

Transcript Details

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Surgical Technique To Implant Diaphragm Pacing System

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DIAPHRAGM PACING SYSTEMS FOR AMYOTROPHIC LATERAL SCLEROSIS PATIENTS

A diaphragm pacing system is an alternative to mechanical ventilators for patients with Lou Gehrig disease. What do physicians need to know about implanting a DPS?

Welcome to the Clinician's Roundtable on ReachMD XM 157. I am your host Dr. Bruce Bloom and joining us to discuss what doctors should know about diaphragm pacing systems for ALS patients is Dr. Raymond Onders, Associate Professor of Surgery at Case Western Reserve University School of Medicine in Cleveland, Ohio. He is also Director of Minimally Invasive Surgery at University Hospitals, Case Medical Center.

Dr. BRUCE BLOOM:

Dr. Onders, welcome to ReachMD.

Dr. RAYMOND ONDERS:

Thanks for having me here today.

Dr. BRUCE BLOOM:

So can you briefly explain the breathing challenges faced by a patient with ALS?

Dr. RAYMOND ONDERS:

As we all know from either reading Tuesdays With Morrie or our own experience with patients with ALS they all basically die from respiratory failure. Eventually, they can't have enough air to go through their lungs that they will start developing increased CO2 levels and so that's our end result for almost all the patients with ALS. Our only present therapies for the patients with ALS is a drug called Rilutek, which increases survival by about 3 months and BiPAP or noninvasive positive pressure ventilation, which helps to take away that breathlessness helps with nighttime sleep dysfunction that most patients with ALS have. We developed the diaphragm pacing

system to try to maintain diaphragm strength and through several studies have shown in their preliminary results that we have been able to maintain diaphragm strength and help patients breathe better in the long term.

Dr. BRUCE BLOOM:

For our physician audience who is not familiar with treating ALS patients, how quickly does this breathing issue happen and how does it progress?

Dr. RAYMOND ONDERS:

Patients will lose 1 to 3% of their predicted forced vital capacity every month. So if we started at 100%, it's slowly declining. Most patients won't feel that they are short of breath until they are somewhere between 50 and 70% forced vital capacity because of our tremendous reserve plus patient's with ALS are no longer running or doing much physical activity, so they won't really notice that they have lost some of their ability to breathe. So we actually at many times when they first see a physician that sees patients with ALS or goes to an ALS Clinic sponsored by ALS/MDA where they will have a pulmonary function test to identify that they are having problems breathing. Many times they may get a sleep study that shows that they are having essential sleep effects at night. At that point in time, some therapies are recommended. Again the only therapy that we presently have is noninvasive positive pressure ventilation. The newer therapies that is in FDA trails in the United States, although already approved in Europe is a diaphragm pacing system, which may be just another tool in our ability to help patients with ALS breathe longer.

Dr. BRUCE BLOOM:

So tell us a little bit about the physiology and anatomy of this breathing breakdown for ALS patients.

Dr. RAYMOND ONDERS:

What occurs in ALS is we initially thought that they would just be losing their phrenic motor neurons. Again our initial look was just that the diaphragm controlled by the phrenic motor neurons in C3, C4, and C5, but we have also found that many of these patients have just lost control. So they have motor neurons with an intact axon to motor unit of the diaphragm. When we initially started doing surgeries on these patients, we could literally see partially denervated areas of the diaphragm. Once you lose a motor neuron and an axon to a strip of the muscle of the diaphragm, we can never stimulate that electrically. It's kind of an interesting aspect as if a phrenic nerve is cut, we can't stimulate the diaphragm. Once you lose all the axons and motor neurons, the diaphragm can't be stimulated, but what we found in many patients that there may be a group of motor neurons that actually do not try for respiration. Therefore, it becomes more like a spinal cord injury patient, so that is true upper motor neuron disease we can stimulate that diaphragm and maintain ventilation.

Dr. BRUCE BLOOM:

So tell us a little bit about the diaphragm pacing system. Where was it invented, how long it has been around and what is it used for?

Dr. RAYMOND ONDERS:

It was actually invented here in Cleveland, Ohio, where I am based at with a group of engineers out of the Case Western Reserve

Medical School in the Engineering Department along with myself that has been working on this project for over a decade now. What we found is that we could actually with laparoscopic surgery, again at that time this was being developed as minimally invasive surgery, is really coming to the forefront is that where we can put a TV camera and see the diaphragm. I actually in one of my most common operations is doing an antireflux operation where I am sewing a hiatal hernia, so I am sewing the diaphragm together and Tom Mortimer who is my mentor in this is the engineer that really began this project, came in and watched an operation and began having some ideas of how we could put these electrodes on the diaphragm using minimally invasive surgery. So the surgery itself is done by really any laparoscopic surgeon and we have put this at the skilled level, this is about as difficult as doing a laparoscopic gallbladder operation which was done over 500,000 times a year in the United States.

Dr. BRUCE BLOOM:

So walk us through that surgical procedure, what are you looking for, how do you test the right places to hook the electrodes up, what else do you do?

Dr. RAYMOND ONDERS:

It is inside we do this laparoscopically so it's a typical laparoscopic operation. I put a TV camera by the belly button. I then put 3 other small incisions. The key aspect of this technology is that to map the diaphragm. After seeing how the diaphragm moves when we stimulate this, to put the electrode in the right spot. We then implant the electrode that allows us to move the diaphragm just like if you were thinking of breathing on your own. Once we do this operation, the system is an external one. So the electrodes come out. Many patients with ALS which has really become one of our own aspects of putting this in require a feeding tube, a PEG tube. We can actually do this at the same time as a feeding tube so we are really getting the 2 operations at the same time; the feeding tube plus the diaphragm pacing system at the same time, which again simplifies this. When we began this project, there literally was no anesthesia literature about doing general anesthesia on ALS patients. It basically said if an ALS patient needs surgery, the patient was going to do very poorly and die. It's just 2 case reports in a total of 4 patients. What we have now just recently published our large experience of doing general anesthesia in ALS saying that it is safe to do general anesthesia. So hopefully most patients with ALS won't be denied surgery for other reasons because of this old literature saying it was dangerous to do surgery in the patients with ALS.

Dr. BRUCE BLOOM:

So tell us about this, you said you have to map the diaphragm. How does that happen? What are you doing to get that map completed?

Dr. RAYMOND ONDERS:

What we developed is a suction cup electrode, and so I put a suction cup on the diaphragm and I stimulate this. I can see the diaphragm contract and I can also quantitatively measure a number. As the diaphragm contracts with laparoscopic surgery, we have air in the abdominal cavity. So I will see a rise in that pressure, so we developed a little computer terminal or clinical station that will tell me a number; the higher the number, the stronger the contraction. Then I will put my electrode in the spot where I get the best contraction of the diaphragm.

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Minimally Invasive Surgery at University Hospitals, Case Medical Center.

Dr. BRUCE BLOOM:

So, typically how many electrodes are you implanting and is it more or less for some patients?

Dr. RAYMOND ONDERS:

What we initially witnessed is one of those interesting things of research is that I initially decided to put two electrodes in each diaphragm in case one broke, I have a backup. The electrodes were developed by one of our graduate students called Peterson; it's a great little electrode. It has 14 stainless steel wires, double helix around each other. We have never had an electrode break in the patient after over a 100 cumulative years of use, but what I then found when I started to program it, for each electrode I can program at different frequency, pulse width, pulse duration, and I became more like an ophthalmologist. I would ask the patient do you like #1 or #2 better, and so I began using both electrodes to get a very smooth contraction of the diaphragm where the patients felt it was just like their own breath, they wouldn't feel anything. So I now use both electrodes so that I can kind of get a much smoother contraction for the patient. So we are able to program it to the patient's benefit where they can feel it. They allows us to actually help these patients in the long-term, as the patient with ALS begins to get weaker and weaker diaphragm function, we start increasing our settings and try to get more contraction of this slowly dying muscle.

Dr. BRUCE BLOOM:

What type of training is required for a surgeon to learn to implant this system and how long would it take?

Dr. RAYMOND ONDERS:

Now this is one of those key things with FDA studies, does it require additional training? So in our initial FDA trial for spinal cord injury we showed that actually the first case that any surgeon did was actually at the same time period with the same morbidity as myself who had done most of these cases worldwide. So in our FDA category for implanting is it just requires a proctor, somebody to watch that surgeon. This has to be a surgeon though that already does laparoscopic surgery. That really is on a difficulty level just as difficult as doing a laparoscopic gallbladder operation, which is done very frequently in the United States. So it is not that difficult to do. We do have a program wherein myself or some other trained surgeons who has done a few of these goes and watches the first surgeon doing it to make sure that they follow the same techniques that have been shown do work on these patients.

Dr. BRUCE BLOOM:

What's the profile of the ALS patient that's a good candidate for DPS, are they all good candidates or does it depend?

Dr. RAYMOND ONDERS:

ALS is a terrible disease; we have no other therapies for it. What we were doing with ALS is we are delaying their death; we are delaying their death from respiration problems. These patients still lose their ability to communicate, they become locked in. What we have now found in our patients is that most patients with ALS will choose to die when they could no longer breathe. In the United States,

only about 3% of patients choose to have a tracheostomy to go on positive pressure ventilation. It's much higher in certain other countries, especially like Japan where most people go on ventilators. The cost for a ventilator is over 150,000 dollars a year. So many patients based on cost or based on discomfort choose not to have that. What we have found in our patients now though is that they choose to die when they can no longer communicate. So we have changed the way they die, which is something we did not expect. It is actually a very interesting ethical problem that we are finding in that we tell our patients before hand is that they at least have a system set up, if they choose that they cannot communicate that somebody may turn off our system thus allowing their diaphragm to breathe.

Dr. BRUCE BLOOM:

What's the cost difference between this implantable DPS and a ventilator?

Dr. RAYMOND ONDERS:

A ventilator costs about 150,000 dollars a year. A ventilator really changes everything. If you are on a ventilator, you are dependent on electricity. We actually published an abstract of patients in this hurricane time period that actually lost their electricity when they are on a ventilator. Most of the patients that died in New Orleans in the hospitals were on ventilators and they could no longer hand bag them. So if you are a patient at home on a ventilator and any storm is coming by, you are worried because your ventilator backup battery is about 6 hours. Once you have a diaphragm pacing system, it is an internal lithium battery, it is a typical battery that lasts over 500 hours and you can use multiple little batteries to keep this running. It is really not a problem for electricity loss anymore. So it is not only the cost of the ventilator, it's actually the difficulty of traveling with a ventilator. For a spinal cord injury patient, it is very difficult to travel on a plane with the ventilator. Once you have our device, you can travel on planes and visit things and travel throughout the country much easier.

Dr. BRUCE BLOOM:

How big is the external battery pack and other mechanical parts of this system?

Dr. RAYMOND ONDERS:

The external battery pack in this is about the size of a TV remote control, so it's fairly small. It's really just powered by a lithium battery, which is a percutaneous system and actually wires are coming through the skin. Again, many of our ALS patients are actually choosing to have their feeding tubes placed at the same time because of lack of their ability to swallow. So actually they are already having a PEG tube at the same time. So it's 2 separate little devices coming through their skin.

Dr. BRUCE BLOOM:

What's the main complications that occur with the implantation of the DPS system?

Dr. RAYMOND ONDERS:

The biggest complication the time of surgery is some air may track from our abdominal cavity to the chest. It's carbon dioxide, that's what we use in laparoscopy and that's just rapidly absorbed. Interestingly when we look at your risk of death from a feeding tube, most patients when they undergo a feeding tube if their forced vital capacity is below 50% predicted is that there is a 30-day mortality rate. We

looked at our patients that were getting the pacing system and the feeding tube, we had nobody die for 30 days. We found that because we are actually changing the ventilation aspect, whenever you get sedated, you get posterior lobe collapse, which is a kind of the pneumonia that people with ALS usually get. When we start pacing the patient, we allow posterior expansion of the air. So therefore there is less risk of that pneumonia that was the usual cause of death just with a feeding tube. So actually we have a less risk of death by having this newer pacing system at the same time as a feeding tube than the historical feeding tube alone.

Dr. BRUCE BLOOM:

I would like to thank our guest, Dr. Raymond Onders.

We have been discussing what doctors should know about diaphragm pacing systems for ALS patients. You have been listening to the Clinician's Roundtable on ReachMD XM 157, the channel for medical professionals. For a complete program guide and podcast, visit www.reachmd.com. For comments and questions, call us toll free at 888MD-XM 157, and thank you for listening.