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Emerging Clinical Data on Endobronchial Valves for COPD

Announcer:

You're listening to *Deep Breaths: Updates from CHEST* on ReachMD. This educational podcast is produced in partnership with the American College of CHEST Physicians and sponsored by Pulmonx Corporation, the manufacturer of Zephyr.

Dr. Scirba:

Hello, I'm Dr. Frank Scirba, Professor of Medicine and Director of the Emphysema/COPD Center at the University of Pittsburgh Medical Center. Zephyr endobronchial valves offer a real opportunity to improve symptoms and quality of life in appropriately selected patients, who have severe COPD and emphysema, and who are maximized really on all other available therapies. I'm here with Dr. Emily Yee, a community pulmonologist who's also here at UPMC, and we're partners in making these valves available to our COPD patients.

Emily, thanks so much for being on the program with us today.

Dr. Yee:

Frank, this is an exciting topic for me. I have referred a number of patients to your program at the Lung Center, and the experience has been great for my patients. Your program has offered real additional options for my patients. I know you've been involved in many of the pivotal trials for endobronchial valves, and you have an active program that's up and running. Would you mind summarizing how the valves work? Tell us a little bit about the benefits and risks.

Dr. Scirba:

Yeah, sure, Emily. Yeah, so we had started doing lung volume reduction surgery, and found that that resulted in significant benefit, but it was a lot for the patients to go through, and so valves wind up being a minimally invasive approach to the mechanisms that benefit these patients through the surgery. And basically, what the mechanism is that we collapse a lobe, and we try and target the worst lobe of the lung, and it allows the better quality of lung now to expand and exhale more completely within that limited thorax. This allows the diaphragms to come up, and it allows really less work at breathing and improved inhalation and exhalation within the thorax. There's been now a series of clinical trials, that have really evolved our understanding not only in showing the benefit but also in helping us to really select those patients who are better candidates, and which we'll be discussing as we move along. What we found is that now we can target that the majority of patients really have clinically important improvement in lung function, but also, almost two times the clinically important difference in quality of life and improvement in exercise tolerance. Patients need to know, though, that there are risks associated with this. The biggest risk is a pneumothorax, that can occur in about a third of the patients, but if we monitor this very closely, in the end these patients often do very well, and there's no long-term negative outcome from these. So Emily, I know you've referred many patients to us. I'd love to know what your experience is with the endobronchial valves in the patients you've sent.

Dr. Yee:

Well, my patients tell me that coming for an evaluation is a really good experience for them. These are patients that are looking for any sort of means of improving their quality of life. So coming for an assessment provides them with the education to learn more about the procedure, and being able to come for an evaluation gives them hope of having a better quality of life. Before I refer them, I tell them that I think that they are potentially a good candidate, but I also tell them that your center will determine whether they're an optimal candidate to go ahead and proceed with having the endobronchial valves.

Dr. Scirba:

I think that's important. You've really gotten very good at understanding how to identify patients and to send us the right patients, and it really does help us be more efficient in moving them along. You know, there is some risk associated with the procedure, in the midst of

really great potential benefit. Do you find that your patients are willing to accept these risks at this stage in their life, for the potential benefits of valves?

Dr. Yee:

Well, I have a very select group of patients with severe emphysema, who have such significant limitations in their exercise tolerance despite being on optimal medical therapy according to the GOLD guidelines, despite smoking cessation, despite pulmonary rehab. Most of this group of patients are interested in finding more about the procedure, and after learning more, many are willing to proceed despite knowing that there are risks. When I consider who to send you for evaluation, I always look at a couple things. One of the things I look at is the patient's pulmonary function tests. I look at their FEV1 typically if somebody has an FEV1 less than 50 percent of predicted, they may be a candidate. I also look at the residual volume. Now, I'm lucky that we have state-of-the-art lung function testing, including lung volumes.

Many people in the community probably also have the ability to get total lung volumes. An increase in residual volume will give me an indication that the patient has significant air trapping, and that's what we're looking for. I also am careful about looking to determine whether the patient primarily has emphysema or are they more of a patient that has chronic bronchitis. Those that have chronic bronchitis tend to have more airway disease, and those with frequent exacerbations will not likely benefit from coming for an evaluation. I also like to look at my patients' prior CT scans. Most of my patients have had a CT scan sometime in their life. Many are getting low-dose CT scans for lung cancer screening. Review of the CT scans helps me determine a little bit better, how extensive is the emphysema. Do they have large bullae? Is their disease homogeneous or is it heterogeneous? Those are the kind of things that I look at, before determining whether I should send them for evaluation. What do you think about that assessment, Frank?

Dr. Scirba:

I think your approach is really thoughtful, and I think you've evolved over time, really, to be able to identify patients who are much more likely to be good candidates as we move them forward. I do tend not to worship individual cutoffs. While you, as you stated, have access to good plethysmography, often we'll get folks from the community where either I don't trust the plethysmographic measurements, or they're not available, and we'll still consider evaluating these individuals, and we can do the lung function testing on site here. But in the end, I'd only move patients forward with valves after a full discussion, with them understanding the expectations realizing there could be great benefit but that there is a path to take that could involve risks, particularly pneumothorax. And I also want to make sure that they have been given guideline-based medical therapy and rehab, to get to the highest place they can before we put the valves in. Your thoughts?

Dr. Yee:

Okay. Yes. My algorithm includes first maximizing and optimizing medical treatment based on the GOLD guidelines; two, making sure we talk about smoking cessation extensively; and thirdly, I make sure that all the patients go to pulmonary rehab. After those three steps, if the patients are severely limited, we should start thinking about non-pharmacologic options, including endobronchial valve, surgical volume reduction and transplantation. These non-pharmacologic options are recommended in the GOLD guidelines. I would send the patients for endobronchial valve evaluation first, as this is a minimally invasive procedure. Frank, that's my general process. Can you tell me what other testing that you might perform, as part of your evaluation?

Dr. Scirba:

I think your process and approach to your patients is correct. I think to the world should start really thinking of going to endobronchial valves when they are preliminarily seeing it's the right candidate, and they've done everything else they can, because it's now an established guideline-based therapy. Also, finding that correct window, where it's not too early, you know, we want patients that are very symptomatic. We're not going to be putting these in mild patients, but we don't want it so late that they've now become frail, or they're overwhelmed with their pulmonary hypertension or comorbidities that now dominate their symptoms, so improving their mechanics is not really going to help them out.

So, to assess comorbidities, we are often going to get a transthoracic echo and a cardiac, often a regadenoson challenge test stress test. Patients who are homogeneous have distribution of emphysema everywhere will often get a perfusion scan to help us target where we might put the valves in very overinflated patients, and we'll often get exercise testing, at least the six-minute walk, and sometimes more advanced cardiopulmonary exercise testing to identify the mechanisms of their symptoms to make sure we're targeting the right thing.

Dr. Yee:

That's good to know. Now that we've discussed who might be a good candidate, can you tell me a little more about what my patients should expect when they come for the valve procedure?

Dr. Scirba:

Yes, once we've selected somebody that we feel is going to be a good candidate they're going to be scheduled for the procedure. Generally, it's the first procedure in the morning. If they come from afar, they'll come into a hotel the night before, and then we'll bring them in in the morning. The procedure involves general anesthesia. They need to know that prior to delivery and after they're under anesthesia, we do have to do one more test, to confirm that they don't have what we call collaterals, which is a connection between the two lobes in the lung that would really prevent the lobe from collapsing. And, you know, there is a small percentage of patients that if this is positive, we cannot move them forward, so we need to make sure they understand that. After the valves are placed, because there is that risk of pneumothorax, we admit the patients to the hospital for at least three overnights, to minimize any risk should they have a pneumothorax. And even if they do have a pneumothorax, they may require a chest tube that may prolong their hospitalization, but these patients, often we can take that chest tube out and they do very well in the long run. In the course of the hospitalization, we gradually increase their activity so that we're comfortable they'll do well after being sent home. Often we see immediate benefit, where patients feel they can take a deeper breath, but their maximum benefit often will occur a couple of months afterwards, after they've continued to do their exercise training in the context of their better lung function.

For those just tuning in, you're listening to *Deep Breaths: Updates From CHEST*, on ReachMD. I'm Dr. Frank Scirba, and I'm speaking with Dr. Emily Yee about identifying candidates for valves available to COPD patients. So Emily, since you're following several patients after we put the valves in, what kind of feedback are you getting from your patients?

Dr. Yee:

I'm getting great feedback. One of the things that my patients tell me that it sometimes takes time to notice a difference, after having the procedure, before they feel that they're less dyspneic. Most of them tell me it was well worth the risk of undergoing the procedure. I have one particular patient in mind. It's a woman in her 70's, severe emphysema, very compliant. She talks to all of her friends at pulmonary rehab and encourages them to ask their pulmonologist whether they could be referred for endobronchial valves. So, this procedure can really be life-changing, and I think it's something that we need to consider sending our patients for an evaluation.

Dr. Scirba:

That's great that you're getting that kind of feedback and that experience, and we've found that when this procedure is effective, it can be transformative, and it's really a pleasure being involved in a program where patients come to you saying that other doctors have said there's nothing else to do, and we actually can then make a difference. So, really, I'd like to summarize the key points. First, patients with severe obstruction in emphysema on imaging should be considered for referral if they're on maximum medical therapy, including rehab, but who continue to have severe limitations in their exercise tolerance and quality of life. Second, there's a real chance of benefit post valve insertion with the majority of patients experiencing meaningful improvement in lung function, walk distance and quality of life. But it's important, and my point three, to set expectations. This is not a new pair of lungs, but a therapy that improves their quality of life and symptoms. It's a real chance for benefit, but they need to understand that there may be risk. Any last thoughts on your part, Emily?

Dr. Yee:

Well, as a community pulmonologist, I think we as a group need to be more proactive in considering sending patients for a valve evaluation. This new procedure has really enabled a number of patients to feel significantly better and changed their quality of life. It can certainly be a game changer. I think, sometimes in the community, we wait for a really long time before we try out new therapies, and I think now is the time to put this in our algorithm, so once the patients have been optimized from a medical standpoint, they've quit smoking, they've gone to pulmonary rehab, but are still limited, I think that's the time that we need to send the patients for an evaluation, and probably sooner is better than later.

Dr. Scirba:

Emily, I'm really pleased that you've agreed to join me on this discussion regarding community referral of these patients for endobronchial valves, since you've really been a great partner.

Dr. Yee:

Frank, thank you so much for inviting me.

Announcer:

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