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Critical analysis of the latest clinical research in cardiovascular medicine

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ABSTRACT & COMMENTARY

Is Left Atrial Appendage Occlusion with the Watchman Device a Reasonable Alternative to Anticoagulation with Warfarin?

By Edward P. Gerstenfeld, MD

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Dr. Gerstenfeld does research for Biosense Webster, Medtronic, and Rhythmia Medical.

SOURCE: Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: The PREVAIL trial. *J Am Coll Cardiol* 2014;64:1-12.

The goal of the Watchman LAA Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy (PREVAIL) trial was to assess the safety and efficacy of left atrial appendage (LAA) occlusion for stroke prevention in patients with atrial fibrillation (AF) compared with long-term warfarin therapy. Patients with AF who had a CHADS2 score ≥ 2, or 1 and another "high" risk factor were eligible for enrollment. Patients were randomly assigned (in a 2:1 ratio) to undergo LAA occlusion with the Watchman device and subsequent discontinuation of warfarin 6 months after implantation (n = 269) or receive continued warfarin therapy (control group, n = 138). There were two coprimary endpoints. The first primary endpoint included a composite of stroke, systemic embolism, and death. The second primary endpoint included the occurrence of stroke or systemic embolism > 7 days after randomization. At 18 months, the rate of the first primary efficacy endpoint was 0.064 in the device group vs 0.063 in the control group, and did not achieve the prespecified noninferiority criteria. The rate for the second primary efficacy endpoint was 0.0253 vs 0.0200, achieving noninferiority. Early safety events occurred in 2.2% of the Watchman device arm, satisfying the prespecified safety performance goal. Pericardial effusions requiring surgical repair decreased from 1.6% to 0.4% with the Watchman device compared to the earlier Watchman Left

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Atrial Appendage Closure Technology for Embolic Protection in Patients With Atrial Fibrillation (PROTECT AF) trial ($P < 0.03$), and need for pericardiocentesis decreased from 2.9% to 1.5% ($P = 0.36$). The authors concluded that LAA occlusion is a reasonable alternative to warfarin therapy for stroke prevention in patients with non-valvular AF who do not have an absolute contraindication to short-term warfarin therapy.

■ COMMENTARY

Stroke remains the most feared complication of AF and stroke prevention is one of the primary treatment objectives in AF patients. While it is well known that clots during AF typically form in the LAA, it had been controversial whether surgical or mechanical exclusion of the LAA would prevent strokes and could be an alternative to long-term systemic anticoagulation. The data are in part limited because our surgical colleagues have not yet performed a proper prospective randomized trial of LAA ligation in patients with AF undergoing cardiac surgery. The PLATO device was the first device developed to allow percutaneous "plugging" of the LAA for stroke prevention.[1] The Watchman device represents the next generation of devices capable of plugging the LAA via an atrial transseptal route. The device contains a permeable polyester membrane coating that allows endotheliazation after implant to prevent thrombus formation, and contains barbs that prevent device migration. However, whether complete occlusion of the LAA could be achieved with acceptable risk and without more proximal clot formation has been unclear. The initial PROTECT AF[2] study demonstrated equivalence to warfarin after the device was implanted; however, a higher than anticipated periprocedural complication rate led the FDA to mandate a second trial. In this current trial (PREVAIL), the complication rate during device implantation (2.2%) was significantly lower than PROTECT AF. The patients enrolled in PREVAIL had a mean age of 74 years and a reasonable stroke risk (mean CHADS2 score = 2.6 ± 1). The primary endpoint for noninferiority, a composite of stroke, systemic embolism, and death, unfortunately was not met by the study endpoints. However, this was largely because the event rate in the control warfarin arm was unusually low (0.063%). The second primary endpoint for noninferiority, the occurrence of stroke or systemic embolism > 7 days after randomization, was met.

Are we now ready to offer our patients left atrial appendage occlusion as an alternative to anticoagulation? Based on the PREVAIL data, I would presume that the FDA will eventually approve the Watchman device. However, I think it is a bit premature to pursue this strategy wholeheartedly. Although the complication rate in the PREVAIL study was considered acceptable, the investigators still had special expertise and training in implantation of these devices. Complication rates in the real world will undoubtedly be higher, particularly in the elderly population with AF. In addition, several alternative anticoagulants are now available that are safer than warfarin, including dabigatran, rivaroxaban, and apixaban. Patients treated with apixaban in the ARISTOTLE trial,[3] for example, had a lower overall mortality and significantly lower intracranial hemorrhage rate compared to warfarin. Anticoagulants also can be taken once or twice daily without any blood tests. Whether the LAA occlusion devices are truly "noninfeiror" to these new agents has not yet been tested. In addition, several other devices are currently being studied, including the Amplatzer LAA plug and epicardial LARIAT device. How these devices compare with the Watchman device is unknown. Certainly patients at high stroke risk who have bleeding risks that preclude long-term anticoagulation with warfarin should be considered candidates for LAA occlusion. Keep in mind that using the Watchman device, a minimum of 45 days of anticoagulation with warfarin was still required (although a preliminary study has suggested that asprin/clopidogrel treatment may be a suitable alternative).[4] In the future, I have no doubt that LAA occlusion will be an option for patients with AF and stroke risk who cannot tolerate long-term anticoagulation. Whether these devices will be considered an "alternative" to systemic pharmacologic anticoagulation remains to be determined. ■

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ABSTRACT & COMMENTARY

Is Less More? Transfemoral TAVR: The Minimalist Approach

By Jeffrey Zimmet, MD, PhD

Associate Professor of Medicine, University of California, San Francisco, Director, Cardiac Catheterization Laboratory, San Francisco VA Medical Center

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

SOURCE: Babaliaros V, et al. Comparison of transfemoral transcatheter aortic valve replacement performed in the catheterization laboratory (minimalist approach) versus hybrid operating room (standard approach): Outcomes and cost analysis. *JACC Cardiovasc Interv* 2014; Jul 22. [Epub ahead of print].

Since its initial FDA approval in November 2011, transcatheter aortic valve replacement (TAVR) has rapidly gained acceptance as a standard therapy in the United States. The adoption of this procedure has by necessity fostered enhanced cooperation among cardiologists, cardiac surgeons, and cardiac anesthesiologists in the management of complex valve patients. This "Heart Team" approach has for the most part spilled over into the procedures themselves, which are performed in many cases in a hybrid operating room environment. In such a standard approach, the patient is managed with endotracheal intubation and general anesthesia, with concomitant use of invasive devices including pulmonary artery catheters, transesophageal echo, and Foley catheters. In the original PARTNER trial that led to U.S. approval of the Edwards Sapien valve, procedure time for transfemoral valve placement averaged 244 minutes, and patients coming out of general anesthesia spent a mean of just over 3 days in the ICU, with total hospital length of stay averaging more than 10 days.

As experience with this technique has increased, some centers have begun to perform transfemoral TAVR via a fully percutaneous technique using only moderate sedation without endotracheal intubation or TEE. It has been reported that 40% of TAVR procedures in Europe are currently performed in this manner. The authors of the current study, from the Emory University School of Medicine in Atlanta, sought to compare the outcomes and costs of such a minimalist approach (MA) TAVR to those of so-called standard approach (SA) procedures performed at their center. This was not a randomized trial — the Emory group made the transition in transfemoral procedures from SA-TAVR to MA-TAVR and sought to describe the results. During the time period from November 2010 to September 2013, MA-TAVR was performed in 70 patients and SA-TAVR in 72 patients.

Patients in the two groups were similar in baseline characteristics and estimated risk, with mean ages in the low 80s, STS scores of approximately 11%, and > 87% of patients in NYHA functional class III or IV. All patients in the MA group underwent successful procedures, while there were three procedural deaths in the SA group. There was no in-hospital mortality with the MA group, whereas there was 4.2% mortality among the SA patients. Procedural time (93 ± 32 min vs 125 ± 46 min, $P < 0.001$) and in-room time (150 ± 48 min vs 218 ± 56 min, $P < 0.001$) were significantly shorter in the MA group. Rates of moderate or severe paravalvular leak were low and were not significantly different between the two groups. Both ICU and total hospital length of stay were reduced in the MA group. After the switch over to the MA approach, the majority of patients spent no time in intensive care at all, but were transferred from the procedure directly to a telemetry floor. Subsequent to the change to the MA technique, only eight transfemoral TAVR patients underwent procedures by the SA approach, and the majority of

these were done in this manner due to scheduling issues. Only three potential transfemoral patients who underwent SA TAVR during this period were managed this way due to medical necessity, due either to a requirement for advanced airway management or to complex aorto-iliac anatomy. The authors concluded that TAVR can be performed with a minimalist approach in the catheterization laboratory with low morbidity and mortality, reduced costs, and equal effectiveness as compared to the standard hybrid operating room approach.

■ COMMENTARY

This intriguing paper makes a convincing argument that with appropriate patient selection and in the right hands, a proportion of TAVR procedures may be safely performed using a minimalist approach. This was not a randomized comparison. All reported procedures were done after Emory had performed more than 100 procedures, so the learning curve was presumably not a big issue. Despite this, however, the MA procedures were performed for the most part later in time, when the operators had more experience. This, or alternatively simple chance in this relatively small data set, is the more likely explanation for the lower procedural mortality among the MA group. Reduced procedure times, room times, hospital length of stay, and costs, however, are certainly real.

It is worth noting that all procedures reported here were performed with the first-generation Sapien valve with its very large 22F and 24F sheaths. Smaller procedural sheaths currently available with the second-generation Sapien and with the Corevalve platforms should make the transfemoral approach available to a greater proportion of patients. With good pre-procedural multimodality imaging (with CT, TTE, and TEE), patients who are good candidates for such minimalist transfemoral procedures can be identified with a high degree of confidence. As the experience of U.S. centers continues to grow and devices with smaller profiles are made available, a shift toward this method appears likely. The need for detailed evaluation by the Heart Team will remain essential, however, to ensure that patients are appropriately selected for this approach. ■

ABSTRACT & COMMENTARY

Colchicine for Recurrent Pericarditis

By Michael H. Crawford, MD, Editor

SOURCE: Imazio M, et al. Efficacy and safety of colchicine for treatment of multiple recurrences of pericarditis (CORP-2): A multicenter, double-blind, placebo-controlled, randomised trial. *Lancet* 2014;383:2232-2237.

Although colchicine has been shown to be effective for the treatment of acute pericarditis and first recurrences, little information exists about its use in patients with multiple recurrences. Thus, Imazio et al reported on the results of the colchicine for recurrent pericarditis 2 (CORP-2) trial. CORP-2 was a randomized, controlled trial performed at four general hospitals in Italy. Recurrent pericarditis was defined as another episode after a 6-week or more symptom-free interval. Recurrence was diagnosed as recurrent pain and at least one of the following: a pericardial friction rub, typical ECG changes, pericardial effusion on echocardiography, or elevated inflammatory biomarkers (white blood cell count, erythrocyte sedimentation rate or C-reactive protein concentration). Two or more recurrences of pericarditis caused by idiopathic/viral, post-cardiac injury, or connective tissue disease were required for enrollment. Patients with purulent pericarditis, myopericarditis, or a contraindication to colchicine (e.g., liver disease) were excluded. Colchicine was given to half the subjects (randomized) at a dose of 0.5 or 1.0 mg daily for 6 months without a loading dose. Recurrences were also treated with non-steroidal anti-inflammatory drugs (NSAIDs) as needed. Corticosteroids were given to those already on them or those who could not take NSAIDs. All patients received a proton pump inhibitor. The primary endpoint was recurrent pericarditis during at least 18 months of follow-up.

Of the 260 patients screened, a total of 240 patients were enrolled, 120 in each group, over about 6 years. No one was lost to follow-up. Adherence to both treatments was 95%. Pericarditis recurred in 22% of the colchicine group vs 43% of the placebo group (relative risk, 0.49; 95% confidence interval [CI], 0.24-0.65; $P < 0.001$; number needed to treat = 5). The Kaplan-Meier curves of event-free survival separated at 2 months and stayed separated for the 18-month minimum follow-up. Colchicine also significantly improved the following secondary endpoints: the frequency of symptom persistence, the number of recurrences, hospital admissions, and recurrences within 1 week. In a multivariate analysis, pericardial effusion at presentation was the only

independent risk factor for multiple recurrences (odds ratio, 3.1; 95% CI, 1.7-5.8; P = 0.0001). Adverse effects occurred in 12% of the colchicine group and 8% in the placebo group (P = NS). Gastrointestinal side effects were most common and occurred at the same frequency in both groups (7.5%). The authors concluded that colchicine added to conventional NSAID therapy reduces the frequency of pericarditis recurrence in patients with two or more recurrences.

■ COMMENTARY

This study completes the Imazio et al trilogy on the treatment of pericarditis and suggests that colchicine is the drug of first choice for acute pericarditis, first recurrences, and multiple recurrences.[1,2] In this study, its beneficial effects were not related to the type of underlying NSAID or corticosteroid therapy. It basically halves the rate of recurrent pericarditis in these challenging patients.

Why is colchicine so effective and conventional treatment not? The pathogenesis of recurrences is poorly understood, but most believe it is immune-medicated. Colchicine concentrates up to 16-fold in white blood cells and disrupts microtubules, even at the low does used in this trial. Often, multiple recurrent pericarditis patients are treated with more potent immune-suppressant drugs such as azathioprine, intravenous immunoglobulins, and interleukin antagonists. However, there is little evidence of their effectiveness. Also, they are expensive and have potentially worse adverse effects. Thus, this colchicine protocol is a welcome addition to the treatment of recurrent pericarditis patients.

For acute pericarditis, Imazio recommends a loading dose of 1 mg (1.2 U.S. formulation) every 12 hours for 1-2 days, then 0.5 mg (0.6 U.S. formulation) once a day for those < 70 kg, and 0.5 (0.6 U.S. formulation) twice a day for those > 70 kg for 3 months. Recurrent pericarditis is treated without a loading dose in the same fashion for 6 months. This only applies to immune-mediated pericarditis — e.g., viral, idiopathic or post pericardiotomy, not bacterial, neoplastic or myopericarditis. Also excluded from these studies were children and pregnant or lactating women. Finally, the duration of therapy in these studies was arbitrary and we don't know if shorter or longer durations would be equally or even more effective. ■

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ABSTRACT & COMMENTARY

Angiotensin Receptor Blockers for Hypertension

By Michael H. Crawford, MD, Editor

SOURCE: Makani H, et al. Antihypertensive efficacy of angiotensin receptor blockers as monotherapy as evaluated by ambulatory blood pressure monitoring: A meta-analysis. *Eur Heart J* 2014;35:1732-1742.

Angiotensin receptor blockers (ARBs) are often used as first-line therapy for the treatment of systemic hypertension because of their perceived efficacy and relatively low incidence of adverse effects. However, there are contradictory reports about the efficacy of individual agents in this class, especially losartan. Thus, these investigators from New York City performed a meta-analysis of studies of ARBs used as monotherapy that employed 24-hour ambulatory blood pressure (BP) monitoring to assess antihypertensive efficacy. The randomized clinical trials included had to have no uptitration of the drugs, so they could clearly compare maximum recommended doses to half-maximum and quarter maximum doses of the ARBs. Also, trial duration had to be at least 1 month and no other classes of antihypertensives could be given. Also, none of the subjects could have severe hypertension. They identified 62 trials that met these criteria that enrolled more than 15,000 patients with a mean treatment duration of 10 weeks.

Reduction in systolic BP averaged 10 mmHg and diastolic BP averaged 7 mmHg at 25% maximum doses. At 50% maximum doses, systolic BP decreased 12 mmHg and diastolic BP 8 mmHg. At maximum doses, systolic BP dropped 13 mmHg and diastolic BP dropped 8 mmHg. When 25% maximum dose was compared to 50% maximum dose, there was a significant further reduction of systolic BP (P = 0.04) but not diastolic BP (P = 0.08). When comparing 50% to maximum dose, there was no significant reduction in systolic or diastolic BP.

Studies that compared losartan to other ARBs showed that losartan at 50% maximum dose (50 mg/day) lowered BP less than other ARBs (differences 2.5 mmHg systolic and 1.8 mmHg diastolic). Also, maximum dose losartan (100 mg/day) lowered BP less than maximum doses of other ARBs (differences 3.9 mmHg systolic and 2.2 mmHg diastolic). Sensitivity analyses showed no evidence of publication bias and no differences in outcomes based on study duration or number of subjects. The authors concluded that this comprehensive analysis of 62 studies of monotherapy at a fixed dose of ARBs showed a shallow dose response curve and that losartan was consistently inferior to other ARBs.

■ COMMENTARY

This analysis shows that ARBS as monotherapy have a similar efficacy as most other antihypertensive drugs; a 10-15 mmHg reduction in systolic BP and 5-10 mmHg in diastolic BP. Surprisingly, uptitrating the dose four-fold had little further effect. This is also consistent with other studies that have shown that combining drugs from two different classes of agents is approximately five times more effective than doubling the dose of one drug. The only exception to this rule appears to be calcium channel blockers, which seem to be more potent than most other agents in comparison studies, with maximum systolic BP lowering effects of up to 20 mmHg. Another reason not to uptitrate antihypertensive agents is to avoid dose-related side effects. This is a particular concern with thiazide diuretics, calcium blockers, and beta-blockers, but not with ARBs. Thus, for all these reasons, combination therapy at well-tolerated doses seems to trump uptitration of monotherapy.

The conclusion that losartan is the least effective of the ARBs has been demonstrated in other clinical studies and in vitro studies of angiotensin II receptor blocking effects. However, the absolute differences shown in this study were modest. Until recently, losartan was the only ARB available as a generic. Now that generic versions of other ARBs are becoming available, I predict the use of losartan will decrease in the United States.

Meta-analyses do have weaknesses. For example, no adjustments for adherence to therapy were made, but drug discontinuation rates are usually low with ARBs. Also, there were insufficient data to compare all the ARBs head to head. In addition, the population of patients studied all had mild-to-moderate hypertension and none had severe hypertension. Although not an ideal study, it supports the shift toward using combination therapy in moderately severe hypertension and the marketing of drug combination pills for hypertension treatment. ■

ABSTRACT & COMMENTARY

Bioabsorbable Coronary Scaffolds: Promise and Peril

By Jeffrey Zimmet, MD, PhD

Associate Professor of Medicine, University of California, San Francisco, Director, Cardiac Catheterization Laboratory, San Francisco VA Medical Center

SOURCE: Capodanno D, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: Early and midterm outcomes from the European multicentre GHOST-EU registry. *EuroIntervention* 2014; Jul 18. doi: 10.4244/EIJY14M07_11. [Epub ahead of print].

Clinical outcomes from percutaneous coronary intervention (PCI) have steadily improved over time, with transitions from balloon angioplasty to bare-metal stenting, and more recently from first-generation drug-eluting stents (DES) to second- and third-generation designs. The latest-generation DES are considered to be more efficacious in preventing repeat revascularization compared with earlier models, but are also thought to be safer in terms of failure events such as stent thrombosis. The permanent lining of the vessel with metallic stents is, however, widely considered to be a major drawback of this approach. The long-term presence of a foreign body may lead to effects on vascular remodeling, and is considered to be a nidus for very late events, including stent thrombosis. Thus, the excitement is centered on the concept of fully resorbable stents, commonly referred to as bioresorbable vascular scaffolds (BVS). Abbott Vascular has been early out of the BVS gate with its Absorb device, which is a semi-crystalline poly-L-lactide (PLLA) framework that elutes everolimus,

similar to its Xience stent platform. Current data suggest that these BVS are fully resorbed in a time frame between 2 and 4 years after implantation. Although FDA approval will hinge on the results of the not-yet-complete ABSORB III and IV trials, the Absorb BVS received the European CE Mark of approval back in 2011 and was launched internationally in 2013. The trials released to date have been small, and have focused on specific patient populations with relatively restrictive exclusion criteria.

The GHOST-EU (Gauging coronary Healing with biOresorbable Scaffolding plaTforms in EUrope) registry is a retrospective study conducted at 10 high-volume European hospitals. The study includes data from 1189 patients enrolled between late 2011 and early 2014. This is truly an all-comers registry, including all patients with coronary artery lesions for whom implantation of an Absorb BVS was intended. Included in the study were patients with acute myocardial infarction (MI), renal and left ventricular dysfunction, ostial and bifurcation disease, and left main disease. Notably, more than 18% of patients received both a BVS and a conventional metallic stent.

Target lesion failure (TLF), defined as the combination of cardiac death, target vessel MI, or clinically driven target lesion revascularization, occurred in 67 of the 1189 patients during the follow-up period, at a median of 109 days after scaffold implantation. By applying the Kaplan-Meier method, the authors calculated a cumulative incidence of TLF of 2.2% at 30 days and 4.4% at 6 months, with a predicted annualized TLF rate of more than 10%. Patients receiving a combination of BVS and conventional stents had an even higher TLF rate, at 5.6% at 6 months. Although this was not a randomized trial and included no comparison group (as the anticipated US ABSORB trials will do), these TLF rates are higher than those reported in similar all-comers trials with second-generation metallic DES (the RESOLUTE All-Comers and TWENTE trials reported 1-year TLF of just over 8%). Of particular interest is the data on stent thrombosis (ST), which is always a concern with coronary stents. Definite ST was seen in 20 patients at a median of 6.5 days from implantation, while probable ST was seen in an additional three patients. The cumulative incidence of ST was 1.5% at 30 days and 2.1% at 6 months, which is significantly higher than would be expected for conventional DES. The authors concluded that BVS hold considerable promise, but current models are not outperforming conventional DES.

■ COMMENTARY

BVS is one of the most highly anticipated technologies in coronary intervention, with the potential to change the way coronary disease is treated. As with many such technologies, however, the full story of promise and peril will only come with more data, and this paper represents the largest numbers reported to date. Much remains to be learned about the optimal use of these devices, including appropriate patient and lesion selection. Because the devices are significantly different from conventional stents, the authors sought to investigate the influence of the learning curve on clinical outcomes. To do this, they compared outcomes of patients who were among the first 50 treated with BVS at any particular center with those who were treated after. In a surprising turn, the TLF rates at 6 months were significantly higher with greater BVS experience. As might be expected, more complex patients and lesions were treated in the latter group, including more ACS patients and more lesions with thrombus and ostial locations.

Scaffold thrombosis rates were clearly higher than anticipated, and this may be cause for tempered enthusiasm. The greater strut thickness (compared with current-generation metallic stents) certainly could play a role in an increased propensity for thrombosis. It may also be that certain types of lesions are not appropriate for BVS, or that these devices may give less margin for error when it comes to lesion preparation and vessel sizing when compared with conventional stents. Ultimately, answering these questions will require a rigorous randomized, controlled trial comparing BVS with current-generation DES. ■

QUESTIONS & COMMENTS:
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CME QUESTIONS

1. Bioabsorable stents compared to conventional drug-eluting stents have shown reduced rates of:

a. target vessel MI.

b. target lesion revascularization.

c. stent thrombosis.

d. None of the above

2. Recurrent pericarditis is best treated with:

a. aspirin.

b. NSAIDs.

c. colchicine.

d. corticosteroids.

3. Which of the following is *not* a characteristic of ARBs for treating hypertension?

a. Low incidence of adverse effects

b. All are highly effective as monotherapy

c. Shallow does response curve

d. Few drug interactions

4. Which of the following is most correct concerning TAVR done in the cardiac catheterization laboratory compared to the operating room?

a. Fewer paravalvular leaks

b. Longer hospital stays

c. Shorter procedure times

d. Higher mortality

5. The watchman percutaneous left atrial occlusion device has shown which of the following vs warfarin therapy?

a. Superior efficacy vs warfarin

b. No inferiority at stroke prevention vs warfarin

c. More serious adverse effects vs the earlier PROTECT-AF trail

d. All of the above

CME 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.