

Transcript Details

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A Step Toward Pain Relief: Targeted Care for Painful Diabetic Peripheral Neuropathy of the Feet

Announcer:

Welcome to ReachMD.

This medical industry feature, titled “A Step Toward Pain Relief: Treatment for Painful Diabetic Peripheral Neuropathy of the Feet” is sponsored by Averitas Pharma, Incorporated. Both Drs. Turck and Navalgund were compensated for their appearances.

Here’s your host, Dr. Charles Turck.

Dr. Turck:

Diabetic peripheral neuropathy—also known as DPN—poses significant challenges for patients living with diabetes. In fact, 2.5 million people are living with unresolved pain associated with DPN. But despite its prevalence and impact on quality of life, the current first-line treatment options often fall short in providing effective pain relief.

This is ReachMD, and I’m Dr. Charles Turck. Joining me to discuss a different path toward pain relief for these patients is Dr. Yesh Navalgund. Dr. Navalgund is the Chief Medical Officer for Ambulatory Surgery at National Spine and Pain Centers, out of Fredrick, MD.

Dr. Navalgund, welcome to the program.

Dr. Navalgund:

Thank you Dr. Turck. It’s a pleasure to be here!

Dr. Turck:

So Dr. Navalgund, let’s first talk about the burden of diabetic peripheral neuropathy. Can you expand on how common it is and how it affects patients with diabetes?

Dr. Navalgund:

Well, to give you an idea, more than 37 million Americans—or just over 1 in 10—have either type 1 or type 2 diabetes. And while up to 50 percent of DPN cases may be asymptomatic, many others may develop painful DPN, which is progressive and potentially debilitating.

Patients with DPN suffer from nerve damage in the feet that results in sensory changes and alterations in neural signaling pathways, especially those involving the C and A-delta fibers. The pain, burning, tingling, and numbness can affect patients’ ability to stand or walk normally, interfere with work or household tasks, and interrupt sleep. Unfortunately, nerve damage from DPN can’t be reversed. So our focus needs to be on preventing DPN’s progression with glucose control, diet and exercise modifications, and treatments to reduce the pain.

Dr. Turck:

Thanks for that background. Now you just mentioned treatments. What’s available to help treat patients with DPN?

Dr. Navalgund:

First-line treatments have included antidepressants, or anticonvulsants. Though systemic drugs are effective in treating pain and calming overactive nerves, systemic medications can be difficult for patients to tolerate due to their side effects. We have to consider the potential for multiple comorbidities, polypharmacy and noncompliance concerns, and tolerability issues. And these treatments for DPN are often associated with inadequate therapeutic response. In fact, more than 50 percent of patients switch to another medication, and

over 30 percent require an additional class of medication. Other challenges can include long titration periods of over two months on average, drug-drug interactions, and the potential for addiction, abuse, and withdrawal. So with 2.5 million people suffering from unresolved diabetic nerve pain as you mentioned. We have to do better by our patients.

Dr. Turck:

And with all that being said, do we have other options to treat patients with DPN?

Dr. Navalgund:

Yes, there's an FDA-approved, non-invasive, first-line *topical* prescription treatment called Qutenza. The Qutenza capsaicin 8 percent topical system is a TRPV1 channel agonist that works differently, in that it's a patch applied directly to the foot by a healthcare professional during a 30 minute in-office procedure. Qutenza is a non-opioid treatment with no drug-drug interactions and provides sustained relief for patients living with diabetic nerve pain for up to three months. Due to the risk of severe irritation, QUTENZA must be applied by a healthcare professional.

Dr. Turck:

For those just tuning in, you're listening to ReachMD.

I'm Dr. Charles Turck, and today I'm speaking with Dr. Yeshvant Navalgund about a different kind of first-line treatment option for painful diabetic peripheral neuropathy of the feet.

So Dr. Navalgund, now that we've introduced Qutenza as a treatment option for DPN, can you tell us how it works to relieve pain?

Dr. Navalgund:

Sure. So, Qutenza uses a matrix system technology that allows high-concentration capsaicin to penetrate the epidermal layers of the feet. When it's applied, the matrix technology creates a forced diffusion to drive capsaicin through the epidermal layers. This high concentration of capsaicin overstimulates and desensitizes the TRPV1-expressing fibers, which causes pain signals to be suspended. Qutenza then triggers a chemical cascade that causes a reversible ablation that temporarily destroys the TRPV1-expressing fibers, preventing the transmission of pain signals and providing significant and sustained relief. At about three months, TRPV1-expressing fibers begin to regenerate and reinnervate, which results in the return of pain. The treatment with QUTENZA may be repeated every three months or as warranted by the return of pain (not more frequently than every three months).

Although patients typically experience clinically significant pain relief—and I can get into the data in a bit—patients may experience pain at the treatment site, during and after the application which can be treated with a cold compress or an analgesic as needed. During the application, the patient may also experience a transient increase in blood pressure, so it's important to monitor blood pressure throughout the entire process. And patients may feel sensitivity to heat from hot showers, sunlight exposure, or vigorous exercise for a few days after treatment. The other most common adverse reactions are erythema, pruritus, and papules at the application site.

Dr. Turck:

Great, thank you Dr. Navalgund. Now let's take a closer look at the data you mentioned. How did Qutenza perform overall?

Dr. Navalgund:

Well, there are several data points to share from a few studies on Qutenza. First, we have a clinical study of adult patients that showed Qutenza provided statistically and clinically significant pain relief for up to three months after a single 30-minute treatment. And the relative difference in pain reduction between Qutenza and placebo was 36 percent. And in a post-hoc analysis of patients using Qutenza alone with no other systemic medications, Qutenza reduced the Numerical Pain Rating Scale score over 12 weeks of treatment. QUTENZA reduced the NPRS score down 31 percent from baseline versus 20 percent for placebo. And here's an open-label, 52-week trial that found that after one year of ongoing treatments, 73% of patients were willing to undergo QUTENZA + SoC again compared to 52.3% of those receiving SoC alone.

So with all that being said, and in addition to its favorable safety profile, Qutenza is really helping patients with DPN manage diabetic nerve pain and find relief.

Dr. Turck:

Thanks, Dr. Navalgund. And as we come to a close today, what final thoughts would you like to leave with our audience?

Dr. Navalgund:

So, it's nice that there's a different option than the systemic or invasive therapies to help treat DPN. In my practice, I'm seeing real relief for my patients with Qutenza treatments, and I'm happy I can help relieve them of their pain. Very often, I end up with significant invasive procedures in order to try and assist these patients but with the advent of Qutenza and ability to treat these patients with non-invasive manner, it's really expanded my ability to help patients in my patient population.

Dr. Turck:

That's a great way to round out our discussion on this topic.

I want to thank my guest, Dr. Navalgund, for helping us better understand the role of Qutenza in helping patients relieve diabetic nerve pain. It was great speaking with you today.

Dr. Navalgund:

Thanks so much for having me!

Dr. Turck:

I'm Dr. Charles Turck.

And before we close, let's take a moment to review some important safety information.

Announcer:

INDICATION

QUTENZA® (capsaicin) 8% topical system is indicated in adults for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) or associated with diabetic peripheral neuropathy (DPN) of the feet.

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Use only on dry, unbroken skin. Only physicians or healthcare professionals are to administer and handle QUTENZA, following the procedures in the label.

Warnings and Precautions

- **Severe Irritation:** Whether applied directly or transferred accidentally from other surfaces, capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin to the healthcare professional, patients, and others. Do not use near eyes or mucous membranes, including face and scalp. Take protective measures, including wearing nitrile gloves and not touching items or surfaces that the patient may also touch. Flush irritated mucous membranes or eyes with water and provide supportive medical care for shortness of breath. Remove affected individuals from the vicinity of QUTENZA. Do not re-expose affected individuals to QUTENZA if respiratory irritation worsens or does not resolve. If skin not intended to be treated comes into contact with QUTENZA, apply Cleansing Gel and then wipe off with dry gauze. Thoroughly clean all areas and items exposed to QUTENZA and dispose of properly. Because aerosolization of capsaicin can occur with rapid removal, administer QUTENZA in a well-ventilated area, and remove gently and slowly, rolling the adhesive side inward.
- **Application-Associated Pain:** Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following application with local cooling (e.g., ice pack) and/or appropriate analgesic medication.
- **Increase in Blood Pressure:** Transient increases in blood pressure may occur with QUTENZA treatment. Monitor blood pressure during and following treatment procedure and provide support for treatment-related pain. Patients with unstable or poorly controlled hypertension, or a recent history of cardiovascular or cerebrovascular events, may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating QUTENZA treatment.
- **Sensory Function:** Reductions in sensory function (generally minor and temporary) have been reported following administration of QUTENZA. All patients with sensory deficits should be assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory loss occurs, treatment should be reconsidered.

Adverse Reactions

The most common adverse reactions ($\geq 5\%$ and $>$ control group) in all controlled clinical trials are application-site erythema, application-site pain, and application-site pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Averitas Pharma, Inc., at 1-877-900-6479 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full [Prescribing Information](#).

Announcer:

This program was sponsored by Averitas Pharma, Incorporated. If you missed any part of this discussion, visit ReachMD.com/industry-feature. This is ReachMD. Be Part of the Knowledge.

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