Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/case-studies-addressing-modern-care-challenges-with-painful-diabetic-peripheral-neuropathy-of-the-feet/12078/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Case Studies Addressing Modern Care Challenges with Painful Diabetic Peripheral Neuropathy of the Feet

Announcer:
Welcome to ReachMD.

This medical industry feature titled, "Case Studies Addressing Modern Care Challenges with Painful Diabetic Peripheral Neuropathy of the Feet", is sponsored by Averitas Pharma.

This program is intended for physicians and the information is for general informational purposes only and should not be relied upon for clinical, care pathway, or reimbursement decisions. The speakers have been compensated by Averitas. This presentation is consistent with FDA guidelines and is not eligible for CME credit.

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

Do not dispense QUTENZA to patients for self-administration or handling. Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle QUTENZA.

Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward. Inhalation of airborne capsaicin can result in coughing or sneezing. Administer QUTENZA in a well-ventilated treatment area. Provide supportive medical care if shortness of breath develops. If irritation of airways occurs, remove the affected individual from the vicinity of QUTENZA. If respiratory irritation worsens or does not resolve, do not re-expose the affected healthcare professional or patient to QUTENZA.

If skin not intended to be treated is exposed to QUTENZA, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.

Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to treat acute pain during and following the application procedure with local cooling (such as a cold pack) and/or appropriate analgesic medication.

Prior to using QUTENZA, please review the QUTENZA USPI's Important Dosage and Administration Instructions, including full instructions for use.

Please listen to Select Safety Information at the end of this podcast and for full Important Safety Information visit Qutenza.com.

Here's your host Dr. David M. Simpson.

Dr. Simpson:
Hello and welcome. I'm Dr. David Simpson. Joining me to discuss case studies addressing modern care challenges with painful diabetic peripheral neuropathy of the feet with the use of the high-concentration capsaicin 8% topical system is Professor Eric Viel and Dr. David Walega. Both panelists joining me today are experts in the treatment and research advancements surrounding chronic neuropathic pain conditions. Professor Viel and Dr. Walega have experience prescribing and applying Qutenza for postherpetic neuralgia and PDPN of the feet. Welcome, Eric and David. Thank you for joining me, today.

Professor Viel:
Thank you, Dr. Simpson, it's great to be here with you and Dr. Walega.

Dr. Walega:
Thank you, David, and thank you, Eric.

Dr. Simpson:
With recent approval of Qutenza for PDPN of the feet, there is a limited knowledge of its real world utilization. With that in mind, I think it's important to discuss clinical experiences and case studies. Today, Dr. Walega and Professor Viel will be sharing some patient and physician experiences regarding the application and efficacy of Qutenza. I'd like to start by asking Eric and David to describe some current challenges in treating patients with PDPN of the feet. Eric, can you provide some insight on this topic?

Professor Viel:
Yeah, of course. As, you know, we in Europe, as well as in France, as well as the U.S. we are currently facing a huge increase of the diabetic population at various stages of the disease. GPs and diabetologists are perfectly aware of eye, arteries, and kidney complications, but PDPN, that is painful diabetic peripheral neuropathy, seems to be a little bit underestimated or misdiagnosed, sometimes for years. On the other hand, most of the patients are suffering from several comorbidities and they are also subject to polypharmacy with, quite often, subsequent adverse effects. Furthermore, the daily consumption of medication is very often too important leading to a serious risk of adverse events and also drug/drug interactions. Considering misdiagnosis, a key point is through correctly analyzing neurologic symptoms. I'm not personally a neurologist, but nevermind, I know how to examine a patient and with a painful patient I must question the patient and I must conduct a careful examination of various instabilities, touch, pain prick, cold, hot temperature, pressure, vibration with a tuning fork, etc. just to be sure of the neuropathic origin of pain. I can use the DN4 questionnaire, pain DETECT questionnaire, and PSI, that is Pain Symptom Inventory and other questionnaire.

Dr. Simpson:
Thank you for those thoughtful insights regarding your diabetic patient population. I agree that PDPN represents an ongoing therapeutic challenge for patients, caregivers and physicians. The symptoms can be debilitating, cause sleep disturbances, and anxiety, as well as interfere with physical functioning. The approach to manage these symptoms often requires a combination of agents with varying mechanisms of action and different administration techniques to ultimately result in the best possible outcome. David, do you experience the same challenges in your practice with your diabetic peripheral neuropathy patients?

Dr. Walega:
Yes, David. I would say that many of the challenges that were discussed by you and Eric, are considerations that, that I experience with the diabetic population that I treat, as well. So, first off, the existing therapies for neuropathic pain are not effective for most patients. In fact, only about a quarter of patients find pain relief that's meaningful, meaning greater than 50% reduction in pain. The treatments that are available act preferentially or selectively on some components of the diagnosis but don't have a uniform and global effect for all patients. Combination therapy or what we call multi-modal treatment is really the name of the game, so patients need to be on multiple medications often. And this may be a pill that they take or a topical treatment that they must administer, which adds to their treatment burden. It's not uncommon for diabetic patients to have, not only lifestyle complications, but a number of comorbidities that play a role in the types of medications that we can prescribe for them. And we also have to be very cognizant of the use of opioids in the treatment of chronic pain because we're concerned about dependance as well as addiction. I see this as being an issue of pain, of treating function, of having knowledge of the patients sleep, and their overall care burden. How many pills do they need to take? How many treatments do they need to administer to themselves in order to be optimally improved with regard to their pain problem?

Dr. Simpson:
Well, thank you, David, for providing those insights and addressing the challenges in your practice. From my experience, most patients suffering from PDPN of the feet have either gone undiagnosed or misdiagnosed for up to 5 to 7 years. Sometimes patients don't even mention the pain in their feet because they don't know it's associated with their diabetes. On the contrary, if patients are receiving current treatments for their PDPN, they sometimes only report a 10% reduction in their pain, very common for patients with other forms of small fiber neuropathies.

Eric, can you walk us through your clinical case? Was there anything remarkable about this patient's painful diabetic peripheral neuropathy?

Professor Viel:
Yes, thank you, David, I'm going to show you the case of a 66-year-old-female patient who is suffering from PDPN of both feet. She was referred to my department by her diabetologist because she's short of an efficient therapeutic option. She tried many medications but no one of the prescriptions barely worked. This lady has an insulin-dependent diabetes after escape from metformin, she's also treated for hypertension, and four years ago, she was suffering a myocardial infarction. She's also suffering from several complications of diabetes, retinopathy autonomic disorders and autonomic neuropathy. Well, at the moment, she was suffering from neuropathic pain with

neuralgic symptoms, electric shocks, burning sensations, pain prick, pins and needles, frozen sensations, itching and so on. A clinical examination of the sole of both feet and also at the toes, we found pain on light touch, also areas of allodynia and numbness to temperature, also to pressure. It means this is a complex neuropathy, as usual in diabetic patients with dysfunction of thin fibers and large fibers. She was previously treated with gabapentin combined with amitriptyline, but this combination doesn't really help. She was then prescribed with duloxetine, but she decided to stop the duloxetine intake because of adverse effects, such as dizziness, nausea, vomiting and when she came to our clinic, she was only taking codeine, a weak opioid, on a b.i.d. or t.i.d. basis and gabapentin 400 mg b.i.d., and it seems to slightly decrease the intensity of pain. Then we decided to take her off gabapentin and we moved to pregabalin 200 mg b.i.d. and the patient was booked to a day hospitalization to receive an application of the high-concentration capsaicin topical system.

After two weeks, the patient described a 60% reduction in pain intensity, walking was easier, and she was again able to wear normal shoes, and there were no more awakening at night. On our prescription, we decided to reduce daily intake of pregabalin to 75 mg b.i.d. without any difficulty; Then we can say that the patient was very satisfied of the global improvement and at the moment, follow-up is still ongoing.

Dr. Simpson:
Eric, thank you for sharing your case study and experience with using Qutenza to treat PDPN of the feet. I think it's very important to note that upon starting Qutenza, it may take multiple applications in order to achieve significant and sustained relief. Some of the advantages of Qutenza are that it can be used alone or in combination with other medications. It's a non-systemic, non-opioid treatment option with no contraindications. It's also important to recognize that Qutenza can help reduce the symptoms of PDPN and also greatly improve function for patients.

David, can you walk us through the clinical case study from one of our colleagues and does the patient in this study reflect similarities to your patients with PDPN?

Dr. Walega:
Certainly, David, so this is a 70-year-old female who has non-insulin dependent diabetes diagnosed at age 40. She's had PDPN of the feet for 15 years in addition to having chronic low back pain; very similar to the patient population that I treat. She has previously tried multiple medications, both systemic and topical medications including antidepressants, opioids, anti-convulsants. She is currently taking gabapentin 800 mg a day using topical lidocaine 5% patches, in addition to a buprenorphine patch, which is a mixed opioid agonist/antagonist. Over the past few years, her pain has gotten worse. Her average pain score is 7 out of 10 in the feet. On examination and history she reports numbness, tingling, intermittent burning and stabbing, a loss of sensation in the feet. She has multiple medical comorbidities, most importantly depression, obesity and fibromyalgia. And Qutenza was selected for her as an additional treatment. And I think in this particular patient, it's an excellent choice, primarily because it is a topical, non-systemic treatment. Treatment compliance is assured because this is administered in a clinical setting.

So, this patient came in for her first application, at which time her pain score was 10 out of 10, really quite severe. Or the topical systems were placed for about 30 minutes. She had some minor burning sensations toward the end of that treatment but overall tolerated the procedure very well. At follow-up, her pain score had dropped to a 4. She reported that she was sleeping at night and could walk more comfortably throughout the day, so she was able to increase her exercise, which is great. And then she came in for another application, and we'll have the third application in a few months, if it's deemed clinically necessary.

Dr. Simpson:
Well, thank you, David for those insights. I would like to ask Eric, now if you could summarize some of your key take-home messages for our audience based on your clinical experience?

Professor Viel:
Yeah, of course. Thank you for the this opportunity to summarize.

First, carefully identify patients who can benefit from Qutenza topical system. I would say that you have to carefully examine the patient to be sure that it is neuropathic mechanism.

Second point, consider the high-concentration capsaicin topical system as soon as possible, because it has a, a very good safety profile with no systemic drug/drug interactions, it is a non-opioid treatment option, and if we are going to have some adverse effects, there will be only topical side effects, local side effects; it is an important point.

Another point, reduction of systemic medication. Most of the time, we are able, when we treat patient with the topical system, we are able to reduce the daily intake of medication or to totally remove all the systemic medications.

Create a follow-up schedule with the patient to monitor changes in pain intensity, quality of sleep, ability to walk, the percentage of improvement and satisfaction of the patent. We can do it by using phone calls, it's quite easy to do.

And last point, inform the patient as soon as possible that we will have several applications and it doesn't mean that this is a failure of the treatment. Three or four applications are very common to treat those patient.

Dr. Simpson:
Well, thank you, Eric for those messages. We've heard some wonderful clinical case studies highlighting the use of Qutenza for patients living with diabetic peripheral neuropathy of the feet. Most importantly, these patients experienced a significant reduction in pain, and improvement in quality of life. With that, I want to thank Professor Eric Viel and Dr. David Walega for joining me today in discussing clinical cases and sharing their experience in addressing modern care challenges with painful diabetic peripheral neuropathy of the feet, with the use of the high-concentration capsaicin 8% topical system with our ReachMD audience.

Dr. Walega:
Thank you for having me.

Prof. Viel
Thank you, David. It's been my pleasure.

Announcer:
INDICATION

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

IMPORTANT SAFETY INFORMATION

Do not dispense QUTENZA to patients for self-administration or handling. Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle QUTENZA.

When administering QUTENZA, it is important to follow the procedures in the Important Dosage and Administration Instructions in the US Prescribing Information.

In patients treated for neuropathic pain associated with diabetic peripheral neuropathy of the feet, a careful examination of the feet should be undertaken prior to each application of QUTENZA to detect skin lesions related to underlying neuropathy or vascular insufficiency.

Contraindications

None

Warnings and Precautions

- Unintended exposure to capsaicin can cause severe irritation of eyes, mucous membranes, respiratory tract, and skin in healthcare professionals, patients, and others. Healthcare professionals should ensure that the recommended procedures and protective measures are used when administering QUTENZA.
- For healthcare professionals, wear nitrile gloves when administering QUTENZA and avoid unnecessary contact with items in the room, including items that the patient may later have contact with, such as horizontal surfaces and bedsheets.
- Do not apply QUTENZA to the patient's face, eyes, mouth, nose, or scalp to avoid risk of exposure to eyes or mucous membranes. Accidental exposure to the eyes and mucous membranes can occur from touching QUTENZA, or items exposed to capsaicin, and then touching the eyes and mucous membranes. If irritation of eyes or mucous membranes occurs, flush eyes and mucous membranes with cool water. Remove the affected individual (healthcare professional or patient) from the vicinity of QUTENZA.
- Aerosolization of capsaicin can occur upon rapid removal of QUTENZA. Therefore, remove QUTENZA gently and slowly by rolling the adhesive side inward. Inhalation of airborne capsaicin can result in coughing or sneezing. Administer QUTENZA in a well-ventilated treatment area. Provide supportive medical care if shortness of breath develops. If irritation of airways occurs, remove the affected individual from the vicinity of QUTENZA. If respiratory irritation worsens or does not resolve, do not re-expose the affected healthcare professional or patient to QUTENZA.
- If skin not intended to be treated is exposed to QUTENZA, apply Cleansing Gel for one minute and wipe off with dry gauze. After the Cleansing Gel has been wiped off, wash the area with soap and water.
- Patients may experience substantial procedural pain and burning upon application and following removal of QUTENZA. Prepare to

treat acute pain during and following the application procedure with local cooling (such as a cold pack) and/or appropriate analgesic medication.

- Transient increases in blood pressure may occur during and shortly after QUTENZA treatment. Blood pressure changes were associated with treatment-related increases in pain. Monitor blood pressure and provide adequate 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.
- Reductions in sensory function have been reported following administration of QUTENZA. Decreases in sensory function are generally minor and temporary. All patients with pre-existing sensory deficits should be clinically assessed for signs of sensory deterioration or loss prior to each application of QUTENZA. If sensory deterioration or loss is detected, or pre-existing sensory deficit worsens, continued use of QUTENZA treatment should be reconsidered.

Adverse Reactions

In all controlled clinical trials, adverse reactions occurring in ≥5% of patients in the QUTENZA group, and at an incidence at least 1% greater than in the control group, were application site erythema, application site pain, and application site pruritus.

Adverse Event Reporting

Physicians, other healthcare professionals, and patients are encouraged to voluntarily report adverse events involving drugs or medical devices. To make a report you can:

- In the US, visit www.fda.gov/medwatch or call 1-800-FDA-1088; or
- For QUTENZA, you may also call 1-877-900-6479 and select option 1, or press zero on your keypad to talk to an operator to direct your call.

Please visit Qutenza.com to view the full Prescribing Information, including Patient Information.

The preceding program was sponsored by Averitas Pharma. If you have missed any part of this discussion, visit ReachMD.com/IndustryFeature.

This is ReachMD. Be Part of the Knowledge.