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Treatment of functional mitral regurgitation by the Carillon® Mitral Contour Device – an echocardiographic analysis of acute effects

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Purpose

Secondary or functional mitral regurgitations (FMR) are associated with increased morbidity and mortality in heart failure patients. Older age, comorbidities and highly impaired left ventricular (LV) systolic function are most striking characteristics of patients who were denied for surgical treatment. Therefore, interventional techniques, e.g. implantation of the Carillon® device, represent a new therapy option in this special patient cohort. The aim of the present study was to verify the acute hemodynamic effect directly after implantation of the Carillon® device in patients with severe FMR.

Methods

Transthoracic echocardiography (TTE) was performed in 30 patients with moderate or severe FMR before and directly after implantation of the Carillon® device. In all patients the following parameter were assessed:

- tenting area, vena contracta, velocity-time-integral ratio of transmitral inflow and LV outflow (VTI_{MV}/ VTI_{LVOT}), regurgitant volume (RegV) and effective regurgitant orifice area (EROA) by the 2D-PISA method (Fig.1).

Further, the RegV was estimated by subtracting the effective forward stroke volume of the left ventricular outflow tract (SV_{LVOT} - obtained by $diameter_{LVOT}$ and VTI_{LVOT} (Fig.1)) from the total stroke volume ($SV_{planimetric}$ - 2- and 4-chamber view by the modified Simpson's rule). The regurgitant fraction (RF) was assessed by RegV (2D-PISA) divided by the total SV and by the RegV (total SV - effective SV) divided by the total SV. Mitral valve diameters (D_{MV}) were measured in the apical long axis and the apical 4-chamber view. Planimetric evaluation of the regurgitant orifice area was performed by using periinterventional 3D-transesophageal (TEE) color Doppler data sets.

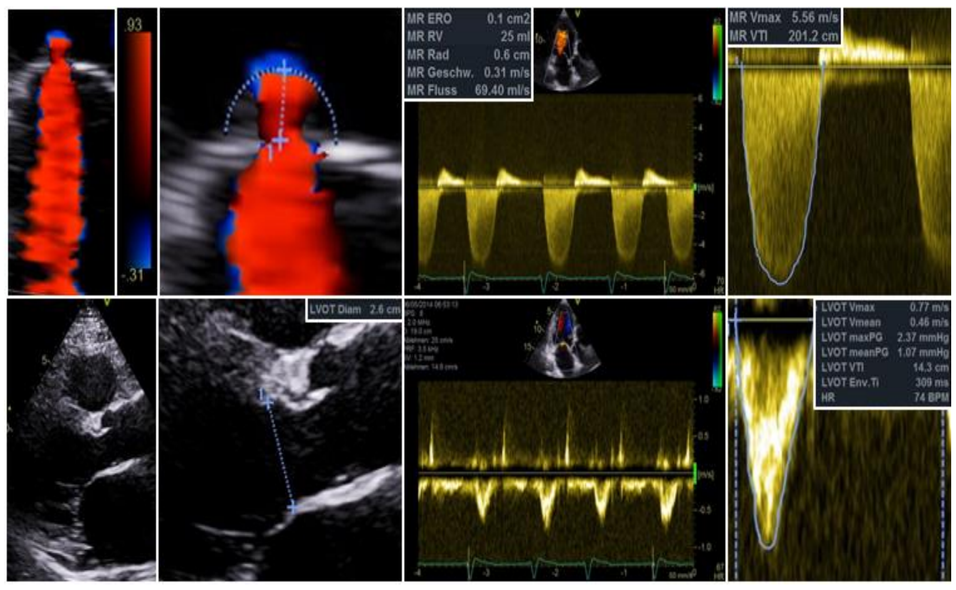

Fig.1 *Assessment of RegV, RF and EROA by 2D-PISA method (top) and assessment of $diameter_{LVOT}$ and VTI_{LVOT} from the pulsed Doppler spectrum of the LVOT (bottom). © "Basiswissen Echokardiografie- "Ars echocardiographica" - Schritt für Schritt zur korrekten Diagnose", Hagendorff and Stoebe (2017)*

Results

Mean RF was significantly reduced from 49 ± 11% to 34 ± 13% (p<0.001, Fig.2), mean RegV from 33 ± 13ml to 25 ± 12ml (p<0.001, Fig.3) and mean EROA from 0.24 ± 0.1cm² to 0.19 ± 0.1cm² (p<0.05).
Furthermore, no significant differences were observed according to both approaches for RF and RegV assessment. Significant decreases were also observed for tenting area, vena contracta, 3D-vena contracta area and VTI ratios. Mean D_{MV} (apical long axis and 4-chamber view) was reduced from 3.8 ± 0.5cm to 3.5± 0.5cm (p<0.001, n=30). In detail, a postinterventional reduction of RF was achieved in 25 (83%) FMR patients (Fig.5). Patients with sinus rhythm (SR) or pacemaker stimulation (n=16) showed 20 ± 12% reduction of RF, patients with atrial fibrillation (n=14) a significantly lower RF reduction of 10 ± 12% (Fig.4).

Parameter	n	preinterventional	postinterventional	*p*
Tenting Area [cm²]	29	2.2 ± 0.7	1.9 ± 0.6	**< 0.001**
VTIMV/VTILVOT	30	1.9 ± 0.4	1.6 ± 0.5	**< 0.05**
Vena contracta [cm]	30	0.52 ± 0.1	0.41 ± 0.2	**< 0.001**
Vena contracta Area [cm²]	27	1.0 ± 0.6	0.7 ± 0.5	**< 0.001**

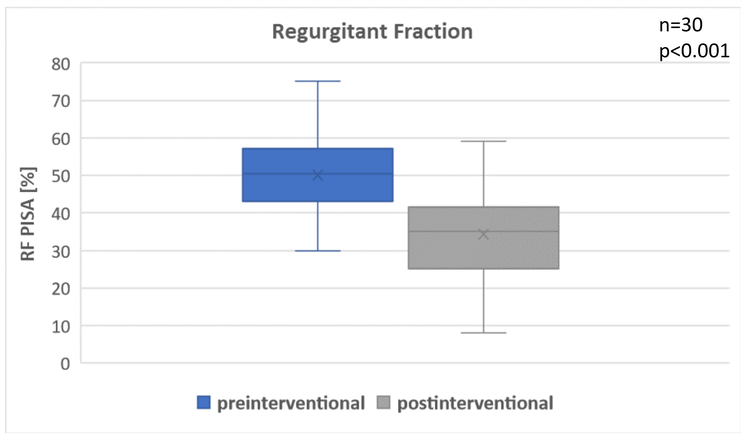

Fig.2 *Mean values of the RF measured by the 2D-PISA method before and directly after implantation. RF was significantly decreased.*

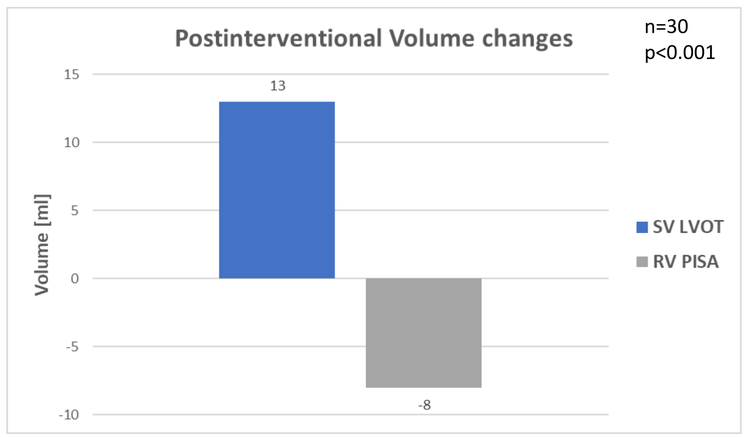

Fig.3 *Mean values of postinterventional volume changes of SV_{LVOT} and RegV measured by the 2D-PISA method.*

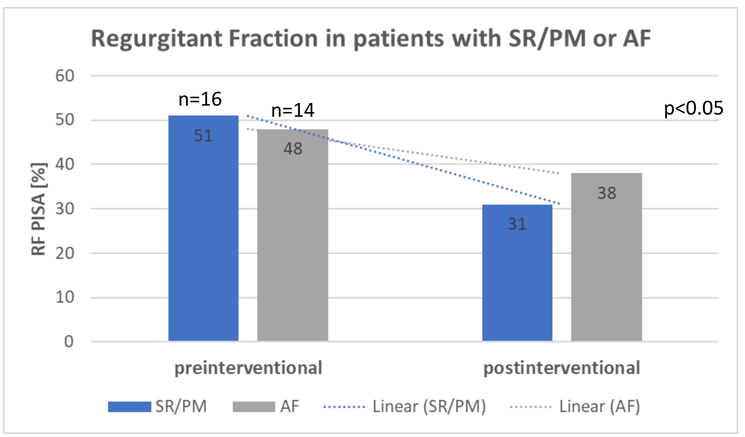

Fig.4 *Mean values of RF measured by the 2D-PISA method before and directly after Carillon® implantation in patients with SR or pacemaker stimulation (PM) and in patients with atrial fibrillation (AF). Both groups showed a siginificant reduction, patients with SR seemed to have a higher benefit.*

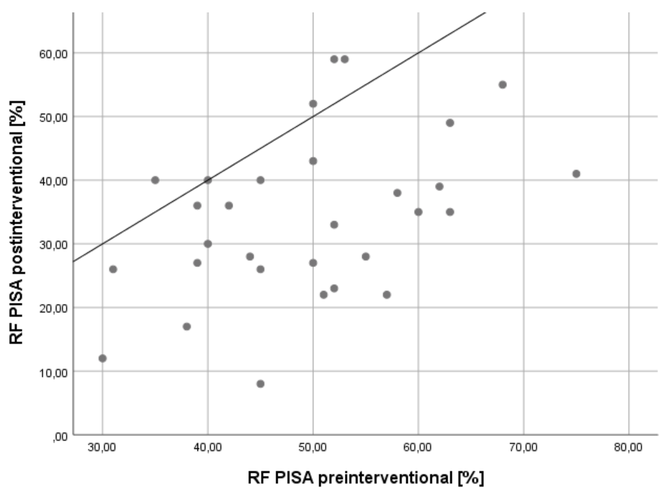

Fig.5 *Detailed values of RF measured by the 2D-PISA method before and directly after Carillon® implantation.*
In 25 patients a postinterventional reduction was observed.

Conclusions

Acute Effects of the Carillon® Mitral Contour device on mitral valve morphology and function can be documented by TTE after device implantation. Thus, TTE enables a quantitative approach of analyzing the interventional success obtained by the Carillon® Mitral Contour device to underline its effectiveness in patients with FMR.

The therapeutical benefit seems to be higher in patients with SR compared to patients with atrial fibrillation.

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