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ABSTRACT & COMMENTARY

Creatinine Bumps and Renal Tubular Injury in Acute Heart Failure

By Van Selby, MD

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

SYNOPSIS: In patients with acute heart failure who receive aggressive diuresis, worsening renal function identified by a rise in serum creatinine or cystatin C is not indicative of kidney tubular injury.

SOURCE: Ahmad T, Jackson K, Rao VS, et al. Worsening renal function in patients with acute heart failure undergoing aggressive diuresis is not associated with tubular injury. *Circulation* 2018;137:2016-2028.

Diuretics are the primary therapy for acute heart failure (AHF) with congestion. Patients receiving diuretics often experience worsening renal function (WRF), identified by a rise in the serum creatinine level. While WRF causes concern among treating clinicians, it is not clear that WRF is evidence of renal tubular injury.

To investigate the relationship between WRF and markers of renal injury, Ahmad et al analyzed data from the Renal Optimization Strategies Evaluation in Acute Heart Failure trial, which concerned the efficacy of low-dose dopamine and nesiritide in patients hospitalized for AHF. All patients received aggressive intravenous loop diuretics (median 560 mg intravenous furosemide or equivalent over a 72-hour study period). For this secondary analysis, the primary outcome was the change in three validated markers of renal tubular injury: N-acetyl-beta-D-glucosaminidase, kidney injury molecule-1, and neutrophil gelatinase-associated lipocalin. WRF was defined as a ≥ 20% decrease in estimated glomerular filtration rate (GFR), calculated using both cystatin C and creatinine.

During the 72-hour study period, WRF occurred in 21.2% of patients. The development of WRF was not associated with an increase in any marker

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of renal tubular injury ($P > 0.2$ for the association with all three markers). Also, there was no correlation between changes in markers of kidney injury and the degree of diuresis or decongestion achieved.

In an adjusted analysis, WRF was not associated with worsened 180-day survival (adjusted $P = 0.84$). Similarly, an increase in markers of renal injury during the study period was not associated with worse survival. In fact, a paradoxical relationship was observed in which patients with evidence of worsening renal tubular injury demonstrated improved survival at 180 days.

The authors concluded that kidney tubular injury is not associated with WRF in patients with AHF who receive aggressive diuresis.

■ COMMENTARY

In patients with AHF who are treated with diuretics, so-called "creatinine bumps" are all too common. The standard reaction to a rise in serum creatinine is either reduction or discontinuation of diuretics, with a goal of avoiding permanent kidney damage, even when the patient remains volume overloaded. This results in both prolonged hospitalization and inadequate decongestion at discharge, increasing the likelihood of readmission.

It is important to understand whether these small-to-medium rises in creatinine are markers of true renal injury or more benign fluctuations in glomerular filtration related to the hemodynamic shifts that occur during diuresis.

Ahmad et al provide strong evidence that in AHF patients, there is no significant association between rises in either creatinine or cystatin C and three markers of renal tubular injury. Furthermore, the authors found that when WRF occurs, it does not affect long-term outcomes significantly. Ahmad et al's findings add to previous studies of diuretic strategies for AHF. For example, the authors of the DOSE trial found that patients randomized to higher-dose loop diuretics were more likely to experience a serum creatinine rise > 0.3 mg/dL, but these elevations were transient and did not increase the risk of renal failure or other adverse outcomes at 60 days.

Although this was a thorough study, several limitations are worth mentioning. First, this was an analysis of a highly controlled clinical trial carried out at large heart failure centers by experienced clinicians. We do not know how medications were adjusted in response to fluctuations in creatinine, nor whether other measures were instituted to improve WRF and mitigate its long-term impact.

Therefore, it is not clear how these findings would translate to other medical centers, providers, or "real-world" patients who may be less clinically stable compared to those enrolled in clinical trials.

Despite these limitations, given the clear lack of an association observed in the present trial, and similar findings reported by other authors, it is reasonable to conclude the association between WRF as measured by creatinine or cystatin C and renal tubular injury is minimal at best.

In AHF with volume overload, achieving adequate diuresis is crucial. Other investigators have found that patients hospitalized for AHF often are discharged without significant decreases in weight, hemoconcentration, or other evidence of fluid loss. Creatinine bumps certainly contribute to this lack of adequate diuresis. Based on the findings from Ahmad et al, it is reasonable to conclude that a mild-to-moderate decrease in the estimated GFR should not automatically prompt cessation or reduction of diuretics.

When the creatinine continues to rise during diuresis, it is important to first make sure the patient remains fluid-overloaded by physical exam and other available markers. Second, treating clinicians should ensure renal perfusion is sufficient, and consider measures to increase it when needed.

Otherwise, when a patient remains fluid-overloaded, it is important to continue diuretics until euvolemia is achieved, with the understanding that mild-to-moderate rises in serum creatinine will resolve without lasting damage. ■

ABSTRACT & COMMENTARY

Is the Type of Myocardial Infarction Important?

By Michael H. Crawford, MD, Editor

SYNOPSIS: An observational study of hospitalized patients with type 1 or 2 myocardial infarction (MI) or myocardial injury showed that mortality is higher in type 2 MI or myocardial injury patients compared to type 1 MI patients.

SOURCE: Chapman AR, Shah ASV, Lee KK, et al. Long-term outcomes in patients with type 2 myocardial infarction and myocardial injury. *Circulation* 2018;137:1236-1245.

The third universal definition of myocardial infarction (MI) established three categories of myocardial injury in patients with elevated troponin levels: type 1 MI due to plaque rupture with atherothrombosis; type 2 MI due to myocardial oxygen supply-demand imbalance in the absence of atherothrombosis; and myocardial injury without other clinical signs of myocardial ischemia besides an elevated troponin. Clinically, the distinction between the latter two often is difficult because of uncertainty about the existence of atherosclerosis, which would carry therapeutic implications.

Investigators from a tertiary cardiac center in Scotland studied patients with type 1 or 2 MI or myocardial injury to improve risk stratification in these patients. Patients with type 3, 4, or 5 MI were excluded. The final study population included 2,122 patients: 55% were classified as type 1, 20% type 2, and 25% myocardial injury. All-cause mortality at five years was higher in those with type 2 MI (63%) or myocardial injury (72%) vs. those with type 1 MI (37%). Most deaths in type 2 and injury patients were due to non-cardiac causes (hazard ratio [HR], 2.3; 95% confidence interval [CI], 1.92-2.81 vs. type 1 MI). However, major adverse cardiovascular event (MACE) rates were similar in types 1, 2, and injury (33% vs. 30% vs. 31%, respectively). Notably, the presence of coronary artery disease (CAD) in type 2 or injury patients was an independent predictor of MACE (HR, 1.7; 95% CI, 1.3-2.2). At discharge, patients with type 2 MI or injury and known CAD compared to type 1 MI were less likely to received aspirin (66% vs. 91%, respectively), a statin (69% vs. 86%), or an angiotensin-converting enzyme or receptor blocker (53% vs. 71%; $P < 0.001$ for all). The authors concluded that in patients with type 2 MI or myocardial injury, identifying underlying CAD may inform decisions about risk reduction in these patients, which could improve their long-term outcomes.

■ COMMENTARY

Clinically, type 2 MI or injury patients are hospitalized for non-cardiac reasons and develop an adverse event that occasions obtaining a troponin level. Rarely are these diagnoses made in outpatients or patients presenting to the ED. Thus, it is not surprising that these patients demonstrate a high mortality rate, largely due to their non-cardiac diseases. It is well-known that an elevated troponin level is a bad prognostic sign, regardless of what is wrong with the patient. What is important about this study is that the rate of MACE was similar in all three classes of troponin elevation at about one-third over five years and that the major independent predictor of future MACE in type 2 and injury patients is the presence of CAD.

How do we identify those with CAD, and what do we do about it? Sometimes, the answer is straightforward if, for example, the patient has a history of CAD, or exhibits evidence of previous MI on ECG or echocardiography. However, the answer often is not straightforward, especially in the myocardial injury group, where there are no symptoms or sign of ischemia. Chapman et al suggested an approach based on the likelihood of CAD. If the likelihood is high, the authors suggested treating with aspirin and statins, as most of these patients would carry a > 7.5% risk of MACE over 10 years and would be candidates for these therapies anyway. If the risk is moderate, Chapman et al recommended coronary angiography by CT or invasive means. The authors did not discuss the low-risk patient.

Many U.S. cardiologists would take a different approach based on our current guidelines. In high-likelihood, high-risk patients, an invasive angiogram would make sense if appropriate for the patient's condition. The intermediate-risk patient would either undergo CT angiography or a stress test, depending on other clinical factors. The low-likelihood, low-risk patient would undergo a stress test. Of course, none of these tests would happen until the patient had recovered from whatever brought him or her to the hospital.

The strengths of this study were the five-year follow-up and the identification of the cause of death. There

also were several weaknesses, including the fact that the distinction between type 2 MI and injury was made by two cardiologists reviewing the records of the primary admission based on their clinical judgment alone. The patients were selected using a certain troponin assay, which may not apply to others with higher or lower sensitivities. Very few patients underwent angiography; thus, the incidence of CAD may have been underestimated. Also, there were few follow-up details beyond the cause of death.

Despite these limitations, this is the strongest study of this issue published to date and reinforces the concept that underlying CAD is common in type 2 MI and myocardial injury patients. Reasonable attempts to discover it or treat it should be taken. ■

ABSTRACT & COMMENTARY

Vegetarian Diet vs. Mediterranean Diet to Reduce Cardiovascular Risk

By Michael H. Crawford, MD, Editor

SYNOPSIS: A randomized, open, cross-over study of a vegetarian diet (VD) compared to the Mediterranean diet (MD) over three months showed that both reduced body weight and body fat mass. The VD decreased LDL cholesterol, and MD reduced triglyceride levels. The MD reduced inflammatory markers, and the VD reduced vitamin B12 levels.

SOURCES: Sofi F, Dinu M, Pagliai G, et al. Low-calorie vegetarian versus Mediterranean diets for reducing body weight and improving cardiovascular risk profile. CARDIVEG study (Cardiovascular Prevention With Vegetarian Diet). *Circulation* 2018;137:1103-1113.

Anderson CAM. Dietary patterns to reduce weight and optimize cardiovascular health: Persuasive evidence for promoting multiple, healthful approaches. *Circulation* 2018;137:1114-1116.

Previous studies of diet and cardiovascular (CV) risk factors have suffered from population bias, lack of randomization, and retrospective analyses. Investigators from Florence, Italy, performed a randomized, open, cross-over study of the lacto-ovo vegetarian diet (VD) to the Mediterranean diet (MD) during two three-month intervals. The authors recruited subjects between the ages of 18-75 years (mean, 51 years; 78% female). Prospective recruits demonstrated a CV risk estimate of < 5% at 10 years, were overweight (body mass index [BMI] > 25 kg/m^2), and presented with one or more of the following risk factors: total cholesterol > 190 mg/dL, LDL cholesterol > 115 mg/dL, or glucose > 110 mg/dL, but < 126 mg/dL. The subjects were told not to change their lifestyle or exercise habits. No weight loss goal was given, and both diets were low calorie.

The primary outcome was the difference in BMI and fat mass (bioelectrical impedance technique) changes between the two diets. Secondary endpoints were changes in blood CV risk parameters, such as lipid levels, glucose levels, oxidative stress profiles, and inflammation markers. Of the 118 patients randomized, 107 completed at least one phase of the study and were included in the analysis, and 100 completed the entire study.

Both diets reduced body weight and composition equally. Significant differences in some biochemical parameters were observed (P < 0.01 for all). Vitamin B12 levels fell in the VD group and increased in the MD group. Uric acid fell in the VD group and rose in the MD group. LDL cholesterol fell in the VD (128 to 121 mg/dL) and remained mostly steady in the MD group (124 to 126 mg/dL). Triglycerides increased among VD subjects (109 to 115 mg/dL) and decreased among MD subjects (115 to 108 mg/dL). There were no significant differences in oxidative stress parameters. Only one of 13 inflammatory markers showed a significantly different response to the two diets: Interleukin-17 increased in the VD group (3.7 to 5.1 pg/mL) and decreased in the MD group (5.5 to 3.5 pg/mL). More subjects in the VD group achieved target levels of at least one CV risk factor compared to the MD subjects (46 vs. 35 patients). The authors concluded that VD and MD were equally effective at lowering body weight and fat mass. VD was more effective at lowering LDL cholesterol, and MD was more effective at lowering triglyceride levels.

■ COMMENTARY

Much has been written about the benefits of the MD and a few studies have shown that it increases longevity. Less is known about the VD, so this comparison study is of interest. Since both diets were in low calories, it is not surprising that they were both equally effective at lowering weight and fat mass and produced equivalent effects on oxidative stress measures. The only differences detected were in inflammatory markers and lipid levels. The VD lowered LDL, probably because of the absence of meat, and the MD lowered

triglycerides, probably because of fewer carbohydrates. Interestingly, the VD increased interleukin-17 levels, perhaps because it lowered vitamin B12 levels, which may have increased homocysteine levels (not measured) and increased inflammation. Disappointingly, neither diet affected HDL levels.

The strengths of this study are its cross-over design and the high adherence rate (85% full adherence). Still, there were several limitations. The number of subjects is small, although relatively large for a diet study. The duration was short, but long enough to show significant differences in some measures. There were no data on sugar intake, salt intake, or blood pressure levels. Only the lacto-ovo VD was tested. Although low in saturated fat, lacto-ovo is not as low in total fat as other similar diets. Since the lacto-ovo VD is low in vitamin B12, the authors recommend testing for B vitamin levels in subjects on this and other vegetarian diets, with supplements provided as needed.

In an editorial that accompanied this study, Anderson summed up the requirements quite well, noting that a healthy diet should be rich in fruits, vegetables, whole grains, legumes, and nuts. Diets also should be low in refined grains, processed food, saturated fat, sugar, and salt. A diet should be sustainable, culturally relevant, and enjoyable. I would add that it should be low enough in calories to keep one's BMI < 25 kg/m². ■

ABSTRACT & COMMENTARY

Prognostic Value of Left Ventricular Strain in Chronic Aortic Regurgitation

By Michael H. Crawford, MD, Editor

SYNOPSIS: A retrospective observational study of the incremental value of echocardiographic global longitudinal strain (GLS) for predicting mortality in asymptomatic patients with moderate to severe aortic regurgitation and normal left ventricular function showed that GLS was a predictor of mortality. However, GLS was not as robust as undergoing surgery was for predicting mortality.

SOURCES: Alashi A, Mentias A, Abdallah A, et al. Incremental prognostic utility of left ventricular global longitudinal strain in asymptomatic patients with significant chronic aortic regurgitation and preserved left ventricular ejection fraction. *JACC Cardiovasc Imaging* 2018;11: 673-682.

Cavalcante JL. Global longitudinal strain in asymptomatic chronic aortic regurgitation: The missing piece for the watchful waiting puzzle? *JACC Cardiovasc Imaging* 2018;11:683-685.

The timing of surgical intervention in patients with chronic valvular aortic regurgitation (AR) remains challenging. Investigators from the Cleveland Clinic performed a retrospective observational study to evaluate the incremental value of left ventricular (LV) global longitudinal strain (GLS) by speckle tracking echocardiography for predicting mortality in asymptomatic patients with 3+ or 4+ chronic AR, preserved LV ejection fraction > 50%, and LV end-systolic dimension index < 2.5 cm/m². Excluded were patients with other valve or other heart diseases, previous heart surgery, or aortic dissection. AR severity was established based on several echocardiographic measurements. The primary outcome was all-cause mortality during follow-up. The average age of patients was 53 years, and 77% were men.

At baseline, the median GLS was -19.5%, with 52% better than the median, and 48% worse. Surgery was performed on 63% at a median of 42 days from baseline. During the seven-year follow-up, 14% died, almost all of a cardiac cause. A higher proportion of patients with GLS worse than the median died compared to those better than median (17% vs. 11%; $P = 0.01$). The risk of death at five years increased significantly with GLS worse than -19%. A multivariate hazard analysis revealed several measures predictive of mortality: surgical risk score, LV end-systolic dimension index, GLS, right ventricular (RV) systolic pressure, and aortic valve surgery (favorable). The C-statistic for the clinical variables of surgical risk score, LV end-systolic dimension index, and RV pressure was 0.61. Sequentially adding GLS and surgery increased the C-statistics to 0.67 and 0.77, respectively. Among those not undergoing surgery, all deaths occurred in patients who did not meet current criteria for surgery. The authors concluded that GLS provides incremental prognostic value in asymptomatic patients with chronic AR who do not meet current criteria for surgery.

■ COMMENTARY

Current guidelines recommend aortic valve replacement surgery in patients with severe AR if they are symptomatic or exhibit evidence of LV dysfunction manifested as an ejection fraction < 50% (class I) or

an end-systolic dimension index > 5 cm (> 2.5cm/m²; class II a), or EDD > 6.5 cm (class II b). These guidelines are largely based on observational studies from 30 years ago. Many clinicians believe that they are based on the point when valve replacement usually is not successful in restoring LV function. Accordingly, there has been a movement to operate somewhat earlier, but the decision points for earlier surgery are unclear. In this study, 3+ or 4+ AR events was considered enough to qualify for surgery. Although not delineated in the study, presumably, this is based on a four-point scale, where 1+ is mild, 2+ is mild to moderate, 3+ is moderate to severe, and 4+ is severe. In this study, and most other recent studies, AR severity is based on a combination of echo measures that are never precisely described, as not all measures are available in all patients.

The first point this paper makes is that the current cutpoint for end-systolic dimension index > 2.5cm/m² is probably too high. Among patients who did not undergo surgery, 84% of the deaths occurred in patients with an end-systolic dimension index < 2.0 cm/m². Also, LV ejection fraction didn't make the cut in the multivariate analysis. One issue here is that the lower limit of ejection fraction by echo is now 55%, according to the American Society of Echocardiography. Perhaps < 55% by echo would be a better criterion.

Several new measures have been advanced as potential replacements or additional criteria for surgery, including exercise testing, LV torsion, brain natriuretic peptide levels, MRI for fibrosis, and GLS. Alashi et al assessed GLS, which was obtainable in > 90% of their patients and showed that values worse than the median add prognostic information for mortality. However, choosing surgery was the best predictor of survival, which complicates this analysis. Clearly, this retrospective observational study suffers from selection bias, so it can only be hypothesis-generating. Also, GLS was only measured once at baseline. Serial measurements may have carried additional value, but as echo experts know, such measurements would have to be obtained from the same machines as there is not an industry standard for GLS. If cardiologists have access to GLS, they probably should start measuring it in chronic AR patients, as it may bolster the decision-making. However, GLS is not ready to be an independent criteria for surgery at this time. ■

ABSTRACT & COMMENTARY

Is It Acceptable to Die of Aortic Stenosis Without a TAVR?

By Michael H. Crawford, MD, Editor

SYNOPSIS: Investigators performed a retrospective analysis of 544 patients undergoing transcatheter aortic valve replacement (TAVR) at one center to assess the contribution of a frailty score to the Society of Thoracic Surgeons (STS) risk score for predicting mortality post-procedure. The frailty score was found to be an independent predictor of 30-day and one-year mortality and additive to the STS score.

SOURCE: Rogers T, Alraies MC, Moussa Pacha H, et al. Clinical frailty as an outcome predictor after transcatheter aortic valve implantation. *Am J Cardiol* 2018;121:850-855.

The assessment of the procedural risk of aortic stenosis (AS) patients considered for transcatheter aortic valve replacement (TAVR) almost always includes the Society of Thoracic Surgeons (STS) risk score. Often, some assessment of patient frailty is included, too, but little is known about the incremental value of adding an assessment of frailty to the STS score for predicting short- and long-term outcomes after TAVR.

Researchers from the MedStar Washington Hospital Center in the District of Columbia studied 544 patients with severe symptomatic AS undergoing TAVR who had the STS score calculated and frailty assessed. A frailty score was calculated based on five parameters, with a score range of 0 to 5. The factors were: body mass index (BMI) < 20kg/m², serum albumin < 3.5g/dL, a Katz activities of daily living index of < 4 (six measures total), low grip strength based on sex and BMI, and a slow 15-foot walk time based on sex and height. Frailty was defined as a score of ≥ 3. The outcomes assessed were in-hospital, 30-day, and one-year all-cause mortality, stroke, vascular complications, bleeding complications, and acute kidney injury.

Frailty was observed in 44% of patients. Frail patients were older, suffered from severe chronic obstructive lung disease, demonstrated high STS scores, and were short in stature. The STS score alone was not associated with higher mortality after TAVR at 30 days or one year. After a multivariate analysis, frailty was a significant predictor of mortality at 30 days (odds ratio [OR], 5.06; 95% confidence interval [CI], 1.36-18.8; *P* = 0.015) and one year (OR, 2.75; 95% CI, 1.55-4.87;

P = 0.001). Patients who were frail and registered an STS score of > 8 demonstrated the highest mortality rate (about 25% at one year). When frailty was added to the STS score, the C-statistic for predicting 30-day mortality increased from 0.59 to 0.67 and from 0.62 to 0.66 for one-year mortality, which in both cases resulted in significant net reclassification improvement. The authors concluded that an assessment of frailty should be part of the pre-procedural assessment of all patients with severe AS under consideration for TAVR.

■ COMMENTARY

A recent paper from France showed a 72% increase in aortic valve replacements from 2007-2015 in the whole country, which was largely due to the introduction of TAVR in 2007. However, the in-hospital mortality rate in those > 75 years of age was not significantly different between TAVR and surgical replacement, whereas in those < 75 years, the TAVR mortality rate was significantly lower.[1] These observations from a national administrative database raise the question of whether TAVR is overused, especially among very elderly patients.

This issue is addressed in part in the Rogers et al study, which analyzed the influence of frailty on outcomes after TAVR. The authors demonstrated that frailty is an independent predictor of short- and long-term mortality and added incremental predictive value to the STS score. This is perhaps not surprising since the STS score was designed to determine the risk of surgical valve replacement, which would be expected to be different from transcatheter delivery. If cardiologists design a new risk score for TAVR, an assessment of frailty should be part of it.

There were limitations to this study. It was a retrospective analysis, but of prospectively collected data. All five frailty indices had to be obtained to be included, which may have excluded some very high-risk patients who couldn't walk 15 feet. Their inclusion likely would have increased the mortality rates observed. Also, Rogers et al did not test each individual frailty measure alone. This would have been useful as there are several frailty measurement tools used.

Based on this study's results and their experience, the authors proposed 10 parameters that, if present, should initiate a discussion about the futility of TAVR in the patient under assessment: unable to complete a short gait speed test, dependent for most activities of daily living, low serum albumin, unintentional weight loss, significant anemia without a reversible cause, advance dementia, oxygen-dependent lung disease, atrial fibrillation, severe chronic kidney disease (especially if on dialysis), and severe liver disease. ■

REFERENCE

1. Nguyen V, Michel M, Eltchaninoff H, et al. Implementation of transcatheter aortic valve replacement in France. *J Am Coll Cardiol* 2018;71:1614-1627.

CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. In a recent observational study, which of the following was *not* an independent predictor of mortality in chronic aortic regurgitation patients?

a. Left ventricular (LV) global longitudinal strain

b. LV end-systolic dimension index

c. LV ejection fraction

d. Right ventricular systolic pressure

2. The most common cause of death in hospitalized patients with type 2 myocardial infarction or myocardial injury detected is:

a. non-cardiac causes.

b. subsequent type 1 myocardial infarction.

c. heart failure.

d. ventricular tachyarrhythmias.

3. In comparison to a vegetarian diet, a Mediterranean diet improved:

a. LDL cholesterol levels.

b. triglyceride levels.

c. body mass index.

d. body fat content.

4. Independent predictors of mortality following transcatheter aortic valve replacement include:

a. Society of Thoracic Society risk score.

b. $CHADS_2$ score.

c. frailty score.

d. both a and c.

5. Mild-to-moderate increases in serum creatinine during diuretic treatment for acute heart failure are usually due to:

a. acute tubular necrosis.

b. renal tubular injury.

c. fluctuations in glomerular filtration rate.

d. overdiuresis to below dry weight.

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- discuss the most current information related to cardiac illness and the treatment of cardiac disease;
- explain the advantages and disadvantages, as well as possible complications, of interventions to treat cardiac illness;
- discuss the advantages, disadvantages, and cost-effectiveness of new and traditional diagnostic tests in the treatment of cardiac illness; and
- discuss current data regarding outpatient care of cardiac patients.