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Antiplatelet Therapy After Drug-Eluting Stent Implantation

You are listening to ReachMD, the Channel for Medical Professionals. Welcome to Heart Matters where leading cardiology experts explore the latest trend, technologies, and clinical development in cardiology practice. Your host for Heart Matters is Dr. Doug Weaver, President of the American College of Cardiology.

It is no longer a question of whether antiplatelet therapy should be used following implantation of a drug-eluting stent, but rather to what extent and to what duration? With this in mind, many new challenges arise from bleeding risk to drug intolerance and product cost. How are we moving to address these concerns? Our guest today is Dr. Peter Berger, an interventional cardiologist and Associate Chief Research Officer and Director of the Center for Clinical Studies at the Geisinger Clinic in Central Pennsylvania.

DR. DOUG WEAVER:

Welcome Dr. Berger.

DR. PETER BERGER:

Hi Doug, great to be here.

DR. DOUG WEAVER:

What is our current understanding about the risk of subacute thrombosis in drug-eluting stents and bare-metal stents? A couple of years ago, there was a lot of press as well as a lot of article saying that this was a serious risk.

DR. PETER BERGER:

Unfortunately, we have to learn more than we currently know, but it appears that for the first 9 or 12 months, the risk for stent thrombosis for drug-eluting stents and bare-metal stents appears to be about the same, but following that first year, some estimates indicate that the risk of drug-eluting stent thrombosis is in the range of 0.3% to 0.5% per year or 3 to 5 per 1000 and some of the data sets suggests that that risk may persist 3 and 4 years and perhaps beyond. So, we have a lot more to learn, but that's the range of the upper boundary of risk and the duration to which we know it.

DR. DOUG WEAVER:

So, currently what do the package inserts for these stents recommend as far as anticoagulation?

DR. PETER BERGER:

It's sort of an embarrassing situation how those package inserts came about. In the trials that let to the approval of the first drug-eluting stents, it was mandated that patients receive 3 months of dual antiplatelet therapy and that's usually aspirin and clopidogrel if it was a sirolimus-eluting Cypher stent and 6 months if it was a paclitaxel-eluting Taxus stent, but the sad reality is there was already data at that time indicating that longer durations of dual antiplatelet therapy might be beneficial in many circumstances. So, in those trials, we know just how many patients received it for the protocol-mandated minimum requirement, but we didn't know how many patients actually continued it for much longer periods of time. So, while the package inserts say 3 or 6 months, most patients undoubtedly receive longer durations and that's partly how we ended up in the mess that we are.

DR. DOUG WEAVER:

So, given the risk of subacute thrombosis and what you have told us, what are your current recommendations or the recommendations

of organizations like the American College of Cardiology?

DR. PETER BERGER:

Aware of the fact that they did not know what the best answer was, it was nonetheless recommended that dual antiplatelet therapy with aspirin and clopidogrel be administered for a minimum of 1 year in all patients who receive a drug-eluting stent and although that sounds like a logical suggestion, I want to make it clear that we do not know that the risk of stent thrombosis at 10 or 11 months is significantly different than the risk at 13 and 14 months. So, that was only a general recommendation and I think it does serve the purpose, and interventional cardiologist and other physicians would not place a drug-eluting stent in patients in whom it is very unlikely they will be able to be on dual antiplatelet therapy for a year, but that should not mislead anyone into thinking that we know that 1-year therapy is sufficient, we do not.

DR. DOUG WEAVER:

And the recommendations for bare-mental stents, you imply they are much safer?

DR. PETER BERGER:

It is interesting. First, I think they were only safer for subsequent years. The risk for the first year appears to be about the same, but there it is a little ironic and that we know that while only 2 to 4 weeks of dual antiplatelet therapy is what is required to prevent stent thrombosis, there have been 2 randomized trials indicating that longer durations of dual antiplatelet therapy are better than shorter, not in preventing stent thrombosis, but in preventing thrombotic events elsewhere in the vasculature. So, the guideline to even recommend 1 year of dual antiplatelet therapy in patients who receive a bare-mental stent, not for stent thrombosis but for MI and stroke remote from the treatment site.

DR. DOUG WEAVER:

Do we have any information about how compliant patients are with this recommendation for dual therapy? Clopidogrel is a relatively expensive drug and I believe that some patients have troubles with bleeding and other side effects.

DR. PETER BERGER:

Doug, you are so right and there is so much research going on in those areas. We are finding out almost weekly from another study that fewer patients are taking their prescribed medications than it was thought and it is interesting to need to note that all of these studies often defer from one another on the reason that patients don't continue the dual antiplatelet therapy as was prescribed. So, some studies indicate that cost is one of the largest obstacles. This point out that physicians don't tell the patients how critically important it is that it be continued. We know that primary care physicians may not have been informed by the interventional cardiologist why the patient needs to be on dual antiplatelet therapy and for how long. So, there are lots of reasons that the studies are coming forth with, but they are all indicating that noncompliance is more common than physicians realize and more common than it were to be.

DR. DOUG WEAVER:

I would like to ask you some specific problems that might be encountered and that would be how do you handle the patient who has a drug-eluting stent, is on these therapies, and then either develops atrial fibrillation and may require warfarin or you are about to implant a stent in these patients on warfarin to begin with.

DR. PETER BERGER:

Two very different situations for the patient who is on warfarin already and for whom there is a strong indication, it's generally worth avoiding placement of a drug-eluting stent. We wrote the first paper on triple antithrombotic therapy, aspirin, clopidogrel, and warfarin and no surprise people bleed more on 3 such agents than they do on 2 and 2 more than 1. So, when you get up to aspirin, thienopyridine, and warfarin, you are really running into high bleeding rates. So, if you know in advance that the patients are going to be on warfarin, it is generally best to avoid placement of a drug-eluting stent. Now, if the patient's indication for warfarin is for example that a 66 years of age can have lone a-fib, although that's a little different, they can probably have their warfarin withheld for at least a year and the risk of stroke will be really, really small, but if the person for example has a tilting disk in the mitral position with atrial fibrillation and can never be off warfarin except for rare instances, they are always to see if a bare-mental stent in a short duration of thienopyridine. Now, if the patient develops the indication for warfarin after placement of a stent that requires long treatments of warfarin, we try to keep the INR a little lower than we otherwise might, in the 2 to 2.5 range, well aware that the data suggests that we are not as able to do that as we like to and we always want to give the lowest dose of aspirin possible, a baby aspirin 81 mg a day, nonenteric coated and often there are some data, although I don't think this rises to the level of proof, but there are data to suggest that the administration of proton pump inhibitor were to be recommended along with aspirin, thienopyridine, and warfarin.

DR. DOUG WEAVER:

So, warfarin really complicates the treatment regimen.

If you are just joining us, you are listening to Heart Matters on ReachMD, the Channel for Medical Professionals. I am you host, Dr. Doug Weaver. Our guest is Dr. Peter Berger, Director of the Geisinger Center for Clinical Studies in Central Pennsylvania. We are discussing the challenges of managing antiplatelet therapy following implantation of a drug-eluting stent.

Now, Peter back to some of the other special situations. How do you handle the patient who needs a dental procedure, colonoscopy, possibly orthopedic surgery?

DR. PETER BERGER:

Doug, I am so glad you raised that because that's a terribly important point for the healthcare professionals, who aren't implanting these stents. There have been lots of studies indicating that for dental procedures, for bronchoscopy, for endoscopic procedures, for cataract surgery, for routine dermatologic procedures, there are hard data to indicate that dual antiplatelet therapy need not be discontinued and those procedures can be performed while the patient is taking aspirin and clopidogrel, depending on the orthopedic procedure and some other more significant procedures that may not be true and then there are some procedures for example like brain and spinal cord surgery where absolutely it has to be discontinued. So, the first point I would like to emphasize is that again a drug-eluting stent would not be placed in a patient known to require those procedures and it's terribly important for the primary care physician to make that known to the interventional cardiologist, who may not learn that critically important data in a short amount of time they have with the patient. When the need first arises after the drug-eluting stent is placed, if it is entirely elective surgery, if it is an elective knee or hip replacement, it were to be deferred and we think it were to be deferred at least a year, but absolutely the first 6 months, we noted for the first several months, the risk of perioperative stent thrombosis is greatest especially, but not only if the patient has to continue one or both of their antiplatelet agents. That is a very important issue you raised, Doug.

DR. DOUG WEAVER:

And what about emergency procedures? Let's say a patient who is a victim of trauma or perhaps had appendicitis, are they at greater risk when these things are stopped and do they have to be stopped?

DR. PETER BERGER:

We know that they are at greater risk and it's a greater risk even than just stopping the medication. Remember that when you stop the medication, the effect is irreversible. Platelets live about 7 to 10 days so that the effects wear off gradually over 7 to 10 days, but it's not only that the drugs are wearing off, it's that eventually you just described and the treatment of those events, trauma and surgery are enormously pro-thrombotic. Furthermore, a lot of the anesthetics and other medications these patients receive are pro-thrombotic. So, the risk of perioperative stent thrombosis particularly when the surgery is performed in the months after placement of a drug-eluting stent are really quite high and the risk is believed to diminish over time. It gets we think under 5% once you can wait 6 months or so and it gets even lower we believe if you can wait a year.

DR. DOUG WEAVER:

So, it sounds like in those kinds of situation, it is good to get an interventional cardiologist involved to help you with the decision-making because it isn't straight forward and you obviously want to protect the patient as much as you can as well as advise the surgeon as to what the real risk of drug-eluting stent thrombosis could be. Is that true?

DR. PETER BERGER:

Fantastic point, I strongly agree and anesthesiologists may also have to be involved and let me just give you 1 other example if the drug-eluting stent was placed in the third obtuse marginal branch that's supplying blood to a small portion of the heart, it may be much more important to stop the medications and perform the surgery as rapidly as possible in contrast to if it is an unprotected left main or left main bifurcation in which case stent thrombosis will be immediately fatal. So, ya, I think that kind of suggestion is terribly important.

DR. DOUG WEAVER:

Peter, is the risk of thrombosis the same for all drug-eluting stents or are there differences?

DR. PETER BERGER:

We are learning that there do appear to be differences, but we have a lot more to learn. The studies indicating what I just said are small, but it is looking like and remains to be proven, but it is looking like the risk may defer for different drug-eluting stents. They may also

defer depending on the clinical situation and anatomic characteristics in which they are placed.

DR. DOUG WEAVER:

We have been talking with Dr. Peter Berger about the challenges of managing antiplatelet therapy following implantation of the drug-eluting stent. Dr. Berger, thank you very much for being our guest today.

DR. PETER BERGER:

My pleasure.

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