Cardiovascular Disease

New Technologies, Efficiency and Medications

Barry Hackshaw, MD; Philip Shaver, MD; and Andrew Frutkin, MD

Statistics recently published by the Centers for Disease Control showed a slight decrease from 6.7 to 6 percent in the prevalence of coronary artery disease from 2006 to 2010. Variations between men, women and ethnic groups not withstanding, the report summarized the decline was due in part to treatment, but equally important, due to a reduction in risk factors like smoking, with an increase in healthier diets and exercise. Healthy Living recently assembled a group of Eisenhower cardiologists to discuss new technologies, procedures and medications which may have great relevance in the decline of cardiovascular disease. Participants included Barry Hackshaw, MD and Andrew Frutkin, MD. The session was moderated by Philip Shaver, MD.

Dr. Shaver : Let's begin with treatment for chest pain and heart attack. How have you found the advent of stents over just balloon angioplasty in treatment of heart attacks? Is that better and has it cut down on your time in the lab?

Dr. Hackshaw: It has made quite a bit of difference. The heart attack patient coming in has a combination of two problems in the artery — they have a cholesterol plaque that has ruptured and then formed a blood clot on it, so you have to deal both with the blockage and the blood clot. The better blood flow you get afterwards, the better job you have of reducing the blood clot complications…The success rate of being able to open that artery and get adequate flow is probably now about 95 percent, where with previous techniques with clot dissolving drugs it was closer to 75 percent. The more blood flow you can get through a blocked artery and the quicker you can get it there, the more likely you are to have a significant long-term beneficial effect on the patient.

Dr. Frutkin: The great success in the treatment of heart attacks has really come with a big push to achieve opening this artery in quick fashion, what we call the "door-to-balloon time," under 90 minutes. At Eisenhower we are probably closer to 60 minutes and that has been shown to benefit patients. They have more preservation of their heart muscle and less risk of heart failure. Time is muscle.

Dr. Shaver: You mentioned that the door-to-balloon time has progressively gotten better. How have you done it?

Dr. Hackshaw: The original things that we did were to coordinate efforts with the emergency room physicians and establish communication links to the cardiologist…such that a patient coming into the emergency room with chest pain would get an electrocardiogram within five to 10 minutes, then a phone call would go out to the cardiac catheterization team. The team would be mobilized and the patient would spend on average 30 minutes in the emergency room with us identifying the situation and explaining it to the patient. We then looked at procedures in the cardiac catheterization laboratory [cath lab] and modified the technique of how the angiogram was performed. For instance, we would not take a picture of the heart muscle beating. Instead of doing a complete diagnostic study, which might be six to eight projections, we would take only three or four projections. We would frequently put in the catheter which we would use for the balloon or stent procedure as a first choice rather than a diagnostic catheter first, and be prepared to, in as brief a period of time, identify all three blood vessels, locate the problem and then immediately proceed to a particular blood vessel that was blocked to open it.

Dr. Shaver: Does treatment start in the field?

Dr. Hackshaw: In the past year, through grants from local organizations, the emergency medical services in the county have been equipped with transmittable 12-lead electrocardiograms. So we have the capability to have an electrocardiogram performed and transmitted from the ambulance to the emergency room. We can be notified that the person is coming, and we can be clearing a catheterization laboratory or, if it's after hours, the cath lab team is called in before the patient even gets to the emergency roon

Dr. Shaver: The payoff to our patients is absolutely amazing — to have a heart attack and know they can come to a hospital and in 60 minutes, there is a good chance they're going to have a significant amount of heart muscle salvaged. It's the doctors committing themselves, the emergency department facilitating the process, and the cardiac team that comes in…to me it is incredible.

Dr. Hackshaw: We've significantly improved our times and have made a big impact. As a result of these efforts, a length of stay for a heart attack now is two to three days. These are some of our shorter hospitalizations for patients because some of these people have minimal or no damage. It's an incredible benefit to the patient.

Dr. Shaver: Barry, let's talk a little bit about heart catheterization and the wrist approach. I recall some time ago you did a national teleconference on this, because at that time it was fairly new. The approach kind of fell into disfavor, and now it's back. What should we know?

Dr. Hackshaw: Catheterization from the wrist gained popularity in the mid-1990s because there was a considerable amount of bleeding complications from catheterizations from the groin. When stents were first implanted, the anticoagulation protocols required multiple blood thinners, and people were having problems with large hematomas in their groin. The wrist technique was utilized because you didn't have the bleeding complications, but there weren't a lot of special pieces of equipment designed for the wrist. We led two teaching courses where cardiologists from all over the western United States came to learn, and in the 500 cases that we did, we had a 97 percent success rate. Then the bleeding complications from the leg decreased, because people were no longer required to take Coumadin after stent procedures and the ability to control the bleeding in the groin was improved with what are called closure devices. The other reason, and probably the primary reason that I stopped doing wrist procedures, was that people were developing a noninfectious reaction at the site in the wrist where the catheters were put in. It eventually was shown that this was related to the coating on the sheaths and it wasn't really an infection, but it was an awkward complication that detracted from the procedure. In the last several years, specific equipment has been designed for wrist procedures and it is internationally probably the preferred treatment. There has been a rebirth of radial procedures in the United States and the teaching programs are now accepting it and are teaching new cardiologists how to do this.

Dr. Shaver: Dr. Frutkin, are you doing this?

Dr. Frutkin: I use the wrist approach as my first approach, so that translates into 80 percent of my cases being through the wrist approach, or the radial artery approach. There is great concern about bleeding in patients who have undergone coronary intervention, particularly in the setting of heart attacks. People who bleed in the setting of heart attack or coronary interventions have a much higher rate of morbidity and mortality. In an effort to reduce that morbidity and mortality, we have been looking for ways to reduce bleeding and the radial artery approach is one of those ways. Also, importantly, patients find the radial artery approach much more comfortable. For instance, a patient undergoing radial artery catheterization is able to sit upright immediately after the procedure and ambulate sooner.

Dr. Shaver: Let's talk about some evolving technologies that our patients and readers will be hearing about if they haven't already. I have had patients come into my office with a condition called aortic stenosis and tell me they have heard that a valve can be placed into a catheter and say they wanted that. This new technology goes by two terms, either TAVI (transcatheter aortic valve implantation), or the more preferred term now is transcatheter aortic valve replacement or TAVR. How is this new technology different? **Dr. Frutkin:** Aortic valve stenosis is a mechanical obstruction of the aortic valve that limits blood flow out of the heart. People ultimately have symptoms of angina, loss of consciousness, or heart failure.

Dr. Shaver: For patients who don't understand the term stenosis, I explain it this way: if there's a fire in a theater and everyone runs to the exit, if the doors fly

open, that's like a normal aortic valve. If the doors open just a crack and everyone has to get through quickly, that's comparable to stenosis.
Dr. Frutkin: It's an excellent analogy. When people are symptomatic, they have a high rate risk of dying from that valvular disease, so survival is about 50 percent at two years once you have symptoms and about 20 percent at five years, once you have symptoms.

Dr. Shaver: Anyone who has symptoms with this condition should theoretically get the valve replaced?
Dr. Frutkin: Historically surgical valve replacement has been very effective and safe. When people have their aortic valve replaced, they can go on to lead full, productive lives without any of those residual symptoms...the surgery is well-tolerated.

Dr. Shaver: Let's delve into the group who are told they can't have surgery — they're just too high risk.
Dr. Frutkin: We have understood for years that in patients deemed too high risk for sugery, we could put a catheter across the severely narrowed aortic valve and dilate it with the balloon. Therefore, the next approach was to create aortic valve prostheses made of animal tissue that could be delivered across the original valve on a stent platform.

Dr. Shaver: Currently, the surgeon actually takes out the diseased valve. How does this new technology, which is done through a catheter, work?
Dr. Frutkin: There are two approaches to how you deliver such a stented valve. One is to access the arterial system, for instance the femoral artery in the groin or the axillary artery in the armpit, and put in a large bore catheter through which this stented valve can then be delivered.

Dr. Shaver: If you don't have big enough arteries, such as is the case for a small woman, you're not a candidate for this approach.
Dr. Frutkin: The other alternative that gets around the issues of the petite individual or the person with bad vascular disease, is to deliver the catheter through the chest where a small hole is made in the left chest, and the catheter is delivered right through the apex of the heart…to the aortic valve.

Dr. Shaver: Doesn't that expose a patient to some risk of stroke or embolization?
Dr. Frutkin: That brings up one of the major points with this technology; it offers a potential solution to these very sick patients…but it certainly exposes them to increased risk compared to surgical aortic valve replacement. The first risk is an increased risk of stroke. In the original trial, called the PARTNER trial, the stroke risk was about six percent for the TAVR compared to one percent if you just had medical therapy or two and a half percent if you had surgical therapy, and the risk of stroke increased 30 days to one year after surgery.
Dr. Hackshaw: There's no question that these procedures have a better outcome, the higher the volume [performed by the physicians] that are doing them. There is not going to be a thrust for every hospital in the country to put in these valves. It's going to be at centers that are willing to commit the resources that are required to properly assess the patients and select the proper treatment. Each center is going to be monitored for the success of implanting valves and will have to apply as a center to get the technology, and then be able to provide the service with the lowest possible rates of complications.

Dr. Shaver: Let's move on to medications and looking in the future. Regarding statins, most cardiologists believe these drugs are lifesavers; they lower LDL, (bad) cholesterol. I think they've been one of the most important advances in my 40 years being a physician. There's a class of drugs called CETP inhibitors and there was a trial of one agent, for example, Torcetrapib, a few years ago…and it increased mortality. There was something wrong with that drug, but industry researchers continued, and recently in The Journal of the American Medical Association, there was a new study on Evacetrapib showing a great increase in HDL, (good) cholesterol, while not raising blood pressure. I think we're not done with this class of drugs.
Dr. Hackshaw: It also showed a significant reduction in LDL. It does both — raises HDL and lowers LDL — which we haven't really had before in a class of drugs. People are under the impression that a high HDL is protective. Once you get above a certain level, it really doesn't add much more protection. The real problem with HDL is that low HDLs are substantial risk factors for coronary artery disease. So just raising HDL is really important if your HDL is between 20 and 30 or 30 and 40. But if your HDL is already 60, I don't believe that 100 is that much better and I think that's why we've tended to miss a lot of women with heart disease. I had a patient come into my office the other day, whose doctor had consistently told her there was no problem with her cholesterol. Her HDL was 80. Her LDL was 166. She is at risk. You can't have enough HDL to counter that.

Dr. Shaver: UCLA did a number of studies a few years ago, showing in some patients with high HDL, that it was actually pro-inflammatory, that it was not protective. We think of HDL as being the particle that goes to the arteries, takes the cholesterol out of the arterial wall and takes it back to the liver for disposal, but in that time, it also transfers some of that to the harmful lipid particles, for example, the LDL and the VLDL. If you can block that passage of cholesterol, and that's what these new drugs, the CETP inhibitors do, you now get these very large HDL particles. The question is, is that beneficial? Are they just big and inert or are they actually taking bad cholesterol out and eliminating it into these particles that are just going to take it right back to the arteries. We don't have outcome data.
Dr. Frutkin: That's going to be critical…this class of drugs is now going to have to prove itself with outcome data in order to be released. We also have another drug on the market, Zetia, that lowers LDL. We're waiting for further outcome data.

Dr. Shaver : Do you still use it?
Dr. Hackshaw: I use it in two indications: those individuals who can't tolerate statins and those individuals who are not at target on statin therapy.

Dr. Shaver : I'm hoping that this is a useful drug. For people maxed out on statins that are high risk, diabetics, have coronary disease, and you can't get their LDL below a 70, that drug works wonders.