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Assessment of coronary sinus anatomy between normal and insufficient mitral valves by multi-slice computertomography for mitral annuloplasty device implantation*

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Abstract

Introduction: Latest techniques enable positioning of devices into the coronary sinus (CS) for mitral valve (MV) annuloplasty. We evaluate the feasibility of non-invasive assessment to determine CS anatomy and its relation to MV annulus and coronary arteries by multi-slice CT (MSCT) in normal and insufficient MV. Methods: Fifty patients (33 males, 17 females, age 67 ± 11 years) were studied retrospectively by 64-MSCT scans for anatomical criteria regarding CS and its relation to MV annulus and circumflex artery (CX). We included 24 patients with severe mitral insufficiency and 26 with no MV disease. Diameter of MV, of proximal and distal ostium of CS, length and volume of CS, angle between anterior interventricular vein (AIV) and CS, caliber change of CX before, under/over and after CS were analysed. Different anatomical correlations were demonstrated: distance of MV annulus to CS, CX to CS. Results: Diameter of proximal CS ostium was significantly larger in insufficient MV compared to normal MV $(11 \pm 2.8 \text{ mm vs } 9.9 \pm 2.5 \text{ mm}; p < 0.024)$. CS was significantly longer in patients with insufficient MV $(125.4 \pm 17 \text{ mm vs } 108.9 \pm 18 \text{ mm}; p < 0.024)$. p < 0.003) with also significant differences in volume of CS (p < 0.039). Significant difference in annulus diameter, 46.1 ± 6 mm (insufficient MV) versus 39.5 \pm 7.5 mm, p < 0.004 was observed. Angle CS-AIV was $103.5 \pm 29^{\circ}$ (range $52^{\circ} - 144^{\circ}$) in insufficient valves versus $118.2 \pm 24.5^{\circ}$ (range $73^{\circ}-166^{\circ}$) in normal valves with a tendency to higher angles in normal valves (p = 0.06). Distance of MV annulus to CS measured 16 ± 4.1 / 14.2 \pm 3.6 mm (insufficient/normal MV) without significant difference between groups. In 15 patients CX ran under CS. Eighty-four percent of these patients (13/15) show a decrease in CS caliber in the area of intersection. In 14 patients CS ran over and in one patient the diameter of the CS at intersecting region was smaller. In 16 patients no direct point of contact was visible, in five patients CX to CS positioning was not evaluable. Conclusion: There is a significant anatomic difference between normal and insufficient MV, which might be the basis for any interventional approaches through the CS. Exact measurements of all structures and its anatomic correlations are possible with MSCT, which allows preinterventional planning.

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Keywords: Coronary sinus; Mitral valve insufficiency; Multi-slice CT; Mitral valve annuloplasty device

1. Introduction

Minimally invasive techniques for treatment of cardiac diseases are increasingly being adopted by cardiovascular surgeons and used in their clinical routine [1–5]. Innovative techniques, which were continuously developed and modified, enable procedures, which not only open complete new therapeutic options but also require new surgical skills. Minimally invasive treatment of functional mitral valve

insufficiency (MVI) in the form of an implantation of a coronary sinus (CS) annuloplasty device represents one of these new emerging techniques [6–10].

In general the less visible the region of interest is, the more important is the knowledge of the anatomy and an accurate preoperative planning. In previous studies the electron beam computertomography (CT) and multi-slice computertomography (MSCT) were already described as a valid imaging tool for cardiac diagnostic and illustration of the anatomy and topography of the heart including the venous system. In addition it enables preoperative planning with a measurement of the coronary venous system including the CS and its adjacent structures [11–15].

MSCT imaging of the CS has also been described as the preferred method compared to a catheter-based direct or

erapeutic options but also require new surgical skills. computertomography (MSCT) were a nimally invasive treatment of functional mitral valve valid imaging tool for cardiac diagnose.

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indirect venography since this invasive procedure does not always deliver sufficient information [16]. Furthermore, it is less convenient for the patients and represents a small risk of complications.

In this retrospective study we assessed the coronary venous system including the CS and the surrounding anatomical structures in patients with and without mitral valve insufficiency by MSCT with regard to annuloplasty device implantation into the coronary sinus...

2. Methods

2.1. Patients

Fifty patients (33 males/17 females, age 67 ± 11 years) who underwent MSCT examinations for preoperative planning in minimally invasive valve surgery in clinical routine were studied retrospectively. Twenty-four patients suffered with a MVI, 26 patients had normal functional and non-pathological MV.

2.2. Multi-slice computertomography and image reconstruction

All scans were performed by a 64-MSCT (GE Healthcare, Milwaukee, USA).

Patients with heart rates >65 bpm were pretreated with 5—10 mg intravenous Metoprolol (Lopresor, Sankyo Pharma AG, Switzerland) and all patients received 2.5 mg sublingual isosorbiddinitrate (Isoket, Schwarz Pharma, Monheim, Germany) prior to the scan if no contraindications were present. Patients with an allergy to iodinated contrast media, renal insufficiency (serum creatinine > 140 mmol/l) were excluded from the study.

Scanning parameters:

• detector collimation: 64 mm \times 0.625 mm

gantry rotation time: 350 ms
scan field of view: 25 cm
tube voltage: 120 kV
tube current: 200 mA

A bolus of $70-100\,\text{ml}$ of non-ionic contrast agent (Ultravist® $370\,\text{mg/ml}$, Schering AG, Germany) was continuously injected intravenously ($50-80\,\text{ml}$ at $5.0\,\text{ml/s}$, then $20\,\text{ml}$ at $3.5\,\text{ml/s}$) followed by a saline chaser bolus of $50\,\text{ml}$ at a flow rate of $3.5\,\text{ml/s}$. CT scan was automatically started when the signal attenuation reached the predefined threshold of $100\,\text{Hounsfield}$ units (HU) in the aorta (bolus tracking).

2.3. MSCT image analysis and evaluation protocol

After image acquisition the complete image data set was transferred to a designated workstation (Advantage Workstation 4.3, GE Healthcare) and was analysed using the CardIQ Express software (GE Healthcare). Image interpretation was performed from axial-source images, multi-planar reformations, and three-dimensional (3D) volume renderings in 75% phase (end-diastole) and with the program 'Tree Volume Rendering'.

2.3.1. Mitral valve characteristics

The mitral valve annulus (MVA) was sized in diameter in a three-chamber view.

• diameter of MV (mm)

2.3.2. Coronary sinus characteristics

The coronary sinus characteristics were measured in 3D volume rendering technique (VRT) and axial 2D view.

- angle between CS and anterior interventricular vein (AIV) (3D VRT) (Fig. 1A)
- length (3D VRT) (Fig. 1B)
- volume (3D VRT) (Fig. 1C)
- diameter of proximal ostium (axial 2D-view)
- diameter of distal ostium (axial 2D-view)
- caliber changes (3D VRT)

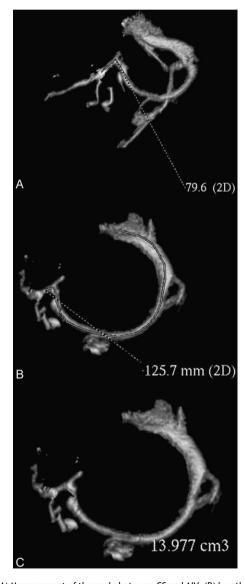


Fig. 1. (A) Measurement of the angle between CS and AIV; (B) length measurement of the CS; (C) volume measurement of the CS.

2.3.3. Relationship between coronary sinus and mitral valve annulus

The position of the CS to the MVA was evaluated in 3D VRT of the heart. The distance measurements were performed in axial 2D view

- CS parallel (above/same level)/oblique to MVA
- distance between MVA and CS: the distance was directly measured from the middle part of the CS to the MVA in the shortest way.

2.3.4. Relationship between coronary sinus and circumflex artery (CX)

Assessment of any significant change of the diameter of the CX before compared to after intersection with the CS between a CS over- and undercrossing CX.

- positioning of CX to the CS: beneath/above/parallel
- distance CS to CX in parallel run
- diameter of the CX before, in and after intersection

2.4. Statistical analysis

Quantitative variables were expressed as mean \pm stanstandard deviation and categorical variables as frequencies or percentages. Statistical analyses were performed with Student's t-test, p-value of <0.05 was considered as statistically significant.

3. Results

In total, 50 patients (age 67 ± 11 ; 33 male/17 female) were included in this study in which the coronary venous system could be accurately visualized, only in five patients could the relationship between the CS and the CX not be illustrated. Twenty-six individuals with normal MV function and 24 with MVI were studied. The proportion of left/right and intermediate coronary dominance was classified in 74% (37/50) right, 6% (3/50) left and 20% (10/50) intermediate coronary dominance. Detailed patient characteristics are listed in Table 1.

All patients of this study suffered with valve disease. The 26 patients with a normal mitral valve had an aortic valve disease (23 patients aortic stenosis, three combined aortic valve disease). Of the patients with mitral valve insufficiency two

Table 2 Measurement parameters of mitral valve (MV) and coronary sinus (CS)

Parameters	Normal mitral valve	Mitral valve insufficiency	Significance
Mitral valve characteristics			
Annulus diameter (mm)	$\textbf{39.5} \pm \textbf{7.5}$	$\textbf{46.1} \pm \textbf{7.6}$	0.004
Coronary sinus characteristics			
Diameter proximal ostium (mm)	$\textbf{9.9} \pm \textbf{2.5}$	$\textbf{11.0} \pm \textbf{2.8}$	0.024
Diameter distal ostium (mm)	4.2 ± 1	$\textbf{4.5} \pm \textbf{0.7}$	0.37
Length of CS (mm)	$\textbf{108.9} \pm \textbf{18}$	125.4 \pm 17	0.003
Volume of CS (%)	17.1 ± 4.3	$\textbf{20.7} \pm \textbf{7}$	0.039
Angle CS—AIV (°)	$\textbf{118.5} \pm \textbf{24.5}$	$\textbf{103.5} \pm \textbf{29}$	0.060
Relation coronary sinus and mitral valve annu	lus		
Distance (mm)	$\textbf{14.2} \pm \textbf{3.6}$	16 \pm 4.1	0.69

Significant differences between normal and pathologic MV.

Table 1
Patient characteristics

	Normal MV	MVI
Age (years), mean \pm SD	68 ± 11	65 ± 11
Gender, male/female	16/10	17/7
EF (%)	$\textbf{58} \pm \textbf{9}$	56 ± 8
Diabetes mellitus	2	0
Hypercholesterolemia	9	6
Hypertension	14	11
Smoking	13	6
Obesity (patients)	5	2
Body mass index (kg/m ²)	$\textbf{25.5} \pm \textbf{3}$	$\textbf{24.7} \pm \textbf{3.9}$
Length (cm)	167 \pm 10	172 ± 11
Weight (kg)	$\textbf{72} \pm \textbf{12}$	$\textbf{73} \pm \textbf{15}$

patients had grade II, four patients grade III and 18 patients grade IV. Twenty-two patients showed structural defects: 17 patients showed a posterior, three patients an anterior and two patients an anterior as well as posterior prolapse. In three patients chordal ruptures could be illustrated. In one patient MVI grade IV was concomitant with an endocarditis and in another patient with a rheumatic disease.

In all patients isolated valve surgery was performed in minimally invasive fashion via a 6 cm right lateral thoracotomy.

3.1. Mitral valve and coronary sinus: characteristics and relationships

We evaluated different characteristics of the MV and CS and could demonstrate a significant difference in almost all of these values between normal MV compared to MVI. The diameter of proximal CS ostium was significantly larger in insufficient MV compared to normal MV (11 \pm 2.8 mm vs 9.9 ± 2.5 mm; p < 0.024). CS was significantly longer in patients with insufficient MV (125.4 \pm 17 mm vs 108.9 \pm 18 mm; p < 0.003) with also significant differences in volume of CS (p < 0.039). In addition a significant difference in annulus diameter in insufficient MV compared to normal valves was noticed (6.1 \pm 6 mm vs 39.5 \pm 7.5 mm. p < 0.004). The angle CS-AIV was $103.5 \pm 29^{\circ}$ (range 52° -144°) in insufficient valves versus 118.2 \pm 24.5° (range 73°-166°) in normal valves with a tendency to higher angles in normal valves (p = 0.06). Distance of MV annulus to CS measured 16 \pm 4.1/14.2 \pm 3.6 mm (insufficient/normal MV) without a significant difference between the groups (Table 2).

In 88% (44/50) the CS was positioned parallel to the MV annulus, on the same level in 34% (17/50) and in 54% (27/50) above the annulus. However, the CS ran oblique to the MV annulus in 12% (6/50) (Fig. 2A/B).

In five patients the CS showed caliber changes from the proximal to the distal part (Fig. 3).

There was no significant influence of the body mass index (BMI) noticeable on any anatomical correlations.

3.2. Relationships between coronary sinus and circumflex artery

We assessed the different relationships between CS and CX (Table 3) whereas in five patients these measurements were not evaluable.

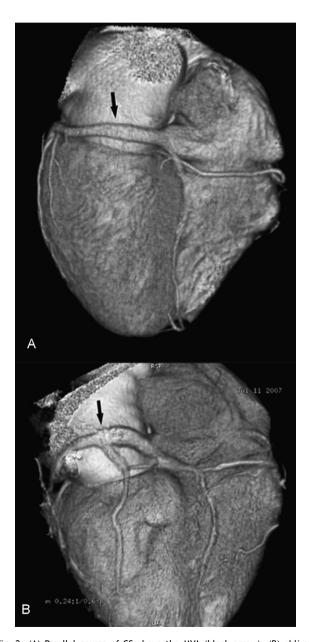


Fig. 2. (A) Parallel course of CS above the MVA (black arrow); (B) oblique position of the CS to the MVA (black arrow).

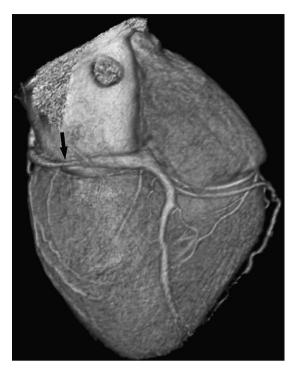


Fig. 3. Caliber jump in the middle part of the CS (black arrow).

Table 3
Circumflex branch (CX) correlation to coronary sinus (CS)

CX-CS constellation	CX above CS	CX underneath CS
No. of patients	14	15
Ø CX before CS intersection (mm)	$\textbf{3.4} \pm \textbf{0.9}$	$\textbf{3.2} \pm \textbf{0.8}$
Ø CX in CS intersection (mm)	$\textbf{3.3} \pm \textbf{0.8}$	$\textbf{2.8} \pm \textbf{0.6}$
Ø CX after CS intersection (mm)	$\textbf{3.4} \pm \textbf{0.8}$	$\textbf{3.3} \pm \textbf{0.7}$

In 33% of the patients (15/45) CX runs under the CS. Of these patients 87% (13/15) show a decrease in caliber in the area of the intersection (Fig. 4), 0.5 ± 0.3 mm (range 0.4-1.1 mm) difference before intersection to the intersection, 0.4 ± 1 mm (range 0.2-0.7 mm) difference from intersection to after intersection. In 31% of patients (14/45) the CX overcrosses the CS and only in 4% (1/14) the diameter was smaller in intersection region. In 36% (16/45) there was no point of direct or indirect contact of the CX and CS visible because no point of intersection or of a parallel run was present (Fig. 5). If both structures were parallel, the distances were in mean 3.3 ± 1 mm.

4. Discussion

The CS is a cardiac structure, which was mainly the focus of interventional electrophysiological approaches, such as pacemaker lead placement for cardiac resynchronization therapy or radiofrequency ablation [17,18].

Since the introduction of CS annuloplasty devices for treatment of functional mitral valve insufficiency, the spectrum of application tools that are being inserted into CS, has been further increased [19,20]. Therefore, a detailed

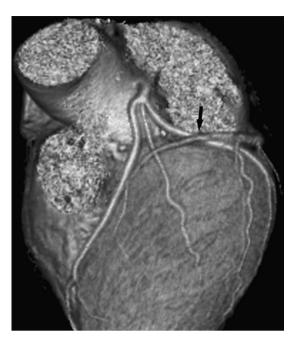


Fig. 4. CX underneath of the CS (black arrow).

knowledge of the coronary venous system including the CS regarding anatomy and size as well as the correlation to the adjacent anatomic structures became increasingly important.

Echocardiography is the gold standard for functional valve diagnostic and detailed description of potential valve pathologies like chordal rupture; however, the illustration of the valve morphology and circumfluent structures is limited. Since the introduction of the MSCT in 1994, CT-



Fig. 5. Parallel run of the CX to CS (white arrow).

technology in the form of the latest models (64-MSCT, DSCT) became a high quality cardiac imaging tool which enables the illustration of heart structures in two- and three-dimensions. MSCT scans enable an optimized preoperative planning for CS device implantation and allows for postoperative follow-up.

This study demonstrates significant differences between normal MV compared to MVI regarding length of the CS and distances of the CS to adjacent structures. It is important to notice that the characteristics of the evaluated mitral valve insufficiencies are mostly of structural nature. Almost all (22/24) insufficiencies in this study are caused by structural changes like prolapse and/or chordal rupture, which could lead to anatomic changes of the surrounding tissue of the mitral valve. Although the changes of the heart in form of size and structure and consequently of the CS caused by chronic MVI are finally equally independent of the character of MVI because the mechanism of volume overload in the left ventricle is identical. These changes could be a reasonable factor for the function of a device implantation into the coronary sinus. Not only will the mitral valve annulus be downsized, the CS itself could be shaped similar to the original form. Especially the combination between CS shaping and MVA downsizing could cause a successful treatment of the mitral valve insufficiency due to nonstructural disorders, i.e. ischemia and annulus dilatation.

In case of structural disorders of the mitral valve more interventional technical options for mitral valve repair like the percutaneously inserted Alfieri Clip are being developed. However, multiple studies are still needed to assess the correct indications for each of these procedures individually [21–23]. In future a combination of CS devices implantation and Alfieri Clip placement might be an additional therapeutic option for patients with structural mitral valve prolapse.

Our data now allows for a description of the anatomical differences of the CS in normal mitral valves compared to MVI, which can then be used for a possible correlation to grade functional mitral valve insufficiency. In addition it would also be interesting to see in a follow-up CT scan possible changes of the different cardiac structures after successful treatment of the MVI. If there were a regression of size of the different structures this would also give additional information of the effectiveness of the implanted device with regard to the function of the mitral valve.

The correlation of the CS to the CX and the influence to each other in form of a possible compression of the CX after device implantation has already been described [6,8]. However, it has not yet been defined what exact position of both structures to each other is leading to this complication. Possible factors which promote coronary artery compression are: force of the direct compression of the CX after device implantation, distance between the CS and CX and the position to each other, quality of the vessel wall and the diameter of the CX. Also the diameter change in the region of the intersection of the CX and CS can be an influencing factor for possible compression of the CX after implantation of a device into the CS. In our study the CX overcrossed the CS in 31% of our patients, which is comparable to the study of Tops et al. [13] (32%). However, in our study only 33% clearly run under the CS compared to 68% in the study of Tops et al. In their study a run of the CX under the CS automatically meant an increased risk for any

coronary sinus device implantation without stating exact reasons. We found in our study that in 87% (13/15 patients) the diameter of the CX was smaller at the point of the intersection if the CX is underneath the CS compared to the parts before and after intersection. This could represent an increased risk for compression of the artery after device implantation. However, the CX did cross over the CS in one patient and showed a decreased diameter in the intersection with the CS. Therefore, we believe that an overcrossing CX does not necessarily mean that it would be safe to implant a device into the CS.

In a situation where the diameter of the CX is decreased a relevant compression after device implantation seems likely.

In all other patients without any caliber changes, which represent 58% of the population, a device implantation is theoretically possible. Whether it would be fully efficient, however, is unclear.

Relevant for the effectiveness of the device besides the distance between CS and MVA is also the positioning of both structures to each other. Maselli at al. [8] demonstrated in their anatomic study that the CS does not run in the proximity of the MA but mainly on the back-wall of the left atrium superior to the MA. This anatomic finding can only be partly confirmed in our study. In 54% of the patients the CS was above the MVA, in 34% the CS was on the same level as the MVA. However, we believe that not only the distance in vertical direction of both structures might be important but also the positioning to each other, if parallel or oblique (Fig. 2A/B). In cases of an oblique constellation between CS and MA an inferior efficacy of the implanted device might be the consequence. In our study in 88% of the patients the CS was parallel (above and same level) and in 12% oblique to the MV annulus.

In addition the distance between CS and MVA may play a role for the device efficiency. Our measurements from the middle part of the CS to the MVA showed a longer distance in the patients with insufficient valves (16 \pm 4.1 mm) but with no significant difference compared to normal valves (14.2 \pm 3.6 mm). Tops et al. [13] measured shorter distances between CS and MVA (4.8–7.3 mm) and also a significant difference between normal and insufficient valves.

Another problem for the CX could occur in form of a possible zigzag of the vessels caused by the device, which can lead to relevant impairment of blood supply to the myocardium.

The mechanism of the CS annuloplasty device is comprehensible but the degree of shrinkage and the force generated by the device has not been completely understood. This mechanism is dependent on many factors, which are individual to the anatomical situation and the position of the device. A few possible relevant factors are described and evaluated in this study. But also the specific morphology of the CS can influence the effectiveness of the device. The MSCT examination was primarily performed for imaging the coronary arteries, however, the illustration of the complete venous system with this protocol was suboptimal. Also when the CS, great vein and AIV were clearly visible in all examinations, the small venous branches of the CS could not be visualized completely. We believe, that these side branches on the convex side of the CS could decrease the elasticity of the surrounding tissue, which attenuates the bending character of the device. If this really is the case it needs to be further evaluated.

From these data we estimate that 42% (19/45) of all evaluable patients would probably not be perfectly suitable for a CS device implantation: two patients with anomalies in the CS (parallel to the annulus) with no caliber change of the CX, 14 patients with decreased diameter of the CX in the intersection with the CS (in two patients combined with CS anomaly) and in three patients with an oblique position of the normal shaped CS to the annulus with no caliber change of the CX.

A final conclusion of the efficacy can only be done after implantation in a clinical trial with short and long-term follow-up. In order to achieve optimal results in the future these devices should be modified to the individual patient according to the preoperative CT measurements.

The validation of the CS measurements by MSCTwas already reported by Muehlenbruch et al. [16] who compared the CT measurements in a 4-slice CT-scanner with conventional angiography. The technical development to 64-slice CT scanners offers higher spatial and temporal resolutions and certainly enables an improved illustration of the venous system.

5. Conclusion

In this study we can confirm that MSCT allows exact depiction and measurements of the CS, coronary arteries and the mitral valve with the surrounding tissue in different planes and that precise preoperative planning could improve device implantation and prevent potential complications.

The function mode of this device seems promising and comprehensible. Especially this study shows significant anatomic differences between normal and MVI, which might be the basis for any interventional approaches through the CS. In addition this study pronounces the importance for precise preselection of patients and planning of the procedure individually modified to the patient before any manipulation of the CS.

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Appendix A. Conference discussion

Dr O. Alfieri (*Milan Italy*): This study reinforces the concept that appropriate imaging techniques are absolutely necessary for percutaneous valve intervention. Specifically, multi-slice CT is clearly providing an excellent assessment of the anatomic details which are necessary for mitral annuloplasty using coronary sinus devices. The idea of custom made devices is put forward for optimization of the results, and this is certainly an interesting perspective, although the practicality remains doubtful. Maybe you can comment a little bit on that.

Considering the clinical material in this study, mostly patients with leaflet prolapse, the coronary sinus annuloplasty is envisioned as a procedure to be added, for instance, to the percutaneous edge-to-edge technique, not as an

isolated procedure. And this is of interest because up to now the coronary sinus annuloplasty has been only used in functional mitral regurgitation.

I have objections in regard to the study design. The anatomical variability in individual patients is certainly more important than the variability induced by the presence of mitral regurgitation. After all, every candidate to coronary sinus annuloplasty has got mitral regurgitation. The control group is not represented by normal hearts but by hearts with aortic valve disease. Actually this didn't turn out in your presentation but that fact in the manuscript is very well described. The differences in the two groups are essentially limited to the size of the coronary sinus, reflecting the pathophysiology in the two groups. Having said that, I have only one question.

Considering the relationship between the coronary sinus and the circumflex artery, and also taking into account other important anatomical features like the distance of the coronary sinus from the mitral annulus, in how many patients in your series could the coronary sinus annuloplasty have been safely applicable?

Dr Plass: Of course, this is a little bit dangerous what I will say now, but I estimate it is around not more than 60% at present, because different factors play a role, for example the fact that the diameter in more than 80% of the circumflex branch decrease if the run is under the coronary sinus. I mean, it is not yet clear if there is now after an implantation of a device for sure also a further compression of the circumflex branch which would cause a hemodynamic situation. There are many discussions in past papers, but the probability is, of course, higher.

And also the question of efficacy, I don't know if the run of the coronary sinus in the back wall of the atrium and not on the same level of the mitral valve annulus decrease the efficacy. In addition there could be other changes of the geometry of the mitral valve annulus, nobody knows exactly. It is only a guess because of the data of this anatomical study, but I think for sure it is not more than 60%.

Dr F. Mohr (*Leipzig*, *Germany*): Just briefly to update you on numbers, they had been presented last week at the EAC. Fifty-five patients had that implant, and obviously in patients who had a feasible anatomy. The effect of these devices was rather poor; a median MR of 2.5 was reduced to 1.8. So I think this has to be kept in mind over here. And also you have to say that the device you showed is off the market right now because of technical problems. So I very much appreciate the studies you do. There is also a similar study from Paris who underlines the same situation as you, and I would rather think that the likelihood that one of these devices would work from these studies is less than 60, maybe 20%, if at all.

Dr R. De Simone (Heidelberg, Germany): I really appreciated what you said about the anatomical relationship between coronary sinus and mitral valve.

My question is: why should we surgeons help cardiologists in performing these procedures, if we just consider that this field represents a domain of interest for cardiologists. In addition, performing these complicated procedures has a very high risk. We have just to consider following major concerns. First, the coronary sinus is a very fragile structure; second, the anatomical relationship to the mitral valve makes the feasibility questionable; third, in case of failure or rupture of such a device, do you have an idea how to rescue this device and how difficult is to repair the coronary sinus. And finally, since this procedure will probably be done by the cardiologists, don't you think that the apical approach to the mitral valve may be the ideal field of interest and further development for heart surgeons?

Dr Plass: I agree in all named facts of Dr de Simone. And also Professor Mohr is right, probably it is only 20%. I only named 60%, if you note the anatomical data, already then it is less than 60%. If you imply the functional mode and the complete constellation, probably it is lower than 20%. And this study should declare that the technique is interesting but otherwise it is not yet the situation to be used in clinical routine. There are playing in so many factors, although the approach, like also Dr de Simone mentioned, could probably be in another direction and for the positioning helpful. This study should pronounce that there should be a critical view to the different devices, and also to pronounce as more you go for minimally invasive as more important is preoperative planning and imaging by navigation intraoperatively. This should be illustrated by this kind of study, the same is true for the study of the anatomy for the valve-in-valve procedure presented by Dr Grunenfelder before.

Dr De Simone: There are cardiologists who are already doing patients.

Dr Plass: I know this, yes.

Dr De Simone: This is an ethical problem, a major ethical problem.