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Pulmonary Hypertension and Lung Transplantation

A discussion on current practice, challenges, and emerging opportunities in lung transplantation for pulmonary hypertension patients was led by guest editor **Deborah Jo Levine, MD,** of the University of Texas Health Science Center at San Antonio. Joining her were **Marc de Perrot, MD**, a thoracic surgeon at Toronto General Hospital, Toronto, Ontario, Canada; **Reda Girgis, MD,** Associate Professor of Medicine, Johns Hopkins Hospital, Baltimore, Maryland; and **Myung Park, MD**, Assistant Professor of Medicine, University of Maryland School of Medicine, Baltimore.

Dr Levine:

Thank you all for being involved. A few of the topics we would like to discuss today are: 1) timing and referral of pulmonary hypertension (PH) patients for lung transplantation, that is, is there a “right” time for these patients to begin evaluation for transplantation; 2) what are some of the problems regarding lung transplantation specific to PH patients; and 3) how the new lung allocation score (LAS) has affected our PH patients. Drs Park and Girgis had some good ideas with which we can begin.

Dr Park:

I think we are struggling with this because we're trying to give our patients the maximal survival and quality of life without needing a transplant. If you look at the percentage of patients getting lung transplants from 1990 to now, that number is significantly reduced, although the total number of lung transplants has significantly increased. Whereas in the '90s, maybe 10% to 15% of the patients with pulmonary arterial hypertension (PAH) received lung transplants; now it's less than 3% to 5%, if I remember the numbers correctly. We are all painfully aware that transplant is something that a certain portion of our patients need. I think one challenge is deciding at what point is the optimal time, considering all these therapies we have now. The second challenge is working with the current United Network for Organ Sharing (UNOS) system so that our patients are not proportionately disadvantaged. And third, how do we appropriately get the word out to community doctors? We have made such a great stride with medical treatment that physicians may think that lung transplant is not really something that we ever need to consider for these patients, but this is far from the truth. In my mind those are the main challenges in considering this topic.

Dr Levine:

I agree. I think patients may be referred to us later in our lung transplant programs with all of the current medications available. I don't know. Dr Girgis, have you seen that patients are referred later in their disease than you would have seen in previous years?

Dr Girgis:

Yes, I would agree with that. With the availability of all these medical therapies that clearly have had an impact on how patients feel, how far they can walk, and, I think most people would agree, a positive impact on survival. Before we had medical therapy it was quite an easy decision. If someone had well-documented idiopathic PAH, transplantation was their only option; it was easy to make the decision on when to list them. But now it's hard because you want to give them any potential benefit from medical therapy that they could have. And because of the morbidity and mortality associated with lung transplantation, you want to

postpone that as much as possible.

Dr Park:

I think trying to identify markers that we should follow carefully is also a very important element. We all get echos and hopefully periodic cardiac catheterization but some other biomarkers are needed, such as total bilirubin. We were discussing this as a marker of right heart failure and hepatic congestion. I know some centers follow B-type natriuretic peptide (BNP) levels, for instance. I think the number of hospitalizations that a patient requires for right heart failure and recurrence is definitely an important predictor of outcome. I think there is definitely a phase where the right ventricle will recuperate and recover after the resistance from the old lung is obliterated, but where that fine line is differs from person to person. I think that's where we really do struggle.

Dr Levine:

From your standpoint in terms of right heart function, are there indices that allow you to say this patient has done well on the therapy started? Clinically, they've improved; they're walking better; their functional class has improved significantly; they feel great. Is there a way of looking at the echo or looking at the right heart catheterization to say, “Well, these haven't changed much.” Are we being blindsided by our clinical vision?

Dr Park:

I think there are 2 components to this. One is right heart catheterization. I think we have worked a lot with the UNOS committee to incorporate some of these hemodynamic features into their scoring allocation equation, such as the right atrial pressure. If you feel you have a patient on effective therapy but you do your right heart cath and the right atrial pressure is still 18, I think that sends a very clear message and you know what you need to do. The cardiac output, cardiac index, of course, is another very important marker; and the other biomarkers we were discussing need to be assessed in conjunction with all these. But when you have a young person for whom you're trying to be proactive and do what's best, it's not always clear as to when it is time for transplantation. You don't want to jump the gun and do it too quickly; but knowing the waiting time and that the scoring system doesn't always play in favor of our patients, especially with certain high risk groups, you really do need to be proactive on their behalf. You need to stress that it's time; we need to do this.

Dr Girgis:

I absolutely agree. The challenge is predicting who is going to do poorly from right heart failure. So the hemodynamics are certainly helpful. High right atrial pressure, low cardiac index, imaging studies that suggest poor right ventricular function, even in someone who is not feeling terrible, are an indication that this is someone who is perhaps heading to transplant. You brought up a very important outcome: hospitalization. I think often we don't really pay a lot of attention to that in the literature. But it comes up again and again that being hospitalized with right heart failure is a bad event. And that should be a sentinel marker to seriously consider proceeding with listing.

Dr Levine:

From your standpoint, Dr de Perrot, are you seeing more of these patients come to you sicker to transplant now than in the past?

Dr de Perrot:

Initially when epoprostenol sodium (Flolan) became available in the '90s, we saw patients who came to the list at very advanced stages in significant right heart failure. It seems that this has changed a little bit. We've tried to be more proactive to at least assess them early in the course of the disease. We don't necessarily list them, but just finish the assessment even if they're in functional class II or III, in order to have everything in place to be able to list them fairly quickly if they don't respond to medical therapy as well as we anticipated. When a patient has to be put on Flolan we often use that as a time for transplant referral. If they respond to Flolan then we hold off listing them. If they don't respond to Flolan, then we can list them relatively quickly after that. That has helped us to decrease the mortality on the list to some extent and to reduce the risk at the time of the transplant. But it's still a problem. We still receive phone calls from different hospitals for young patients in florid right heart failure, and they want an urgent assessment and urgent transplant. Usually that doesn't work out well.

Dr Park:

We need to educate the community doctors to let them know that despite how good medical therapy is, there are certain groups of people in whom it's really not effective, such as those with pulmonary veno-occlusive disease (PVOD) or pulmonary capillary hemangiomatosis (PCH). I think for those patients evaluation and listing upon diagnosis is crucial. The other category of patients is those with scleroderma. This is a very, very difficult patient population

to care for, especially to answer the question about risk and benefit of transplantation. The other challenging group for me is young females presenting with syncope and PH, especially if there is any hint of a hereditary marker. I think that is a very high risk population—and one that you need to be very aggressive with from the start.

Dr Levine:

If there's not a lung transplant program associated with the PH center, those patients probably should be referred pretty quickly after starting an intravenous therapy. This would be important when discussing patients who may be referred from the community who may have been on Flolan or treprostinil sodium (Remodulin) or even some of the oral therapies. Most transplant physicians would rather see a patient earlier.

The US donor lung allocation system was changed in 2005 to the LAS system from our prior system where the allocation of donor lungs was based on time accrual on the transplant list. Marc, I know in Canada there are different allocation systems depending on the province. How is your center doing it at this point?

Dr de Perrot:

In Toronto we are a little bit privileged in the sense that only Montreal has a program in the eastern part of Canada. The allocation to the recipient is based on the degree of sickness of the recipient on the waiting list, so we can choose to prioritize the sickest patients for the transplant. If we have a patient who is on our list and seems not to respond to Flolan and to progress quicker than expected on medical therapy, we could favor them on the list and transplant them faster than a patient who has been stable and can wait longer. That's helped us to decrease the waiting time for these patients to about 2 months. In addition, we are seeing more patients who are being bridged to transplant with either inotrope therapies, or Novalung® (Novalung GmbH, Talheim, Germany) or ECMO. Often we've been able to bridge these patients very quickly—sometimes within a few days. So the waiting time has decreased over the past few years as we've been more aggressive with our management on the waiting list in order to bridge them. We have been able to decrease our waiting list mortality for idiopathic PAH from around 20% initially to 0% currently by bridging them with Novalung or inotropes.

Dr Levine:

Are you doing many heart-lung transplants?

Dr de Perrot:

In Toronto we now do about 100 transplants a year and 4 or 5 of them are heart-lung transplants. As long as the left ventricle is good we will do a double lung. It's very difficult to say when the right ventricle is too far gone to be able to do a double lung transplant. The theory is that the right ventricle always recovers whatever the degree of failure, which is probably not true. But we still don't have a good way to say whether the right ventricle is going to recover or not. I think the BNP has given us some help. With a very high BNP, these are patients that potentially should have a heart-lung transplant, but so far we haven't really used that as a tool.

Dr Park:

I would think that if the organ shortage was not such a dire problem, it probably would be utilized more often.

Dr Girgis:

The problem is you can't really demonstrate any difference in outcome between combined heart and lung versus bilateral lung. Of course, they're not randomized, so it's not clear if there is a bias toward performing heart-lung transplant in those with more advanced right ventricular dysfunction. We do know that if you can get patients through that critical early postoperative period that the right ventricular function recovers to normal.

Dr Park:

Right, and the numbers are so small to begin with that it's really difficult to get an idea for that. If you list a patient for a heart-lung block, the waiting time just becomes so prohibitive, practically speaking.

Dr de Perrot:

We can usually transplant them fairly quickly with a double lung. If they get sicker we will

usually be able to bridge them for a few weeks and transplant them. For heart and lung, we've been able to bridge them quickly a few times, but it's much less predictable. That's certainly one of the reasons why we still prefer to list them for a double lung transplant rather than a heart-lung transplant.

Dr Girgis:

I'd like to ask you when, from a surgical perspective, is it too late for a patient to get transplanted? Obviously, the sicker they are, the worse their immediate postoperative outcome is going to be. So from a medical standpoint, how long should we be giving these patients to see if they're going to respond to therapy? When are we really increasing their surgical risk? You mentioned you are able to support people with inotropes and sometimes Novalung. Can you tell us more about that?

Dr de Perrot:

Yes; the interventional lung assist (ILA)—Novalung—is like a mobile oxygenator. The advantage compared to the other oxygenators that are used for ECMO is the low resistance across the membrane. Novalung was designed to be connected between the femoral artery and the femoral vein and the cardiac output of the patient will generate flows through the Novalung without any pump. When using it in that setting, the blood is already oxygenated when it goes through the Novalung so you don't get much oxygenation with the device. You can normalize the CO_2 by using it that way, so it's mostly for hypercapnic respiratory failure. But for the PAH patient, the interesting thing is that we've been able to connect it between the pulmonary artery and the left atrium so the right ventricle basically generates the flow through the Novalung without a pump. So you have about 2 or 3 liters of flow going through the Novalung and ending up in the left atrium. You get a right to left shunt with oxygenation.

Dr Levine:

So when do you use this device?

Dr de Perrot:

We use it when patients are dying on the list despite maximal therapy including inotropic supports. We've used it in about 4 patients now with PAH. These were patients hospitalized

with right ventricular failure who were not responding to inotropes. We proactively, urgently bring them to the OR to put them on ECMO first to stabilize them. Once they're on ECMO, we do a sternotomy and insert the cannulas into the pulmonary artery and the left atrium and then wean the ECMO support.

Dr Park:

How long can you support them on this?

Dr de Perrot:

The longest we've done was for 29 days, another one was 27 days, and the other 2 were 10 to 20 days.

Dr Levine:

How did they do?

Dr de Perrot:

They did well. It's quite an interesting way to use the Novalung because as soon as you connect that device the right ventricle gets unloaded even though all 4 patients were on ECMO. The ECMO was inserted under local anesthesia in order to stabilize them before inducing them for anesthesia. Once they're on ECMO and anesthetized, we inserted the Novalung through the sternotomy. But even on ECMO the right ventricle was still distended and not very functional. Once you put them on the Novalung, the right ventricle immediately decreases in size and you immediately generate flow of 2 to 3 liters through the Novalung. The 2 patients who had been on Novalung for 27 and 29 days could be extubated. One was able to sit on the side of the bed and one was even starting to ambulate in the unit.

Dr Levine:

Have you ever used this to assist the right ventricle after transplant?

Dr de Perrot:

Not after transplant. We thought of it, but have not done it yet.

Dr Levine:

I know this technique of extubating the patient and removing conventional mechanical ventilation while on this type of lung support is innovative and new. In the US, the logistics of updating the LAS while on this type of support are not yet completely clear. The question is whether the UNOS thoracic committee will in time consider this as a form of mechanical ventilation and adjust the LAS accordingly. At this time, an increased requirement of FiO_2 and conventional mechanical ventilation will increase the LAS score significantly.

Actually, this brings up the one aspect of how PAH patients can be disadvantaged at this time by the LAS. PAH patients may be functional class IV on intravenous therapy and yet still not require a lot in the way of oxygen support as do patients with other end-stage lung diseases. When the score was devised, unfortunately, there weren't provisions that really consider what these patients truly suffer from: right ventricle failure.

Dr de Perrot:

Looking at the waiting list mortality since the introduction of the LAS score in 2005, it is still around 15% to 20% mortality for idiopathic PAH.

Dr Park:

Yes, it's quite high.

Dr Levine:

Myung and Reda, have you seen changes in terms of waiting times for your patients since the score was established in 2005?

Dr Park:

I don't take care of many of the other categories listed, but the sense I get from my interactions with my pulmonologists is that the PH patients do get scored lower for the degree of illness, and their waiting time is longer. To compensate for that requires petitioning, writing letters, and just being very meticulous so that all the factors are stated. Otherwise, it doesn't come across on the scoring system. It is a very difficult, labor intensive matter to make sure that everything we deem important is carried across, because otherwise it just disappears.

Dr Levine:

Reda, I don't know how many times you've appealed for a higher score. Have you been satisfied with the adjustments in scores the patients received once you have made that attempt?

Dr Girgis:

The handful of cases that I've appealed have all met the hemodynamic criteria that we worked on with UNOS, which is either a right atrial pressure of 15 or higher or a cardiac index of 1.8 or less.

Dr Levine:

That's been our experience. Patients with high RAP and low CI who may or may not be on inotropes are patients most likely to receive these higher scores.

Dr Girgis:

All the ones that have gone to transplant did need that exception to get to an LAS at the 90th

percentile.

Dr Park:

I know they are in the 30% to 40% range otherwise, so I think recognizing this and taking those steps with the UNOS system has really made a difference. It would be more applicable if it were more of an automatic thing rather than having to make exceptions each time.

Dr Girgis:

But at the same time I've heard from a lot of other centers where certain patients may not meet those hemodynamic criteria, but they're still felt to be quite ill. So, the LAS doesn't reflect the severity of their illness. And a lot of people are still struggling with those types of patients. I think beyond the hemodynamic criteria for appeal, we still need to be persistent with UNOS to work on developing some additional prognostic indicators. I had another question for Marc. Obviously, we don't want to wait until people need to be bridged with artificial devices. I'm sure the outcomes in those types of patients may not be ideal. Or am I wrong? Would you prefer someone that is not as ill?

Dr de Perrot:

For sure. Ideally you want to transplant them just before they cross that bridge and their right ventricle starts failing. It's just very difficult to predict. Certainly if a patient has a good right ventricle and the liver is not engorged and they have good renal function, these are patients who will do much better postoperatively. We've seen some patients who were reaching the point that their creatinine was rising preoperatively and they developed renal failure postoperatively. Some of these patients do recover eventually, but it prolonged their recovery phase.

Dr Park:

That's what I've noticed, too. Especially for idiopathic PAH patients—they do okay for a time, but there seems to be a cusp beyond which there is recurrence and hospitalization with more hepatic congestion and a waxing and waning of their renal function. It sort of happens at the same time. Of course, that's why they are in the hospital more often and the frequency increases. I do think that is another strong signal that things need to be moving more

aggressively.

Dr de Perrot:

I agree. The BNP may also be a parameter that can give some sense of how dysfunctional the right ventricle is going to be postoperatively. If you have a very high BNP, there's potentially a high chance that the right ventricle is going to create some problem on the left ventricle postoperatively due to the ventricular interdependence. This observation is based on our experience with the transplant and the pulmonary endarterectomy as well. If the BNP goes beyond 1000 or 1500 pg/ml (our lab cutoff is 100 pg/ml), these are patients who will have major issues postoperatively. I don't think there are a lot of published data, and we don't have enough patients to really say that yet for sure, but I think it's an important parameter to consider.

Dr Park:

Unfortunately it is. We have studied BNP in right heart failures in different clinical trials and different centers. I think one thing that we agree on is that you want to see a significant decline in BNP within the first 3 to 6 months of treatment, but it's really hard to come up with a definite number and a cutoff point. It's definitely more complex than how we use the marker for left heart failure.

Dr de Perrot:

I agree. It provides a good sense of the degree of right ventricular dysfunction and a sense of the risk and the degree of potential problems postoperatively.

Dr Park:

With the availability of more convenient PAH medications such as oral and inhaled therapies, often initiated outside PH centers, we're seeing a trend toward delay in initiation of intravenous prostacyclins. Such a delay may lead to “undertreatment” and delay in transplant referral. While it's great that we have so many modalities to treat the patients, identifying those with high risk features is important because you really cannot lose too much time trying another, adding one on top of another. I think the real challenge is knowing when you need to be aggressive.

"… we're seeing a trend toward delay in initiation of intravenous prostacyclins. Such a delay may lead to 'undertreatment' and delay in transplant referral."

Dr de Perrot:

I agree.

Dr Levine:

I agree as well. These therapies are easier to use for both the patient and the practitioner. Many of these patients come to a PH center or to a lung transplant center later in their course and may not yet be on the aggressive therapy they need. Going from there, I wonder just how many patients who are on either intravenous therapy or subcutaneous therapy that are doing "well" should be evaluated for transplant earlier than they are. In our last few minutes, I'd like to discuss outcomes post transplant, both early complications (ie, reperfusion injury, hemodynamically) and longer term outcomes.

Dr Park:

Outcomes can really depend on the timing of the transplant. You want to get to them before they have any significant other end-organ damage, with right ventricle at the top of the list and hepatic and renal there too. Looking at the outcomes from all the registries, if PH patients can make it 3 to 6 months, I think their long-term survival is parallel with other disease groups. It's just that there is greater risk of immediate perioperative morbidity and mortality.

Dr de Perrot:

I agree. I think the perioperative mortality risk is higher. In the long term, they really do similarly to the other groups. If anything, they may do a bit better because usually they get better organs than some other patients do.

Dr Girgis:

I agree with that. Actually, in the International Society for Heart & Lung Transplantation (ISHLT) Registry, among 90-day survivors, the PAH group actually has the best subsequent survival because, as Marc mentioned, they probably get better organs, they're generally younger, and they're otherwise healthy people. So now the challenge is getting them through the perioperative period because they have the sick right ventricles and they have a very unstable perioperative course. I think that has a lot to do with the surgical expertise and the ICU care at the transplant centers. They may need to be managed a little differently from the other lung transplant recipients. I think a lot of it does have to do with local expertise—surgical expertise. I'd like Marc's input on that. Do you approach these patients differently, the procedure itself, the use of bypass, and postoperative support? Is there a difference?

Dr de Perrot:

I think experience is very crucial and we've seen more patients with PH come to our program over the years. We also have the pulmonary endarterectomy program and we are managing these patients more aggressively in our ICU preoperatively. So the ICU staff is seeing a lot more patients with right ventricular problems pre- and postoperatively. Our mortality for PAH patients after lung transplant has really decreased over the past few years. Our mortality now at 30 days post-transplant for PAH patients is about 7%. I think the ICU care really makes a huge difference. We put all PAH patients on cardiopulmonary bypass for their transplant. Postoperatively, we usually keep them asleep for 2 or 3 days on propofol or Versed and fentanyl. If they have any type of bleeding, it must be very aggressively managed since the volume status is very crucial in the first few days postoperatively. The other tool we have used is the oximetric Swan. This device has helped us to have an optimal volume status without giving them too much fluid. So all these points have helped us to improve the immediate postoperative outcome. The other thing that has changed over the past few years is the assessment of the preformed anti-HLA antibody. My feeling is that we see more patients with antibodies, particularly in the idiopathic PAH population. That may support the theory that this is potentially an immunologic disease. So we plasmapherese intraoperatively and postoperatively patients with preformed anti-HLA antibody if their virtual cross-match is positive. If they also have a positive actual cross-match we give them thymoglobulin in addition to the plasmapheresis. I think that's also helped us to decrease the risk of primary graft dysfunction and other problems that eventually could have led to more right ventricular problems.

Dr Levine:

From a perioperative care standpoint in lung transplantation, we have seen a difference now compared to the late '90s, especially in the case of PAH. At that time, we were still often doing single lung transplants for PAH. Now, most centers are performing bilateral lung transplantation for patients with PAH. There has been less hemodynamic instability

postoperatively, and if there are problems with hypoxemia and reperfusion, they have been less difficult to handle.

Dr de Perrot:

We are doing bilateral lung transplant in all patients with PAH. Overall, about 85% of the lung transplants are bilateral in our program.

Dr Levine:

Marc, what are your thoughts on transplanting patients with scleroderma?

Dr de Perrot:

Yes, we do transplant them. We're certainly very selective to make sure that they don't have any peripheral cutaneous disease and that they're not at too high risk of systemic problems postoperatively. But if not, we've listed them. The scleroderma patients with PH are still at very high risk of dying on the waiting list despite the short waiting time. If you look at the long-term outcome, they do very similarly to the other PH patients, so we certainly still consider them as long as they don't have too many systemic problems.

Dr Girgis:

Marc, the main concern for those patients has been their esophageal dysmotility. Your center has taken the lead on this issue in terms of treating reflux and things like that.

Dr de Perrot:

We fully assess their esophageal function. It is usually not a major problem perioperatively. We will keep them on a feeding tube for a while postoperatively if necessary. If I remember correctly we haven't rejected someone because of esophageal problems only, although it can certainly be a major concern. I just looked at the PAH scleroderma patients and they don't

seem to be doing differently than the other PAH patients after their transplants in our experience. In particular, they don't seem to be at higher risk of problems in the long term despite their underlying disease.

Dr Levine:

Based on the evaluation of the patient's esophagus, how are you going about listing these patients?

Dr de Perrot:

They often have esophageal dysmotility. That's very frequent. But unless they have evident chronic aspiration, we usually will go ahead and list them. I can't recall anybody that we disqualified from transplant just because of esophageal dysmotility.

Dr Girgis:

Well, that's very helpful. I think this is an area where it would be beneficial to see some data and see what different centers are doing. We do the same thing. We assess these people, but we've been hesitant lately. We see a lot of esophageal aperistalsis, for example, and we get worried about that. Now whether there are any data to back that up or not—I don't think there are. I think it would probably be useful to have some kind of consensus opinion as to what level of gastroesophageal dysfunction would be tolerated and what's the best way to handle these cases.

Dr de Perrot:

Yes, I agree.

Dr Levine:

I agree with that as well. Does anyone have any more topics that you think we should discuss

that we haven't covered?

Dr Girgis:

Well I think maybe we should add just one quick comment regarding PH complicating parenchymal lung disease like chronic obstructive pulmonary disease, interstitial lung disease, and sarcoidosis. I think in that type of situation, if they have severe PH, that's a strong indication to get those patients transplanted. Fortunately the UNOS LAS does work quite nicely for them when the patient with idiopathic pulmonary fibrosis, for example, does have PH. Their score goes up considerably and appropriately so. I think in that situation the LAS has worked well. Because the presence of significant PH in someone with parenchymal lung disease dramatically worsens their survival, they should be transplanted immediately.

Dr Levine:

Absolutely, that is an excellent point. Many of our patients—more with interstitial lung disease than with obstructive lung disease—do have significantly elevated pulmonary arterial pressures. These patients often come pretransplant without a prior diagnosis or evaluation for PH. Many patients are found to have coexisting severe PAH. However, some of these patients do have a previous diagnosis of PAH and have been started on PAH therapy with variable results.

Dr Girgis:

In addition, medical therapy for pulmonary hypertension generally hasn't been shown to be effective in that type of setting.

Dr Levine:

Absolutely. Results from ongoing and future trials looking at the outcomes with these therapies in patients with hypoxemic lung diseases will be very important.

Reda, Myung, and Marc, thank you all so much for all of your thoughtful and valuable insights on these ongoing and challenging issues. We are all pioneering new territory including PAH and the right heart, the LAS, and even the new lung assist devices. Importantly, our knowledge on many of these topics is based on each center's experience and the consensus

of these combined experiences. It has been a pleasure to share ideas in this forum with all of you. I look forward to working with you in the future as we continue to learn about these and other topics relevant to these complicated patients.

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