An Expert's Perspective: The Controversy on Drug Coated Heart Stents
Hot Topic
December 7, 2006
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Introduction

Andrew Schorr:
This is Andrew Schorr from Patient Power. One of the controversies that is going on right now, a hot topic, is for people who have blocked or narrowed heart arteries, what's the best way to approach it. Are drug-coated stents safe, effective, a good way it go, or are there concerns about clotting that could cause other serious problems? We're visiting with someone who has had broad experience with stents and certainly drug-coated stents since they've been on the market. That's Dr. Larry Dean. He's a professor of medicine and surgery at the University of Washington in Seattle. He's also director of the University of Washington Medical Center's regional heart center. Dr. Dean, thanks for being with us.

What are the Risks?

Dr. Dean:
Thanks very much, Andrew.

Andrew Schorr:
Dr. Dean, tell us what is the concern? There are studies that have come out and I know you always want more study to understand it better, but studies that raise concern, and the FDA has now had hearings today and then again tomorrow with leading experts, some of your peers, to try to understand how serious. Is there some unanticipated risk of these drug-coated stents? What's the concern?

Dr. Dean:
Well, the concern that has been raised over the last couple of months has been thrombosis or clotting of the stent. We've known that there has always been a problem with stents when they're placed, either drug-eluting stents, drug-releasing stents or bare metal stents for that matter. But more recently several studies have come out where they've combined studies in what is called a meta-analysis, first one out of Europe and several out of the United States more recently, suggesting that perhaps there is a problem with increased clotting or thrombosis of these drug-eluting stents. We know for a fact that the drug-eluting stents are very effective and that they decrease the renarrowing of blood vessel blockages somewhere between 50 and 70 percent, but in the process of doing that they actually inhibit healing and so it exposes the stent material to the bloodstream for a longer period of time. So it looks like there may be an increased
incidence of stent thrombosis or clotting, and it also looks like it may go on for several months, maybe even over a year perhaps, so the concern is not only about thrombosis but how long do patients need to be treated appropriately.

Andrew Schorr:
Okay. So let's talk about the significance of this. There are millions of people with heart disease, and there are hundreds of thousands at least of people who are treated with some of these devices, and then there are people in previous years. Typically my understanding is they are given medicines to prevent some coagulation to reduce the risk of clotting. I know there's one drug, Plavix, you can give us the other name, the generic name, and then people take aspirin too. What's the typical follow-up care for people, and how does that come into play here?

Dr. Dean:
Well, I think the cornerstone of the treatment of coronary disease has always been aspirin, been around for many, many years and we've known the positive benefit of that. With the development of these stents, and that's actually a foreign body that's placed inside the blood vessel, it's a permanent implant so to speak, we have to give blood thinner while that's healing in place. So aspirin is given but also Plavix, or clopidogrel is the generic name for that drug, are given in combination for several months. With bare metal stents it's probably approximately four weeks. With the drug-eluting stents it's probably between three and six months. Now, the concern has been raised that perhaps even that's not adequate. There are some reports of these devices closing very late, even after a year, so at this point it's not clear exactly how long we need to continue both aspirin and clopidogrel, or Plavix.

Andrew Schorr:
Now, with any drug therapy there are always compliance issues, people either forgetting to take their medicine or certainly we have had with seniors where some of these heart medicines are expensive--I've heard Plavix can be as much as four dollars a pill--where somebody may say, well, maybe I can cut back on that or not do that at this time, and it sounds like that's the concern, that that could have serious consequences for someone.

Dr. Dean:
I think a very important take-home message from today's conversation is really that particular problem. We know that it's absolutely critical with anyone who has had a drug-eluting stent placed be on dual antiplatelet drugs, aspirin and Plavix, for a number of months, or they're at risk to have the device close suddenly. So it's really very, very important that patients not stop these drugs. I know everyone has gotten concerned about what's been in the newspapers and what not, but the important take-home message is do not stop the clopidogrel and aspirin unless you're told to do so by your immediate caregiver, cardiologist, primary care physician, because it is critically important that those medicines be taken together.
Further Study Needed

Andrew Schorr:
So now we have a vote with experts like yourself advising the FDA and say, well, we think these drug-coated stents are safe and continue, stay on the market and are highly effective, but, and they say that unanimously now, but there seems to be some agreement that there needs to be further study.

Dr. Dean:
I think that's very true. One of the problems we have right now is that these devices when they're looked at by the FDA are looked at from the standpoint of treating coronary disease, and so they really weren't being looked at from the standpoint of thrombosis or blood clotting as a primary point of concern. Because we've always known there has been some clotting in all these devices if you don't take your medications in particular until they heal up.

So I think it's fair to say that at this point we don't really know, and there are several potential issues around that. One is we don't know, as you alluded to a moment ago, in the studies that have been done so far, how many people really took their Plavix, or clopidogrel, as directed. Did they take it the full length of time or did they not? That might explain why some of these are closing. Was it properly placed? I think these devices do require very meticulous technical expertise to place them properly. They don't have as much leeway from the standpoint of being placed properly, so that's very important. And then I think finally we don't know exactly which patients are closing. Is there something else going on here? Is there some other problem with the blood vessel for example? We don't really have that kind of detail. So what we really need to know is more information about exactly why these are closing, how many are closing, and then try to figure out how to stop this from occurring.

Andrew Schorr:
And when you say closing you mean clotting forming around the device?

Dr. Dean:
Exactly. That's obviously of grave concern, that would produce a heart attack.

Andrew Schorr:
Stroke?

Dr. Dean:
Not necessarily a stroke, no. These stents we're talking about today are in the coronary circulation, the heart circulation, so they only cause a heart attack. Not that that's anything you would want to have necessarily, but that would be the problem more than a stroke.
How to Prevent Problems with Stents

Andrew Schorr:
So people need to continue to take their medicine. Now, you in the medical community and you as an interventional cardiologist this is a staple of what you do. Are you doing things differently now as far as thinking about, well, who are these devices--while we have some concerns, we need further study, am I going to use them as frequently or as broadly? Am I going to have a change in maybe who I would want to go forward with this, who I would recommend this too?

Dr. Dean:
I think it has modified our practice to a fairly small degree actually. It has had some impact across the country in variable amounts. Some people have had great impact on their practice. We think these devices are very, very important tools in the treatment of coronary disease. As I mentioned a moment ago, they are very effective at stopping renarrowing, so they've essentially stopped people from having to have multiple procedures done, which is an important thing for patients.

But having said that, clearly if we have patients that need to have surgery in the near future where we might have to stop drug to let them have surgery safely then we would factor that into the equation more carefully. Patients who may not have the means to afford the medicine or aren't compliant for other reasons, it's just difficult to take medications. Anybody who has taken more than one it's tough to take medications consistently. So if we have any concern about that, then we would avoid using a drug-eluting stent. Outside of that I think our practice has been pretty much the same, and that is in the bulk of patients we think the benefit of these devices far outweighs any risk, although again we are concerned about the problem of clotting.

Andrew Schorr:
And then in someone's discussion with their cardiologist, though, there are other ways of approaching this that are--have been around a long time, whether it's bypass surgery or using stents that are not coated. And I imagine you still use balloons to open up arteries too, right?

Dr. Dean:
Well, the older guys in the community, including myself, yes, we still use some balloons. I think the younger cardiologists don't have as much experience with that because stents have been around now for over a decade. But, yes, we still do balloon angioplasty on rare occasion. We do use bare metal stents or noncoated stents. Those are very effective in larger blood vessels. Where we really run into trouble with renarrowing is really in the smaller blood vessels, which a lot of people have fairly small blood vessels. But if we have a very large blood vessel then we would go with a bare metal stent. And then if somebody had multiple blood vessel blockages in multiple blood vessels and/or had diabetes, then we would probably lean much more toward bypass surgery rather than putting in, you know, half a dozen stents of any kind, bare metal or drug-eluting, for that matter.
Andrew Schorr:
So how would you characterize what has been in the news now and the FDA looking at closely with cardiologists around the country? Is this sort of a slight yellow light? Is it a red light? Is it something where you think these procedures will still go on and have their place in daily care?

Dr. Dean:
Well, I think to a certain degree the lay press has made it a bit of a red light. I think it's a yellow light. I think the FDA with their panel recommendations, it will be a yellow light. It will not be a red light. These devices will not be taken off of market, and I think because of that it's nice that we have the scientific approach to this, a measured approach to this, look at the information, try to figure out what's going on, rather than getting things into the press that sometimes frighten people significantly. We've had people call us very, very concerned about this and rightly so. We're not trying to minimize that. But on the other hand it's important to understand the magnitude of the problem and the fact that this is not as clear cut as has been alluded to in some of the lay press.

Andrew Schorr:
And it seems like that's coming out of the FDA hearings too, is that unanimously the experts support the use of these products. So, take your medicine if you have had one of these devices. Be in close communication with your cardiologist. Certainly don't make a change on your own, and then have a considered discussion with your doctor should you need a procedure like this to see what's right for you. Does that sum it up pretty well?

Dr. Dean:
Absolutely correct. I think that last point you made is very, very important. Rather than taking the word of some of the things that have been published out there I would work closely with my physician whom I have confidence in to make that kind of decision along with me.

Andrew Schorr:
Okay. Thank you so much for being with us again on Patient Power, Dr. Larry Dean, who is the director of the University of Washington regional heart center and a professor of medicine and surgery at the University of Washington. Thanks for being with us.

Dr. Dean:
Thank you very much. Again, it's a pleasure.

Andrew Schorr:
This is Andrew Schorr with Patient Power. And as always, remember, knowledge can be the best medicine of all.