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Clinical Cardiology [ALERT]

Critical analysis of the latest clinical research in cardiovascular medicine

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ABSTRACT & COMMENTARY

The Promise and Perils of the Apple Heart Study

By Joshua D. Moss, MD

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Dr. Moss reports he is a consultant for Abbott, Boston Scientific, and Medtronic.

SYNOPSIS: A large study with virtual enrollment of Apple Watch users helped illustrate the positive predictive value of wearable, pulse-based atrial fibrillation detection technology, as well as the ability to enroll and follow huge numbers of research subjects in a short period.

SOURCE: Turakhia M, Perez M. Results of a large-scale, app-based study to identify atrial fibrillation using a smartwatch: The Apple Heart Study. Presented March 16, 2019, at the 2019 American College of Cardiology Scientific Sessions, New Orleans.

The Apple Watch can measure heart rate and regularity via photo plethysmography, which uses changing absorption of green or infrared light to detect the pulse in the wrist. The goal of the Apple Heart Study was to evaluate the ability of this watch to identify subjects with atrial fibrillation (AF) and help guide subsequent clinical evaluation.

U.S. residents who were at least 22 years of age, did not already have a diagnosis of AF or atrial flutter, and were not using anticoagulation were given the opportunity to enroll virtually via their Apple Watch and iPhone. Over eight months, 419,297 subjects enrolled. Once enrolled, the watch would take periodic, opportunistic measurements of the pulse rate and regularity via generation of a tachogram. A positive finding, suggestive of AF, would trigger more frequent passive measurements. Then, five confirmations would generate a notification to the subject of an irregular pulse. Those subjects were connected to a telehealth doctor who could refer them for additional care or mail them an ECG patch. The primary endpoints were AF confirmed by the ECG patch in subjects ≥ 65 years of age and simultaneous AF noted on the ECG patch and via the watch.

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This activity is intended for the cardiologist. It is in effect for 36 months from the date of the publication.

The mean age of enrolled subjects was 41 ± 13 years. Eighty-four percent of subjects were younger than 55 years of age. A majority of subjects were younger than 40 years of age. About 6% of the enrolled population were ≥ 65 years of age. Over the course of the study, 2,161 subjects (mean age, 57 years) received an irregular pulse notification. The notification rate was about 3% in subjects ≥ 65 years of age, about 0.37% in subjects 40-54 years of age, and about 0.16% in subjects 22-39 years of age.

Of these 2,161 subjects, 945 completed a first telehealth visit, and 658 went on to receive an ECG patch. A total of 450 subjects wore the patches and returned them for analysis (0.1% of the original cohort and 21% of those who received irregular pulse notifications). The CHA_2DS_2-VASc score was ≥ 2 in 13% of the original cohort, 33% of the cohort who received an irregular pulse notification, and 38% of those who wore and returned an ECG patch. The patch yielded a diagnosis of AF for 34% of subjects. The longest episode was one hour or longer in 89% of subjects with AF on the patch. A 90-day survey of subjects who received an irregular pulse notification revealed that 15% of those subjects had received an AF diagnosis prior to study enrollment. While wearing the patch and the watch, an irregular tachogram carried a positive predictive value of 0.71 for true AF (0.60 in patients ≥ 65 years of age). An irregular pulse notification carried a positive predictive value of 0.84 for true AF (0.78 in patients ≥ 65 years of age).

■ COMMENTARY

The Apple Heart Study received a great deal of attention both at the American College of Cardiology Scientific Sessions and in the media — and for good reason. It was remarkable in its size and scope, particularly considering that enrollment and data collection occurred over only about eight months. The data accrued add valuable information about the demographics of AF in the United States, although limited to a small subset of the population with the means and desire to purchase and wear an Apple Watch, as well as the willingness to complete the less passive portions of the study (only 21% of the enrolled subjects who received an irregular pulse notification went on to wear and return an ECG patch for analysis).

It is safe to say that the study confirmed the ability of the watch to detect AF via background monitoring. Virtually all cardiologists who treat AF commonly have now met patients who discovered their arrhythmia via a watch notification. However, the actual sensitivity of the algorithm is unknown, considering the lack of gold-standard diagnostic information (or almost any information) about the vast majority of patients who never received an irregular pulse notification. How many of them actually had AF while wearing the watch? A basic analysis of the available data from the tiny subset (0.1% of the overall cohort) who simultaneously wore an ECG patch and the watch suggests that 81 of the 450 must have had true AF on the patch yet received no irregular pulse notification, compared with 72 who had AF and did receive a notification. The calculated "instantaneous" sensitivity is only 47%, although the watch had generated an irregular pulse notification for every one of those patients at some point. False-positive pulse notifications were less common, but about 5% of patients without AF on the ECG patch still received a notification from their watch.

It is interesting that the positive predictive value for watch notifications was slightly *lower* in older patients compared with the rest of the population. A similar analysis of the cohort of ECG patch wearers who were ≥ 65 years of age suggests an "instantaneous" sensitivity of only 40% and specificity of 94%. While chance could play a role, I suspect older patients simply experience more frequent atrial and ventricular ectopy, the irregularity of which could result in a false-positive tachogram. In a large population, even a relatively small rate of false-positive indications (which will be amplified with longer periods of wearing the watch) may generate a tremendous amount of unnecessary anxiety, testing, and treatment. Therein lies one potential peril. Treatment of AF and anticoagulation for stroke prevention both carry risks, and confirmatory monitoring will undoubtedly reveal other abnormalities that may or may not have become clinically significant. On the

other hand, if the true sensitivity of the watch is less than 50%, there also is risk of false reassurance and undertreatment of true disease.

That said, I find it difficult to argue that patients should not be empowered to monitor themselves for conditions that potentially put them at risk. Any motivated patient can check their own pulse many times per day; the watch simply makes that process easier. The added burden to clinicians will come largely from the need for much more discussion with patients about the relative merits and risks of all the potential downstream tests, medications, and procedures. The healthcare community will need to learn how to build an infrastructure to handle this added burden, which will undoubtedly extend to more disease processes going forward. In the meantime, we will need to use the opportunity and technology to conduct more rigorous studies, even if on a smaller scale, to test the true benefit and risk of continuous pulse screening so that patients can be advised accurately. ■

ABSTRACT & COMMENTARY

Sacubitril-Valsartan Reduces Functional Mitral Regurgitation

By Van Selby, MD

Assistant Professor of Medicine, University of California, San Francisco Cardiology Division, Advanced Heart Failure Section

Dr. Selby reports he is a consultant for Alnylam Pharmaceuticals and Akcea Therapeutics.

SYNOPSIS: In patients with chronic heart failure and functional mitral regurgitation, sacubitril/valsartan was associated with greater reduction in mitral regurgitation compared to valsartan alone.

SOURCE: Kang DH, Park SJ, Shin SH, et al. Angiotensin receptor neprilysin inhibitor for functional mitral regurgitation. *Circulation* 2019;139:1354-1365.

In patients with chronic heart failure (HF), left ventricular (LV) dysfunction and remodeling often lead to the development of functional (secondary) mitral regurgitation (MR). Sacubitril/valsartan, an angiotensin receptor neprilysin inhibitor (ARNI), was shown in a large clinical trial to be more effective than enalapril for reducing the combined outcome of cardiovascular mortality and HF hospitalization. However, the effect of sacubitril/valsartan on functional MR severity has not been studied.

The authors of the Pharmacological Reduction of Functional, Ischemic Mitral REgurgitation (PRIME) study randomized 118 patients with chronic HF and functional MR to sacubitril/valsartan or valsartan alone. All patients presented with stable functional class II-III symptoms, LV ejection fraction (EF) between 25% and 50%, and functional MR that had been present for at least six months despite medical therapy (including beta-blocker and either an ACE inhibitor or ARB). All patients exhibited "significant" MR, defined as an effective regurgitant orifice area (EROA) > 0.1 cm^2 measured by echocardiography. The primary outcome was change in EROA at 12 months of follow-up. The average subject age was 62.6 years, and mean EF was 34 ± 7%. The cause of functional MR was ischemic in 42 patients and nonischemic in 76 patients.

For the primary outcome, patients randomized to sacubitril/valsartan showed significantly greater reduction in EROA (-0.058 cm^2 vs. -0.018 cm^2 in the valsartan group; $P = 0.032$). Also, the authors observed significant improvements in secondary outcomes, including regurgitant volume (a mean difference of -7.3 mL; $P = 0.009$) and LV end-diastolic volume index. Serious adverse events occurred in seven patients in the sacubitril/valsartan group and nine patients in the valsartan group. The authors concluded that sacubitril/valsartan reduces functional MR to a greater extent than valsartan. Sacubitril/valsartan might be considered optimal medical therapy for patients with HF and functional MR.

■ COMMENTARY

Functional MR develops due to factors that include LV and mitral annular dilation, leaflet tethering, dyssynchrony, and reduced contractility. Optimal treatment of functional MR is a source of ongoing debate. Medical therapy for HF has been shown to improve LV remodeling and thereby functional MR, although the associated morbidity and mortality remain high. The authors of two recent trials evaluated the use of a percutaneous clip for the treatment of functional MR, with conflicting results. The PRIME study arrives at an important time when the cardiology community is actively debating which treatments

work best for which patients with functional MR. Sacubitril acts by increasing circulating levels of natriuretic peptides. This reduces both afterload and preload, important factors in the severity of MR. The sacubitril/valsartan group also experienced greater reduction in LV volume, which reduces contributing factors such as annular dilation and leaflet tethering. Regardless of the mechanism, the authors demonstrated greater reduction in MR severity. Although the magnitude of change in the primary endpoint is difficult to put into clinical context, the degree of reduction in MR was substantial: EROA decreased by 30% in the sacubitril/valsartan group vs. 9% in the valsartan alone group.

The authors made an interesting decision to include patients with EF up to 50%. They (correctly) noted that MR allows ejection into the low-pressure left atrium; therefore, EF overestimates the true systolic function of the left ventricle. While their point is valid, sacubitril/valsartan is only approved for HF with reduced EF. Treatment of patients with an EF > 40% would be off label, although ongoing clinical trials are evaluating the efficacy of sacubitril/valsartan in HF with preserved EF.

How do the results of PRIME fit into the evolving approach to treatment of functional MR? The authors of the landmark Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (COAPT) trial recently demonstrated significant reductions in hospitalization and mortality associated with percutaneous mitral repair. Patients enrolled in PRIME were younger, less symptomatic, and presented with less severe MR at baseline. Direct comparison of the two groups is challenging. Furthermore, the COAPT investigators evaluated clinical endpoints, whereas PRIME investigators only studied echocardiographic measures of MR severity. Therefore, we cannot conclude that sacubitril/valsartan is comparable to percutaneous repair. However, it seems reasonable to initiate sacubitril/valsartan in patients with HF and functional MR while determining whether they also may benefit from invasive therapies that have been shown to improve functional MR, such as revascularization, cardiac resynchronization therapy, and percutaneous mitral repair.

The PRIME authors concluded that sacubitril/valsartan should be considered part of optimal medical therapy for patients with chronic HF and functional MR. While certainly true, this is not a change from current guidelines. All patients in PRIME presented with class II-III symptoms despite treatment with an ACE inhibitor or ARB. Current guidelines already give a class I indication for switching such patients to an ARNI (assuming they have reduced EF). Rather, the findings serve as a reminder of the importance of making sure patients with chronic HF and functional MR receive the best guideline-directed medical therapy possible as the foundation of their treatment regimen. ■

ABSTRACT & COMMENTARY

When to Operate on Chronic Aortic Regurgitation Patients

By Michael H. Crawford, MD, Editor

SYNOPSIS: A retrospective observational study of patients with moderate to severe aortic regurgitation followed for five years showed that symptoms or a left ventricular end-systolic dimension index > 20 mm/m^2 were multivariate predictors of death.

SOURCES: Yang LT, Michelena HI, Scott CG, et al. Outcomes in chronic hemodynamically significant aortic regurgitation and limitations of current guidelines. *J Am Coll Cardiol* 2019;73:1741-1752.

O'Gara PT, Sun YP. Timing of valve interventions in patients with chronic aortic regurgitation: Are we waiting too long? *J Am Coll Cardiol* 2019;73:1753-1755.

Deciding when to intervene surgically in patients with chronic aortic regurgitation (AR) remains challenging. Investigators from the Mayo Clinic conducted a retrospective observational study of patients with moderate to severe AR. They excluded patients with aortic dissection, active endocarditis, valve stenosis, more than mild mitral regurgitation, previous valve surgery, or other cardiac diseases such as coronary artery disease. All patients underwent a complete transthoracic echocardiogram. The primary outcome was all-cause mortality. The study population included 748 patients who met the criteria, and the authors studied this cohort from 2006 to 2017. Mean age was 58 years, and 82% were men. Aortic valve replacement (AVR) was performed in 361 patients, of whom 93% met

class I guideline indications. Only 10% had left ventricular ejection fraction (LVEF) < 50%. In 14% of this group, ascending aortic aneurysm was the main indication. The median time from echo to surgery was 34 days. In 65% of patients, the valve was repaired or replaced with a bioprosthesis. The most common concomitant procedure was root or ascending aorta repair (30%). Over a median follow-up of five years, 17% of patients died. Multivariate predictors of death were symptoms and LV end-systolic dimension index (LVESDi). Also, AV repair or replacement within six months of the baseline evaluation was associated with better survival (hazard ratio [HR], 0.36; 95% confidence interval [CI], 0.24-0.53; $P < 0.0001$). In addition, when dichotomized for class I surgical indications, patients undergoing surgery for class I indications (symptoms, dilated aorta, or LVEF < 50% demonstrated a worse survival rate (HR, 7.98; 95% CI, 1.71-142; $P = 0.003$). The authors concluded that class II indications for surgery are associated with better survival postoperatively and should be strongly considered. LVESDi was the only echo measure independently associated with survival. The ideal cutoff appears to be > 20 mm/m^2.

■ COMMENTARY

When to intervene in chronic AR remains a challenge because it almost always means valve replacement surgery. It is difficult to sell surgery to asymptomatic patients. This retrospective, observational experience at one tertiary center confirms current practice in that 61% of the patients undergoing surgery exhibited symptoms. In only 2% of patients was LVEF < 50% the only criterion. In 4% of patients, aortic dilation was the sole criterion. Accounting for overlap, 284 patients met one or more of the three class I guideline indications for surgery. In the remaining 77 patients, 50 met class II indications: LVESD > 50 mm in seven; LVEDD > 65 mm in 39; and four met both LV dimensional indications. The remaining 27 patients met no class I or II indications. In surgical patients, only one died and three suffered a stroke during the first 30 days (total death or stroke, 1.1%). Counterintuitively, patients with only class I indications for surgery had a higher risk of post-AVR all-cause mortality than those with class II indications. Among class II indications, only LVESDi was a predictor of mortality, and a measurement of > 20 mm/m^2 seemed to be the inflection point, which is lower than > 25 mm/m^2 — the cutpoint in the European Society of Cardiology guidelines. U.S. guidelines still use LVESD > 50 mm, which was not a significant predictor in this study. This observation speaks to the importance of adjusting LV dimension measurements to the size of the individual.

Waiting for symptoms in patients with chronic moderate to severe AR may not be the best approach as symptoms seem to be a late manifestation. However, most patients with symptoms did not meet LV dimensions or functional criteria for surgery. Perhaps some symptomatic patients had other comorbidities that adversely affected survival, and their symptoms were attributed falsely to AR. If symptomatic patients do not meet dimensional criteria for surgery, a search for other explanations for their symptoms should be undertaken to avoid symptom persistence after aortic valve surgery. LVEDD alone is not particularly predictive of outcomes, and an LVESDi of 20-25 mm/m^2 should occasion consideration of surgery.

There were limitations to this study besides its retrospective, observational design. Patients with coronary artery disease were excluded. Stress tests were not performed to confirm symptom status. There are no data on symptom duration, hypertension, atrial fibrillation, or medical therapy. Also, there are no data on parameters other than those in the current guidelines such as LV volumes, regurgitant volume, late gadolinium enhancement on cardiac MR, and brain natriuretic peptide levels. In addition, perhaps three-dimensional echo or cardiac MR-determined LV size and function, would be superior to echo LV dimensions. Since surgical mortality was so low in this study, a push for earlier surgery in such low-risk patients is justifiable. Waiting for clearly valve-related symptoms or LV dysfunction probably is too conservative. ■

ABSTRACT & COMMENTARY

What Echo Measures Predict Progression of Mitral Valve Prolapse?

By Michael H. Crawford, MD, Editor

SYNOPSIS: A study of patients with mitral valve prolapse and mild to moderate mitral regurgitation showed that over a 4.5-year follow-up period, only mitral annular diameter among several echo parameters predicted the development of severe mitral regurgitation.

SOURCE: Ma JI, Igata S, Strachan M, et al. Predictive factors for progression of mitral regurgitation in asymptomatic patients with mitral valve prolapse. *Am J Cardiol* 2019;123:1309-1313.

In patients with mitral valve prolapse (MVP) and mild to moderate mitral regurgitation (MR), it is unclear which echocardiographic measurements predict progression to severe MR, which can be a criterion for surgical intervention. Investigators performed a retrospective, observational study of patients with MVP identified by echocardiography between 2010 and 2015. They excluded patients with left ventricular ejection fraction (LVEF) < 60%, symptoms, severe MR, or prior adverse events. Of the 254 patients with MVP discovered, 82 met the inclusion criteria. Their mean age was 65 years. Thirty-six patients had mild MR, and 46 had moderate MR. The primary endpoint was progression to severe MR defined as a regurgitant volume of > 60 mL, a regurgitant fraction > 50%, or an effective regurgitant area of > 0.4 cm^2.

Several echo parameters related to the mitral valve and the left heart chambers were obtained. Of note, baseline mean tricuspid valve peak regurgitation gradient was 18 mmHg, mean left atrial volume index was 35 mL/m^2, mean LV end-diastolic volume index was 56 mL/m^2, and mean LVEF was 62%. During the 4.5-year follow-up period, severe MR developed in 50% of patients with moderate MR. Moderate MR developed in 17% of mild MR patients, but no mild MR patient developed severe MR. Mitral E wave velocity (> 85 cm/s), LV end-diastolic volume index (> 65 mL/m^2), and mitral annulus diameter (> 39 mm, an average of four-chamber and two-chamber views) were highly sensitive for predicting the development of severe MR. After adjustments for age and sex, only annulus diameter significantly predicted progression to severe MR (hazard ratio, 1.14; 95% confidence interval, 1.03-1.26; $P = 0.01$). The authors concluded that mitral annular diameter may be of value for predicting which asymptomatic patients with mild to moderate MR due to MVP will progress to severe MR.

■ COMMENTARY

According to U.S. guidelines, there are no indications for surgical intervention in MVP patients with moderate MR unless they are undergoing cardiac surgery for some other reason. Thus, the achievement of severe MR is an important milestone. It is recommended that patients with moderate MR be followed by echocardiograms every one to two years. Based on the results of this study, the authors recommended more frequent follow-up in moderate MR patients with mitral annular diameters > 39 mm. This finding is unique since annular diameter is not mentioned in the guidelines, presumably because the available data did not support its use. The only echocardiographic parameters mentioned in the guideline are end-systolic volume, LVEF, and estimated pulmonary artery systolic pressure (PASP). LVEF < 60% was an exclusion criterion in this study. End-systolic volume index and estimated PASP were not predictive. Other than mitral annulus diameter, the only other echo measures that looked promising due to high sensitivity for developing severe MR were mitral E wave velocity and LV end-diastolic volume index. Still, neither was significant in the adjusted multivariate regression analysis.

Since none of the patients with mild MR developed severe MR over the 4.5-years follow-up, the results of this study are driven by the 46 moderate MR patients, 50% of whom developed severe MR. This was a small, select group, which the authors admitted limits the ability to control for all potential confounders. Also, in this retrospective, observational study, there was no control over when patients underwent repeat echoes. In addition, there are no data on whether outcomes would improve by using annular diameter to predict who was going to develop severe MR. Finally, the quantitation of MR in patients with MVP, who often exhibit eccentric jets, is challenging. In this study, 17% of patients with moderate MR exhibited improvement in the severity of MR over the follow-up period. Is this real or a methodologic issue? Considering the difficulty in identifying the patient with MVP and moderate MR who needs surgical intervention instead of more watchful waiting, I am going to add annular diameter to the echo measures I follow to determine the frequency of follow-up. ■

ABSTRACT & COMMENTARY

Informed Consent for Cardiac Catheterization: Is Shared Decision-Making an Illusion?

By Jeffrey Zimmet, MD, PhD

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Dr. Zimmet reports no financial relationships relevant to this field of study.

SYNOPSIS: Researchers studied how well patients retain the information imparted during the informed consent process for cardiac catheterization and concluded that shared decision-making as currently practiced is not particularly robust.

SOURCE: Schwarzman L, Miron-Shatz T, Maki K, et al. Shared decision-making in femoral versus radial cardiac catheterization. *Am J Cardiol* 2019. [Epub ahead of print].

It is no secret that patients do not understand every aspect of the information presented during informed consent for medical procedures. Through shared decision-making (SDM), the expectation is that patients can understand the risks and benefits of procedures so that they may be partners in their healthcare decisions. In a newly published study, Schwarzman et al reported that patients undergoing cardiac catheterization retain little of the consent discussion, despite an overall high degree of satisfaction with their level of involvement in the decision-making process.

The authors studied patient knowledge of transradial and transfemoral cardiac catheterization following their procedures. They performed a prospective study in a single large, urban, tertiary care, academic center where patients undergoing diagnostic or interventional cardiac catheterization were approached for consent within 48 hours of their procedures, with adequate time such that the effects of sedation had worn off. Then, the investigators verbally presented subjects with an 11-item, open-ended questionnaire designed to assess patient knowledge of cardiac catheterization and the relative risks and benefits of radial and femoral access. A patient knowledge index (PKI) score also was developed to assess each patient's decision-making, with a maximum score of 6. One hundred patients were enrolled in the study. The mean age was 57 years. Sixty percent were men, 30% were white, and only 23% had completed a college education. Eighty-two percent of patients had radial access for their procedures, with the remainder transfemoral. Forty-three percent of patients expressed a preference for the transradial approach, with only 8% preferring transfemoral and the remainder deferring choice to their physician. Ninety-nine percent of patients correctly named the procedure they had undergone, and 84% could adequately describe the general purpose of their procedure. However, aside from these basics, further understanding was low. Regarding the choice between radial and femoral, fewer than 20% of patients could recall procedure risks for either approach. Only 15% could identify the risks of the approach that they experienced, and 19% correctly identified the risks of the alternative access site. Thirty-one percent correctly described relative benefits of the procedural approach that they underwent, compared with only 11% of the alternative procedural approach ($P < 0.001$). The average PKI score was 2.6 ± 1.1, with no significant difference in PKI scores between transradial and transfemoral patients. A multivariate analysis identified college-level education with higher PKI scores, while black race was associated with lower scores.

Despite the overall poor retention of knowledge, 96% of study participants indicated that they were satisfied with their degree of involvement in the decision-making process. When asked to rate their level of involvement on a 10-point scale, with 10 representing maximum physician-patient collaboration, patients reported an average score of 8.3. The authors concluded that the implementation of true shared decision-making in the cardiac catheterization laboratory "will require additional efforts."

■ COMMENTARY

At first glance, this study appears to illustrate fatal flaws in the current informed consent paradigm for cardiac catheterization. Before considering this conclusion, we should understand that Schwarzman et al did not test understanding during and immediately after the informed consent process. Rather, they examined information retention by

patients up to two days after procedures were performed. The fact that patients did not retain much information about what the investigators were trying to test (specific information about the pros and cons of transradial vs. transfemoral access) is not surprising.

The decision to assess knowledge about specific access site risks and benefits is somewhat artificial and is predicated on the idea that this is one area where patient preference may have some impact. It assumes that patients are a significant part of the decision regarding access site choice under the SDM paradigm. Although patients may wish to receive information about this aspect of the cardiac catheterization procedure, in the majority of cases, physicians choose the access site that they believe will complete the procedure using the best balance of safety and efficacy. In most instances, this depends on the preference and experience of the operators rather than on patient input. Patients who are involved in the decision-making process perceive that they play an active role in their health, which, in theory, can translate into better outcomes through improved medication adherence and lifestyle changes. One fascinating finding in this study was the disconnect between retained patient knowledge and their perceived satisfaction with the decision-making process. Is deeper knowledge unnecessary for patients to make informed decisions? We recognize there is significant variability in patient involvement in preprocedure decision-making, with a sizable proportion of patients wanting their physicians to make the final medical decisions. However, we can do a better job educating patients about the risks and benefits of cardiac catheterization so that informed consent is a robust process for most patients. ■

CME/CE QUESTIONS

1. **The Apple Watch study for detecting atrial fibrillation showed that:**

   a. investigators could enroll many patients quickly.

   b. 25% of subjects received an irregular pulse notification.

   c. 90% of those notified responded.

   d. the positive predictive value for finding true atrial fibrillation was 0.50.

2. **A study of sacubitril/valsartan therapy in patients with functional mitral regurgitation (MR) showed:**

   a. 25% of subjects experienced serious side effects.

   b. a reduction in the severity of MR.

   c. an increase in left ventricular ejection fraction.

   d. reduced mortality.

3. **A prospective study of the efficacy of informed consent for cardiac catheterization showed:**

   a. 75% of patients understood the risks of the femoral vs. radial approach.

   b. 50% of patients were satisfied with the process.

   c. the average knowledge score was 4 out of 6 possible points.

   d. 99% of patients could identify the procedure they had undergone.

4. **Progression of mild to moderate MR to severe MR in mitral valve prolapse patients is best predicted by:**

   a. mitral E wave velocity.

   b. left ventricular end-diastolic volume index.

   c. left ventricular end-systolic volume index.

   d. mitral annular diameter.

5. **The strongest predictor of mortality in asymptomatic patients with chronic moderate to severe aortic regurgitation is:**

   a. an ascending aorta diameter > 4 cm.

   b. left ventricular ejection fraction < 50%.

   c. left ventricular end-systolic dimension index > 20 mm/m^2.

   d. left ventricular end-diastolic dimension > 65 mm/^{2}.