Stents: Bhaskar Rao, MD

Intro

I am Bhaskar Rao, a practicing vascular surgeon for the last 20 years. And I work- ours is a private practice, and we are a group of four vascular surgeons. And there are about eight vascular surgeons in our community in the northern part of Delaware. We all work together providing care for close to a million population. We work out of three hospitals in town. They are Christiana Hospital, St. Francis, and Wilmington. And we also provide care through transfers. And we get patients from Maryland, the rest of the Delaware, Pennsylvania, and New Jersey. And what I do is I deal with problems which are the result of diseases affecting the veins and arteries. That could be a blockage or a clot. And we deal with life threatening problems such as stroke, aneurysm ruptures, and also blood flow-related problems to the legs- blood clots in the legs that can go to lungs, what we call DVT, deep vein thrombosis, pulmonary embolism. And those clots can travel to the lungs and can result in suffering, or sometimes unfortunately deaths. And also deal with blood clots related to the legs. Or the blockage is related to the legs that can cause in terms of difficulty in walking or in diabetics who lose legs. And so one of my passion is to work on technologies that will save diabetic limbs and so that we can prevent amputations in these patients. So that's in general, that is my field of work.

Why are stents used?

There are three different areas commonly we use stents. One is in the neck artery. We use stents in the carotid artery to prevent strokes- plaque breaking out into small little pieces like snowflakes. We call them emboli, and reaching the brain that can result in a stroke or a brain attack, much similar to a heart attack, and that can result in disability or even death. So in that context, we work on- either by doing surgery or by putting a stent- to trap that plaque so that it is less likely to break and fragment and go to the brain. Similarly, we work, we place stents in the peripheral arteries. What we mean by peripheral arteries is the arteries that are not part of the heart- peripheral arteries. That could be the arteries that go to the arm or legs or some of the solid organs in the abdomen such as liver or kidneys. And then these arteries when they have most commonly a blockage, what we call stenosis or atherosclerotic plaque, we place stents in them to open the artery back and re-establish the flow through the native artery. And then we also use a different kind of a stent for the aorta, called aneurism. That is a- here in the peripheral arteries, very often the artery narrows from a plaque, and the aneurism the problem is the other way where the artery gets weaker and develops into an aneurism. And we use stents covered with a fabric to address ruptures and potentially save lives.

How do you define the success of a stent?

How do we define the success of a stent? One is immediate and intermediate and long-term. Immediate result is that we are technically able to deploy the stent successfully. So immediate concern is safety. That means there are no unintended consequences. So that the stent is reliably placed where we want it to be. And second, in other parts of the body, such as if you were to place in a vein, the stent we placed stays there and does not float and go elsewhere. And that is another definition of a success. Second thing is the stent opens up the vein or the artery we put in so that the flow goes- flow happens through the stent and the circulation- what we call distal, that means below the stent, is restored so that patient. So that is immediate- is a technical success with no residual blockage. And the procedure could be accomplished without rupture. Procedure could be accomplished without a clot formation and giving secondary problems below the stent. And there is no rupture. So that in other words, we finish the procedure, and patient does not require another procedure to fix the secondary, second-order problems. That is immediate success. Intermediate successes: patient's symptoms are relieved, their quality of life has improved. And, or we prevented a stroke, or we saved a leg, or we saved a life. That is intermediate- immediate and

intermediate success. The long-term success is actually what we use the word-- first, immediate and intermediate, we say safety. And the long-term success, we call it efficacy. In other words, efficacy means how effective it is so that it can continue to perform the function for which it was intended to be placed without requiring another procedure in the same place. So that is what the efficacy is. And the efficacy when we, we interpret efficacy as many years because we expect this patient to live longer for many years and continue to have a meaningful, functional life.

How do you determine where to place a stent?

In order for us to place a stent precisely where we want it to be- First, we start with examining the patient and defining the problem. That involves history taking, examining the patient, feeling the patient pulses. Because it is incredibly important- a good history-taking for a physician. Because based on certain clues from clinical exam, we may pick a particular device over other, which is in turn depends the preciseness with which we can place a stent.

Especially what is important for us is diabetes and smoking history- very important. And also physical exam. Based on that, we order the imaging. The imaging is of several types, but the most important imaging is either an ultrasound or a CAT scan. And when we plan for somebody to have a stent, very often, we go in with an intention to treat. So before we place a stent, we already made a diagnosis. So unlike other procedures, there is no exploration here. This is an intention to treat imaging. That is the arteriogram. The arteries are imaged by placing a small catheter, very often in a groin artery or a artery in the elbow area or in the wrist area. We get into the artery. And then we inject a radiopaque contrast or we call dye, so that the arteries are outlined. And we measure where the blockage is. Sometimes the precise location of the blockage may not be possible because there are other shadows overlying the stents such as bowel gas. So we take multiple views and we map it with a technology called roadmapping. Much like Photoshop layers-- we have that image layered on to the fluoroscopy we are using. And then we pass a wire through it. And we pass a large catheter, through that we pass a balloon. And then sometimes even we simply mark it with erasable markers on the screen. And the stent has markers at the beginning and at the end. And we try to align the markers with the roadmap or with the dry erase markers and deploy the stent. Sometimes we are very mindful of the branches so that we're not blocking some of these branches we do not intend to block.

What are your issues or concerns when deploying a stent?

There are two types of stents. One stent is mounted on a balloon. And then we-- expandable. We expand the balloon and the stent expands. And we deflate the balloon and the stent stays in place. So we've oversized the stent in some situations, but most of the times in the arteries, the migration is not the issue. So for a precise placement, the balloon expandable stents are very precise. And they are often used in heart arteries or kidney arteries, but not often in the leg below the groin level. The other one, the second type of stent is a self-expanding stent, which is loaded on a sheath and a dilator. And by pulling the outer sheath, the stent is expanded. And these stents are like a coil, like a slinky. They're made of either stainless steel or some of these stents may have a thermal memory from nitinol. And the self-expanding stents, because so much potential energy is stored when they are trapped in a sheath, it gets released. And sometimes they have a tendency to jump or move forward. That has become- that was a big problem in the first-generation stents, which are Elgiloy alloy it was but it is lesser of a problem with some of the advances that happened with the sheath design and delivery systems. But still with the second type of a stent, migration could be a problem. But that's why we try to be as precise as possible in terms of measuring the lengths. There are still certain kinds of stents where we may cover an area which we do not intend to cover.

How do you choose which stent to use?

The type of stents we use- very often based on what type of stent we want. Do we want a balloon expandable stent or a self-expanding stent? Suppose we want to put stents in the part of the arteries which are in the abdomen and pelvis, we tried to use balloon expandable stand because they have a very predictable radial strength. But they have- they tend to be shorter. Most of them are under six centimeters. The radial strength comes at the expense of flexibility. There are two trade-offs in the design of stents. Radial strength that are more expandable. You can expand it against the tough tissues, but they are not flexible. And self-expanding stents don't have the radial strength, but they're flexible and they're more useful across the joints or when the artery describe say, a steep course from front of the body to the back of the body. The brands are less relevant because most of these stent designs are out of patterns. Therefore, there is very little qualitative differentiation whether the stent is manufactured by a X company, or Y company. And the third reason is, of course, the cost. Very often the cost plays a big role, but not at the expense of the right stent for the right patient. Fortunately, most of the doctors are not influenced by the cost factor alone. I think that the relevance of a given stent to a given problem is much more important than the costs. But very often, one can find a stent that is desired for a given problem manufactured by different manufacturers or companies. So that competitive advantage a given company may not have. So you can, you can get by, by using a stent from any manufacturer- very often that boils down to the right length you're looking for, right diameter you're looking for, and the cost factor.

What improvements do you recommend?

Most of the stents you have right now- they are made of universal, same physical characters. In other words, they have a metal laser cut and the meshing of the stent and the geometric configuration of the struts of the stent is uniform from the beginning to the end. And most of these stents, with very few exceptions, don't take into consideration some of the anatomical challenges a given artery has. Or some of these stents have crowns or sharp points and these stents are not designed to address future problems that may arise in an artery that is away from the standard position. Because in order to treat a problem which is elsewhere on the same artery, we have to go through the stent. So these stents were not designed. How that interface between the native artery and the beginning of the stent will behave for me to pass a wire or a catheter maybe three years, five years later. And sometimes it can be challenging to go through the stent. So that is one design consideration. Second consideration is that the human arteries are biological systems, are not fixed structure, even though they may travel from groin to knee or from knee. Because the properties and some of the structural and functional demands on the arteries change from upper part of the thigh to the mid part of the thigh to the lower part. Because these arteries are traversing through different parts of the muscles and different compartments, different environment within the same muscle group. But these stents are designed- The physical properties of the stent is uniform from the beginning to end. Therefore, it doesn't have that different qualities of the stent in different parts of the body. So I think the future in future stents, the stent is created at the beginning and end has more radial strength, perhaps. Different parts of the body the stent may have a different flexibility so that they become complimentary, not necessarily competitive, either you can have one over the other. So that is one design consideration I would keep in mind.

What advice do you have for biomedical engineering students?

How can a biomedical engineer be a better designer? There is no shortcut to it. I always had some degree of interest in design process. And I happened to read some design as a hobby. And one of the greatest German designers who influenced me or my readings were Dieter Rams, who was a Bosch designer and who in turn influenced the Apple Chief Designer, Jony Ive. And I think you should be focused on surgeon who is using the stent. And the only way the students can be good designers is spending time in the operating room with the surgeons as it is being done, chatting with them, seeing their problems. And the real lab is in the operating room by the patient bedside. And not necessarily in the brainstorming white

board in the classroom. I think the real design process or understanding the problem, a deep study- it happens in the cardiac cath labs or in the operating rooms. So that is my recommendation to students. And seek out the mentors, the clinical mentors, and mentors who are willing to work with the faculty because the students are there for a defined time. But universities should create that collaboration so that there is a great relationship between the faculty and the clinicians. I think that is the key to creating the next generation of biomedical engineering students.