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The Real Story on Stents: A Bright Future?

DRUG-ELUTING STENTS OR BARE-METAL STENTS, CAN PATHOLOGICAL DATA ACTUALLY SHED LIGHT ON THE MATTER

Drug-eluting stents or bare-metal stents, can pathological data actually shed light on the matter. Welcome to The Clinician's Round Table. I am your host, Dr. Larry Kaskel, my guest today is Dr. Renu Virmani, President and Medical Director of the CV Path Institute in Gaithersburg, Maryland and a Clinical Professor of Pathology at Georgetown University, The University of Maryland, George Washington University, and Vanderbilt University. Dr. Virmani is internationally recognized and has received numerous awards and honors for her work in cardiovascular pathology.

DR. LARRY KASKEL:

Dr. Virmani thanks for coming on the show.

DR. RENU VIRMANI:

Thank you.

DR. LARRY KASKEL:

Well you have looked at every stent on the market, it seems, and you have seen the stents do their job in animals and humans. So what is your current opinion in 2008 of the usage of stents for let's say someone with stable angina.

DR. RENU VIRMANI:

I think in stable angina, there is certainly use for drug-eluting stents. They do reduce restenosis. That's what their main function was, that's why they were created and they certainly reduced restenosis, but the question really is in a large vessel, which is 3 mm or greater, do we need a drug-eluting stent, you know they also cost a lot more. So I would say that in a large vessel, there is no need to put a drug-eluting stent and we could use a bare-metal stent, but in small vessels, certainly I think bare-metal stents do not work very well and, in fact, you do require drug-eluting stents, but there are drawbacks of drug-eluting stents as I think you know and all of you know and that's you have to keep the patient on antiplatelet therapy for at least 1 year, so if it is an elderly patient, 70 years or greater should you be putting because drug-eluting stent, because you may need to go to surgery and nobody wants to do surgery, the surgeons don't want to

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do surgery if the patient is on antiplatelet drugs.

DR. LARRY KASKEL:

So is DES worth the trouble. Are these people living any longer than someone who does not have a DES stent.

DR. RENU VIRMANI:

I mean, as yet we do not have any data to prove that.

DR. LARRY KASKEL:

So there is a lot of money going into DES stents without the evidence.

DR. RENU VIRMANI:

So far, you are right. We do not have evidence, but they've not been on the market that long either. They have been on the market only since 2003, I believe, in this country, and at the moment, there are only 3 of them on the market. There is the Cypher, the Taxus, and the Endeavor. So these 3 are on the market and the first 2 are, Cypher and Taxus are the 1st generation. They have been sold in Europe for a while, I think 2002 or so. So they really have captured the market and in the United States, we were using them in 80% to 90% of cases which I don't think was required and then you know whether you should use them on-label, off-label, on-label being these are stable patients or acute coronary syndrome patients, but not acute myocardial infarct, not for left main, not in vein grafts, not in bifurcation lesions, so there are indications for which they have not been approved.

DR. LARRY KASKEL:

There is a new stent out or coming out or in research by a company called Xstent. Are you familiar with that?

DR. RENU VIRMANI:

I am familiar with that, certainly.

DR. LARRY KASKEL:

So that is I think just longer stents, which because I think one of the problems when you stent is, okay you have solved that problem, but then they go on an infarct from another plaque downstream. So does the XStent stent solve that problem?

DR. RENU VIRMANI:

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One of the things that drug-eluting stents have had, this came out in 2006 in European Society of Cardiology, that there was a higher incidence of late-stent thrombosis, but large trials that have been, there is a slight increase in the rate of late-stent thrombosis in stable patients. I think in stable patients beyond 1 or 2 years, I think these tend to heal those, lesions tend to heal in stable patients, but I think when you start putting them everywhere where you don't know what type of lesion it is, you have an acute myocardial infarction, these drug-eluting stents are being used in patients with acute myocardial infarction. I don't think they should be used in those because there are data which suggest they have a higher incidence of late-stent thrombosis, so I think they should be used judiciously, not in every patient. I don't think there is need to use them in 80% of patients. I would say that 30%, 40%, 50% at most.

DR. LARRY KASKEL:

So we need to have a clone of you in every cath lab talking to the cardiologist before he stents somebody.

DR. RENU VIRMANI:

I don't think you can get a clone or you can get a person who will agree with me all the time. Most of them don't, but I think the data will suggest to you that they do cause problems.

DR. LARRY KASKEL:

Right, well you are challenging their belief systems.

DR. RENU VIRMANI:

Yes, but I think they are beginning to believe what I am saying. We published data that we show that if we could identify cases where patients who have uncovered stent, means the stent strut doesn't have any neo intima on top of it, there are no smooth muscle cells, no endothelium on top. Those, the more that the struts are uncovered, i.e. we showed that if there are 30% per section, you don't have uncovered struts, those are ones that are going to thrombose.

DR. LARRY KASKEL:

If you have just tuned in, you are listening to the Clinician's Round Table. I am your host, Dr. Larry Kaskel. My guest today is the world famous, Dr. Renu Virmani, President and Medical Director of the CV Path Institute in Gaithersburg, Maryland and we are talking about the real story on stents.

Dr. Virmani is there some sort of futuristic systemic approach like cryotherapy that would actually take care of the problem, so we wouldn't need stents.

DR. RENU VIRMANI:

I am not convinced cryotherapy is necessarily going to solve our problem. May be in the future, they will be you know, they put paclitaxel on a balloon and they are saying that will solve the problem. We don't have to put stents, but I think these as yet have to be proven. The

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newer technologies have to be proven. I think overall you know drug-eluting stents are a good idea, it is not a bad idea, but we can improve upon it. Part of it is, you know, the polymers, you have to have better polymers. Part of it is we loaded too much of the drug on it and we don't need that much drug for such a long-time delivery. So there are things that we are beginning to learn that will improve the next generation of drug-eluting stents like you suggested XStent. XStent certainly has bioerodible polymer instead of a non-erodible polymer, it doesn't overlap. That's another thing, which is very nice. One of things we showed was when stents are overlapped, those are where we get into problem of stent thrombosis. Because there is much more drug there. You now concentrated the drug where you put 1 stent on top of another, so you know there are things we can avoid that the new generation of drug-eluting stents will be better. I think we will master this. I think and we will also learn, which lesions need to be treated with a drug-eluting stent, which don't need to be treated. I think the future is bright. It is not to say that everybody should be getting drug-eluting stent. Absolutely not.

DR. LARRY KASKEL:

Can you tell me a little bit about what your experience has been with the newer bioabsorbable stents and can you actually put a drug-eluting polymer in that stent and do these struts allow them to stay open.

DR. RENU VIRMANI:

Yes they have done this, Abbot has a stent called BVS, that stent is totally bioerodible. They have implanted these in about 40 patients in Australia, New Zealand and they published the data on that. That they showed in very pristine small lesions that these worked and that they didn't cause, there was only 1 incidence of thrombosis and there was no restenosis and they have put drug on top of it and they have now shown that 2 years out that the stent disappears, so it is a thought, I mean it is a process, but I think it is a difficult process because the stent loses its integrity fairly quickly and then if you had very calcified lesions, you couldn't apply them. So I think, especially in think where they will be very useful are in young congenital heart disease, like you have pulmonary stenosis, aortic stenosis, because as you know if you put a metal stent, it doesn't grow with the patient. So that's where I think they have a great future.

DR. LARRY KASKEL:

I would like to ask some more personal questions if you don't mind. How did you become really the queen of coronary histology, because it seems like your name is everywhere and everything flows through your labs.

DR. RENU VIRMANI:

Well I wouldn't call myself the queen, but I would say that yes, I do see a lot and I trained at NHLBI under 1 of the best cardiac pathologists at that time, I will say, William C. Roberts who is very well known in the field of cardiovascular pathology and is still going strong. He has a journal called the American Journal of Cardiology. He is the editor of it and I learnt a lot from him and then I branched off, went to the Armed Forces Institute of Pathology where I had a laboratory of my own and continued to do research and publish, and I think everything is publishing and hard work, that is I think all what I did.

DR. LARRY KASKEL:

What do you do when a new company comes to you with a new stent and you do their research and their data is not so good. Do you have the power to essentially kill a stent.

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DR. RENU VIRMANI:

I don't know that I have the power, but I certainly will tell them, their stent is not very good. Don't put it in patients.

DR. LARRY KASKEL:

But then does that data just not get published?

DR. RENU VIRMANI:

Sometimes it gets published, sometimes it doesn't, I have to be honest. Some data will get published and some will die in the research fields because it depends on the polymers emerging, they put a polymer on a stent and the polymer is no good and we find huge inflammation, we do it in animals and we don't bring it to, we don't what to show that everything is bad because it could be that it had impurities and it was nothing to do with the polymer itself, so there are many factors which play a role in all these, but anything that comes in the market, I can guarantee you that we try and publish. My first goal, I am a non-profit organization, my first goal is to publish things.

DR. LARRY KASKEL:

So there is no product out there that you did the research on and advised them not to do it and it hit the market.

DR. RENU VIRMANI:

Well, yes, I would say one of the early stents, I was not in favor, but then the clinicians wanted t do it and I said, no I think this is a bad drug, you shouldn't be putting this stent in people, but they did it anyway because they listen to clinicians and not to me, but I really was the first one to tell them this will never work.

DR. LARRY KASKEL:

Dr. Virmani what treatments or therapies that are emerging are you really excited about.

DR. RENU VIRMANI:

I think, you know there are newer ways of bioerodible is 1 way, but I think bioerodible on a metal stent is another way. I think just nitinol stents is another one that I like, nitinol self-expanding stents I believe is the way, CardioMind has such a stent, which is meant for small vessels, so there are new technologies and also there are ways of treating heart valves for example percutaneously, that's very exciting.

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DR. LARRY KASKEL:

You said you are a not-for-profit organization, so let's pretend for a moment that you were interested in money, and you had a $100,000 to invest in the hottest company that you believe is going to hit it big and have the stent that's going to take over the world, what would it be?

DR. RENU VIRMANI:

It hasn't come on the market as yet, but Terumo makes a very nice stent. It is a company, Japanese company, makes a very nice stent and I think with the newer technology, bioerodible material on it, that is likely to come on the market, will be very exciting.

DR. LARRY KASKEL:

Well Dr. Renu Virmani thank you so much for talking with me and coming on the show.

DR. RENU VIRMANI:

Thank you, thank you for having me.

DR. LARRY KASKEL:

I am Dr. Larry Kaskel and you have been listening to the Clinician's Round Table on ReachMD XM-157. To comment or listen to our full library of on-demand podcasts, please visit our web site at reachmd.com and if you register with the promo code "radio", we will give you 6 months free of streaming reachmd you can listen to day or night. You can also reach us by phone now with your comments and suggests at (888 MD-XM157) and thank you for listening.

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