



## A FATAL STANDARD OF CARE FOR HEART ATTACK VICTIMS?

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Medical negligence wrongful death cases involving a delay in diagnosis and treatment of cardiovascular disease often present a common fact pattern. Autopsies reveal atherosclerotic narrowing of coronary arteries with the left anterior descending artery the most common site of disease. In the weeks and sometimes months prior to their deaths, patients report chest pain radiating to their shoulders and arms or a tightness in their chests that was aggravated by exercise. Physicians ruled out cardiac problems based on exercise testing and electrocardiograms (EKG), and treated for a variety of ailments including ulcers, gallstones, and panic disorder. The opportunity was thus lost for a diagnosis of ischemic heart disease and use of life-saving procedures such as angioplasty or bypass surgery.

In retrospect these erroneous diagnoses are disturbing. However, the medical literature is far from clear in establishing a standard of care for the patient with ongoing chest pain. For years, physicians have relied on exercise stress testing (treadmill test), but this reliance is misplaced and may be fatal. Recent publications have concluded that "false negative" results from an exercise test are common, and that under certain circumstances the test may not be useful in identifying someone with coronary artery disease

and a risk of sudden death from cardiac arrest. *Annals of Emergency Medicine* 19:1-170 (1997) and *Am Heart J.* 123:1312-1323 (1992).

Recent reports advocate placing greater importance on a quantitative analysis of risk factors and symptoms. A study by the National Institutes of Health identified the acute cardiac ischemia (ACI) predictive instrument, which is a computer program that yields a single number percent risk of ACI based on risk factors, symptoms, and EKG profiles. The results may be printed at the top of an EKG monitor strip. In one recent report, the ACI predictive instrument was rated as very accurate with a large clinical impact based on high quality clinical studies. *Annals of Emergency Medicine* 29:38-43 (1997).

Another study places great importance on analysis of three basic pieces of data: age, sex, and symptom characterization (typical, atypical, nonanginal). For example, the probability is 92% that a man, aged 50-59, and presenting with typical angina, has coronary artery disease. Chest pain is characterized as typical angina if it is substernal, precipitated by exertion, and is relieved within 10 minutes by rest or nitroglycerin. Atypical angina is discomfort that has the same qualities as typical angina but is not reproducibly brought on with exertion or reproducibly relieved with rest and/or nitroglycerin. Nonanginal pains are those not falling

in the previous two categories. For individuals reporting symptoms of angina, an analysis of typical risk factors such as smoking, diabetes, hypertension, or cholesterol is not as useful as it is in patients who are asymptomatic. *Am Heart J.* 123:1312-23 (1992).

When a patient reports to the hospital with chest pain, the "level" of the pain is not important:

An important corollary to the modern classification of angina pectoris is the following: Mild angina (does not equal) Mild disease. This important corollary serves to emphasize the fact that even mild discomfort can be associated with very severe degrees of obstructive coronary artery disease. Therefore it is not correct to treat patients with mild angina pectoris one way and patients with more severe forms of angina pectoris another way.

*Am Heart J.* 123: 1317 (1992).

The presence of typical angina pectoris should trigger a full investigation into its cause, with coronary artery disease at the top of the differential diagnosis list.

Based on these analytical tools, many patients who are sent home from an emergency room, or referred for gastrointestinal workup after a normal exercise stress test, should receive further evaluation for coronary artery disease.

What should be done in further evaluation is not so well established. The literature abounds with studies

of diagnoses in the emergency room or of assessment after a myocardial infarction, but it is deficient in studies of diagnostic tools to use for the individual experiencing chest pain with no prior history of heart disease. The diagnostic steps available for physicians evaluating chronic chest pain can be broken down as follows. The early tests are: (1) Symptoms, risk factors, history; (2) Nitroglycerin leading to diagnostic pain relief and vasodilation; (3) Heart Muscle Enzymes such as creatine kinase-MB; and (4) EKG. The intermediate tests are: (5) Exercise Stress Test; (6) Thallium - Exercise Stress Test; (7) Echocardiography with or without Exercise Test; and (8) Holter monitor. Advanced tests: angiography or coronary arteriography.

These tests are listed approximately in the order of their preference; however, some physicians choose thallium exercise stress test, echocardiography, and Holter monitoring without preference to order. Angiography is more invasive and expensive than the other testing procedures, but it is also the “gold standard” for diagnosis of coronary artery disease. One report suggests that a patient of either sex suffering from typical angina should be analyzed by coronary arteriography directly, without any of the intermediate tests. It is suggested that men over 40 and women over 50 with symptoms of atypical angina should also receive coronary arteriography directly. The intermediate tests are appropriate only in lower risk individuals such as men under 40 years old or women under 50, or those patients suffering from non-anginal discomfort. *Am Heart J.* 123:1312-23 (1992).

### *Symptoms and History*

The first step in evaluating chest pain is analysis of the readily available patient data including age, sex and symptom characterization. The physician should determine whether the patient has typical angina pectoris by examining whether the pain is sensitive to exertion and nitroglycerin therapy. The most striking statistic is that typical angina pectoris is diagnostic of coronary artery disease with very high probability. In the age range of 40 to 69 the probability of coronary artery disease in persons with typical angina ranges from 55% to 94%. *Am. Heart J.* 123:1317.

### *Nitroglycerin*

Nitroglycerin is useful as a pain killer, as a vasodilator, and as a diagnostic tool. Sublingual nitroglycerin is critical to characterizing anginal pain as typical or atypical. Nitroglycerin relaxes smooth muscle causing blood vessels to dilate. The effect is to reduce both preload and afterload (or back-pressure) on the heart and reduce the amount of work the heart must do. The primary action of nitrates is on venous tone where dilation reduces the return of blood to the heart. The reduced volume of blood decreases ventricular dimensions, lowers tension on the heart muscle and reduces oxygen demand.

Vasodilation also can appreciably widen the opening of a coronary artery narrowed by plaque formation. Because the victim of angina is at the threshold of myocardial infarction, even a small increase in the opening of a narrowed artery can be important and may be life-saving. It can provide the additional time to allow further diagnostic or treatment steps to be taken. An emer-

gency room physician who fails to use nitroglycerin as a diagnostic tool for patients older than 40 years with chest pain is potentially liable for substandard care if the patient subsequently succumbs to coronary artery disease.

### *EKG*

The next two steps often taken in the emergency room are an EKG and enzyme tests. The EKG is a sensitive indicator of ischemia when recordings are taken at the time of an ischemic event. The National Institutes of Health identify EKGs as the “standard of care” in emergency rooms: “[S]ensitivity for the [EKG]...is 61%...and specificity equals 95%. Positive predictive value for AMI [acute myocardial infarction] is 73%..., and negative predictive value is 92% ..” Although EKGs are the standard of care they “should not be relied on to make the diagnosis but should rather be included with history and physical examination characteristics to identify patients who appear to be at high risk for ACI [acute cardiac ischemia].” “Accuracy in diagnosis is not perfect but is very high for AMI and is lower for unstable angina.” *Ann. Emergency Med.* 29:19 (1997). The NIH study also notes that the accuracy of an EKG is dependent on the experience of the operator. Negligent reading of abnormal EKGs is a common source of malpractice claims.

While positive results from an EKG are very important, a normal EKG does not rule out ischemia resulting from coronary artery disease. Even patients with severe heart disease may at discrete times show normal EKG tracings, especially when the EKG is done while the patient is not experiencing chest pain.

### *Myocardial Enzymes*

Enzymes that are normally a component of heart muscles are released into the blood when heart muscle cells die during a myocardial infarction. These enzymes are indicative of a myocardial infarction, but not ischemia alone. For example, a patient suffering chest pain from ischemic events caused by a narrowed coronary artery may have undetectable levels of cardiac enzymes in her/his blood despite the seriousness of the artery disease. For this reason, enzyme analysis has little value in characterizing ischemic events during unstable angina pectoris.

Enzymes may be detected during a fairly narrow window of time following a myocardial infarction, and should be measured serially over a period of 12 to 24 hours and not on a one-shot basis. The first signs of enzymes in the blood appear 6 to 10 hours following a myocardial infarction with the peak of enzyme concentration in the blood occurring 17 to 24 hours post infarction. Serum levels of enzymes return to normal in 36 to 72 hours.

Interestingly, the NIH study found there were no controlled clinical studies that showed that enzyme tests were effective for deciding what care is required for a patient reporting with chest pain. The study suggested that future research into other heart muscle proteins might increase the sensitivity of the tests or broaden the window of sensitivity; however, at the times many patients are treated for chest pains, enzyme tests are of little value.

### *Exercise Stress Testing*

Exercise stress testing is the intermediate level diagnostic tool of choice

for most physicians. Many cardiology negligence cases involve patients who had a negative exercise stress test which, when coupled with negative enzyme analysis, led physicians to conclude that a patient's chest pain was noncardiac, despite all the hallmark symptoms of cardiac ischemia. Several recent studies are highly critical of exercise stress tests because once a patient has presented with symptoms that characterize angina, the exercise stress test adds little to the diagnosis. The NIH study notes that known unstable angina with recent chest pain is a contraindication to exercise stress testing. *Ann. Emergency Med.* 29:34 (1997).

The diagnostic value of exercise stress testing is greatly enhanced by the addition of imaging of the blood flow over the surface of the heart with radioactive tracers such as radioactive thallium - 201 injected intravenously. The NIH study suggested that the use of thallium in the emergency room should be restricted to specialized and limited situations in which the clinical triad of history, ECG changes, and enzymatic/laboratory measurements is not available. However, for non-ER evaluations the use of a thallium stress test is likely to be more predictive than a "plain" test in diagnosing cardiovascular disease.

### *Echocardiography*

Echocardiography creates images from reflected sound waves and reveals the motion of surfaces of the heart walls, the valves, blood flow, and the cardiac chambers. The transducer may be placed on the chest wall or inserted into the esophagus in a procedure called transesophageal echocardiography (TEE). Cardiac ischemia causes the

motion of the myocardium to change almost immediately to either smaller amplitude motions (hypokinetic) or to uncoordinated motions (dyskinetic). These changes in motion as well as cardiac wall thickenings and dissected arteries may be detected by the echocardiographer.

The difficulty with echocardiography is that patients suffering from chronic chest pain may not be ischemic when they report to the hospital, and may not show the characteristic changes in the motion of the myocardium. *Ann. Emergency Med.* 29:73. An additional complicating factor is that the accuracy of echocardiography is highly dependent on the skill and experience of the operator. In short, echocardiography is a highly specialized method with limited practical application which, if available, may provide useful results during episodes of chest pain. The NIH study concludes that echocardiography "still has a false-negative rate that precludes discharging all patients with negative echocardiography findings."

### *Holter Monitor*

The Holter monitor is an electrocardiogram produced while the patient wears the monitor continuously while going about his/her activities. The advantage of Holter monitoring is that it can pick up EKG changes during an episode of ischemia when those changes are most dramatic. "In patients with unstable angina, predischARGE Holter monitoring may be helpful in detecting continuing ischemia and stratifying patients into groups who can continue on a conservative medical therapy regimen." Eugene Braunwald: *Heart Disease: A textbook of cardiovascular medicine.* W.B. Saunders Co. (1992).

A 1993 study concluded that Holter monitoring identified a group of patients with increased risk of adverse cardiac events where exercise stress testing was nondiagnostic. Holter monitoring identified those patients unlikely to have a serious cardiac event with a predictive value of 99%. “No exercise variable considered was a predictor of adverse events, and a negative Holter monitor, even when coronary artery disease had been documented, reliably predicted a very low cardiac risk.” *Am J Cardiology* 72:892 (1993).

A recent trend in remote monitoring of cardiac function is telephonic “event monitors.” These devices send electrocardiographic information over telephone lines to the hospital and are triggered by the patient in response to pain episodes. Event monitoring is preferred over Holter monitoring in recent studies comparing the two. *Ann Intern Med.* 124:16 (1996); *Arch Intern Med* 157:537 (1997). Event monitoring may become the future standard of care for the diagnosis of cardiac disease, but it has not yet achieved that status.

#### *Arteriography or Angiography*

Angiography or arteriography are the “gold standards” for diagnosis of coronary artery disease. Most of the other methods described above have been characterized by comparison to angiography. Physicians are slow to use these methods because they are expensive, invasive, and require a catheterization laboratory. This reluctance to utilize the more expensive diagnostic tests is reinforced by the dictates of managed care cost standards and the use of primary care physicians as “gate-

keepers” who must justify referrals for more expensive procedures.

Considering the accuracy and sensitivity of angiography, its underuse may be false economy in cases of patients reporting symptoms of angina. Coronary arteriography has been identified in some reports as the logical second step for anyone with typical angina and for men over 40 and women over 50 reporting with atypical angina.

The American College of Cardiology/American Heart Assoc. Task Force issued guidelines for coronary angiography. Their list of “conditions for which there is general agreement that coronary angiography is justified in patients with known or suspected coronary heart disease includes symptomatic patients with angina pectoris that is unresponsive to medical treatment, unstable angina pectoris, variant angina pectoris, angina pectoris with other listed risk factors, and atypical chest pain of uncertain origin that EKGs or thallium stress tests indicate high probability of coronary artery disease.” *J. Am Coll Cardiol* 10:935-950 (1987).

#### **CONCLUSION**

The current standard for treatment of patients with chest pain is an EKG, nitroglycerin, and enzyme tests followed by an exercise stress test. Based on this protocol patients have been told that their chest pain was not cardiac, but caused by emotional stress, gastrointestinal problems, or gallbladder disorders. These diagnoses are often tragically wrong and based on a misplaced faith in the value of an EKG or a negative exercise stress test. If stress testing is to be used, it should be

supplemented with thallium imaging of the blood flow supplying the heart. Such imaging increases the dollar costs of an exercise stress test about three fold; however, the human costs of the present standard of care are unacceptable.

An attorney faced with a potential medical negligence claim involving a heart attack after complaints of chest pain, must evaluate the medical records to determine if the physician negligently relied on tests which have proven to be inadequate for diagnosing ischemic heart disease. Regardless of current or common practice, the standard for medical negligence is that of a “reasonably prudent” physician. Recent studies and reports have established that prudence calls for more than simply following outdated standards. There is ample medical literature that provides the attorney with a basis for challenging long-held standards and mandating consideration of further diagnostic testing for chest pain that may lead to myocardial infarction and death.

#### **ACRONYMS**

ECG = EKG = electrocardiogram. This analysis of the electrical events occurring during a heart beat was developed in Holland which explains the wide usage of K instead of C in the acronym.

ETT is an exercise treadmill test. An treadmill is used to raise the rate at which the heart beats and increase the heart’s demand for blood flow. The patient is monitored by electrocardiography (ECG). The typical test lasts about 10 minutes and involves increases in the speed of walking and the incline. These graded changes in the test

most often follow an agenda called the “Bruce Protocol.”

ACI is acute cardiac ischemia. Ischemia is the starvation of muscle cells for oxygen brought on by a reduction of blood flow.

MI is a myocardial infarction. An infarction is muscle cell death caused by an extended starvation of muscle cells for oxygen. The area of the heart that has died will not recover well and if the infarction is extensive, a transplant may be the only treatment.

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