RADIOMD Interview Transcript

Melanie Cole: Welcome to the podcast series from the specialists at Penn Medicine. I'm Melanie Cole. Today we're discussing CardioMEMS technology at Penn medicine. Joining me is Dr. Monique Tanna. She's an Assistant Professor of Clinical Medicine at the Perlman School of Medicine at Penn Medicine. Dr. Tanna, I'm so glad to have you join us today. Hospital readmissions are common and failure to successfully transition patients from inpatient to outpatient care can result in readmission to the hospital. What have you seen as far as readmissions?

Dr. Tanna: Heart failure is a disease with significant morbidity and mortality. Unfortunately our patients with heart failure often have frequent heart failure readmissions, which not only affects their quality of life, but also leads to increased mortality. And it also leads to a significant burden on our healthcare system and there's a significant cost associated with it.

Host: So then tell us a little bit about CardioMEMS. How does this technology work? **Dr. Tanna:** So the CardioMEMS is the pulmonary artery sensor that is implanted via a right heart

catheterization. It's a small device that sits in one of the branches of the Pulmonary artery and it's able to measure the pulmonary artery pressure and the patient can transmit this information wirelessly on a daily basis.

And this information is sent to us via a website and we can track the pulmonary artery pressures. When a patient with heart failure begins to accumulate fluid and has volume overload and fluid retention, the current markers that we use today are really patient symptoms and increases in weight. And by the time that we see these markers, it is oftentimes too late.

And when we see that patients are having more symptoms or gaining weight, we do try our best to augment their outpatient diuretics and sometimes we're successful, but other times it's already too late and patients end up in the hospital. And the reason for that is that when we see these symptoms and weight changes, this is really happening only a few days before the patient ends up in hospital. And this is a period known as clinical congestion.

And what we're trying to do with the pulmonary artery sensor is to detect fluid retention much earlier before the patient develops clinical congestion, when the patients are still in a phase called hemodynamic congestion. So in that these, the patient is really in the early stages of fluid retention and in that early stage, the filling pressures in the heart and the pulmonary artery start to increase. And this is way before patients have any symptoms or even changes in weight. We think that this happens about three weeks before a possible hospitalization and monitoring the patient's pressures gives us the ability to detect hemodynamic congestion, which is again much earlier in the process of fluid retention, and allows us to augment their diuretics much earlier and really prevent those hospitalizations.

Host: Dr. Tanna, speak a little bit about the clinical indications, patient selection and any patients that it might be contraindicated for.

Dr. Tanna: So the CardioMEMS device was studied in the champion trial, which was published in 2011 and based on that trial, the current FDA approved indication for this device is patients who have heart failure, either preserved ejection fraction or reduced ejection fraction. So patients with heart failure in any ejection fraction who have NYHA class three symptoms and also a heart failure hospitalization in the prior year. So those are really the indications for the device itself.

I think in patients who have had a hospitalization in the last year, this is really something to think about early on so that we can prevent future recurrent hospitalizations. And I also want to add that there is a currently ongoing trial guide heart failure, Guide HF, which is looking at expanded indications, namely NYHA class two to four and also having either a heart failure hospitalization in the past 12 months or an elevated BNP. But currently that's not included in the FDA approved indications. But once we have the results of the Guide HF trial, that may change.

Host: So what about cost effectiveness, is it proven to be cost effective Doctor?

Dr. Tanna: That's a great question, so looking at the results of the Champion trial, which was a randomized trial. All the patients received the CardioMEMS device, but only half of them had the pressures managed and the other half clinicians were blinded to the pressures. In that trial, we saw that there was a significant reduction in heart failure hospitalizations. At 15 months there was a 37% reduction in heart failure related hospitalizations. Looking at costs. There have been some smaller studies that have shown that there is a cost benefit. Also keeping patients out of the hospital not only reduces the cost of the hospitalization but patients also have improved quality of life, which was also shown in the Champion study. So that also is a, as a cost savings in terms of patient's quality of life and wellbeing.

Host: For it to be effective. How important is the input from multiple independent elements to achieve this effect?

Dr. Tanna: When we screen patients for the CardioMEMS device, one of the things that we look for is to make sure that we enroll patients who are going to be able to transmit their pressures every day and be compliant with this therapy. The pressures are transmitted wirelessly, so the patients go home with a CardioMEMS device, which they lie down on every morning and press a button. It takes less than a minute for the patient to actually transmit their pressures. So it's something that's relatively easy to do, but it is something that the patients do have to do every day. That said, even if they don't do it every day, as long as we have a few readings a week, that's actually more than adequate to use this device to manage the patients. And because as it is, even if the patient, for example, sent a pressure reading today and it was elevated, I wouldn't necessarily act on a pressure reading from one day.

We look at the trends. So if the patient is trending in a certain direction or is out of the range for a period of three days, that's when we act. So given that if the patient misses their day or two here and there, that's still okay and it still gives us the benefit of the device itself. We still encourage, of course, the patients to transmit their pressures every day. On the other side, the receiving of the pressures and the management of the device itself is really a great question because oftentimes people ask me and are concerned and worried appropriately about the data that is being sent to us. The CardioMEMS device is really designed in a great way because when we do the implantation itself, we set individualized goals for each patient.

So each patient has their goal Omro artery pressure and it's nice because you can individualize this for every patient and the system is set up so that we get a alert notification twice a week for patients who are out of their range. So it's not something that we have to constantly keep looking at every day and spend a lot of time analyzing and looking at. We get notifications via email that these patients are out of their range. And the time that is spent in reviewing that data and calling that patient is really much smaller even though it feels that you're doing more work upfront. If you look at it, the extra time that you spend reviewing the data and calling the patient

is much less compared to the alternative where the patient continued to get worse and then called in with symptoms, and you were addressing the issue at that stage and oftentimes having heart failure hospitalization.

Host: So interesting. Tell us how your outcomes have been and what do your patients think of it. **Dr. Tanna**: So our outcomes, you know, we've really seen a benefit in patients who are compliant with the device and we are able to manage. We really are able to reduce their heart failure hospitalizations and we have a lot of our patients who feel the same way that it's really benefited them and really helped them keep them out of the hospital. And studies that have been done on a more broad scale, you know, approval marketing studies as well as studies from other centers, have similarly shown that using the CardioMEMS device really does reduce hospitalizations and improve quality of life.

Host: How has CardioMEMS aided you in the early prediction of upcoming decompensation and optimization of patients therapy and thereby avoidance of hospital readmissions, and what you would like other providers to know about referral?

Dr. Tanna: The CardioMEMS device allows you to predict and to see fluid retention early on, prevent heart failure hospitalizations. So the patients, when you see they're elevated pulmonary artery oppression pressures, not only do we augment their diuretics, but we also increase hydralazine, nitrates, other medications. So I think it really also helps get people on guideline directed heart flare therapy. And I think that we don't think of this device often enough. One of the takeaways is that it's important to really refer patients early for this therapy. Oftentimes when patients have NYHA class three heart failure and are relatively doing well, we don't have that momentum to try to do something else. But this is really sort of a preventive therapy and it really does help people, keep people out of the hospital. And the other thing I wanted to add is that for heart failure with preserved ejection fraction, this is really the only therapy that has been shown to have a benefit. We really don't have any other medications or other therapies that have shown to be beneficial in heart failure with preserved ejection fraction, but this really has shown that it does reduce hospitalizations and improve quality of life in that group of patients as well.

Host: Thank you so much, Dr. Tanna for such great information and for joining us today to share your expertise on CardioMEMS. That concludes this episode from the experts at Penn Medicine. To refer your patient to a specialist at Penn Medicine, please visit our website at pennmedicine.org/refer or you can call 877- 937-PENN, for more information and to get connected with one of our providers, please remember to subscribe, rate, and review this podcast and all the other Penn Medicine podcasts. I'm Melanie Cole.