Real-World Echocardiography in Patients Referred for Mitral Valve Surgery: The Gap Between Guidelines and Clinical Practice

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J Heart Valve Dis 2014;23(6):721-26

ABSTRACT

Aim

Mitral regurgitation (MR) is a common disorder for which mitral valve surgery is an established therapy. Although surgical indications are clearly defined for the management of valvular heart disease, a gap exists between current guidelines and their effective application. The study aim was to provide an insight into the diagnostic information provided for cardiac surgeons before performing mitral valve surgery.

Methods

The source documents and echocardiographic studies of 100 patients, referred by nine hospitals, were screened for arguments for MR severity justifying referral for surgery. Details of the documented MR mechanism, mitral annulus (MA) size, tricuspid regurgitation (TR) severity and annulus size were also noted.

Results

According to the referring physician, MR was severe in 83% and moderate-to-severe in 17%. In the great majority of patients (98%) the MR mechanism was mentioned, although specific information on the prolapsing scallops was available in only 17% of cases. The recommended primary determinants of MR severity, vena contracta and proximal isovelocity surface area (PISA) were measured in only 22% and 31% of patients, respectively. In 94% of patients with available PISA information this was described only qualitatively. Correct image expansion using the zoom mode was performed in only 25% of these patients, and a correct adaptation of the Nyquist limit in only 6%. Tricuspid annulus measurements guiding the need for concomitant tricuspid valvuloplasty in patients with less than severe TR were reported in only 6% of patients.

Conclusion

These data demonstrate a clear and important gap between current guidelines and real-world practice with regards to the echocardiographic diagnostic information provided to the surgeon before performing mitral valve surgery.

INTRODUCTION

Mitral regurgitation (MR) is a common disorder [1] for which mitral valve surgery is an established therapy [2]. In both Europe and the United States [3,4], the guidelines clearly state that a surgical class I indication only exists when MR is severe, unless patients primarily undergo coronary artery bypass surgery. Although the definition of MR severity requires the integration of blood flow data from Doppler with morphological information as well as careful cross-checking on the validity of such data against the consequences on left atrial dimension, left ventricular dimension and function and systolic pulmonary artery pressure, the primary determinants are the vena contracta (VC) and the proximal isovelocity surface area (PISA) [5,6].

As with many fields of cardiovascular medicine, the management of valvular heart disease includes a gap between existing guidelines and their effective application [7,8]. Unfortunately, to the best of the present authors' knowledge, there is no information available on the establishment of an echocardiographic diagnosis of severe MR in the real-world in patientsreferred for mitral valve surgery. Also, little is known about the information provided on associated tricuspid regurgitation (TR) and tricuspid annulus size, defining the need for additional tricuspid valvuloplasty [3].

Hence, the aim of the present study was to provide an insight into the information provided to cardiac surgeons before performing mitral valve surgery.

CLINICAL MATERIAL AND METHODS

Patients

A total of 107 consecutive patients who had been referred, by nine different hospitals, to the authors' institution for primary mitral valve repair or replacement between November 2009 and January 2012 was included in the study. Source documents were defined as the referral letter from the treating cardiologist, the echocardiography repor,t and the report of the heart team's decision.

Seven patients were excluded from the analysis because one of these reports could not be obtained; thus the final study population included 100 patients (the nine hospitals referred 1, 1, 2, 5, 8, 11, 13, 18, and 41 patients, respectively).

All source documents and echocardiographic studies were screened for arguments for MR severity, justifying referral for surgery according to existing guidelines [5,6]. Specific signs for severe MR included: VC ³ 7mm, PISA ³ 9mm with lower thresholds in ischemic MR according to Grigioni et al [9], and systolic reversal in pulmonary veins. Supportive signs included a dense, triangular continuous-wave Doppler jet and E-wave dominance mitral inflow (E > 1.2 m/s) or an enlarged left ventricular (LV) and/or left atrial (LA)

size, in absence of LV dysfunction or (paroxysmal) atrial fibrillation. Also noted were the documented MR mechanism, mitral annulus (MA) size, TR severity and tricuspid valve annulus size; if different gradings were scored at transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE), the most severe TR grade or largest annulus size was noted.

Approval to conduct the study was granted by the Institutional Review Board at the authors' hospital.

Statistical analysis

All statistical analyses were performed using SPSS version 17.0 (SPSS, Inc, Chicago, Illinois). Categorical data were presented as numbers and percentages, whereas continuous data were summarized as mean ± standard deviation (SD) or median value (range). The body surface area (BSA) of patients was calculated using the DuBois and DuBois formula [10].

RESULTS

Population characteristics

At study inclusion, all patients (56 males, 44 females; mean age 64 ± 11 years) were primarily referred for mitral valve surgery and operated on. Among the patients, 12, 42, 34 and 12 were in NYHA classes I, II, III, and IV, respectively. Concomitant coronary artery disease, hypertension and diabetes were present in 30, 49, and 17 patients, respectively.

Echocardiographic procedures

All patients underwent TTE, and 91 underwent TEE (the latter procedure was not performed in eight patients because the MR mechanism was known, and one patient refused due to fear of the procedure).

Mitral regurgitation mechanism

Information on the MR mechanism was provided for all patients but two. The most common mechanism was prolapse (58%), followed by restriction due to cardiomyopathy (11%), MA dilatation (16%) and endocarditis (3%); the remaining patients had a combination of mechanisms.

In 42 of the 58 patients with prolapse (72%), the involved leaflet was mentioned; specific information on the prolapsing scallops was available in 10 of these patients (17%). Among all patients, no information about the MA was available for 67%, in 20% a qualitative description was present, and in only 13% was MA quantitatively described.

Mitral regurgitation severity

According to the referring physician, the MR severity was moderate-to-severe in 17% and severe in 83%. The recommended [5,6] primary determinants of MR severity, VC and PISA were mentioned in only 22% and 31% of patients, respectively. In five of the 22 patients with available VC information, the condition was described only qualitatively ('present' or 'wide'); likewise, in 29 of the 31 patients with available PISA information, the condition was described only qualitatively ('present' or 'large'). No information was provided for any of the patients on effective regurgitant orifice area (EROA) or regurgitant volume (RV). Even when the presence of any (qualitative or quantitative) description of VC or PISA was considered evidence for significant MR (justifying surgery), it was present in only 45% of patients (quantitative information in 18 patients, qualitative information in 27 patients; see Fig. 1). In 14 of the remaining 55 patients (25%), reversal in one or more pulmonary veins was seen (left upper pulmonary vein at TEE in two patients, right upper pulmonary vein during TTE in nine patients, and both the left and right upper pulmonary veins in three patients). In the remaining 41 patients, significant MR according to the referring physician was based on supportive signs such as dense, triangular continuous-wave Doppler jet (n = 1), E-wave dominant (E > 1.2 m/s) mitral inflow (n = 1) or an enlarged LV and/or LA size, an absence of LV dysfunction or atrial fibrillation (n = 1). Hence, in 38% of patients it was unclear which criteria had been used for the diagnosis of significant MR justifying referral for surgery.

Quality of the VC and PISA recordings

As noted above, a PISA was described in 31 patients. Correct image expansion using the zoom mode was performed in only eight (25%) of these patients, and a correct adaptation of the aliasing velocity (by reducing the Nyquist limit to 15-40 cm/s) in only two (6%). When measuring the VC, correct image expansion using the zoom mode was performed in eight patients (36%).

Measurements in NYHA class 1 patients

Among 12 patients in NYHA class I, the primary determinants of MR severity, VC and PISA were measured in only four (33%) and two (17%) patients, respectively. In two of the four patients with available VC information, the condition was described only qualitatively ('present' or 'wide'); likewise, in all patients with available PISA information the condition was described only qualitatively ('present' or 'large'). When the presence of any (qualitative or quantitative) description of VC or PISA was considered evidence for significant MR (justifying surgery), it was present in only four of 12 (33%) patients. In one of the remaining eight patients (13%), a reversal in one or more pulmonary veins was seen, but in the remaining seven patients it was not clear on what bases significant MR was defined. Consequently, among 58% of patients in NYHA class I it was unclear which criteria had been applied for the diagnosis of MR justifying referral for surgery.

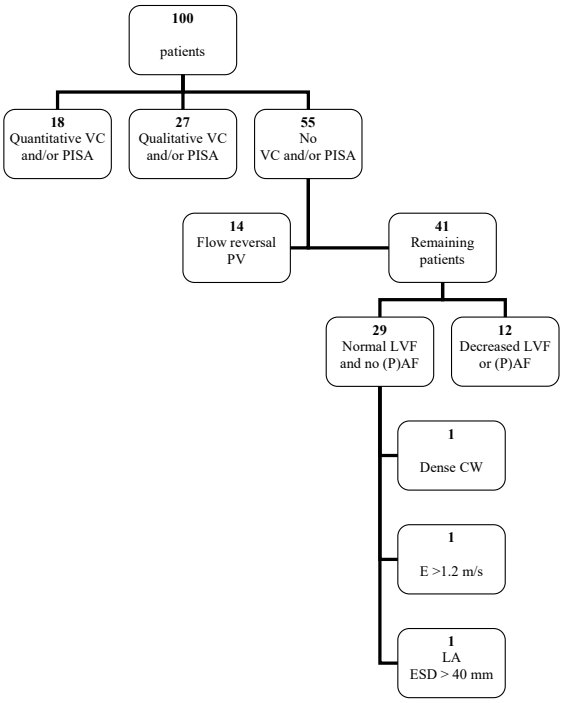

Figure 1. The criteria used by referring physicians for the diagnosis of MR severity. CW: Continuous-wave; ESD: End-systolic diameter; LA: Left atrium; LVF: Left ventricular function; (P)AF: (Paroxysmal) atrial fibrillation; PISA: Proximal isovelocity surface area, PV: Pulmonary vein; VC: Vena contracta. Patient numbers are shown in bold text.

Tricuspid regurgitation and tricuspid annulus size

TR severity was none or trace in 17% of patients, mild in 52%, moderate in 18%, and severe in 5%. The tricuspid annulus was measured in only 6% of patients (in two with severe TR, in one patient with moderate TR, and in three with mild TR). Tricuspid valvuloplasty was performed in all patients with known severe TR, in seven of 18 (39%) with moderate TR, and in four of 52 (8%) with mild TR according to preoperative assessments of the tricuspid annulus at the surgical center. In all patients but two with non- severe TR, the reason for tricuspid valvuloplasty was a dilated annulus (>40 mm or >21 mm/m2); in one patient with mild TR the reason for tricuspid valvuloplasty was unknown, and in one patient with moderate TR valvuloplasty was performed for 'surgical inspection'. Among the 11 patients with moderate TR but without tricuspid valvuloplasty, a dilated tricuspid annulus was not present in any case.

DISCUSSION

The main findings of the present study were that, in patients referred for MV surgery: (i) the severity of MR is often not based on VC and PISA parameters, as advised in current guidelines; (ii) the technical quality of VC and PISA recordings is questionable; and (iii) data on tricuspid annulus size, defining the need for additional tricuspid valvuloplasty, are virtually absent. These data clearly show an important gap between guidelines and real-world practice.

In the Euro Heart Survey on valvular heart disease, the characteristics of 499 patients with severe MR from 92 centers from 25 countries were described in detail [8,11]. Valvular interventions were advised in about halve of symptomatic patients and one-third of asymptomatic patients. Unfortunately, in this survey no diagnostic information was available other than the etiology of the MR. To the authors' knowledge the present study is the first real-world investigation describing the diagnostic process in terms of the details of patients with MR referred for MV surgery.

Echocardiographic diagnostic procedures

TTE was performed in all patients, and TEE in 91%. In the Euro Heart Survey on valvular heart disease, additional TEE was performed in only 103 of the 227 patients (45%) in whom the decision had been taken to operate for MR [11]. In a 2011 report on "Appropriate Use Criteria for Echocardiography", the evaluation of valvular structure and function by TEE to assess suitability for, and assist in planning of, an intervention was given the highest possible appropriateness score [12]. How often TEE is really necessary to establish the mechanism (or occasionally the severity) of MR is not clear, and highly dependent on sonographer and physician expertise [13].

Diagnostic information on the mitral valve

The presumed mechanism of MR was mentioned in the great majority of patients, although detailed information on, for example, the specifically involved prolapsing scallop (defining the difficulty of surgery) was available in only a small minority of patients. Of note, no attempt was made to verify the mechanistic findings. Data on MR severity were in many cases incomplete. According to current guidelines, the primary determinants of MR severity are the VC and PISA. Despite the intensive echocardiographic study of patients (i.e., including TEE in the vast majority), these parameters were assessed in only a minority of patients (22% and 31%, respectively).

No investigation was undertaken to determine why, in specific patients, specific measurements were not made. In general, the VC is more difficult to measure than is claimed in guidelines, in particular in non- degenerative MV disease. This issue was noted recently by Biner et al. who found that the interobserver agreement for VC and PISA measure-

ments between clinically experienced, practicing echocardiologists (even within the same institution) was disappointing, with kappa values ranging from 0.28 to 0.37 [14]. For PISA measurements it should be recognized that, even in the most simplified ways, the calculations may be time-consuming, especially for the inexperienced. Measurements also assume a perfectly symmetric spherical unconstrained flow acceleration, whereas the geometry in the real world is often irregular and asymmetric, or there is non-hemispherical flow convergence with flattening. In addition, PISA measurements vary substantially during the cardiac cycle, since the PISA is usually dynamic throughout systole and some physicians may not believe in the concept of defining the maximal flow representative for the overall MR. The VC is also dynamic, and it may be difficult to visualize the essential components that define the VC: the proximal flow convergence, the VC, and the downstream jet expansion[15]. Finally, it is unknown how to deal with multiple regurgitant jets.

The even more disappointing technical quality of the recordings (optimal PISA recordings were achieved in only two patients) show that there is a long way to go in the education and training of sonographers and cardiologists. In this respect it is also noteworthy that, in a substantial number of patients, the diagnosis of severe MR was made because of systolic flow reversal in one pulmonary vein. In none of the echocardiographic studies was more than one pulmonary vein visualized, and in only three patients was a reversal in more than one pulmonary vein shown by combining TTE and TEE data, visualizing the right and left upper pulmonary veins, respectively. As the MR jet may selectively enter one or the other pulmonary veins, sampling through all pulmonary veins is recommended, especially during TEE [5]. In the real-world, as represented by the present study, only two pulmonary veins were studied: the right upper during TTE and the left upper during TEE. All of these data raise serious concerns, in particular in a world in which patients may be treated even before they develop symptoms, when the indication for surgery is based solely on an assessment of MR severity (and its consequences).

Diagnostic information on the tricuspid valve

The treatment of TR in mitral valve disease is an unresolved issue. The recommendations in patients undergoing MV surgery during the time-frame of the present study (2009-2011) were, according to the 2006 AHA/ACC guidelines [4]: Class I “severe TR” and Class IIb “…may be considered for less than severe TR when there is pulmonary hypertension or tricuspid annular dilatation”; and according to the 2007 ESC guideline [16]: Class I “severe TR” and Class IIa “moderate secondary TR with dilated annulus (>40mm)”.

Since the time-frame of the present study (2009-2011), a 2012 ESC update [3] has been implemented that now includes Class I ‘severe TR’ and Class IIA ‘mild or moderate secondary TR with dilated annulus (>40 mm or 21 mm/m2)’. It is disappointing to note that tricuspid annular measurements were almost never provided by the referring center to the surgeon. Patients with severe or moderate TR in the present study were treated in

compliance with the 2006/2007 guidelines on the basis of intraoperative assessments of the tricuspid annulus at the surgical center. In addition - and in compliance with the 2012 guidelines - some patients with less than moderate TR were also treated in the presence of a large tricuspid annulus.

Study limitations

The main study limitations were that: (i) the sample size was relatively limited; and (ii) the results were based only on patients referred to a single surgical center in one country, and should not be generalized because the degree of expertise in managing valvular heart disease may vary widely between regions and countries. The present study may also plead for a more pronounced role of cardiologists specialized in the management of valvular heart disease, in order to better implement and apply accepted valvular guidelines, especially for asymptomatic patient with MR. Notably, in September 2014, the present study results were discussed with the cardiologists from the referring centers and, as a consequence, a new, prospective observational study will shortly commence, hopefully to demonstrate an improvement in adherence to guidelines.

CONCLUSION

Among patients referred for MV surgery the severity of MR is not based on solid recommended criteria in a substantial number of patients. Also, when data on VC and PISA were suggested as being indicative of severe MR, the technical quality of these measurements was questionable. TV annulus measurements guiding the need for concomitant tricuspid valvuloplasty in patients with less than severe TR were reported in only a very small minority of patients. Taken together, these data demonstrate a clear and important gap between current guidelines and real-world practice.

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