

M. M. Kreusser^{1,2} · S. T. Pleger^{1,2} · H. Abu Sharar¹ · N. A. Geis¹ · R. Bekerredjian^{1,2} · H. A. Katus^{1,2} · P. W. Raake¹

¹ Department of Internal Medicine III, Division of Cardiology, University of Heidelberg, Heidelberg, Germany

² DZHK (German Centre for Cardiovascular Research), Partner site Heidelberg/Mannheim, Heidelberg, Germany

Transient elevation of high-sensitive troponin T after Cardioband implantation

In the past decade, severe mitral valve regurgitation (MR) has been shown to be an independent negative predictor of mortality in severe systolic heart failure (HF) including aggravation of adverse cardiac remodeling and worsening of clinical symptoms [1–4].

The MitraClip (Abbott Vascular, Santa Clara, CA, USA) device was developed in 2008 and demonstrated safety and effectiveness for the repair of severe MR in high-risk surgical patients [5–9]. However, surgical mitral valve reconstruction, still considered to be the gold standard, uses direct mitral valve annuloplasty by implanting rings in patients with severe functional MR and dilation of the left ventricular (LV) annulus [10]. The Cardioband system mimics this approach using percutaneous femoral vein access, transseptal puncture, and anchors deployed in the dilated LV annulus region [11–13]. A final cinching process achieves LV annuloplasty.

The effects of LV annuloplasty via the Cardioband system have been described and include significant MR reduction as well as functional improvement [11, 12]. However, the sophisticated process of anchor deployment in the LV annulus

could potentially cause regional myocardial damage. Moreover, the close proximity of the left circumflex coronary artery (LCX) bears the risk of damaging the vessel during deployment, especially of the first anchors. Therefore, monitoring of ST-segment elevation during the procedure is mandatory so as to detect potential damage of the LCX and to immediately address this complication.

Here, we report on the significant periprocedural elevation of high-sensitive cardiac troponin T (hsTnT) levels in five patients who received the Cardioband, which was not correlated with clinical and echocardiographic parameters of myocardial infarction such as worsening of LV function, new onset of reduced regional LV wall motion, ST-segment elevation, and ventricular arrhythmia. This nonischemic hsTnT kinetics is compared to a sixth patient experiencing proximal damage of the LCX and ST-segment elevation during the procedure. Thorough intraprocedural monitoring of ST-segment elevation enabled immediate repair of the LCX, and thus structural damage of the LV could be avoided.

Methods

Patient selection

From June 2017 to March 2018, five high-risk surgical patients (Society of Thoracic Surgeons [STS] score: $2.7 \pm 0.7\%$) with advanced systolic HF and severe

functional MR caused by dilation of the LV annulus were treated with the Cardioband system (Valtech Cardio/Edwards Lifesciences, Irvine, CA, USA). One additional patient is reported on, in whom the procedure was not successful (see Results). Data were analyzed in a retrospective study design. All patients were highly symptomatic (New York Heart Association [NYHA] class III or IV) and their cases were discussed for surgical options by the interdisciplinary heart team. Main exclusion criteria were morphological aspects that would make Cardioband implantation unlikely to result in successful reduction of MR such as mitral valve prolapse, chordae rupture, restriction of the leaflets, and concomitant mitral valve stenosis [11]. For that purpose, transesophageal echocardiography (TEE) as well as computed tomography of the heart were performed for pre-interventional patient screening. A detailed overview of the patient characteristics is given in **Table 1**. Patients undergoing MitraClip implantation during the same period (June 2017 to March 2018) served as a control group for periprocedural hsTnT kinetics. From the 105 MitraClip patients during this period, only patients with LV ejection fraction (LVEF) of $\leq 35\%$ were included ($n = 55$). Patient selection for the MitraClip device and implantation technique have been described elsewhere [2, 14].

The Cardioband procedure (as well as MitraClip) was explained to the pa-

M.M. Kreusser and S.T. Pleger contributed equally and should be considered as joint first authors.

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors. All authors have approved the manuscript.

Table 1 Patient characteristics^a

Age (years)	51 ± 8
Male sex	5/5 (100%)
NYHA class	3.2 ± 0.1
Systolic heart failure	5/5 (100%)
Optimal medical treatment	5/5 (100%)
Dilated cardiomyopathy ^b	4/5 (80 %)
Society of Thoracic Surgeons score (%)	2.7 ± 0.7
Echocardiography	
Left atrial diameter (mm)	50 ± 2
Left ventricular end-diastolic diameter (mm)	71 ± 4
Systolic pulmonary artery pressure (mm Hg)	51 ± 4
Left ventricular ejection fraction (%)	17 ± 1
Invasive hemodynamics	
Cardiac index (l/min/m ²)	1.9 ± 2.1
Mixed venous O ₂ -saturation (%)	56 ± 2
Mean pulmonary artery pressure (mm Hg)	34 ± 6
Pulmonary wedge pressure (mm Hg)	26 ± 5
Cardiac biomarkers	
N-terminal pro-BNP (ng/l)	29,678 ± 22,245
hsTnT (pg/ml)	34 ± 6
Cardiac diagnoses	
Significant coronary artery disease	1/5 (20%)
ICD	5/5 (100%)
CRT	3/5 (60%)
Prior cardiothoracic surgery	1/5 (20%)
Atrial fibrillation	3/5 (60%)
Comorbidities	
Prior stroke	2/5 (40%)
Renal insufficiency (GFR <30 ml/min)	3/5 (60%)
Severe obstructive pulmonary disease ^c	1/5 (20%)
Diabetes mellitus	1/5 (20%)
Cancer	1/5 (20%)

NYHA New York Heart Association, **BNP** brain natriuretic peptide; **hsTnT** high-sensitive cardiac troponin T, **ICD** implantable cardioverter-defibrillator, **CRT** cardiac resynchronization therapy, **GFR** glomerular filtration rate estimated by MDRD (modification of diet in renal disease)

^aCharacteristics of five consecutive patients who underwent Cardioband implantation at our institution between June 2017 and March 2018. All data are derived from pre-interventional assessment. Variables are expressed as mean ± standard error of the mean or given as numbers (%)

^bRemaining patient had ischemic cardiomyopathy

^cDefined as FEV₁ (forced expiratory pressure in 1 s) <1 l or COPD (chronic obstructive pulmonary disease) grade ≥ GOLD III (global initiative for chronic obstructive lung disease)

tients along with the options for continued medical treatment, other interventional techniques, or high-risk mitral valve surgery. Every patient gave informed written consent for percutaneous mitral valve repair with the Cardioband system and for data acquisition. The study protocol was in accordance with the local ethics committee and con-

forms with the principles outlined in the Declaration of Helsinki [15].

Assessment of mitral regurgitation

Mitral regurgitation was initially characterized using transthoracic echocardiography (TTE), TEE, LV angiography, and invasive measurements of pulmonary artery pressure and pulmonary wedge

pressure (Table 1). All patients were on stable optimized individual target HF medication for at least 6 months and were treated with percutaneous angioplasty and stent implantation, implantable cardioverter-defibrillator (ICD), and cardiac resynchronization therapy (CRT) devices before treatment with the Cardioband, if applicable (Table 1).

Echocardiographic examination

Transthoracic and transesophageal echocardiography were performed using commercially available ultrasound diagnostic systems (e.g., iE33, Philips Medical Systems, Andover, MA, USA) according to current recommendations [2, 16]. At least three cardiac cycles were stored in cine loop format for offline analysis. Offline analysis of echocardiography examinations was conducted on a commercial workstation (Centricity Cardiology CA1000 2.0, GE Medical Systems, Milwaukee, WI, USA) by two independent investigators who were unaware of the patients' clinical status and were not involved in the Cardioband procedures. MR was graded according to current guidelines [17, 18] in a semiquantitative manner with color Doppler imaging, added to the assessment of the width of the vena contracta. This was similarly used for the postimplant grading of MR.

Cardioband implantation

Percutaneous surgical-like mitral valve annuloplasty using the Cardioband has been described previously [11]. Briefly, via a transfemoral venous access (24F) and transseptal puncture, the device was anchored supra-annularly using 12–17 screws. Afterwards, the device was cinched to achieve reduction of the mitral septal–lateral diameter resulting in mitral valve annuloplasty. All procedures were performed with the patient under general anesthesia and TEE guidance. Vital parameters and the electrocardiogram (ECG) were permanently monitored. Patients were transferred to our intermediate care unit after the procedure.

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Abstract

Background. The Cardioband system enables percutaneous surgical-like direct mitral valve annuloplasty and, thereby, repair of severe functional mitral valve regurgitation (MR) in patients with advanced systolic heart failure (HF) and dilation of the left ventricular (LV) annulus. Since the device is anchored by screws in the LV annulus, limited myocardial injury is likely to occur.

Methods and results. Five patients (Society of Thoracic Surgeons score: $2.7 \pm 0.7\%$) with severe HF (LV ejection fraction [LVEF]: $17 \pm 1\%$; LV end-diastolic diameter [LVEDD]: 71 ± 3 mm) were treated with the Cardioband (sizes C–F) receiving 14–17 screws in the LV annulus region. Myocardial injury was

monitored by measuring high-sensitive cardiac troponin T (hsTnT) levels and by echocardiography. All patients showed significant periprocedural increase in hsTnT levels. Peak hsTnT concentration was reached between day 1 and day 6 (593 ± 141 pg/ml). None of the patients showed clinical signs of myocardial infarction, ST-segment elevation, new onset of deteriorated myocardial wall motion, or new ventricular tachycardia.

hsTnT levels normalized in all patients after 14 days (hsTnT on day 0: 34 ± 6 pg/ml vs. hsTnT on day 14: 36 ± 6 pg/ml; $p = 0.604$). This nonischemic hsTnT kinetics was compared to a sixth patient who experienced proximal damage of the left circumflex artery (LCX) and

ST-segment elevation during the Cardioband procedure, followed by immediate repair of the LCX, avoiding structural damage of the LV.

Conclusion. Cardioband implantation is accompanied by significant elevation of hsTnT without causing structural myocardial damage or clinical symptoms such as worsening of LV function, new-onset LV regions exhibiting reduced wall motion, or ventricular tachycardia.

Keywords

Heart failure · High-sensitive cardiac troponin T · Mitral valve regurgitation · Mitral valve repair · Cardioband device

Transienter Anstieg des hochsensitiven Troponin T nach Cardioband-Implantation

Zusammenfassung

Hintergrund. Vergleichbar mit einer operativen Mitralklappenrekonstruktion ermöglicht das Cardioband-System eine perkutane direkte Mitralklappenannuloplastie und somit eine Rekonstruktion bei schwerer funktioneller Mitralklappeninsuffizienz (MR), insbesondere bei Patienten mit fortgeschrittener systolischer Herzinsuffizienz und Dilatation des linken Ventrikels (LV). Da das Cardioband-System mittels Schrauben im LV-Anulus verankert wird, ist das Auftreten einer begrenzten Myokardschädigung durch den Eingriff wahrscheinlich.

Methoden und Ergebnisse. Mittels des Cardioband-Systems (Größe C–F) wurden 5 Patienten (Score gemäß Society of Thoracic Surgeons: $2,7 \pm 0,7\%$) mit schwerer Herzinsuffizienz (LV-Ejektionsfraktion, LVEF: $17 \pm 1\%$; LV enddiastolischer Durchmesser, LVEDD: 71 ± 3 mm) behandelt. Dabei wurden 14–17

Schrauben in die LV-Anulusregion inseriert. Das Ausmaß der Myokardschädigung wurde mittels hochsensitivem kardialen Troponin T (hsTnT) und Echokardiographie gemonitort. Alle Patienten wiesen einen signifikanten periprozeduralen Anstieg der hsTnT-Werte auf. Die höchsten Werte für hsTnT wurden zwischen Tag 1 und Tag 6 erreicht (593 ± 141 pg/ml). Bei keinem der Patienten bestanden klinische Symptome eines Herzinfarkts, eine ST-Streckenhebung, neu aufgetretende regionale Wandbewegungsstörungen oder ventrikuläre Rhythmusstörungen. Die hsTnT-Werte normalisierten sich bei allen Patienten nach 14 Tagen (hsTnT an Tag 0: 34 ± 6 pg/ml vs. hsTnT an Tag 14: 36 ± 6 pg/ml; $p = 0,604$). Diese hsTnT-Kinetik wurde mit der eines 6. Patienten verglichen, bei dem intraprozedural eine proximale Verletzung der linken Arteria circumflexa (LCX) mit konsekutiver ST-

Streckenhebung während der Cardioband-Implantation auftrat. Durch eine unmittelbare Intervention der LCX konnte ein struktureller Schaden vermieden werden.

Schlussfolgerung. Die Cardioband-Implantation geht mit einer signifikanten Erhöhung des hsTnT einher, ohne einen strukturellen Myokardschaden oder klinische Symptome wie die Verschlechterung der LV-Funktion, regionale Wandbewegungsstörungen oder ventrikuläre Rhythmusstörungen zu verursachen.

Schlüsselwörter

Herzinsuffizienz · Hochsensitives kardiales Troponin T · Mitralklappeninsuffizienz · Mitralklappenrekonstruktion · Cardioband-System

Follow-up

Each patient underwent TTE, ECG, and blood analyses including N-terminal pro-brain natriuretic peptide (BNP) and hsTnT at least 1, 6, and 14 days as well as 2 months after mitral valve annuloplasty with the Cardioband. High-sensitive cardiac troponin T was measured on an individual basis in the periprocedural period up to day 14 for assessment of periprocedural hsTnT kinetics. ECG was

monitored continuously while patients stayed on our intermediate care unit for at least 6 days.

Statistical analysis

Data are expressed as means \pm standard error of the mean or as numbers of patients/all patients (%). A paired Student's *t* test was used for comparison of pre- and postinterventional measurements. For statistical analysis, GraphPad

Prism (GraphPad Software, La Jolla, CA, USA) was used. A value of $p < 0.05$ was accepted as statistically significant.

Results

Patient cohort

All patients implanted with the Cardioband displayed advanced HF, documented by severe systolic dysfunction and LV dilation (LVEF $17 \pm 1\%$; LV end-

Table 2 Follow-up 2 months after Cardioband implantation^a

	Before Cardioband implantation	After Cardioband implantation	<i>p</i>
NYHA stage	3.1 ± 0.1	2.0 ± 0.3	0.022 ^b
6-Minute walk test (m)	433 ± 35	487 ± 78	0.559
Echocardiography			
Left atrial diameter (mm)	50 ± 2	52 ± 1	0.638
Left ventricular end-diastolic diameter (mm)	71 ± 4	71 ± 4	0.621
MR grade	3.0 ± 0	1.5 ± 0.2	0.026 ^b
Systolic pulmonary artery pressure (mm Hg)	51 ± 4	43 ± 4	0.057
Left ventricular ejection fraction (%)	17 ± 1	18 ± 2	0.283
Cardiac biomarkers			
hsTnT (pg/ml)	34 ± 6	36 ± 6	0.604
N-terminal pro-BNP (ng/l)	29,617 ± 19,964	20,943 ± 13,969	0.356
Serum creatinine (mg/dl)	2.07 ± 0.40	2.01 ± 0.35	0.599

NYHA New York Heart Association, MR mitral regurgitation, BNP brain natriuretic peptide, hsTnT high-sensitive cardiac troponin T

^aFive patients were visited in our outpatient clinic after implantation of a Cardioband system. Variables are expressed as mean ± standard error of the mean. Differences were tested for significance by using a paired Student's *t* test. A value of *p* < 0.05 was considered statistically significant

^bDenotes significant difference

diastolic diameter [LVEDD] 71 ± 4%) as measured by echocardiography and right heart catheterization (Table 1). Pulmonary pressures displayed distinct postcapillary pulmonary hypertension. The cardiac biomarkers hsTnT and N-terminal pro-BNP were elevated (Table 1 and 2). As indicated by NYHA class and the 6-minute walk test (Table 2), functional capacity was significantly impaired in the patients, who also presented with a high burden of comorbidities (Table 1).

Cardioband implantation

Successful percutaneous surgical-like mitral valve annuloplasty was achieved in all five patients, whereas in a sixth patient, the procedure was aborted owing to damage of the LCX (success in 5/6; 83.3%). A significant reduction in MR could be achieved in all patients receiving the Cardioband (5/5; 100%, Fig. 1).

Functional and clinical results two months after procedure

Cardioband implantation resulted in significant immediate reduction in MR

that was sustained over the 2-month observation period (Fig. 1; Table 2). In all patients who underwent Cardioband implantation (100%), the device successfully reduced MR to grade I or II: grade I, 40% (*n* = 2); grade I–II, 40% (*n* = 2); and grade II, 20% (*n* = 1; Fig. 1). None of the patients presented with MR grade III. Successful mitral valve annuloplasty translated into improved NYHA functional class after 2 months, as all patients presented with NYHA class ≥III before the procedure, which was reduced to 2.0 ± 0.3 (*p* = 0.022; Table 2). We observed a trend toward reduced systolic pulmonary artery pressure (51 ± 4 mm Hg vs. 43 ± 4 mm Hg; *p* = 0.057) while LVEF remained unaltered. LVEDD as well as LA diameter were likewise unchanged 2 months after mitral valve annuloplasty (Table 2), in line with data from patients after MitraClip implantation, in whom those parameters changed not earlier than 12 months after mitral valve repair [2]. N-terminal pro-BNP values as well as renal function remained unchanged 2 months after Cardioband implantation.

Periprocedural hsTnT kinetics after Cardioband implantation

The baseline hsTnT value before mitral valve annuloplasty was 34 ± 6 pg/ml (reference <14 pg/ml; 3–50 pg/ml observational zone; >50 pg/ml elevated). Intriguingly, all patients experienced a significant increase in hsTnT values (maximum 593 ± 141 pg/ml; Fig. 2) after percutaneous mitral valve annuloplasty with the Cardioband. The peak concentration of hsTnT was reached between day 1 (*n* = 3 out of 5 patients) and day 6 (one patient on day 5 and one patient on day 6). One patient with prolonged hsTnT elevation (patient GB33, Fig. 2), peaking on day 6, had severely impaired renal function with a glomerular filtration rate (GFR) of only 22 ml/min (calculated with the modification of diet in renal disease formula), while two patients with a GFR of <30 ml/min had peak hsTnT on day 1. Importantly, 14 days after Cardioband implantation, hsTnT levels returned to the baseline hsTnT levels before the procedure (34 ± 6 pg/ml vs. 36 ± 6 pg/ml; *p* = 0.604; Table 2). This hsTnT kinetics after Cardioband implantation was compared with hsTnT in patients undergoing MitraClip implantation (*n* = 55), which increased from 45 ± 5 pg/ml before MitraClip implantation to a maximum of 70 ± 6 pg/ml (*p* = 0.0021) on day 1 after the procedure, thus by far not reaching the values seen after the Cardioband procedure.

Clinical and echocardiographic parameters of myocardial infarction

During mitral valve annuloplasty, patients were continuously monitored for ST-segment elevation, cardiac arrhythmia, and worsening of cardiopulmonary hemodynamics. After the procedure, patients were continuously monitored while on the intermediate care unit and a standard 12-lead ECG including left-posterior recordings was performed daily to monitor arrhythmia and ST-segment elevation. TTE was performed on day 1, between day 8 and day 14, as well as 2 months after Cardioband implantation

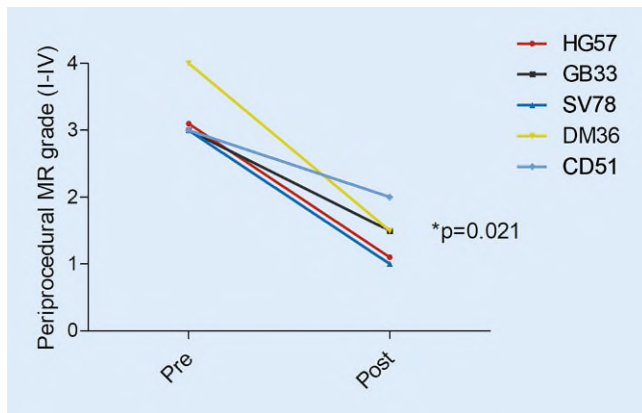


Fig. 1 ▲ Periprocedural mitral regurgitation (MR) during Cardioband implantation; MR grade was assessed at the beginning of the procedure and after the procedure by peri-interventional transesophageal echocardiography. It is shown for five patients who underwent the procedure individually, indicated by patient initials and age at implantation. Differences were tested for significance by using a paired Student's *t* test. A value of $p < 0.05$ was considered statistically significant

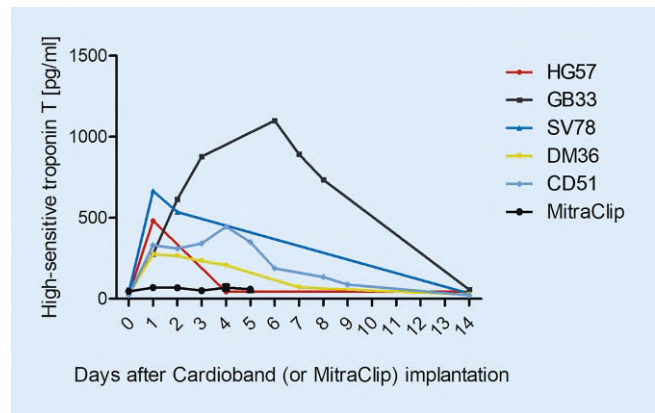


Fig. 2 ▲ Periprocedural kinetics of serum high-sensitive cardiac troponin T (hsTnT) levels after Cardioband implantation. Serum hsTnT level is shown individually for five patients who underwent the procedure, indicated by patient initials and age at implantation, starting with the day of implantation (day 0) until day 14 after implantation. As comparison, periprocedural serum hsTnT levels are shown of 55 patients with left ventricular ejection fraction $\leq 35\%$ who underwent MitraClip implantation (mean values)

(or MitraClip implantation). Special attention was given to evaluate MR as well as regional and global LV function using the 17-segment model [19]. Of note, during the 2-month observation period, global and/or segmental LV function did not significantly deteriorate in any of the patients. One patient had two episodes of ventricular tachycardia (VT) terminated by antitachycardia pacing of the ICD within 24h of the procedure. However, the same patient had a history of electrical storm and did not tolerate amiodarone therapy owing to liver toxicity. Further, he developed pneumonia requiring intravenous antibiotic treatment after Cardioband implantation, and thus the presence of VT was likely not immediately related to myocardial damage caused by the Cardioband procedure. None of the other patients developed VT, ST-segment elevation, or any clinical symptoms such as angina, acute cardiac decompensation, and acute worsening of dyspnea.

Case of procedure-related temporary occlusion of the proximal LCX

In one 44-year-old patient with dilated cardiomyopathy (LVEF: 15%; LVEDD: 84mm; STS score: 1.38%), ST-segment elevation was observed during Cardioband implantation. ST-segment elevation occurred during deployment

of the third anchor and was immediately noticed thanks to continuous monitoring. Contrast-dye fluoroscopy of the coronaries revealed damage and occlusion of the proximal LCX. Consequently, the Cardioband anchor was unscrewed and the integrity of the LCX was restored by direct drug-eluting stent implantation (Synergy; Boston Scientific, Marlborough, MA, USA). TIMI III flow (flow grades based on results of the Thrombolysis In Myocardial Infarction trial [20]) could be achieved accompanied by immediate normalization of the ECG. During manipulation, the first two anchors detached from the mitral valve annulus and the Cardioband was removed. As a bail-out strategy, during the same procedure a MitraClip device (Abbott Vascular) was used for mitral valve repair as described previously [2, 14]. This patient experienced an increase in hsTnT levels starting from 21 pg/ml (before the procedure) to 568 pg/ml (peak on day 1). At 14 days after the procedure, hsTnT levels dropped to 88 pg/ml. Likewise, this patient developed neither worsening of LV function nor arrhythmia. After MitraClip implantation, MR was reduced, similarly to patients treated with the Cardioband device (from severe to moderate).

Major adverse events within 30 days

In order to avoid any underestimation of major adverse events within 30 days, data from all patients receiving the Cardioband procedure are discussed here ($n=6$). None of our patients died intraprocedurally. None of our patients died during the observation period. One patient developed procedure-related damage of the LCX as described earlier (1/6; 17%). One patient had a prolonged intensive care unit stay due to pneumonia, which was treated with intravenous antibiotics. Another patient (1/6; 17%) developed pseudoaneurysm at the access site, which was refractory to manual compression and was treated with thrombin injection. During this study, no event of pericardial effusion, stroke, severe gastrointestinal bleeding, or tearing of the Cardioband was observed.

Discussion

Our data support previous results describing the safety and effectiveness of the Cardioband system, which mimics direct mitral valve annuloplasty in patients with advanced HF and severe functional MR [11, 12]. In line with previous reports, the procedure led to a significant reduction in MR; moreover, clinical

symptoms of HF and dyspnea were relieved significantly. However, by peri-/postprocedural monitoring of hsTnT levels, we demonstrate for the first time that the Cardioband procedure is associated with notable myocardial damage.

An increase in the cardiac biomarker hsTnT was previously reported in relation to a variety of cardiovascular procedures such as transaortic valve replacement (TAVR; [21, 22]), radiofrequency catheter ablation of atrial fibrillation (AF; [23]) and cryoablation of AF [24]. A number of pathophysiological mechanisms were suggested to explain periprocedural hsTnT elevation such as reduced myocardial perfusion due to rapid-pacing during TAVR procedures, direct myocardial damage due to ablation, and direct injury of small coronaries [21, 24, 25]. Importantly, hsTnT is associated with all-cause mortality [26], major adverse events, and mortality in TAVR procedures [21, 27]. Moreover, in advanced HF, hsTnT is chronically elevated and correlates with mortality [2, 25, 28, 29].

We speculated whether the increase in hsTnT could be simply secondary to atrial septum puncture or atrial manipulation during the Cardioband procedure. But when we analyzed the serum hsTnT course in a patient cohort with severe HF and MitraClip implantation, where the same size (24F) catheter is used for atrial septum puncture and possible left atrial manipulation during the procedure is comparable, we observed merely a much lower increase in hsTnT levels than during the Cardioband procedure. With regard to the Cardioband, one might hypothesize that hsTnT elevation might be due to both direct myocardial injury during anchor deployment and/or injury/occlusion of small coronary vasculature. However, in the present study the number of deployed anchors did not significantly correlate with the peak hsTnT level. Kidney function might additionally influence peak hsTnT values and kinetics [30]. Peak hsTnT tended to be higher in patients with a GFR value of <30 ml/min ($p = 0.15$) while hsTnT kinetics remained unaltered.

Importantly, postprocedural cardiac damage, worsening of LV function, or

cardiac arrhythmia was not observed after the Cardioband procedure. Thus, Cardioband implantation is considered safe. However, major adverse events such as injury of the LCX may occur during implantation. Although the Cardioband procedure could not be successfully completed in one patient in whom this complication occurred, implantation of the MitraClip device served as a bail-out strategy, demonstrating that in patients with advanced HF and functional MR, both methods may potentially be used in a complementary manner.

Conclusion

In conclusion, temporary hsTnT elevation occurs as a result of the Cardioband procedure, which is in line with a number of cardiovascular procedures such as TAVR and radiofrequency/cryoablation of AF. However, in contrast to, e.g., TAVR, periprocedural hsTnT concentration was not associated with major adverse cardiac events in our study, although conclusions are limited owing to the small number of patients and the short-term follow-up. However, significant structural damage of the LV was not observed in patients treated with mitral valve annuloplasty via the Cardioband. For future Cardioband procedures, we stress that intraprocedural ECG monitoring is mandatory in order to instantly detect and manage injury of the coronary vessels.

Corresponding address

M. M. Kreusser, MD

Department of Internal Medicine III, Division of Cardiology, University of Heidelberg
Im Neuenheimer Feld 410, 69120 Heidelberg, Germany
michael.kreusser@med.uni-heidelberg.de

Compliance with ethical guidelines

Conflict of interest. M.M. Kreusser, S.T. Pleger, H. Abu Sharar, N.A. Geis, R. Bekerredjian, H.A. Katus, and P.W. Raake declare that they have no competing interests.

All procedures performed in studies involving human participants were in accordance with the ethical stan-

dards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. The study protocol was in accordance with the local ethics committee (Heidelberg). Informed consent was obtained from all individual participants included in the study.

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