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PRESENTATION

Dr. Michael Vasquez:

Welcome everyone, my name is Michael Vasquez and I am a clinical assistant professor of surgery at the University of Buffalo. And I want to talk to you today about something that's very near and dear to my heart, and that is chronic venous insufficiency in association with lymphatic dysfunction, what is some of the evidence and what is some of the new treatment modalities associated with this. It's my first real webinar, so I'm going to advance you with the slides 'cause I understand some of you are dealing with handouts and I'll say next slide when we need to advance. Today, venous insufficiency is known to most of you because I understand you're a group of vascular surgeons and vein specialists, so I'm not going to talk too much about that, but I do want to introduce this new term. It's called phlebolymphe^m and that's the association of venous insufficiency and lymphedema. What are the new treatment considerations and some of the latest evidence? As a disclosure, I speak for Tactile Medical on behalf of this and because of this passion of mine for phlebolymphe^m. I'm a principal investigator with Medtronic, the V-Close, which is now Venous Seal and I speak on behalf of them. I'm also a principal investigator for BTG International, the product Verithena and their studies a number of years ago. And part of my own background is that I am co-author of the Revised Venous Clinical Severity Score, put together with Dr. Rutherford, that is really the landmark model for how we follow outcomes for patients who are treated with many different modalities of superficial treatment. And fortunate to be co-author of the Chronic Venous Disease Clinical Guidelines, put out by the Society for Vascular Surgery and the American Venous Forum. Next slide.

This of course, because I'm speaking in part about Flexitouch, I refer you to the company website or to some of the local distributors and representatives that may service you for all the indications and contraindications of use. But specifically, I use this product, my primary indications for use are those that may have primary/secondary lymphedema, as well as those that have venous insufficiencies and vein ulcers specifically, and contraindicated are those folks that have heart failure, acute heart failure especially, those that have any acute thromboembolic disease, those of course that have severe peripheral arterial disease, as well as active, inflamed skin infections, active cancer, and any circumstance where you're thinking about not increasing lymphatic return or venous return to the heart, and of course, those folks who are pregnant. Next slide.

Venous insufficiency of course affects, as we know, many, many millions of Americans. It's ten times more prevalent than peripheral arterial disease and approximately seven million patients have more severe disease, especially those that have edema or skin changes or venous ulcers. It's a significant clinical problem for the patient. Next slide.

There's two primary causes of venous insufficiency. One of course is reflux, which I'm sure you're quite familiar with. Dilatation of the vein wall leads to valvular dysfunction and destruction of valves, which of course then results in retrograde flow and venous congestion, venous hypertension. Of course, there's also obstruction. It could be acute, but a lot of patients we see now are chronic obstructive patients with fibrosis of vein walls and outflow obstructive problem leading to backlog and congestion in the leg, and of course, venous

hypertension. And the presence of both is far worse than the presence of either one alone. Next slide.

Anatomy, I don't need to go too much over with you, but most importantly, my perspective on the anatomy is that the two systems, the superficial and deep system work in a very interesting way. Ninety percent of the blood, of course, is conducted out of the leg through the deep veins. The superficial system is really more of a collecting system. Not a lot of blood really leaves the superficial veins, but of course, in situations where there's reflux, that's where most of the reflux is seen. And of course, there's the muscular venous pump, which actively pumps the blood out of the leg in a normal situation. Next slide.

Briefly, overgoing this muscular venous pump, you can see in the first (a), the foot is primed, the blood gets put into the calf, it fills into the calf in (b) and then as the patient is walking and stepping, that blood is forcefully ejected out of the leg. That then creates a bit of a syphon in the deep venous system so that blood in that superficial collecting system, now comes into the deep system, it's drawn into the deep system, so that blood is then brought in inward and upward. Next slide.

'Cause that of course is the direction that this venous blood is supposed to be moving— inward and upward, not downward and outward. Valves of course help in that process, but when there's destruction of valves, fibrosis of valves, you now get blood moving in the wrong direction. There is bidirectional flow in the foot, if you didn't know that, I draw that as one little caveat of information that you may not know. We're on the next slide now.

So, treatment of superficial venous reflux, many of you know a lot about. It is currently recommended in the proper situations, of course, but it's recommended in the Society of Vascular Surgery and American Venous Forum guidelines, both in the guidelines for the management of venous ulcers, as well as the care of patients with varicose veins and CVD. And on the bottom there of that slide, the guidelines, the clinical guidelines, in which I outlined and which I'm happy enough to be a co-author in. but that's there and they're great guidelines and if you haven't reviewed them, I recommend that you do. Next slide please.

So, is there more to the story than just superficial reflux or chronic obstruction? And of course, the answer to this question is yes. I show this picture 'cause I think it's a great example of a congested leg. And you've seen this over and over again. And on the right side there, there's a picture which is the near infrared fluorescence, which is a way of studying veins. It's not real available as a test we can get yet, but it's a way of studying lymphatic flow in legs. And as you can see here, there is a delay and a congestion of the lymphatic space with this contrast imaging of this leg. And that's what's happening in these legs. Next slide.

Phlebolympology of course, has been very well discussed, more in Europe than it has in the United States and there's a journal that I show here that shows that it is a serious, it is a serious study and a whole journal devoted to this. Next slide.

The venolympatic connection is a complex one. And I'm going to spend a couple moments going through what this is, so that you understand my way of thinking about this now, which has changed in the last couple years. Next slide.

The lymphatic movement is complex. The venous system is a prime system, so beginning in the venules, there's already blood in there. The lymphatic system, really in a normal situation, functions more like a weak vacuum, so that after blood goes through the capillary systems and there's movement into the interstitial space, fluid is drawn into the lymphatic system because of this weak vacuum, and flaps will then open to allow fluid to go

into the lymphatic capillaries and then be conducted out of the leg. And this fluid is not just watery fluid, this can be watery fluid, it can be thicker fluid, proteinaceous fluid. You can have lipids, enzymes, antibodies, lymphocytes and of course, bacteria can be in this fluid, leading to some of the more chronic states. Next slide.

The Starling Principle, which I'm sure you learned about in medical school, has been revised. It was revised in 2010 and it's a little different than it used to be. To the left you can see the older classical model, where there was this idea of blood coming through arterials into the capillary system and then there's a hydrostatic pressure that pushes fluid now into that interstitial space. And that can occur both, could occur in both the arterial side and the venial side of this capillary system. That's changed, that's not how it is anymore. We've learned that there is now a glycocalyx lining of the membrane on the venule side of the capillary system. So, although there's hydrostatic pressure in the arterial side of the capillary that pushes fluid into the interstitial space, it's not seen on the vein side. So if you look at the right hand, the glycocalyx model, there is no reabsorption of fluid into the veins. So instead of, on the left side again, 90 percent of blood, I'm sorry, 90 percent of fluid that gets into the interstitial space heading back into the capillary systems, we now know that almost 100 percent of fluid that's pushed into the interstitial space, has to leave through the lymphatic system. So this is a separate system that we are very dependent on to move vast volumes of fluid every day through. Next slide.

As a matter of fact, there's estimated now between four to eight liters of lymphatic fluid that is moved through our body every day, far more than we ever really appreciated in the past. So, on this slide here, let's look through at least what lymphatic function is in normal situation and this progression to lymphatic failure. And I liken it to the difference of renal insufficiency and renal failure. There's a progressive process there. Most of you haven't thought about that with lymphedema. You think of lymphedema as this cut or dry thing, but the first bullet point in the normal system, interstitial fluid builds, that increases the luminal pressure, which opens the flaps, and this fluid is pushed into the lymphatics and conducted out. In system overuse, there's increased venous filtration into the interstitial space and this can increase up to ten times. It's a preclinical edema. So you have some reflux, but you're not really seeing leg swelling. Why is that? 'Cause there is compensatory mechanism involved that allows this fluid to get out, up to ten times. Now if the system is overloaded more, there's more venous reflux, there's some chronic obstructive component, now you have excess fluid building up into the tissue, and this is lymphatic insufficiency. The lymphatics can no longer keep up with the fluid that's accumulating in the tissue, and of course, then that can lead to long-term damage and lymphatic failure, where now you have damage of the lymphatics, damage of the flaps, damage of the pump mechanism, whatever it is, you have chronic backup. And this can be permanent; it can be reversible in part, but it can also be permanent. So, that leads me to this final point of this slide, is that all chronic edema is a form of lymphedema and not lymphedema that your grandmother knew about necessarily, but lymphedema that we talk about now, this spectrum of disease. Next slide.

In the literature, there's really very little on the prevalence of lymphedema and part of the reason is that physicians, for the most part, diagnosis relatively infrequently. So, there's no codes to really follow this as closely as we'd like. But we do estimate that about one in a thousand patients have some type of chronic leg swelling. This increases with age, especially after age 65. Thirty percent of people with lymphedema have some sort of cancer treatment or cancer therapy, and of course, nearly 30 percent of them experience some type of recurrent cellulitis, many of them that prompt hospital admissions. Next slide.

The most common form worldwide is filariasis, but we're going to speak here more about in the Western World, phlebolympedema, secondary phlebolympedema.

Phlebolympheidema is the mixed ideology swelling due to chronic venous insufficiency and lymphatic insufficiency, that's how it's defined. Next slide.

Lymphedema can be debilitating. Certainly recurrent cellulitis, you seen a million times, not to mention fibrosis and long-term damage of lymphatic transport, decreased mobility and dexterity in the limbs, pain, and even the development of Kaposi sarcoma. Next slide.

This progression is seen and recognized and documented over and over, but this transition of lymphatic insufficiency to lymphatic damage is, I think, really the take-home point in many ways in what it is that we can do for these folks. Next slide.

This again is the NIRF imaging of how this fluid builds from both healthy tissue, all the way down to the patients who have venous ulcers or healed venous ulcers. Next slide.

On ultrasound we see this all the time. I don't know how many of you are actually documenting this in some of the ultrasound reports that you dictate, but if you're not, you should be, because there's now a coding system here in the Journal of Vascular Surgery in 2017, they actually have a term now. It's called SEFS or SEGS, depending on what you're looking at and I recommend you at least look at it. In my reports now, I tend to say mild, moderate or severe lymphatic fluid or fluid in the lymphatic fluid in the subcutaneous tissue of these folks, lower leg, upper leg. But you can see, it's very well documented now and I encourage you look at this article. Next slide please.

Stemmer Sign. Stemmer Sign can be present, can not be present. If it's present, it's more indicative of a more chronic phase of lymphedema, but all leg swelling is some type of lymphedema. So you may have a non-positive Stemmer Sign, but that's what it is and it's worth documenting in your exams. And on this next slide...

Other types of phlebolympheidema. Here this patient has lipodermatosclerosis with the so-called champagne bottle leg. Next slide.

Phlebolympheidema with nodular sclerosis. Next.

Lymphedema Rubra, this is venous congestion in this leg. It leaves this red look. A lot of times, we treat these folks and this red look goes away, even though the leg may be somewhat swollen. Lymphedema Rubra, next slide.

There are forms of different types of compression, graduated compression. For many people it's fine, for lots of people, especially with these really swollen legs, they're rolling down, they're obese, maybe they can't get them on, they're uncomfortable. Intermediate really patient compliance is what I see in some of the more severely affected patients, next slide.

Short stretch compression has become much more used in our practice. There's lots of new models of things, things that can stay up in some of these more swollen legs, in ulcer patients. Even thigh compression now that can be used for some of the oversized patients and definitely have a role there. Look at some of these new models of things because I think that's very useful for some of your patients. Next slide.

And of course, advanced pneumatic compression has to be part of the armamentarium of what you use. Patients who don't wear their compression, have persistent swelling after treatment, maybe they're obese, maybe they have limited mobility or limited muscle pump mechanism, these patients need lymphatic support. The Flexitouch has become something

that's very prominently used in our practice. It's more programmable and intelligent type of compression, better than other types that I've seen and I'm an advocate. It's the only pneumatic compression that's clinically-proven to stimulate the lymphatic system in ways that others don't. Next slide.

I wanted to touch a couple studies regarding venous ulcers and venous patients. The first one, of course, is the ESCHAR Trial. You've heard, I'm sure, many times, and to review it very briefly, this was a trial of 500 patients out of the UK that looked at both patients that were treated with open superficial venous reflux surgery and compression versus compression alone. The outcomes were analyzed for both healing time, primary recurrence and ulcer-free time. The results demonstrate that whether patients had open surgery and compression or compression alone, the healing time for ulcers was approximately the same. This is open surgery now by the way. The ulcer recurrence rates were however significantly different. At four years it was lower in favor of the surgery group and the ulcer-free time was also somewhat lower, statistically significant at least for the patients who had open surgery and compression versus compression alone. Next.

This brings us now to this New England Journal article that I hope you're familiar with, published just this last year, also out of the UK. The EVRA study, Early Venous Reflux Ablation Study. Because there's been this debate—should we do surgery early, should we not do surgery early. Of course, we have to make sure that people are properly screened and they're appropriate for some type of procedure. But these were two parallel groups, nearly 450 patients with venous ulcers. There was an early intervention and a deferred intervention group. So the early intervention had early endovenous ablation and compression and the deferred ablation we waited, we tried to heal the ulcer with compression alone before treating these folks. There was, the primary outcome was time to healing from the date of the randomization, and the secondary outcome was the rate of healing at 24 weeks, the rate of recurrence, ulcer-free time, and patient-reported health outcome scores, their quality-of-life scores. Next.

The time to healing was significantly improved for those patients who were randomized to the early intervention group—56 days versus 82 days for the deferred group. Next.

The rate of healing at 24 weeks was also better for those patients who had early intervention versus a late intervention—85 percent versus 76 percent. Next slide please.

And the ulcer-free time at the one year was also improved. Early intervention group 306 days, deferred group is 278 days. Interesting that the patient reported quality of life, although it trended toward the early intervention group, it didn't totally get there and it wasn't as significant as I thought it might be, possible 'cause of the outcome measure that they used or maybe there is something else, which brings me to a question that I ask you. And you can jot it down on the side, but my question is this: How many patients of yours, the more severely diseased patients, with leg swelling, skin changes or possibly ulcer, how many patients of those, despite successful treatment and despite successful ablation of the majority of their reflux, how many of these people still have swelling? Maybe you've healed their ulcer. How many still have swelling? I don't really know the answer and I don't know that there's any good study that documents that, but for me, I'd put it somewhere in that ten percent range. People still need some type of lymphatic support despite elimination, appropriate elimination of their superficial venous reflux and other modalities of conservative therapy. Next slide please.

This brings me to the study regarding Flexitouch in real-world outcomes for patients. In this study design, this article was published in the European Journal of Vascular and

Intravascular Surgery in 2013. In this study, there was a significant improvement in the limb volume and reduction of fluid in patients that were treated to it with Flexitouch. And important to note that CVI was the leading cause of the lymphedema in the majority of these patients that were looked at. Next.

This is important because there are cost implications associated with patients that have edema or persistent edema in their legs, even if they may have had successful treatment, both we can reduce the cost of readmission to hospitals that patients that have recurrent cellulitis or recurrent venous ulcer. As a matter of fact, the majority of patients who are admitted are treated in our offices. They may have complete healing, they may not, we may have a wound care center involved with them, but many of these patients will develop recurrent cellulitis and need admission to the hospital. That's the primary cost driver, I think, for continued lymphatic support for many of these patients. Next slide please.

Earlier this summer, there was an article published in the Journal of Vascular Surgery with Dr. Rockson, who I've come to know, and Dr. O'Donnell who I've known for many years, regarding the health and economic analysis of phlebolympheidema patients. In the study of a thousand patients, they either had primary or secondary lymphedema or they had primary or secondary venous insufficiency. This was an insurance claim, it was matched, a case-controlled insurance claim study, where they looked at these patients over time. They compared the healthcare cost in utilization of Flexitouch treatment versus alternative types of treatment. Patients were looked at and followed for a period of up to two years. Next slide.

In conservative therapy and Flexitouch versus alternative treatment modalities, there was a statistically significant improvement in healthcare cost savings in patients who were treated with conservative therapy and Flexitouch versus all the other treatment modalities. In that first column, there's a significant reduction in the cost of treatment in patients who were treated just with conservative therapy alone versus conservative therapy and Flexitouch, versus the second column where there's an 85% reduction in patients who were treated with conservative therapy and simple pneumatic compression. And then the last one is conservative therapy and other types of advanced pneumatic compression devices where there's a 53% reduction. And I'm going to break down those in the three successive slides. Next slide.

Conservative therapy and Flexitouch versus conservative therapy alone. The majority of improvement you see if you look at the middle column, is the lower inpatient cost. If we don't bring patients to the hospital, you can save a lot of money. Hospitals are expensive places, not to mention that patients get exposed to all kinds of other things. But that's where we see the primary driver in this improvement in cost, as well as if you can improve their swelling, you can reduce their outpatient cost as well. Next slide.

Conservative therapy and Flexitouch versus conservative therapy and simple forms of compression or simple pneumatic compression. Here again, we see a significant improvement in patients who are treated with a more programmable intelligent type of advance pneumatic compression versus simple pneumatic compression. There's a 93% decrease in inpatient cost as well as significant reduction in outpatient cost as well. Next slide.

Last is conservative therapy and Flexitouch versus alternative types of pneumatic compression and conservative therapy. Again, it's not as big a difference as we've seen with other things, but there still is a significant reduction in cost and outpatient cost especially for these patients. And to the right side of the column, cellulitis, recurrent cellulitis, recurrent venous ulcers, are really the driving force behind most of these hospital readmissions. Next slide.

I have a case presentation to show you. This is one of my patients, who is more advanced disease type of patient and he had significant superficial venous reflux. And here you can see the size of this great saphenous vein, getting close to the sapheno-femoral junction that we treated. It was up to 2.14 centimeters. Next.

This is the old catheter, but I show that because it illustrates the size of the vein that we're looking at. In the left side we're positioning it distal to the sapheno-femoral junction and on the right side with the old electrodes opened up, it's not even touching the walls of that vein. So in this slide here, we can see that the electrodes are open, but it's not even touching the walls of the saphenous vein in this older catheter. Next slide.

After the administration of Tumescent, we can see that the fluid has narrowed the space, closed the vein down, so now you can actually see the electrodes touching the walls of the catheter so that we can get a good closure of this vein. Next slide.

And in this last slide, we see that the vein is appropriately closed and there's still some residual Tumescent fluid around. Next slide.

This patient here had a significant reduction in their leg volume and their leg swelling and they had healing of the ulcer. And you can see that in the left side versus the right side, which is approximately about a month out. However, this patient will continue to need lymphatic support. I don't care what you use and despite the marketing of many different types of procedures that you can use saying maybe you don't need stockings, maybe you don't need afterwards, I would always recommend that this patient have some type of lymphatic support. Why? Because you're going to see this patient come back in a year or two years with swelling or maybe their swelling doesn't go down completely when they don't have, here you can see that they had their stocking on, when that stocking is removed. Because they are at a more advanced stage of lymphatic insufficiency, lymphatic failure possibly. This is a patient that lymphatic support additionally is necessary and I advocate consistently. Maybe they can be in some type of a garment, maybe they need more. I leave that to you, but these are these types of patients specifically that I'm talking about. Next slide.

So there's a progressive spiral of lymphatic dysfunction. This is a two to three-system function. We're looking at lymphatics, we're looking at veins and we're looking at that interstitial space. It's a progression of disease that although we can eliminate the primary insult, you cannot necessarily fix their lymphatic dysfunction. And maybe you can't even reduce their venous insufficiency. Maybe they have a chronic outflow obstruction, maybe they're obese. Lots of reasons that these patients will need this continued support. Next slide.

So in conclusion, phlebolympheidema is a dual-system failure, dual-system, that can lead to a progressive spiral of worsening symptoms. From the EVRA Study we see that early ablation can reduce ulcer healing time and reduce the ulcer-free recurrence, but nevertheless, in the more severely diseased patients, we need to support the lymphatics. Simple compression may be enough; however, I also believe that the Flexi-touch system has a significant improvement for those patients that need additional help. Thank you very much.

Dan Carlson:

And thank you Dr. Vasquez on behalf of Tactile Medical that was really a great talk. And thank you everyone across the country who has logged in to participate. Please, as the questions come in over the phone, if you will identify yourself and your location, as there are many of

you signed in across the country. We'd like to start with one question that came in over the web. Dr. Vasquez, what physical symptoms are you looking for to determine if the lymphatics are temporarily overloaded or if there is permanent lymphatic damage that has taken place?

Dr. Michael Vasquez:

Well there's no easy answer to that question. And I guess the first thing that I think of is certainly the chronicity of this. I guess that things that we see in the skin frequently translate into what we're seeing in the lymphatics. And if you have that tendency of like a woody induration to the skin and that woody sense in the palpations, you're probably getting that type of fluid that you're seeing, that more proteinaceous fluid, that thicker more fibrotic type of fluid in the lymphatics, that's less easy to drain.

Dan Carlson:

Alright, thank you, so it sounds like it's largely what you're looking for in skin changes, is that right?

Dr. Michael Vasquez:

Well I think that's accurate. I think if you're getting that sense of that thicker fluid, the dermal lymphatics are certainly an indication of what's going on in some of the deeper lymphatics. So I think yes, that's the answer.

Dan Carlson:

Alright, thank you.

Physician Caller:

This is Dr. in Mesquite, Texas. My question is the lymphatics, are they in all the tissues and when we do lymphatic testing, we inject the webs between the toes and that's the skin lymphatics. So do the skin lymphatics cover the deeper structures like subcutaneous tissue, the muscles and so forth and so forth, and if so, why do we only study the lymphatics of the skin? And you know, I personally used to do, in the olden days, injections in the webs of the toes to inject dye to study the lymphatics in the 60's and 70's and that's because we didn't have CTs and MRIs to see if there are filling defects in the pelvic lymph nodes to diagnose the aesthetic lesions. So the question I guess, to restate it, is are the lymphatics in the skin and underlying structures and why do we only study the skin lymphatics when we study that? And the other question is, why don't we call edema lymphatic edema, because that's what it comes down to?

Dr. Michael Vasquez:

Well thank you Dr. Well the answer to the second question is an easy one and I think that the terminology is changing. As a matter of fact, I just came back from a national conference of the American College of Phlebology and this was a prominent section of discussion is in lymphedema, and that I think we're learning to understand that all leg edema is a form of lymphedema. Which brings me then to your first question, and that is that the interstitial space is a lymphatic space. It may not be a discreet lymphatic vessel, but it is the lymphatic space, so even though the injection for lymphedema of the legs is done in the, basically it's the most dependent portion of the leg, that space between the toes that isn't, often may not have severe skin disease so you're not going to create a wound that may not heal. But you're injecting it into those dermal lymphatics and that substance, that radioactive contrast is then

going to be, it's going to follow its path that it normally follows, that that fluid follows. But you do have lymphatics within muscles. That interstitial fluid is within the muscle. I'm sure that even some of the deeper spaces in other structures have a lymphatic component that drains. But mostly where we see it is in that subcutaneous tissue.

Physician Caller:

Thank you very much Dr. Vasquez.

Dr. Michael Vasquez:

You're welcome.

Dan Carlson:

Alright, Dr. Vasquez, one additional question that came in online is can you please discuss more about how you use ultrasound for looking at lymphedema?

Dr. Michael Vasquez:

Well before I began to report extra fluid in the subcutaneous tissue, I noticed it. And I always felt that I wasn't really doing justice for my reports in not reporting this more. And prior to this report that I elude to in the program, in the presentation, I began to report seeing basically those linear changes of hypo??? space, that's what they refer to as subcutaneous echo-free space, which is basically fluid within, interspersed within fatty tissue in the subcutaneous layer. So I began to report mild, moderate, and severe fluid in the subcutaneous tissue. And then further characterizing it saying you know, it's at the ankle, it's in the lower leg or maybe it extends up into the thighs, which may be helpful to any clinician who's reading that report. And it wasn't until this Journal of Vascular Surgery article that I actually saw the term referred to as subcutaneous echo-free space, and then they characterize it further, classify it into zero one or two. And so I began, I haven't used that term yet because if I say Class II SEF, no one's going to know what I'm talking about. But mild, moderate, severe fluid in the subcutaneous tissue I think is something that I think everyone can relate to.

Dan Carlson:

Alright great, and an additional question came in online Dr. Vasquez. It's a two-parter, so the first part is how are the findings from the EVRA Study you mentioned changing your decision making and then the second part is the same question with regard to the Journal of Vascular Surgery study regarding phlebolympheidema and lymphoedema pumps?

Dr. Michael Vasquez:

Well I think the EVRA Study also was a study that was referenced frequently at this meeting that I was at. Personally, I have become a bit of an early adopter of treatment for patients who come in with more severe skin damage and certainly those patients who have venous ulcers. And then there was a survey that was passed out that I thought was interesting too, is how we changed our practice, right in line with this question. I personally have been of the opinion of treating ulcer patients early, maybe not within the first day or two of seeing them, but certainly getting them into some type of compressive garment or possibly a multi-layered wrap and scheduling a mapping and scheduling an intravenous treatment for that appropriately chosen patient with obviously no deep obstruction or other contraindicator. So

I've found this to substantiate my personal experience of treating these patients early. And the second part of that question Dan?

Dan Carlson:

The second part was really the same with regard to the Journal of Vascular Surgery study on phlebolymphe'dema and ??? such as the Flexi-touch, how is that study changing your decision-making for your patients?

Dr. Michael Vasquez:

Well it's interesting, that's almost the flip side. So if we talk about early intervention for ulcer patients, now that study seems to elucidate some of the information on what we see if we don't treat these patients early, at least with some type of an intervention, meaning some type of endovenous ablation procedure. And certainly, we can improve as we saw with the ESCAR trial, that we can certainly improve and heal ulcers with some type of compression. So with the use of pneumatic compression of all types, and compression of all types, we know that we can improve leg ulcers and even the amount of leg swelling in these patients. The study was different in that in the study design, they were actually able to tease out the Flexi-touch advanced pneumatic compression with conservative therapy versus all other types of compression, which were not listed. The reason for that I don't know if I'm exactly clear, it was eluded to in the study and I think it has to do in part with the fact of how it's coded or how it's run through Tactile. But be that as it may, the information was able to be teased out from these claims made in patients who have a diagnosis given both of lymphedema and chronic venous insufficiency. So when they had both of those diagnosis codes, they were able to separate the information in patients who did not have a procedure in patients who had conservative therapy in the Flexi-touch versus conservative therapy in other modalities of treatment. So it's kind of that flip side of the early intervention with compression alone, and we know that if we treat people with compression alone, we can at least improve their leg situation.

Dan Carlson:

Alright, well it looks like we have no other questions at this time, so for everyone who did dial in, thank you very much for taking the time to join us on this webinar and thanks again Dr. Vasquez for sharing your experience and your knowledge with us.

Dr. Michael Vasquez:

Thank you everyone for your time.