

Treatment of a patient with intractable Painful DPN and Raynaud syndrome using high concentration capsaicin 8% topical system: case report

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Background

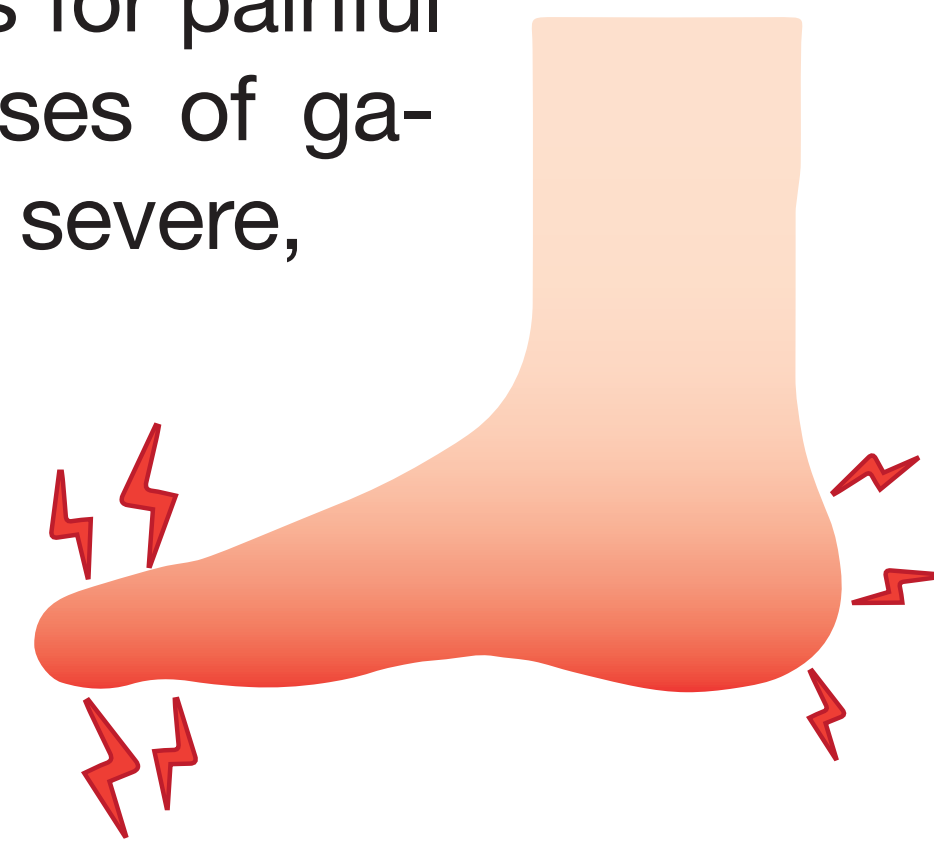
The capsaicin 8% topical system is an FDA-approved treatment for pain associated with postherpetic neuralgia and painful diabetic peripheral neuropathy (DPN) of the feet. Currently, and to our knowledge, there is no literature reporting the use of the high-concentration capsaicin 8% topical system for the treatment of painful DPN in patients with Raynaud's syndrome.

Purpose

This case report describes a patient diagnosed with painful DPN of the feet (with severe allodynia and comorbid Raynaud's syndrome) who was treated with the high-concentration capsaicin 8% topical system

Case description

The patient is a 76-year-old female with type 2 diabetes mellitus and progressive painful DPN. She has attended our clinic for the past 15 years and has a 7-year history of painful DPN extending into the dorsal and plantar regions of the feet with especially painful left 4th and 5th toes. Glycemic control, as determined by blood sugar levels and HbA1c, is reported as good and has no evidence of diabetic retinopathy. Previous treatments for painful DPN include tramadol and increasing doses of gabapentin. However, the pain has become severe, forced early retirement from work, limits her ability to walk, and most days the allodynia prevents her from wearing shoes. The patient is a non-smoker and reports limited alcohol use during her lifetime.



Medical history

- » Type 2 diabetes mellitus
- » Hypertension
- » Dyslipidemia
- » Right nephrectomy, renal cell carcinoma
- » Hypothyroidism
- » Lymphoma
- » Degenerative joint disease of the spine
- » Raynaud's syndrome with symptoms in the feet (rubor), extending from the tips of all toes, 1/3 of dorsal forefoot, 1/2 of plantar

Clinical Findings

A complete history and physical examination were obtained. An in-depth foot examination showed bilateral callouses, monofilament test absent, dorsalis pedis pulse +1, posterior tibialis +1, vibratory diminished, sharp/dull discrimination moderately reduced. Marked Raynaud's-related red skin tone (rubor) extending from the toes to one-third of the dorsal forefoot, and half of the plantar region. Baseline clinical examination of the feet was very painful, and she indicated that most days the pain was 10/10 with minimal relief from her current pain medications. Generally, the pain extended into the dorsal and plantar regions of the feet and was especially painful in the left 4th and 5th toes. The patient was unable to tolerate her feet being touched or massaged.

Differential diagnosis

- | | |
|------------------------|-----------------------------------|
| » Painful DPN | » Diabetic lumbosacral plexopathy |
| » Raynaud's syndrome | » Toxic exposures |
| » Alcoholic neuropathy | » Hypothyroidism |
| » Multiple sclerosis | |

Treatment

The patient was offered treatment with the capsaicin 8% topical system for her painful DPN. Risks and benefits were discussed, and she was informed that the topical system has not been studied in patients with extensive Raynaud's syndrome. She had previously failed multiple therapies and was eager to try the capsaicin 8% topical system to help alleviate her painful DPN, which was reported as 7-8/10 on the day of the procedure. The patient declined topical anesthetic prior to the application of capsaicin 8% topical system. Four capsaicin 8% topical systems were applied to the affected areas (2 per foot) for 30 minutes.¹ Following application, the feet were wrapped in plastic to optimize the absorption of capsaicin. The patient had a very difficult time tolerating the procedure due to the pressure from the plastic wrap on her feet. During the application, she ranked her pain as 10/10 as a result of the



plastic wrap tightly securing the topical systems to her feet. Despite her discomfort, she was able to complete the 30-minute treatment. At the end of the procedure, her feet were cleaned with soap and water, dried, and cooling gel was applied generously for a least one-minute before being washed and removed.

Results

Patient Response to the first application of the capsaicin 8% topical system

- » Some immediate relief of application site pain (possibly due to the plastic wrap being removed)
- » The reddened area from the Raynaud's syndrome was unchanged (no changes in sensation)
- » After 1-week the patient reported a pain reduction of 25%, but no change in Raynaud's symptoms
- » Follow-up at 6 weeks (phone call) a 50% reduction in painful DPN symptoms was recorded and the patient had stopped taking tramadol and could wear shoes
- » She also stated that her 4th and 5th toes still have flare-ups of pain but had improved markedly

The patient has continued treatment with the capsaicin 8% topical system over 12 months at 3-monthly intervals with the following findings:

- » Immediately prior to her second treatment she reported that she was using minimal amounts of tramadol prn, and that her pain had returned to level 7
- » The second treatment was applied as described for the first application
- » At the third treatment she reported that the pain was still improved, but the amount of reduction from first to second treatment was markedly better than her second to third treatment
- » Her current pain just prior to her fourth application was 0/10. A visit conducted 3 weeks later she still reported a pain level of 0/10.
- » A few weeks after the fourth application (the most recent) her pain was still reduced and the prn tramadol remained decreased

Conclusions

Over-the-counter formulations of capsaicin have been used by patients with Raynaud's syndrome in the past, and case reports have indicated possible benefits.^{2,3} To our knowledge, this is the first report of the use of high concentration capsaicin 8% topical system to a patient with painful DPN and co-morbid Raynaud's syndrome. This patient presented with intense, unbearable pain and severe allodynia. As noted, the first application of 8% capsaicin was challenging for the patient and we hypothesize that this was due to the pressure of the tight plastic wrap on the feet exacerbating her allodynia. Also, this patient had severe pain prior to treatment with the capsaicin 8% topical system, reflecting the challenge when treating patients with severe allodynia. While no relief in Raynaud's syndrome symptoms were recorded, treatment with the capsaicin 8% topical system allowed her to significantly reduce tramadol and wear shoes.

Three learning objectives

- » This patient with refractory painful DPN of the feet and co-morbid Raynaud's syndrome attained life-changing pain relief following treatment with the capsaicin 8% topical system.
- » Although the patient's Raynaud's symptoms were not improved, the application of capsaicin 8% topical system reduced her pain, allowed for the discontinuation of her current tramadol regime and ability to wear shoes again.
- » Despite discomfort during the first application process, the patient was willing to undergo subsequent treatments every 3 months with the capsaicin 8% topical system.

References

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Disclosures

GG has no conflicts of interest to disclose.
OK is a full-time employee of Averitas Pharma.