment of secondary mitral regurgitation. Conventional cardiac surgery has a high procedural risk and therefore new techniques for percutaneous repair of mitral valve are being developed. The CARILLON™ system is one of devices that is implanted into the coronary venous system, which enables tension of the mitral ring in order to improve coaptation of the leaflets.

Aim: Echocardiographic analysis of the CARILLON™ system implantation efficacy evaluated directly and one month after implantation.

Methods: The study included 9 patients, aged 58.56 ± 6 years, with severe functional mitral regurgitation, who fulfilled the following echocardiographic criteria: large central jet ≥ 4 cm² or $\geq 20\%$ of the left atrium area or wall-impinging eccentric jet reaching the pulmonary veins, vena contracta (VC) ≥ 0.30 cm, effective regurgitant orifice area (ERO) ≥ 0.2 cm², regurgitant volume (RV) ≥ 30 ml or regurgitant fraction (RF) $> 30\%$. Exclusion criteria were: concomitant severe tricuspid valve insufficiency, significant organic mitral valve pathology, chronic atrial fibrillation, foreign body in the coronary sinus, or thrombus in the left atrial appendage. The prerequisite for implanting the device was a significant reduction in the mitral regurgitation jet observed by transesophageal echocardiography (TEE), seen during the procedure. After one month, a transthoracic echocardiography (TTE) was performed to evaluate mitral regurgitation by analysing the same parameters assessed before implanting CARILLON™ to the coronary sinus.

Results: A significant improvement of VC after the procedure, in comparison to the value before the procedure (0.43 ± 0.12 vs. 0.66 ± 0.14 cm, $p < 0.05$), was observed. This improvement was lower one month after the implantation of the device (0.35 ± 0.1 cm, $p < 0.005$). The ratio of the jet area to the left atrial area was reduced from $54.96 \pm 11.18\%$ to $38.57 \pm 9.79\%$ ($p < 0.005$) and sustained after a month at $36.33 \pm 10.15\%$ ($p < 0.005$). Other echocardiographic parameters of evaluation of mitral regurgitation tended to improve, however the differences did not reach statistical significance. The ERO in subsequent studies was: 0.25 ± 0.09 cm², 0.23 ± 0.07 cm², and 0.24 ± 0.07 cm², and RV decreased from 33.06 ± 11.81 ml before the procedure, to 32.33 ± 7.84 ml one month after the procedure.

Conclusions: The CARILLON™ system implantation to the coronary venous system in patients with secondary mitral regurgitation can lead to the improvement of selected echocardiographic indices of mitral regurgitation.

Key words: mitral regurgitation, percutaneous techniques, echocardiography

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Introduction

Dilated cardiomyopathy (DCM) is characterised by a significant enlargement of cardiac chambers with concomitant systolic dysfunction, leading to the development of heart failure symptoms. DCM may be caused by ischemic heart disease or has non-ischemic aetiology. In 30% of cases, chamber dilatation is accompanied by functional mitral regurgitation (MR), which

has a clear negative effect on prognosis in these patients. A yearly mortality rate in patients with end-stage heart failure and MR is 30% [1]. Functional MR in patients with DCM results from lack of appropriate leaflet coaptation that is mainly caused by enlargement of the mitral annulus [2, 3]. Currently accepted treatment of secondary MR is cardiac surgery [4]. However, not all patients are good candidates for such treatment due to limitations related

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to age or concomitant disease, and thus search continues for alternative effective treatment methods for this condition. In the current era of intensive development of interventional cardiology techniques, percutaneous repair of MR secondary to cardiac chamber dilatation has been attempted. One of the first of such devices using transvenous approach through cardiac veins that is currently under clinical evaluation has been the CARILLON™ system (Cardiac Dimensions, Inc.) [5].

The purpose of this study was to evaluate the effectiveness of the CARILLON™ system implantation using echocardiographic assessment immediately after the procedure and at one month follow-up.

Methods

From July 2006 to June 2007, nine consecutive patients were studied, including eight men and one woman. All patients had to fulfil the following inclusion criteria: established diagnosis of ischemic or non-ischemic DCM, MR severity corresponding to grade 2 or higher, type I regurgitation according to the Carpentier classification, left ventricular end-diastolic diameter (LVEDd) > 55 mm or LV end-diastolic diameter indexed for body surface area (LVEDd/BSA) > 3.0 cm/cm², LV ejection fraction (LVEF) < 40%, and symptoms of heart failure corresponding to the New York Heart Association (NYHA) class II or higher. The exclusion criteria included pathologic organic lesions within mitral valve leaflets, recent (< 3 months) hospitalisation due to myocardial infarction, coronary artery bypass grafting (CABG) or unstable angina, hospitalisation for coronary angioplasty within last 30 days, heart failure due to causes other than DCM, permanent atrial fibrillation, thrombus in the left atrial appendage, significant tricuspid regurgitation, presence of a foreign body in the coronary sinus or the great cardiac vein, serum creatinine level > 2.2 mg/dl, and grade 2 MR in a patient in NYHA class II. All patients underwent a 6-minute walking test before the procedure and at one month follow-up.

Echocardiographic criteria

Transthoracic echocardiography

To establish indications for the device implantation transthoracic echocardiography (TTE) was performed within 42 days before the procedure and included standard imaging views (parasternal long- and short-axis views, apical 2-, 3-, 4-, and 5-chamber views). Measurements of LVEDd and LVEDs, left atrial diameter, interventricular septum thickness and posterior wall thickness were performed using the M-mode view. Two-dimensional imaging in the parasternal long-axis view was used to measure mitral annulus and LV outflow tract (LVOT). The apical four-chamber view was used to calculate LV end-systolic and end-diastolic volume, maximum and end-systolic left atrial area, and mediolateral and superoinferior

left atrial dimensions. A colour Doppler study was used to determine the radius of the isovelocity shell within the flow convergence area (PISA method) and the Nyquist limit. Vena contracta (VC) was calculated in the parasternal long-axis and apical three-chamber views. The area of the regurgitant jet was determined in the parasternal long-axis, apical four-chamber and apical three-chamber views. Measurements of peak and mean mitral inflow velocity, transaortic flow, peak LVOT flow velocity and its integral, peak MR jet velocity and its integral, and pulmonary venous systolic and diastolic flow integral were performed using pulsed-wave Doppler spectrum. The LV ejection fraction (LVEF) was calculated using the Simpson method. Calculations were performed in accordance with the American Society of Echocardiography guidelines, and so was the choice of parameters to assess the severity of MR, which was based on the following criteria: MR jet area and its relation to the left atrial area, VC, effective regurgitant orifice (ERO), regurgitant volume (RV), regurgitant fraction (RF), saturation of the continuous-wave Doppler spectrum of the MR jet, pulmonary venous flow pattern, and left atrial dimension.

Moderate MR was defined as the presence of the following five criteria: MR jet area ≥ 6 cm² or $\geq 20\%$ of the left atrial area, VC ≥ 0.3 cm, ERO ≥ 0.2 cm² or RV ≥ 30 ml or RF $\geq 30\%$, ability to identify the full spectral Doppler envelope of the MR jet, systolic to diastolic pulmonary venous flow ratio (S/D) < 1 or flow reversal.

Transesophageal echocardiography

Transesophageal echocardiography (TEE) was used to monitor MR in the periprocedural period until the device was placed in its final position. The TEE monitoring was started after induction of general anaesthesia. Reduction in the MR jet as assessed by TEE was the basis for the decision to leave the device in its position in the coronary sinus and the great cardiac vein. Pre-implantation TEE included mid-esophageal views at 0-180 degrees to visualise pulmonary veins and the left atrium, including the left atrial appendage (to exclude the presence of a thrombus), and at 0, 30, 60, 90, and 120 degrees to evaluate mitral leaflets and definitely exclude the presence of organic lesions. Calculations of the echocardiographic parameters were performed at the following angles of visualisation: mitral annulus dimension, MR jet area, and left atrial area at 0, 30, 60, 90, and 120 degrees; LVOT flow and diameter at 0 and 120 degrees; VC, ERO and RV at 30 and 120 degrees. During the device implantation, TEE was used to monitor the procedure, including periodic evaluation of the severity of MR. The coronary sinus was imaged with the probe in a low esophageal location, allowing visualisation of the proximal anchor of the device during the implantation. Post-implantation TEE included the same views and calculations as the pre-implantation study. At the same time, images were evaluated for the

presence of possible complications such as mitral stenosis, cardiac tamponade or formation of a thrombus. During the procedure, blood pressure was recorded every 10-15 min, with particularly careful monitoring during implantation of the device. Every blood pressure change exceeding 20 mmHg required a separate annotation. Evaluation of reduction in the MR jet following device implantation could only be performed if blood pressure did not exceed baseline values by more than 10 mmHg. The TTE examinations were performed using the Aloka 5500 system, and TTE examinations using the Alfa 10 system with a multiplane probe.

Procedure description

Implantation procedures were performed under general anaesthesia using a previously described protocol [5]. The initial stage was coronary angiography with visualisation of the venous phase. Next, the coronary sinus was cannulated using internal jugular venous approach and coronary venography was performed. To enable precise measurements of cardiac veins, a calibration catheter was advanced to the anterior interventricular vein. Then, an appropriately sized CARILLON™ device was introduced into the coronary venous system and its distal anchor was deployed. After confirmation of uncompromised flow in the left circumflex artery, tension was applied to the mitral annulus and the proximal anchor was deployed. Finally, after echocardiographic verification of the improvement of MR parameters, the implanted device was decoupled from the delivery system and the guiding wire was removed.

Results

The entry criteria were fulfilled by 15 patients who were considered appropriate candidates for percutaneous mitral valve repair. The CARILLON™ device was implanted successfully in 11 patients, and one-month echocardiographic follow-up was completed in 9 patients. In four cases, the device was introduced into the coronary sinus but finally not implanted for reasons including lack of expected reduction in the MR jet as assessed by TEE in two patients, and unfavourable local coronary vessel anatomy precluding safe delivery of the device (due to compression of the left circumflex artery) in the remaining two patients. In two patients, device implantation was attempted twice, with a thrombus in the left atrial appendage found during TEE in one patient, and the other patient requiring initial coronary vessel dilatation and stenting. The mean age of patients in the study group was 58.56 ± 6.3 years (range 67-48 years). All patients were in NYHA class III-IV. Deployment of the CARILLON™ device did not preclude subsequent implantation of a cardiac resynchronisation therapy device and defibrillator (CRT-D). Table I shows clinical characteristics of the study group.

In patients who underwent the CARILLON™ device implantation, baseline echocardiographic MR parameters were as follows: VC 0.66 ± 0.14 cm, MR jet area relative to the left atrial area $54.96 \pm 11.18\%$, ERO 0.25 ± 0.1 cm², and RV 33.06 ± 11.81 ml. The first two of these corresponded to grade 3 and 4 MR, respectively, while MR severity as evaluated using the PISA method corresponded to grade 2 MR. Following the device implantation, improvement in selected echocardiographic parameters was noted,

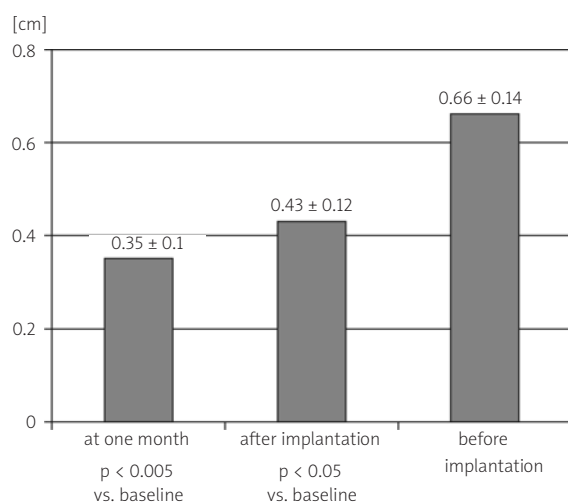


Figure 1. Comparison of the vena contracta before and after the procedure and at one month follow-up ($p < 0.05$ baseline vs. one month)

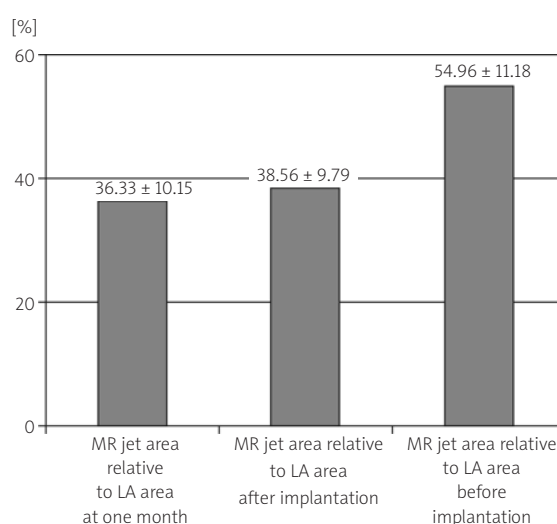


Figure 2. Comparison of the mitral regurgitation jet area relative to the left atrial area before and after the procedure and at one month follow-up ($p < 0.005$ baseline vs. one month)

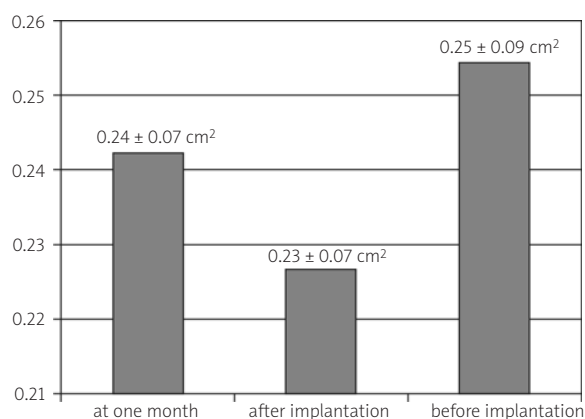


Figure 3. Comparison of the effective regurgitant orifice (ERO) before and after the procedure and at one month follow-up (differences NS)

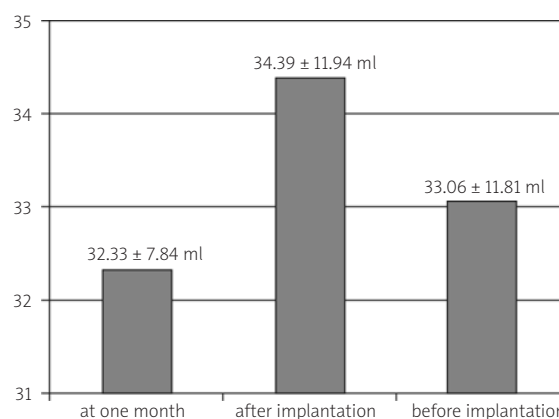


Figure 4. Comparison of the regurgitant volume before and after the procedure and at one month follow-up (differences NS)

Table I. Demographic and clinical characteristics of patients undergoing percutaneous mitral valvuloplasty

Number of patients	9
Age [years]	58.56 ± 6.3 (67-48)
Men	8
Women	1
NYHA class III-IV [%]	100
Sinus rhythm [%]	100
Left bundle branch block [%]	56
Previous myocardial infarction [%]	78
Left ventricular end-diastolic dimension [mm]	61-77 (69.7)
Left ventricular ejection fraction [%]	18.1-38.9 (28.6)

including reduction in VC (to 0.43 ± 0.12 cm, $p < 0.05$), MR jet area relative to the left atrial area (to $38.57 \pm 9.79\%$, $p < 0.005$), and ERO (to 0.23 ± 0.07 cm², NS) (Figures 1-4). Statistically significant reductions were noted in VC and MR jet area relative to the left atrial area, corresponding to reduction in MR severity by one grade. Follow-up echocardiographic examinations at one month confirmed these effects and showed reduction in RV (Figures 1-4). All these patients also showed improvement in NYHA class and in the distance of the 6-minute walking test (360.4 ± 75 m before the device implantation and 421.78 ± 90.5 m after the device implantation).

Discussion

Left ventricular remodelling after myocardial infarction or in the early stages of DCM may lead to a significant MR

[6]. Significant limitation of spatial changes of LV during the cardiac cycle and LV dysfunction may result in annular dilatation and papillary muscle displacement [7-8]. Limited valve leaflet mobility related to apical and posterolateral papillary muscle displacement leads to a decreased leaflet coaptation and results in MR that occurs despite a structurally normal valve. Development of MR in this group of patients has significant prognostic consequences. In patients with ischemic heart disease, such a functional MR may significantly increase the risk of heart failure [9] and is an adverse prognostic factor even if MR severity is only mild or moderate [10, 11]. Grigioni et al. found that 5-year survival was significantly reduced if ERO was 20 mm² or more [11]. Prognosis in severe MR is poor even if it has an asymptomatic course [10, 11]. In patients with significant ischemic MR, 5-year survival was $38 \pm 5\%$ [11]. Optimal medical treatment may reduce this risk only in some cases.

Currently, a standard approach to treatment of such patients is CABG combined with mitral annuloplasty. According to the revised 2007 European Society of Cardiology guidelines [12], indications for surgical treatment depend on the aetiology of chronic MR. In non-ischemic MR, surgery is recommended in patients with LV dilatation and dysfunction (LVEF < 60%) even without clinical symptoms (NYHA class I), and in patients with LVEF < 30% and no response to medical therapy, if a sustainable improvement of MR is likely and there are no significant comorbidities (class IIa indication). In ischemic heart disease (i.e. post-myocardial infarction), mitral valve repair is generally indicated in any severe MR, if coronary revascularisation is feasible [12]. Surgical treatment options include annuloplasty and mitral valve replacement.

Numerous reports documented benefits from early surgical treatment. Currently, the preferred approach is annuloplasty [13] which is associated with reduced mortality and less frequent complications as compared to valve replacement [14]. Outcomes of ring annuloplasty in the treatment of secondary MR in DCM were presented by many authors. The most commonly performed mitral valve repair surgery in MR is restrictive (down-sized) ring annuloplasty (using size 24 or 26 rings). The result is reduction in the mitral annulus with improved leaflet coaptation. However, indications for surgery are often limited by such factors as low LVEF. Patients with low LVEF are at high operative risk, as low LVEF is a predictor of increased mortality [15], and particularly post-operative mortality [16]. In these circumstances, percutaneous repair might prove safer but equally effective.

Currently, the most promising approach involves the use of the coronary sinus which is located behind the posterior mitral annulus and runs parallel to the latter. It has also been shown that displacement of the posterior mitral leaflet toward the anterior leaflet improves their coaptation and reduces MR. Recently, percutaneous mitral annuloplasty has been suggested as an alternative treatment approach. In 2005, initial results were presented with the use of adjustable Viacor ring that is implanted into the coronary sinus. In six sheep with postinfarction MR, regurgitant jet area was reduced from 5.4 to 1.3 cm². In that study, ERO and RV could not be evaluated due to difficulties with the assessment of flow convergence [17].

In 2006, results of percutaneous mitral annuloplasty using the Edwards Life Sciences system (two stents connected with a nitinol spring) in patients with chronic functional MR were presented [18]. The MR severity was reduced in these patients on average by 1.5 grades (from 3 to 1.6). However, detachment of the connecting spring from stents was noted in patients in this study at 22, 28, and 81 days after the device implantation. In addition, published results of the echocardiographic assessment were limited to reports on improvement of MR severity at subsequent time points during follow-up, without detailed data regarding individual echocardiographic parameters.

In the same year, results of animal studies using the percutaneous septal-sinus shortening (PS3) system were presented. This system consists of an anchor introduced into the coronary sinus and an occluder placed in the foramen ovale of the interatrial septum, connected by a bridge. Through progressive tensioning of the bridge element, mitral annulus geometry is modified, leading to reduction in MR severity. These procedures were performed in 19 sheep. Echocardiographic results were reported as an overall reduction in the mean MR severity grade from 2.1 before the procedure to 0.4 immediately following the device implantation and 1.7 at 30-day follow-up [19].

Similar results were presented in 2006 with the use of the percutaneous Myocor iCoapsys device. It is composed

of two pads connected by a dedicated cord that passes through the LV lumen [20]. Shortening of the cord not only decreases the anteroposterior diameter of the mitral annulus, but also results in displacement of the papillary muscles. Another percutaneous approach is based on the idea of the Alfieri side-to-side surgical suture technique. The Evalve MitraClip system is inserted through the vena cava inferior to the right atrium, and then, by puncturing the interatrial septum superiorly and posteriorly from the foramen ovale, the device is introduced transeptally to the left atrium. Under echocardiographic and fluoroscopic guidance, the clip is then opened to grasp free margins of both mitral leaflets, creating a double-orifice mitral valve. In 2009, results of the EVEREST study in 107 patients were published. The MR severity was reduced to grade 2 or less in 74% of participants, and 76.3% of patients did not require surgical treatment at 36 months of follow-up [21]. Specific echocardiographic criteria for these procedures included central MR with coaptation length > 2 mm, coaptation depth < 11 mm, and prolapse of A2 and P2 scallops. Thus, these morphologic criteria effectively excluded patients with severe annular dilatation.

In our study, we used the CARILLON™ device (Cardiac Dimensions) that generates pressure acting on the mitral annulus to change mitral valve geometry. After the device was placed in the coronary sinus, its tension was modified under echocardiographic guidance until safe maximal reduction in MR severity. Following the device implantation, we observed improvement in the semiquantitative and quantitative echocardiographic indicators of MR severity, corresponding to its reduction by one grade. This beneficial effect was sustained during one month follow-up. Changes of echocardiographic parameters based on the assessment of flow convergence did not reach statistical significance, which might have resulted from the limited number of patients. It cannot be excluded, however, that various echocardiographic parameters currently used to evaluate the severity of the abnormal function of native valves will ultimately prove to have a different value in this regard.

In the present study, we focused on a detailed description of the methods used, as the echocardiographic assessment is of a paramount importance for the proper selection of patients for this treatment approach. On the other hand, we only presented data regarding changes in those parameters that were measured during the procedure as specified in the protocol, prior to final anchoring of the device, and were useful for the final decision whether to leave the device in place in the coronary sinus. To ensure patient safety, some time constraints during the procedures had to be introduced and thus the study protocol included measurements of only selected parameters from all recommended ones. Such parameters as leaflet coaptation depth, defined as the distance between the mitral annulus and the farthest point of leaflet coaptation, and the mitral valve tenting

area, or the area between the mitral annulus and the mitral valve leaflets, which are used to determine the degree of the mitral annulus deformation, were not evaluated during these procedures either. These findings are preliminary in nature. Definite echocardiographic assessment of this approach to percutaneous mitral valvuloplasty requires studies involving larger groups of patients and longer follow-up. Determination of the clinical value of specific echocardiographic parameters in the evaluation of percutaneous mitral valvuloplasty using the CARILLON™ system will be possible after performing a larger number of these procedures.

Conclusions

Implantation of the CARILLON™ system to the coronary sinus in patients with secondary MR may result in improvement of selected echocardiographic parameters describing the size of the reduction in MR jet severity.

References

- Junker A, Thayssen P, Nielsen B, et al. The hemodynamic and prognostic significance of echo-Doppler-proven mitral regurgitation in patients with dilated cardiomyopathy. *Cardiology* 1993; 83: 14-20.
- Kono T, Sabbah HN, Rosman H, et al. Mechanism of functional mitral regurgitation during acute myocardial ischemia. *J Am Coll Cardiol* 1992; 19: 1101-5.
- Sabbah HN, Kono T, Rosman H, et al. Left ventricular shape: a factor in the etiology of functional mitral regurgitation in heart failure. *Am Heart J* 1992; 123: 961-6.
- Swedberg K, Cleland J, Dargie H, et al. The Task Force for the Diagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology. *Eur Heart J* 2005; 26: 1115-40.
- Siminiak T, Firek L, Jerzykowska O, et al. Percutaneous valve repair for mitral regurgitation using the Carillon Mitral Contour System™. Description of the method and case report. *Kardiologia Pol* 2007; 65: 272-8.
- Enriquez-Sarano M, Loulmet D, Daniel Burkhoff D. The conundrum of functional mitral regurgitation in chronic heart failure. *J Am Coll Cardiol* 2008; 51: 487-9.
- Yiu SF, Enriquez-Sarano M, Tribouilloy C, et al. Determinants of the degree of functional mitral regurgitation in patients with systolic left ventricular dysfunction: a quantitative clinical study. *Circulation* 2000; 102: 1400-6.
- Watanabe N, Ogasawara Y, Yamaura Y, et al. Geometric deformity of the mitral annulus in patients with ischemic mitral regurgitation: a real-time three-dimensional echocardiographic study. *J Heart Valve Dis* 2005; 14: 447-52.
- Lamas GA, Mitchell GF, Flaker GC, et al. Clinical significance of mitral regurgitation after acute myocardial infarction: Survival and Ventricular Enlargement Investigators. *Circulation* 1997; 96: 827-33.
- Enriquez-Sarano M, Avierinos J, Messika-Zeitoun, et al. Quantitative determinants of the outcome of asymptomatic mitral regurgitation. *N Engl J Med* 2005; 352: 875-83.
- Grigioni F, Enriquez-Sarano M, Zehr KJ, et al. Ischemic mitral regurgitation: long-term outcome and prognostic implications with quantitative Doppler assessment. *Circulation* 2001; 103: 1759-64.
- Vahanian A, Baumgartner H, Bax J, et al. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. *Eur Heart J* 2007; 28: 230-68.
- Savage EB, Ferguson B Jr, DiSesa VJ. Use of mitral valve repair: analysis of contemporary United States experience reported to the Society of Thoracic Surgeons National Cardiac Database. *Ann Thorac Surg* 2003; 75: 820-5.
- Grossi EA, Goldberg JD, La Pietra A, et al. Ischemic mitral valve reconstruction and replacement: comparison of long-term survival and complications. *J Thorac Cardiovasc Surg* 2001; 122: 1107-24.
- Avierinos JF, Gersh BJ, Melton LJ 3rd, et al. Natural history of mitral valve prolapse in the community. *Circulation* 2002; 106: 1355-61.
- Mirabel M, Lung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J* 2007; 28: 1358-65.
- Daimon M, Shiota T, Gillinov AM, et al. Percutaneous mitral valve repair for chronic ischemic mitral regurgitation: a real-time three-dimensional echocardiographic study in an ovine model. *Circulation* 2005; 111: 2183-9.
- Webb JG, Harnek J, Munt BI. Percutaneous transvenous mitral annuloplasty: initial human experience with device implantation in the coronary sinus. *Circulation* 2006; 113: 851-5.
- Rogers JH, Mackoviak JA, Rahdert DA, et al. Percutaneous septal sinus shortening: a novel procedure for the treatment of functional mitral regurgitation. *Circulation* 2006; 113: 2329-34.
- Pedersen WR, Block P, Feldman T. The iCoapsys Repair System for the percutaneous treatment of functional mitral insufficiency. *Euro Intervention* 2006; 1 (Supl. A): A44-8.
- Ted Feldman, Saibal Kar, Michael Rinaldi, et al. Percutaneous mitral repair with the MitraClip System. Safety and midterm durability in the initial EVEREST (Endovascular Valve Edge-to-Edge REpair Study) cohort. *J Am Coll Cardiol* 2009; 54: 686-94.

Echokardiograficzna ocena niedomykalności zastawki mitralnej u pacjentów poddanych przezskórnej walwuloplastyce mitralnej przy użyciu systemu CARILLON™

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Streszczenie

Wstęp: Kardiomiopatia rozstrzeniowa charakteryzuje się znacznym powiększeniem jam serca, które może prowadzić do istotnej niedomykalności zastawki mitralnej o charakterze funkcjonalnym. Powszechnie akceptowaną metodą leczenia wtórnej niedomykalności mitralnej są zabiegi kardiologiczne. Obecnie pojawiły się próby przezskórnych zabiegów naprawczych niedomykalności zastawki mitralnej w przebiegu rozstrzeni jam serca. Jednym z urządzeń wprowadzanych do żyły wielkiej serca, które umożliwia wytworzenie nacisku na pierścień mitralny w celu zmniejszenia fali niedomykalności, jest system CARILLON™.

Cel: Analiza echokardiograficzna skuteczności zabiegów implantacji systemu CARILLON™ przeprowadzana bezpośrednio po implantacji i w okresie miesiąca po zabiegu.

Metody: Badaniem objęto 9 kolejnych pacjentów w wieku $58,56 \pm 6,3$ roku z funkcjonalną niedomykalnością zastawki mitralnej, którzy w badaniu echokardiograficznym przezklatkowym (TTE) spełniali następujące kryteria: wielkość tali fali zwrotnej (VC) $\geq 0,3$ cm, pole powierzchni fali zwrotnej ≥ 6 cm² lub $\geq 20\%$ pola powierzchni lewego przedsionka, efektywne pole ujścia fali niedomykalności (ERO) $\geq 0,2$ cm² bądź objętość fali zwrotnej (RV) ≥ 30 ml albo frakcja niedomykalności (RF) $\geq 30\%$. Kryteria wyłączenia stanowiły: współistniejąca istotna niedomykalność zastawki trójdzielnej, zmiany organiczne na płatkach oraz migotanie przedsionków. Warunkiem pozostawienia implantowanego urządzenia było stwierdzenie poprawy hemodynamicznej w echokardiografii przezprzetykowej (TEE). W okresie miesiąca wykonywano kolejne badanie TTE w celu oceny wielkości fali niedomykalności i analizowano parametry oceniane przed założeniem urządzenia CARILLON™ do zatoki wieńcowej.

Wyniki: Stwierdzono istotną poprawę w zakresie wymiaru tali fali zwrotnej po zabiegu ($0,43 \pm 0,12$ cm) w porównaniu z wartościami przed zabiegiem ($0,66 \pm 0,14$ cm, $p < 0,05$), która utrzymywała się po miesiącu od implantacji urządzenia ($0,35 \pm 0,1$ cm, $p < 0,005$). Stosunek powierzchni fali zwrotnej do powierzchni przedsionka zmniejszył się w wyniku zabiegu z $54,96 \pm 11,18\%$ do $38,57 \pm 9,79\%$ ($p < 0,005$) i utrzymywał się po miesiącu, kiedy wynosił $36,33 \pm 10,15\%$ ($p < 0,005$). Pozostałe echokardiograficzne parametry oceny niedomykalności mitralnej uległy poprawie, ale wartości nie osiągnęły istotności statystycznej. Efektywna powierzchnia ujścia fali niedomykalności w kolejnych badaniach wynosiła: $0,25 \pm 0,09$ cm², $0,23 \pm 0,07$ cm², $0,24 \pm 0,07$ cm², natomiast objętość fali zwrotnej uległa zmianie od wartości $33,06 \pm 11,81$ ml przed zabiegiem do $32,33 \pm 7,84$ ml po miesiącu. U wszystkich pacjentów z badanej grupy zaobserwowano poprawę w zakresie wydolności krążenia ocenianej wg skali NYHA.

Wnioski: Implantacja systemu CARILLON™ do zatoki wieńcowej u pacjentów z wtórną niedomykalnością mitralną może prowadzić do poprawy wybranych wskaźników echokardiograficznych określających wielkość fali zwrotnej.

Słowa kluczowe: niedomykalność mitralna, techniki przezskórne, echokardiografia

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