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Uses for a Diaphragm-Pacing System Beyond ALS

DIAPHRAGM PACING SYSTEM

What is a diaphragm pacing system and which patient can benefit most by having one. Welcome to the Clinician's Roundtable at ReachMD, the Channel for Medical Professionals. I am your host, Bruce Bloom, DDS, JD and joining us to discuss usage for diaphragm pacing system beyond ALS it is Dr. Raymond Onders, M.D., F.A.C.S., 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 Hospital Case Medical Center.

DR. BRUCE BLOOM:

Dr. Onders welcome to ReachMD.

DR. RAYMOND ONDERS:

Thank you for having me here today.

DR. BRUCE BLOOM:

Tell us about the diaphragm pacing system and how it helps ALS patients to regulate their breathing?

DR. RAYMOND ONDERS:

Well what we found our initial pilot trial and we have just completed a large multicenter trial throughout the United States they allows us to maintain diaphragm strength, allow us to maintain the good type 1 muscle fibers that we need in patients with ALS. We have actually changed the way of the patients are dying from this need for ventilator to having unfortunately with ALS are still losing all of their other motor neurons. They are still unable to move and eventually can't communicate. We have changed kind of the usual way of death from respiratory failure to when they choose to die because they can no longer communicate or they have developed other problems from ALS.

DR. BRUCE BLOOM:

And explain the mechanics of what the DPS does for these patients? Why does it help ALS patients?

DR. RAYMOND ONDERS:

In ALS patients as in our other groups of patients we are implanting electrodes directly on the diaphragm. The diaphragm is a very interesting muscle at one of key, New England journal articles that just came out in March of this past year that showed that just one night on a ventilator you lose 50% of your type 1 muscle fiber as we sit here talking about 70% of my diaphragm is type 1 slow-twitch muscle fiber that can fire every minute of everyday without tiring out. What occurs is that the diaphragm actually very rapidly from disuse with 50% of the muscle mass lost within one day of being on a ventilator. What we found in ALS patients is that when they have lost some central control of the diaphragm, develop type of central sleep apnea, so at night when they are on their usual therapy of noninvasive positive pressure ventilation their diaphragm muscle is not firing at all and therefore that diaphragm is getting a little bit weaker from disuse. We also found that there is a much higher proportion of type 2B muscle fiber in ALS patients that we can convert that to type 1, so those are kind of some basic effects that we have seen in our ALS patients especially those with more of the upper motor neuron involvement of ALS.

DR. BRUCE BLOOM:

So the ALS patients are a new cohort that you are trying this on. Tell us about the other types of patients that use DPS.

DR. RAYMOND ONDERS:

Well our initial research was in the spinal cord injured patients. Obviously you had a catastrophic C2 injury, will become a quadriplegic ventilator dependent it changes your life completely. A 40-year old that becomes a ventilator dependent quadriplegic has a life expectancy of only 7 years if they are on a ventilator, that's a significant change in the life expectancy. If you are one of those few that actually could still breath the exact same injury your life expectancy is 20 years, still not great for a 40-year old, but as we all know when you on a ventilator you have a high incidents of pneumonias. Ventilator system ventilate the anterior lobe and due to this chronic posterior lobe collapse. We have chronic positive pressure built trauma on your lungs, so that significantly effects your survival. So our initial the research group on those patients. Interestingly Christopher Reeve was our second successful patient. The first one not on first try, the first patient we had to do is second time to get it to work as we had changes in how we looked at things and he said even before the surgery you know "what do I have to lose it is a simple laparoscopic procedure. I am a quadriplegic so I can get off the ventilator it is a huge change in my lifestyle". We subsequently did a 50 patient multicenter trial and got FDA approval as a monitoring device in June of this past year and what we showed on those 50 patients was that we got all of them off the ventilator except the second patient which changes their quality of life significantly. That really was our initial group that led to our ALS group and really the data from those two groups have shown us that we may be able to help just anybody on a ventilator with this percutaneous system.

DR. BRUCE BLOOM:

How long does the surgery take and what is involved in it?

DR. RAYMOND ONDERS:

Well the surgery takes little over an hour. It is about the same technical difficulty as a gallbladder operation, which is done over 500, 000 times in United States. It is a laparoscopic procedure where we put a TV camera in by the belly button. However, the key technical detail of this operation, which was developed, was that we can't just randomly put the electrodes in the diaphragm. We have to map the diaphragm. So, then they have developed the suction-cup electrode where we move it around the diaphragm to stimulate the diaphragm, we can measure change in abdominal pressure, so the higher the pressure increase, the stronger the diaphragm contraction. We can also visualize this so this is both a quantitative look at the diaphragm and a qualitative look at how the diaphragm is contracting. Once we identify the best diaphragm implantation we put the electrodes in there. We put 2 electrodes in each diaphragm initially because that 1 electrode might break. Fortunately, our graduate student that developed this electrode Peterson, we named it the Peterson electrode after him, this electrode has never broken in the patients, a great little electrode, and we subsequently develop a way because for each electrode I can stimulate them with different settings so that I can try to maximize the contraction and get the best breadth by setting each electrode separately and then I kinda feel like an ophthalmologist saying be like #1 or #2 better with how they breath as opposed to how we see things.

DR. BRUCE BLOOM:

And these breathing for those patients 24 hours a day have any impact on the diaphragm or the other muscles of the area?

DR. RAYMOND ONDERS:

It is very interesting because some of the older list for ALS that is that over exercising can make it worse where obviously exercising on diaphragm keeps stimulating it 24 hours a day. From an evolutionary standpoint the diaphragm is made to be utilized every minute of every day and so really stimulating every minute of every day is just like our own natural breathing, it does not cause any problem as that New England journal article showed that just not moving a diaphragm for just one night cause the change in the muscle composition that converts the type 2B muscle fiber faster than any other muscle. The atrophy is faster than every other muscle. It needs to move every minute of everyday. You should never rest the diaphragm.

DR. BRUCE BLOOM:

If you have just tuned in you are listening to The Clinician's Roundtable on ReachMD, The Channel for Medical Professionals. I am your host, Dr. Bruce Bloom, DDS, JD and joining me to discuss usage for a diaphragm pacing system beyond ALS is Dr. Raymond Onders, M.D., F.A.C.S., Associate Professor of Surgery at Case Western Reserve University School of Medicine and director of minimally invasive surgery at University Hospital Case Medical Center.

So where are else in the world is this being used and for what indications?

DR. RAYMOND ONDERS:

It has completed year being approval for spinal cord injury and for ALS and any neuromuscular disease, so we have actually implants that have been done in Paris at Pitié-Salpêtrière Hospital and Charity hospital in Berlin and Barcelona, in Iceland and we have numerous other sites starting in Europe. Again interesting is that I have been involved to this research for over a decade now that we doubled the amount of patients being implanted every 6 months. In the United States, we just got approval for spinal cord injury indication and presently we are just in the waiting pattern with FDA for our ALS applications. We have completed our long-term multicenter trial and we are just looking and waiting for the final announcements for the data before we apply for FDA approval for ALS in United States. In our future application, we are really looking on just anybody on a ventilator utilizing our data from spinal cord injury in ALS it looks like we may help any patient that is on a ventilator as we recently learned in the United States is that hospital won't get

paid if the patient develops ventilator associated pneumonia. Why do people get pneumonia on the ventilators? The ventilators only cause expansion of the anterior lobe so you get the chronic posterior lobe collapse. We have shown already that by stimulating the diaphragm in conjunction with the ventilator at the same time, which causes the air, go to the posterior lobe and therefore we do not get that posterior lobe collapse. So we also have a temporary type of diaphragm pacing system where we just would utilize at the same time they are on the ventilator to maintain type 1 muscle fibers help maintain posterior lobe ventilation and hopefully decrease ventilator associated pneumonia.

DR. BRUCE BLOOM:

What other kinds of physicians you need to work with to make sure that the patient is eligible for this. Are you are working with the neurologist and others that are treating the patient?

DR. RAYMOND ONDERS:

Absolutely, I mean, this has been a team aspect to start initial aspect. We have had critical care nurses, or pulmonologist here, neurologist here, and really for ALS patient you know the interesting I am a general surgeon and I treat lot of ALS patients as my researches take me in that area, but the first thing I tell any ALS is the most important thing is that get yourself a good neurologist who will take care of all aspects of your ALS. There are the one specialized in this. So, I really even in my own practice here I do not even see a patient for consideration of this until the neurologist has helped manage all of the other conditions that they will have with ALS. ALS is a terrible disease and they need to have a good neurologist to help take care of all those other aspects that will actually help the quality of life and then, once they have kind a stabilized from that aspect then we can try and do something to help them even further.

DR. BRUCE BLOOM:

And wha date are you hoping to get approval from the FDA for its use in ALS.

DR. RAYMOND ONDERS:

I think that would be a whole other segment is the role of the FDA in trials. I think as we all know the FDA is overworked. There is no doubt that at presently we don't have enough manpower at FDA. There is one aspect that the government has called humanitarian used designation and that is what we utilize for our spinal cord injured patients that still is a very slow process with FDA and presently we are in negotiation with FDA to try to offer this for patients with ALS. Unfortunately we think it will probably be a good 6 months before anybody in United States any further ALS patients will be offered this. Obviously, we have full approval in Europe and our data looks good but just is a slow process, which is appropriate. I mean the FDA has a lot of work to do and we need to support them in their work, but if you are an ALS patient, obviously having to wait for approval it is between living and dying.

DR. BRUCE BLOOM:

Could you go outside at the United State if you are an ALS patient and get this done?

DR. RAYMOND ONDERS:

Presently, you know we have approval in Europe and it was an interesting aspect though is that it is to difficult to travel with ALS and you know this is common question ALS patients ask me and if you are fairly far along on your disease course just traveling on an airplane and all other aspect may be enough to push over the edge. I think that there is a lot of risks with doing that and it gets the medical tourism industry. It is a difficulty industry because officially if they are plant somewhere else is that they can't get product support here in United States. So I think it is difficult aspect. I hope that the working closely with our government agencies that will be able to offer this for ALS patients in United States.

DR. BRUCE BLOOM:

Tell us about it use in critical care patient who don't have ALS and how would you be using this and why?

DR. RAYMOND ONDERS:

It seems that obviously we have been looking at this very carefully. Now this is a whole new avenue of surgery that is called node surgery, which my all other research aspect is this other minimally invasive surgery. May have heard of natural orifice transluminal endoscopic surgery where we can actually now take out gallbladders through the patient's mouth or a female patient's vagina with no abdominal incisions. We actually developed the way to actually put this diaphragm pacing system and just at the same time as our percutaneous endoscopic tubular PEG. Interestingly, I met the same hospital where the PEG was initially developed Jeff Hopkins my chairman and so we have a very long experience with these aspect for helping patients in the ICU and so we believe that at the patient beside in the ICU we can actually implant the diaphragm pacing system at the same time as our feeding tube. The data looks very promising by maintaining diaphragm strength we can help patients to get off the ventilator, 40% to 50% your time after initial injury is just to re-strengthening the diaphragm by electrically stimulating it earlier we will maintain that strength decrease the posterior low collapse that can lead to pneumonia and hopefully improve the quality and survival benefits in ICU.

DR. BRUCE BLOOM:

Is your group looking at using electrical stimulation in any other area of the body?

DR. RAYMOND ONDERS:

Case West Reserve where I am actually and faculty has had the functional electro stimulation area. Over the years, they have had system for spinal cord injury. They moved their hand for quadriplegic, we have walking system are being developed, it is kind of you know as we all would like to cure spinal cord injury and get that spinal cord to regenerate or kind of get pass the bruise and the electrical problems. We can now learn implanting enough electrodes to get the body to move. It is never as good as it was initially. So we have a group working on a freehand system where you can move the arm or walking system for patient, a standing system, as we would like to say is that we believe we can put electrode just in any muscle that will help the patient. The diaphragms are very interesting one because if the diaphragm contracts you breath. Any other muscle like your hand muscles are so complicated the grasp, the move that 360 is lot harder to control, it is much more difficult but we are doing a lot of positive work in that area.

DR. BRUCE BLOOM:

I want to thank our guest Dr. Raymond Onders, M.D., F.A.C.S. We have been discussing usage for diaphragm pacing system for the patients beyond ALS.

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