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Catching Up on Current & Future Breast Cancer Clinical Trials

Announcer:
Welcome to Medical Breakthroughs from Penn Medicine, Advancing Medicine Through Precision Diagnostics and Novel Therapy.

Dr. Ari Brooks refers to clinical trials, some of which involved devices or techniques that are considered to be investigational at this time.

Dr. Caudle:
This is *Medical Breakthroughs from Penn Medicine* on ReachMD. I'm your host Dr. Jennifer Caudle and joining me on this episode is Dr. Ari Brooks, Director of the IntegratedBreastCenter and Chief of Endocrine and Oncologic Surgery at PennsylvaniaHospital.

Dr. Brooks, welcome to the program.

Dr. Brooks:
Thank you. It's a pleasure to be here.

Dr. Caudle:
Well, it's great having you here. So, just to start us off Dr. Brooks, can you tell us a little bit more about some of your team's research interests at Penn Medicine?

Dr. Brooks:
I wanted to talk really about three different areas in research that we're pursuing down at Pennsylvania Hospital. The first one has to do with breast diagnostics. We are looking at devices that will help in global medicine to kind of reduce the disparity that we see in the diagnosis and treatment of breast cancer globally. As you know in the United States, we have an unbelievably robust breast screening machine. We bring women in for screening mammograms, and they participate, and they have awareness and they have access. In the rest of the world, they don't have that. And it probably isn't coming any time soon. So, places like India, Africa, South America, don't have the infrastructure to do the screening the way we do. So, we're very interested in devices that can be used at point of care for health workers to identify breast masses on exam and we've run a couple studies through Pennsylvania Hospital looking at a device called the iBreastExam which uses a kind of palpation technology to do a breast exam with a machine. And then you can identify women who should move on for additional imaging. And probably about 250,000 women worldwide have already been tested with this, and I think we are making some good progress. So, you'll see some new studies coming out with that device as well.

The second area has to do with image-guided surgery. So, as you know, the University of Pennsylvania has a very big push in image-guided surgery. We are working with a small company called OncoNano and they have a fluorescent dye that lights up in cancer, but not elsewhere in the body. And so when you put this fluorescent dye into a patient--we've been doing it a few hours before surgery, but it could even be done the day before surgery when you bring them to the operating room, their tumor lights up and that helps us with precision.

So, I think that's another area that we're going to see a lot more studies coming out, especially at Pennsylvania Hospital, trying to lead the charge on that image-guided breast surgery. And really the third area has to do with technologies that just improve our ability to be less invasive when we do our breast surgeries, and so you're going to see other trials hopefully with devices that help us work through smaller incisions more cosmetically and hopefully less morbidity for patients.

Dr. Caudle:
That's excellent. Thank you for sharing that. And from a broader perspective, what are some of the most common barriers when

screening, diagnosing, and treating breast cancer in general?

Dr. Brooks:
I think that's a great question. As I eluded to earlier, we are very lucky here in the United States, especially here in Philadelphia to have cutting edge diagnostics. But one of the ironies about Philadelphia and most of our major cities is that access to screening in the city is really limited. If you don't have insurance, you don't have great access. One of the programs we've been running here at Penn Medicine is called The Penn Medicine Breast Health Initiative and that provides access to screening mammograms for uninsured women and we get those women in for diagnostic treatment. And once the diagnosis is made, we can get them insured. So that's a barrier that exists even here. Globally, access to screening is a big problem. As far as diagnostics in breast cancer, we really are working on ways to be less invasive. Part of breast cancer treatment is identifying if there's lymph node involvement when cancer is in the breast. And that involves a surgery taking out some lymph nodes, and we are participating in a study to see if we can reduce the morbidity of lymph node surgery. It's actually called axillary reverse mapping. We inject some dye in the arm and make sure that we don't cut anything blue when we go in under the arm and try to reduce the risk of lymphedema. So, definitely reducing toxicity of diagnostics is important, and lastly for treating breast cancer, I would say again on the surgical side, just being less invasive overall. Women are very concerned about the toxicities from radiation and from major surgery, and we really, really are working hard here to see if we can do things to lower those toxicities.

Dr. Caudle:
Right. That makes a lot of sense. You know, before we dive into the future of clinical trials, what can you tell us about how there're currently designed and how they end to combat some of the barriers that you actually just mentioned?

Dr. Brooks:
So, breast cancer is a very common cancer. We have come a long way in the last 40, 50 years in breast cancer diagnostics and treatment and we have a problem of success. In the past we would do a randomized study. We would say, well let's try this versus that. And if your success rate is 50% with one thing and you try something else, you don't need that many patients to show a statistically significant difference. Right? If you go from 50% success to 80% success, you don't need that many patients. Well now with breast cancer, especially stages one and two, you need thousands and thousands and thousands of patients to be enrolled in a standard randomized clinical trial. So, I think that's one of the problems we are going to be looking at in the future.

Dr. Caudle:
Interesting. So, Dr. Brooks, how will these or maybe even other approaches, have an impact on the way that clinical trials for breast cancer are designed for the future?

Dr. Brooks:
Well I think that's a really interesting area in breast cancer research. There's two study designs that we are looking at specifically. One has to do with implementation. So, I mentioned before that we have a device that's being tested in 250,000 women worldwide. That's a nice large number of people. The problem is that device can't be tested against the standard of care. There is no access to routine screening mammograms, you know, in these places in India that we've been testing it. So, you can't do a randomized trial there. So, what we have to do is called an implementation study. And so an implementation study is a way to look at how, when you roll out a new way of doing something, you impact the culture of diagnostics how it gets done, how people are identified and diagnosed, and in this system, how does that compare to another system. Implementation studies, I think, are the wave of the future for a lot of these new devices, especially as we get out there in the global area.

Dr. Caudle:
How will future clinical trials impact diagnostics and surgical therapies?

Dr. Brooks:
I think at least on the surgery side and the diagnostic side, most of the emphasis here in the United States is going to be towards reducing morbidity. In breast cancer, we do lumpectomies. We don't have to do mastectomies all the time now. So, breast conservation is key, but we're finding that sometimes, it may be even up to half the time, we have to go back and redo surgery because we had what's called a positive margin. So, a lot of research is heading towards trying to reduce the positive margins to reduce the number of times we go back to surgery, to reduce the morbidity of axillary surgery, as I mentioned before. And I think that's really what you're going to see here in the United States.

Dr. Caudle:
Excellent. And, you know, what unmet needs in breast cancer treatment do you hope to see resolved in future clinical trials?

Dr. Brooks:

As I mentioned before, access to care in the United States is one unmet need. As a lot of these companies pour money into new, you know, cooler devices, and our success rate is in the 90-something percent, we have to keep remembering that there's plenty of women that don't have access, and we need to pour more money into taking care of those women and then studying the reasons that there are barriers. We can get all those women screened if they show up. How do we get them? How do we educate them? So that's an area of research that's really needed.

Dr. Caudle:
Finally, before we close, Dr. Brooks, how and when should physicians refer their patients to Penn Medicine?

Dr. Brooks:
Well, I think we have a very active website. We have an 800 number, to get people in. There are nurses that help with access to clinical trials as well, even just in the breast division.

Dr. Caudle:
That's excellent. Well, I would really like to thank you, Dr. Ari Brooks, for sharing your insights on this innovative breast imaging to really help improve patient outcomes. It was a pleasure speaking with you Dr. Brooks.

Dr. Brooks:
It was great. Thank you.

Announcer:
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