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Functional assessment of patients after percutaneous mitral valvuloplasty with Carillon™ device: a preliminary report

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Abstract

Background: Functional mitral regurgitation (MR) due to dilated cardiomyopathy or coronary artery disease remains a significant clinical problem. These clinical entities lead to left ventricular enlargement, which results in annular dilation and MR. Surgical valvuloplasty is associated with a high perioperative risk. This is the reason why percutaneous techniques for mitral valve repair are under development. One of the most advanced devices for mitral annuloplasty is the Carillon™ system.

Aim: Functional assessment of patients who have undergone mitral annuloplasty using the Carillon™ device.

Methods: Fourteen consecutive patients with functional MR who had undergone successful implantation of the Carillon™ device were enrolled. The device was implanted into the venous system of the heart and applied tension to the mitral annulus in order to improve coaptation of the cusps and reduce MR. In implanted patients echocardiographic MR parameters (vena contracta, effective regurgitant orifice area) were assessed before, immediately after the procedure and during 1-month follow-up. Furthermore, the 6-minute walk test (6MWT), Naughton stress test and the NYHA functional class assessment were performed before the procedure and at 1 month. Quality of life was evaluated by the Kansas City Cardiomyopathy Questionnaire. One month after the procedure patients were also asked to compare their health status with their baseline condition.

Results: In implanted patients improvement of echocardiographic MR parameters was observed, both immediately after the procedure and during 1 month follow-up. These parameters included vena contracta (0.36 ± 0.03 and 0.31 ± 0.03 *vs* 0.65 ± ± 0.04 cm, both $p < 0.001$) as well as effective regurgitant orifice area (0.18 ± 0.02 and 0.20 ± 0.02 *vs* 0.28 ± 0.04 cm^2, $p < 0.05$ and $p < 0.005$, respectively). One month after the procedure the 6MWT (390 ± 26.25 *vs* 311.9 ± 15.71 m, $p < 0.001$), Naughton treadmill exercise test (5.06 ± 0.47 *vs* 3.49 ± 0.27 min, $p < 0.005$) and NYHA classification (1.93 ± ± 0.20 *vs* 2.93 ± 0.07, $p < 0.005$) were significantly improved. Quality of life improved from 67.93 ± 3.30 at baseline to 88.31 ± 4.02 at 1 month ($p < 0.001$). All the patients reported some degree of improvement at 1 month compared to baseline.

Conclusions: Implantation of the Carillon™ device in patients with functional MR leads to increased exercise capacity and improvement of selected echocardiographic MR parameters. Randomised trials are needed to assess the clinical value of the technique.

Key words: mitral regurgitation, percutaneous techniques, functional assessment, exercise capacity

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INTRODUCTION

Mitral regurgitation (MR) is one of the most common acquired valvular diseases [1]. Functional MR is one of the forms of this disease entity. Studies have shown that MR considerably worsens the prognosis and is a common cause of heart failure (HF). Four-year survival in patients with significant MR is 30% compared to 90% in patients without significant MR [2]. What is more, the available data suggest that even asymptomatic MR adversely affects the prognosis, both in patients with MR of ischaemic aetiology and patients with MR from other causes [3, 4].

Surgical valvuloplasty is the standard method of treatment in patients with functional MR. However, in patients with considerable left ventricular (LV) dysfunction this technique is associated with high perioperative risk, which often results in not attempting surgical treatment in these cases [5]. The dynamically developing percutaneous techniques may offer an attractive alternative in this group of patients. One of the most promising and technically advanced methods using access through cardiac veins is mitral valvuloplasty with the use of the Carillon™ system [6]. This device, passed through a catheter leading to the venous system of the heart, puts pressure on the mitral annulus, resulting in an improved coaptation of the cusps and a reduced regurgitant jet.

The aim of the study was to perform a functional assessment of patients undergoing implantation of the Carillon™ system at our facility.

Table 1. Characteristics of the study population

Number of patients	14
Age (range) [years]	61.1 ± 1.9 (45–71)
Men	11
Women	3
Severity of heart failure:	
NYHA I	0
NYHA II	1
NYHA III	13
NYHA IV	0
Chronic obstructive pulmonary disease	2
Diabetes mellitus	6
Hypertension	3
Hyperlipidaemia	7
Ischaemic cardiomyopathy	12
Dilated cardiomyopathy	2
Peripheral vascular disease	2
A history of PTCA	8
A history of CABG	3
A history of stroke	2
A history of MI	9
Smoking	6

PTCA — percutaneous transluminal coronary angioplasty; CABG — coronary artery bypass grafting; MI — myocardial infarction

METHODS

We enrolled 14 consecutive patients (11 men and 3 women, aged 45–71 years, mean age 61.1 years) with grade 2 to 4 functional MR secondary to dilated cardiomyopathy or ischaemic heart disease who had undergone successful implantation of the Carillon™ device. The other inclusion criteria were: Carpentier type 1 MR, NYHA functional classes II to IV, a walk distance in the 6-minute walk test (6MWT) from 150 m to 450 m, LV ejection fraction (LVEF) < 40%, LVEDD/BSA of 3.0 cm/m^2, LVEDD > 55 mg and age 18 years and above. All the patients received standard drug therapy for HF, unless any of the drugs was not tolerated. Table 1 summaries patient characteristics. Exclusion criteria were as follows: coexistent significant tricuspid regurgitation, structural changes in the mitral valve cusps, indications for surgical revascularisation, recent (< 3 months previously) hospitalisation for myocardial infarction, unstable angina pectoris or coronary artery bypass grafting, coronary angioplasty in the past 30 days, thrombus in the right atrial appendage, a foreign body in the coronary sinus (CS) or the great cardiac vein, serum creatinine exceeding 2.2 mg/dL and grade 2 MR in a patient with NYHA functional class II HF. Before, immediately after and one month after the procedure the patients underwent echocardiography, in which such parameters of MR as vena contracta and the effective regurgitant orifice area (EROA) were assessed. All the measurements were performed in accordance with the American Society of Echocardiography guidelines. In addition, before and one month after the procedure exercise tolerance was assessed by the 6MWT and the Naughton stress test. The severity of HF symptoms was assessed according to the NYHA functional classification. Before and one month after the procedure we also assessed the qualify of life with the Kansas City Cardiomyopathy Questionnaire. In addition, one month after the procedure the patients assessed their well-being compared to how they had felt before the procedure.

The study protocol was approved by Poznan University of Medical Sciences Bioethics Committee. All the enrolled patients gave voluntary informed consent to participate in the study.

Device implantation

The idea behind percutaneous mitral valvuloplasty via the CS is based on the anatomical relationships between the venous system of the heart and the mitral annulus. The main segments of the large cardiac veins run along the mitral annulus, embracing it nearly along the entire length of the attachment of the posterior mitral cusp. Therefore, the anatomical interrelations of the mitral annulus and the cardiac veins make it possible to deploy into the coronary veins devices that apply pressure on the mitral annulus. One such device is the

Table 2. Effects of valvuloplasty on NYHA functional class, 6-minute walk test (6MWT), duration of stress test and the quality of life

Parameter	Before the procedure	After the procedure	P
Mean NYHA functional class	2.93 ± 0.07	1.93 ± 0.2	< 0.005
Mean distance in the 6MWT [m]	311.0 ± 15.7	390 ± 26.3*	< 0.001
Mean duration of stress test [min]	3.49 ± 0.27	5.06 ± 0.47*	< 0.005
Mean quality of life score	67.9 ± 3.3	88.3 ± 4.02*	< 0.001

*Assessed in 13 patients

Carillon™ system, which causes approximation of the cusps and improves their coaptation by modifying the shape of the annulus. The loops serve as anchors facilitating fixation of the device in the venous system of the heart. The very implantation procedure consists of several stages. The first involves the passage of a 9 F guiding catheter to the CS through the jugular vein and the performance of CS venography. Then, along the guidewire, an appropriately sized kit is passed and the distal anchor is placed in the great cardiac vein or in the initial segment of the anterior interventricular vein. Following expansion of the distal anchor by applying traction to the system the surgeon applies controlled pressure to the mitral annulus and then expands the proximal anchor. Due to the risk of compressing the circumflex artery, before the final deployment of the device, an angiographic check of the coronary vessels is performed. The unique advantage of the Carillon™ system is the possibility of removing the device by reinsertion into the guiding catheters after the check but before the decision to leave it there have been made.

Statistical analysis

The statistical calculations were performed using GraphPad Prism 3.0 for Windows. The results are presented as means ± ± standard errors. The analysis of the parameters before and after the procedure was performed using the non-parametric Wilcoxon test for related variables. The p value (the statistical significance level) was set at < 0.05.

RESULTS

Percutaneous mitral valvuloplasty reduced the severity of HF, as reflected by a significant improvement in the NYHA functional classes (Table 2). While before the procedure 93% of the patients were in NYHA functional class III, after the procedure 71% of the patients were in class II and 21% in class I (Table 3).

The functional improvement was also reflected by the increased walking distance in the 6MWT by an average of 78.1 m, which translates into a relative improvement of 25%. We also noted prolongation of the Naughton stress test (5.06 ± 0.47 min one month after the procedure *vs* 3.49 ± ± 0.27 min before implantation of the Carillon™ system; Table 2).

Table 3. Severity of heart failure symptoms before and one month after the procedure

NYHA functional class	Before the procedure (n = 14)	One month after the procedure (n = 14)
I	0% (0/14)	21% (3/14)
II	7% (1/14)	71% (10/14)
III	93% (13/14)	0% (0/14)
IV	0% (0/14)	7% (1/14)

The echocardiographic parameters, namely vena contracta and EROA, also improved with vena contracta decreasing from 0.65 ± 0.04 before the procedure to 0.36 ± 0.03 directly after the procedure and 0.31 ± 0.03 one month after the procedure ($p < 0.001$ for both differences) and EROA decreasing from 0.28 ± 0.04 cm^2 before the procedure to 0.18 ± 0.02 cm^2 directly after the procedure ($p < 0.05$). One month later EROA slightly increased to 0.20 ± 0.02 cm^2, although the reduction compared to the values before the procedure was still statistically significant ($p < 0.005$).

Valvuloplasty resulted in a significant improvement of the quality of life (Table 2). One month after the procedure all the patients reported that they were feeling better, much better or considerably better (Table 4), while 69% of the patients were feeling considerably better or much better.

One patient failed to report for a follow-up visit and did not undergo the 6MWT and stress test and did not complete the quality of life questionnaire. That patient did, however, report for an echocardiogram.

DISCUSSION

Cardiac surgery is currently the principal method of treatment in patients with functional MR. It mainly involves repair procedures, which — compared to mitral valve replacement procedures — are associated with a lower perioperative risk and no need for using long-term anticoagulant treatment [2]. In patients with dilated cardiomyopathy, a restrictive annuloplasty procedure developed by Bolling et al. [7] is performed. This technique has also been adapted for the treatment of

Table 4. Patient well-being compared to how they were feeling before implantation of the Carillon™ device (a survey completed one month after the procedure

How are you feeling now compared to how you were feeling before the implantation of the Carillon™ device? (n = 13)	
Considerably worse	0% (0/13)
Much worse	0% (0/13)
A bit worse	0% (0/13)
No change	0% (0/13)
A bit better	31% (4/13)
Much better	54% (7/13)
Considerably better	15% (2/13)

patients with MR of ischaemic aetiology and complements in their case coronary artery bypass grafting.

However, despite the undisputable progress that has been made in cardiac surgery and cardiac anaesthesia, the perioperative risk associated with hear surgery continues to be a significant limitation when establishing eligibility of functional MR patients for surgery. This particularly applies to patients with LV dysfunction [8]. It is in this group of patients, in whom surgical treatment is often not attempted due to the high perioperative risk, percutaneous techniques may offer an alternative.

One of the currently investigated percutaneous techniques is the technique mimicking the Alfieri procedure involving a point suturing of the free margins of the valvular cusps with the formation of a two-orifice mitral valve. In the case of the percutaneous technique the MitraClip device (Evalve, Inc.) is used to clip the cusps. In 2009 the results of the EVEREST study were published in which the efficacy and safety of the MitraClip device was assessed in 107 patients [9]. The study enrolled patients with ACC/AHA class I indications for surgery for MR [10]. Patients with severe MR and considerable dilation of the mitral annulus were, however, excluded.

While implantation of the MitraClip system may be used in patients with structural and functional MR, procedures utilising the CS approach are intended for treatment of functional MR only. Taking into account the fact that the number of patients with functional MR is several times higher than that of structural MR patients, it does not preclude the potential future role of these techniques [11–13], especially since in contrast to the recommendations on the management of structural MR, surgical treatment of functional MR, especially functional MR of ischaemic aetiology, is not so well established.

One of the first test devices that took advantage of the anatomical relations between the venous system of the heart and the mitral annulus was the MONARC device. After initial failures associated with a design fault the device underwent the necessary modifications [14]. Another device that has been tested in several patients is the PTMA system (Viacor, Inc.). Preliminary results suggest that this device may reduce the size of the mitral annulus thus beneficially affecting the severity of MR [15]. Currently, the device is being assessed in the PTOLEMY II study.

Our results, covering one month of follow-up, indicate that implantation of the Carillon™ system beneficially affects both the functional status of patients and the echocardiographic parameters of MR. Both directly and one month after the procedure there was a significant reduction in EROA and vena contracta. In another study to assess the efficacy and safety of valvuloplasty using the Carillon™ system, directly after a successful implantation of the device, Siminiak et al. [16] also observed a significant decrease in such echocardiographic parameters of MR as vena contracta, EROA, regurgitant volume and the ratio of jet area to left atrial area. Jerzykowska et al. [17] assessed the effect of the Carillon™ system implantation on the echocardiographic parameters of MR directly and one month after the procedure and found a significant reduction in vena contracta and the ratio of jet area to left atrial area at both time points. There was also an improvement in EROA and regurgitant volume, but these changes were not significant, which might have resulted from the small number of patients. The results of the AMADEUS study, on the other hand, showed an improvement in each of the assessed echocardiographic parameters of MR [18]. Given the dynamic nature of functional MR, it may safely be assumed that the reduction of MR as a result of Carillon™ system implantation may be even more pronounced during exercise [19], as is the case with cardiac resynchronisation therapy (CRT) which minimises the effect of physical exercise on the severity of MR [20].

Implantation of the Carillon™ system also had a positive effect on the functional status of our patients in the broad sense. One month after the procedure we observed a statistically significant increase of the walking distance in the 6MWT. The improvement was comparable to that seen in the AMADEUS study and twice as high as that in the case of CRT [18, 21]. In the CRT arm of the MIRACLE study, the walking distance in the 6MWT increased by 39 m *vs* 10 m in the placebo arm [21].

Valvuloplasty using the Carillon™ device improves NYHA functional class and the improvement is comparable to that seen during the AMADEUS study [18]. It also results in a significant elongation of the stress test performed according to the Naughton protocol and in an improvement of the quality of life. All our patients reported an improvement in their well-being compared to how they had been feeling before the procedure.

Our study has significant limitations, the most important ones including: a small number of patients, a short follow-up period and the absence of the control group. A complete assessment of the clinical value of the technique in question would require its comparison with other techniques of treatment, including heart surgery.

CONCLUSIONS

Implantation of the Carillon™ device in patients with functional MR improves the functional status and selected echocardiographic parameters of MR one month after the procedure. A complete assessment of the technique will require longer observation and a larger patient group.

Conflict of interest: *Ludwik Firek is an employee of Cardiac Dimensions Inc., other authors declared no conflict of interest.*

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Ocena czynnościowa pacjentów poddanych zabiegowi przezskórnej walwuloplastyki mitralnej z wykorzystaniem systemu Carillon™: doniesienie wstępne

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Streszczenie

Wstęp: Czynnościowa niedomykalność zastawki mitralnej (MR), występująca w przebiegu kardiomiopatii rozstrzeniowej lub choroby niedokrwiennej serca, stanowi istotny problem kliniczny i epidemiologiczny. W przebiegu tych jednostek chorobowych dochodzi do postępującego powiększenia lewej komory (LV), co skutkuje rozciągnięciem pierścienia zastawki mitralnej i wystąpieniem niedomykalności. Walwulopastyka chirurgiczna, będąca metodą referencyjną w leczeniu tej grupy chorych, wiąże się z dużym ryzykiem okołooperacyjnym, szczególnie u pacjentów z upośledzeniem czynności LV. Niejednokrotnie jest to przyczyną odstąpienia od próby leczenia zabiegowego, dlatego trwają intensywne prace, które mają na celu rozwój przezskórnych metod terapii niedomykalności zastawki mitralnej, mogące stanowić szansę dla pacjentów wysokiego ryzyka. Jednym z takich obiecujących sposobów leczenia są zabiegi wykonywane z dostępu przez zatokę wieńcową. Wykorzystują one relacje anatomiczne między pierścieniem mitralnym a układem żylnym serca. Jednym z urządzeń do anuloplastyki mitralnej z dostępu przez zatokę wieńcową jest system Carillon™ (Cardiac Dimensions, Inc).

Cel: Celem pracy była ocena czynnościowa pacjentów z MR, poddanych zabiegowi przezskórnej walwuloplastyki mitralnej z wykorzystaniem systemu Carillon™.

Metody: Do badania włączono 14 kolejnych pacjentów, którym skutecznie implantowano urządzenie Carillon™. Jest ono wprowadzane do układu żylnego serca, dzięki czemu, poprzez wywieranie nacisku na pierścień zastawki mitralnej, poprawia koaptację płatków zastawkowych i zmniejsza niedomykalność mitralną. Przed zabiegiem i miesiąc po nim przeprowadzono test 6-minutowego marszu, test wysiłkowy wg protokołu Naughtona, oceniono poziom jakości życia za pomocą kwestionariusza *Kansas City Cardiomyopathy Questionnaire* oraz nasilenie objawów niewydolności serca wg klasyfikacji NYHA. Po miesiącu od zabiegu zapytano także pacjentów o subiektywną ocenę ich samopoczucia w porównaniu ze stanem sprzed wykonania procedury. Ponadto, przed zabiegiem, bezpośrednio po nim oraz po upływie miesiąca u wszystkich chorych oceniono wybrane parametry echokardiograficzne MR (*vena contracta*, efektywne pole powierzchni ujścia niedomykalności).

Wyniki: U chorych poddanych skutecznej implantacji urządzenia Carillon™ zaobserwowano poprawę w zakresie parametrów echokardiograficznych MR, zarówno bezpośrednio po zabiegu, jak i po upływie miesiąca. Poprawa dotyczyła zarówno *vena contracta* (0,36 ± 0,03 i 0,31 ± 0,03 *v*. 0,65 ± 0,04 cm, w obu przypadkach $p < 0,001$), jak i efektywnego pola powierzchni ujścia niedomykalności (0,18 ± 0,02 i 0,20 ± 0,02 *v*. 0.28 ± 0.04 cm^2; odpowiednio $p < 0,05$ i $p < 0,005$). Miesiąc po zabiegu zaobserwowano także poprawę tolerancji wysiłku fizycznego, wyrażoną wydłużeniem dystansu w teście 6-minutowego marszu (390 ± 26,25 *v*. 311,9 ± 15,71 m; $p < 0,001$), wydłużeniem czasu trwania próby wysiłkowej przeprowadzonej wg protokołu Naughtona (5,06 ± 0,47 *v*. 3,49 ± 0,27 min; $p < 0,005$) oraz poprawą klasy czynnościowej NYHA (1,93 ± 0,20 *v*. 2,93 ± 0,07; $p < 0,005$). Poprawiła się także jakość życia oceniana za pomocą *Kansas City Cardiomyopathy Questionnaire* (88,31 ± 4,02 *v*. 67,93 ± 3,30; $p < 0,001$). Ponadto, porównując swój stan zdrowia ze stanem sprzed zabiegu, wszyscy chorzy zgłaszali poprawę swojego samopoczucia, a 69,23% pacjentów uznało, że czuje się dużo lepiej lub znacząco lepiej.

Wnioski: Implantacja systemu Carillon™ u pacjentów z czynnościową MR powoduje zwiększenie tolerancji wysiłku fizycznego, poprawę jakości życia i wybranych parametrów echokardiograficznych MR. W porównaniu ze stanem sprzed zabiegu wszyscy chorzy odczuli poprawę samopoczucia.

Słowa kluczowe: niedomykalność mitralna, techniki przezskórne, ocena czynnościowa, tolerancja wysiłku fizycznego

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