Oh SM, Diaz YA, Stilli L, et al. High-Dose 8% Capsaicin Patch in Treatment of Chronic Neuropathic Back Pain in a Pregnant Woman: A Case Report. *Orthopedic Reviews*. 2025;17. doi:10.52965/001c.140712

General

High-Dose 8% Capsaicin Patch in Treatment of Chronic Neuropathic Back Pain in a Pregnant Woman: A Case Report

Seung Mi Oh, MD[1,2], Yerissa A Diaz, FNP, BC[1], Ludovica Stilli[3], Kateryna Slinchenkova[3], Karina Gritsenko, MD[1,2], Amaresh Vydyanathan, MBBS, MS[1,2], Kathryn Breidenbach, MD[1,2], Blaze Borowski, B.S.[4], Sarang S. Koushik, MD[5,6], Omar Viswanath, MD[6,7], Naum Shaparin, MD, MBA[1,2]

[1] Anesthesiology, Montefiore Medical Center, [2] Anesthesiology, Albert Einstein College of Medicine, [3] Medical Student, New York Medical College, [4] Medical Student, Creighton University School of Medicine , [5] Anesthesiology, Valleywise Health Medical Center, [6] Anesthesiology, Creighton University School of Medicine, [7] Anesthesiology, LSU Health Sciences Center School of Medicine

Keywords: Chronic back pain, Neuropathy, Pregnancy, Capsaicin patch, Post laminectomy syndrome

https://doi.org/10.52965/001c.140712

Orthopedic Reviews

Vol. 17, 2025

Introduction

Managing pain during pregnancy is challenging due to fetus safety and limited data on perinatal pain treatments. We report the first successful management of neuropathic back pain with high dose 8% Capsaicin patches (Qutenza) in a pregnant patient who failed other modalities.

Case Presentation

A 34-year-old female with a history of migraines, childhood scoliosis status-post T5-L3 posterior spinal fusion complicated by post-laminectomy syndrome, presented with myofascial and neuropathic back pain. Her pain was refractory to oral agents, injections, field stimulator, and partial surgical revision. During patch treatments, she became pregnant.

Management and Outcomes

A review of the patient's record and consent were obtained. Trial of an 8% capsaicin patch provided significant relief of her pain twice. Following OB/GYN consultation, she continued patch treatment, achieving significant relief without pregnancy complications into a subsequent pregnancy.

Conclusion

Following further study, 8% capsaicin patches may be suitable alternatives for pain management during pregnancy.

INTRODUCTION

Neuropathic pain is caused by diseases affecting the peripheral or central nervous system with a prevalence of 7% in the general population. Pre-existing neuropathic conditions may deteriorate during pregnancy,[1,2] prohibiting use of effective treatment options for risk of fetal harm. For example, NSAIDs have been linked to teratogenic effects and are ineffective in neuropathic pain.[3,4] Opioids, while effective, require careful care and administration, typically resulting in alternative approaches in pregnancy.[5,6] Thus, appropriate treatment and optimization of pain for pregnant patients becomes nuanced when desiring a safe pregnancy.

To date, acetaminophen and 8% capsaicin patches are classified as category B for pregnancy medication. While animal studies show no harm to the fetus, no human studies on pregnant populations exist.[7,8] However, new studies link acetaminophen with fetal neurological changes, leading to doubt in its consideration.[5,9] In this report, a pregnant patient received a successful analgesic treatment of chronic neuropathic back pain with the use of Qutenza (8% Capsaicin patches).

Capsaicin is the active chemical in perception of spice. It is a potent, highly selective agonist of the transient receptor potential vanilloid-1 (TRPV1), a thermal nociceptor.[1] This receptor is aggregated in high concentrations within the somatosensory nervous system, especially the primary afferent neurons that relay sensation of irritation.[10] Capsaicin's anti-nociceptive mechanism involves activation of TRPV1 expression on the skin, causing attenuation of cutaneous hypersensitivity and pain reduction through defunctionalization of nociceptor fibers due to the long-lasting refractory period.[1] High-dose 8% capsaicin patches (Qutenza) have been approved for treating peripheral neuropathy in nondiabetic patients in Europe,[11] as well as treatment of

postherpetic neuralgia (PHN) and diabetic neuropathy (DPN) in the U.S.[7]

Over-the-counter capsaicin creams (0.025%, 0.075%, and 0.1%) require thrice daily applications and provide pain relief for approximately 14 days. Only the 0.075% cream has been demonstrated to improve DPN and PHN.[12] Due to its inconvenience, adherence to capsaicin creams is lower compared to the 8% capsaicin patches, although currently there is no research comparing creams and patches directly.[12] 8% patches have less systemic effects compared to oral drugs (pregabalin, gabapentin), while showing similar tolerability.[13] Main capsaicin patch side effects are skin irritation, burning, and nausea.[12,14] If needed, pretreatment with local anesthetics and oral analgesics can ameliorate reactions and improve tolerance, optimizing patient adherence.[15]

CASE PRESENTATION

ETHICAL CONSIDERATIONS

A comprehensive review of the patient's electronic medical record was performed. Data regarding the patient's symptoms, radiology reports, treatments, and responses were collected. As the case report is devoid of patient identifiable information, it is exempt from IRB review requirements as per Montefiore Medical Center policy. Patient signed a written informed consent. As the patient received her OBGYN care outside of our healthcare system, data collection regarding patient's obstetric history was performed retroactively from patient self-report.

A 34-year-old female with a history of chronic migraines, childhood scoliosis status post T5-L3 posterior spinal fusion, complicated by post-laminectomy syndrome, presented to our pain center in 2014 with myofascial and neuropathic back pain. The patient developed chronic complex migraines in 2009 and thoracic back pain in 2012, 6 years after her initial surgery. Repeat spinal imaging did not explain her symptoms. The patient's pain on presentation was primarily in the mid-thoracic back, described as stabbing and burning with muscle spasms. Patient had tried yoga, massage, and pharmacotherapy including acetaminophen, NSAIDs, hydrocodone/acetaminophen, tramadol, cyclobenzaprine, gabapentin, pregabalin, amitriptyline, and nortriptyline without relief. Trials of oxycodone/acetaminophen, methocarbamol, and tizanidine proved to be intermittently helpful. Concomitantly, she tried creams including over-the-counter capsaicin, which was stopped due to burning sensation. Between 2014-2017, interventions including paraspinal trigger point injections, TENs, steroid injections, medial branch blocks, and subsequent ablation provided impermanent partial >50% pain relief. The patient received a peripheral field stimulator trial and implant in 2017 with 40% relief.

By 2019, the patient exhausted all reasonable medications and interventions including physical therapy and acupuncture yet had 10/10 pain. X-ray of the patient's spine with markers in the region of patient's pain (Figure 1) showed the upper marker just proximal to the Harrington rods (T4). Despite no evidence of hardware failure, the patient underwent elective partial Harrington rod removal with neurosurgery, which decreased muscular pain but caused burning pain in the thoracic region. She continued gabapentin and tizanidine with a taper of methocarbamol and oxycodone/acetaminophen with referral for medical marijuana and cognitive behavior therapy. In 2020, the patient requested to remove the peripheral field stimulator due to discomfort and loss of efficacy.

In 2021, the patient returned with neuropathic thoracic back pain. Following consideration of past treatments, the patient was introduced to an 8% capsaicin patch and subsequently received her first application in May 2022. She tolerated the procedure throughout a 60-minute cycle, reporting initial discomfort halfway through treatment, with mild redness over the edges of the patch. Skin remained intact, vital signs remained stable, and the patient tolerated the procedure well. Afterwards, the patient endorsed significant relief to the areas in contact with the patch and wished to repeat application. On repeat application, the patient was observed for 1 hour and 20 minutes post-procedure. No skin reactions were noted. She denied any complaints and reported significant relief. After the third treatment in March 2023, she reported significant relief and stopped opioid use, only using acetaminophen.

In June 2023, the patient returned for a repeat Qutenza application, informing the practice she was 14 weeks pregnant. The team consulted her OB/GYN, reviewed existing literature/package inserts, and weighed the risks and benefits with the patient. At the time of literature review, there was no reported case on the use of Qutenza patch during pregnancy. However, reports existed demonstrating the safe use of topical capsaicin cream.[16,17] After consultation, the patient chose to continue planned treatment, undergoing her 8% capsaicin patch treatment in July 2023 and tolerating her fourth Qutenza application without any skin/vital sign issues. In October 2023, she postponed her repeat application due to preterm delivery at 30 weeks' gestation. At time of delivery, the patient was a G1P0, with early labor at 27 weeks and 6 days. The patient was admitted for antenatal care with anesthesia consultation for high-risk pregnancy with complex back history at 28 weeks. The patient delivered vaginally at 29 weeks with epidural analgesia, reporting her pain was managed with acetaminophen and ibuprofen post-partum. She returned to pain clinic in December 2023 and reported her back pain was 4/10, taking only acetaminophen. She underwent repeat patch application post-delivery. Presently, the patient's baby is 1 year old with no health concerns and is meeting all developmental milestones. The patient is pregnant with her second child and continuing Qutenza treatment.

MANAGEMENT AND OUTCOMES

In women suffering from chronic pain, pregnancy can be daunting due to fear of worsening pain during gestation and concerns of fetal risks. Back pain is a common pregnancy related complaint that has conflicting data on treatment modalities. Post-laminectomy syndrome is a condition of chronic pain that is exhibited in up to 40% of

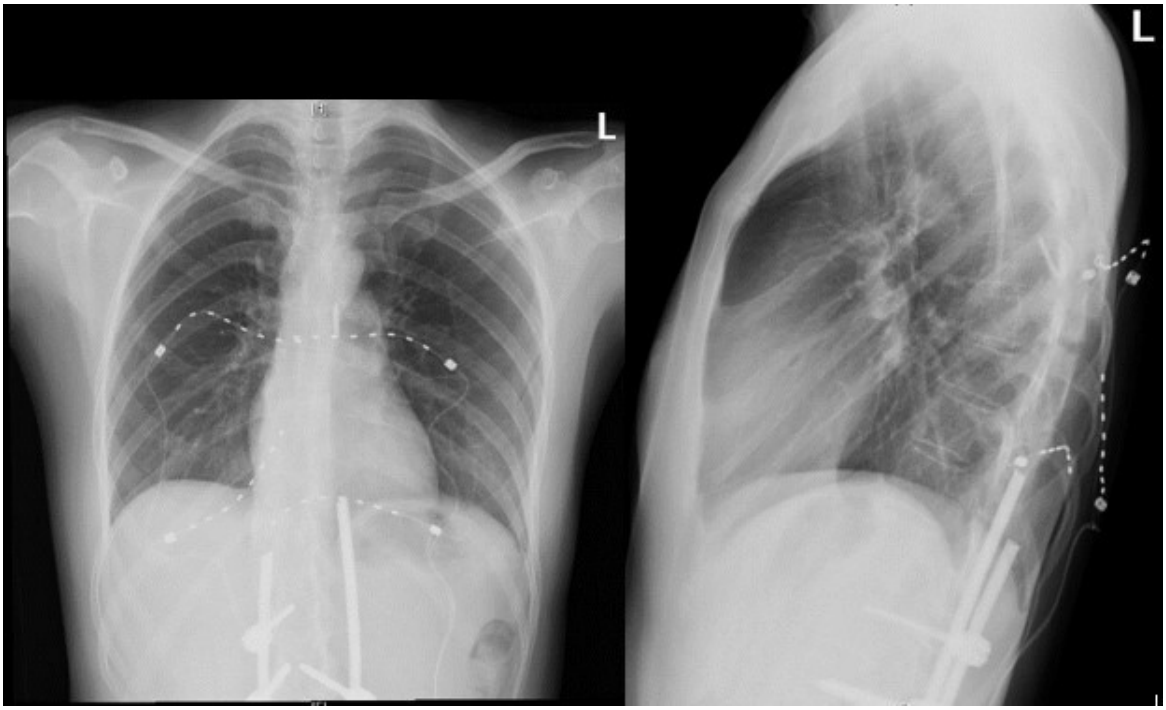

Figure 1. Chest X-ray: anteroposterior and lateral views of patient's thoracic spine with markings denoting regions of pain.

patients after lumbar spinal surgery, while neuropathic pain is a secondary condition that can exacerbate the condition.[18] Patients who develop tolerance to spinal cord stimulation therapy are at risk for exhausting therapies, leaving opioid treatment as a final option. For example, spinal cord stimulation, when successful, results in significantly less dosages of oral morphine required to control pain.[19] When it fails, rebound pain puts patients in a predicament where opioid use becomes highly sought after, putting pain patients of reproductive age at an increased risk of opioid exposure.[18] In the United States, there is a rate of 69.5% of unplanned pregnancies for women who take opioids.[5,20]

Most medications approved for pregnancy lack human data regarding gestation.[8] 91.2% of medications approved for pregnancy lack human data and rely on animal studies, as ethical principles prevent prospective randomized controlled trials being conducted on pregnant populations.[21] Thus, women often change medical management upon discovery of an active pregnancy, and a third do so without seeking medical advice.[5,20]

According to the Centers for Disease Control and Prevention, an estimated 7% of pregnant women use opioids to relieve pain; however, chronic maternal opioid use has been linked to neonatal abstinence syndrome.[22,23] In comparison, side effects of high dose capsaicin patches are dermatologic, mainly possible permanent desensitization and hypertension requiring physician monitoring in use.[1,24] Existing animal studies of the capsaicin patch show no evidence of fetal malformations and no adverse effects in a peri- and postnatal developmental period, even at high doses.[7]

8% Capsacin patch application is considered a safe procedure, with a report in the literature about a successful self-application at home with physician supervision through telehealth that occurred during the Covid-19 Pandemic.[25] Multiple studies have shown high-dose topical capsaicin statistically improves pain with minimal bloodstream concentration with no CNS effects.[1,11] Additionally, capsaicin is rapidly cleared in the bloodstream with a half-life of 1.64 hours, making dose adjustments for patients with liver/ kidney failure, or lactating mothers unnecessary.[7,11]

Currently, high dose capsaicin patches are not first-line agents for neuralgia.[24] Side effects of opioids include drowsiness, nausea, vomiting, and possibility of tolerance which could lead to dependence.[26] Evidence suggests that opioid use in the first trimester is linked to birth defects.[27] Another side effect of opioid use during pregnancy is neonatal abstinence syndrome, which affects the CNS and the gastrointestinal system of the fetus.[28] Most opioids are classified as category C, as they do not have any human studies linking them to teratogenic effects, but some animal studies link them to adverse effects in the fetus.[27] Conversely, 8% capsaicin patches are classified as category B, as animal studies have shown no adverse effects in pregnancy, however no human studies are available.[11] Capsaicin patches may provide an alternative to opioids and other class C drugs in this delicate population.

In addition to fetal risks, a cost-benefit analysis can be considered with capsaicin versus standard pharmacotherapy options. The price of the 8% capsaicin patch is comparable to a 3-month supply of oral medications.[12-14] In a cost analysis by Banerjee and McCormack of patients with PHN, the capsaicin 8% patch was more cost effective com-

pared to pregabalin, tricyclic antidepressant, gabapentin, pregabalin, or duloxetine.[13] In our patient's case, the 8% capsaicin patches negate drug interaction with other medication that had been prescribed, lowering the potential cost of unintended drug interactions.[29] Comparing the capsaicin 8% patches to the over-the-counter capsaicin creams (0.025%, 0.075%, and 0.1%), which require four daily applications, the patches have greater intrinsic compliance, as one application is effective for 3 months. This increase in patient compliance can lead to significant reduction in wasteful healthcare spending, as one study showed when 25% of patients are noncompliant with medications, it can increase avoidable health care costs up to $300 billion.[30]

This case report shows the patient had 3 prior successful pain treatments with an 8% capsaicin patch showing no adverse effects and continued treatment during the peripartum period. Due to the nature of our observational report, no conclusion can be drawn regarding the implication of capsaicin patch in preterm delivery. Considering risk factors such as age and complex migraines,[31] along with delivery being more than 3 months post-application, we do not see relation of Qutenza application to preterm labor. The patient was able to breastfeed after Qutenza treatment without issues, suggesting that it is safe during lactation.[7] Thus, we suggest consideration of high-dose capsaicin patches in chronic neuropathic pain treatment for pregnant patients following proper consultation with OB/GYN, review of patient history, and continued monitoring of the patient during use.

CONCLUSION

High dose capsaicin patches may provide an alternative solution in pregnant patients with chronic neuropathic back pain due to its transdermal route of administration, minimal systemic absorption, and infrequent dosing schedule of 12 weeks.[14] Per this report, future application of this medication for neuropathy during pregnancy could benefit from a large-scale assessment of its efficacy and side effects.

ACKNOWLEDGEMENTS

We acknowledge the support of the patient's primary care physician, Dr. Joel Posner.

CORRESPONDING AUTHOR INFORMATION

Seung Mi Oh, MD
seoh1@montefiore.org \

AUTHOR CONTRIBUTIONS

Each author listed met the standards of author contribution. All authors agree to be accountable for all aspects of the work.

Seung Mi Oh: conduct, manuscript writing. Ludovica Stilli: conduct, manuscript writing. Kateryna Slinchenkova: data analysis, manuscript writing. Karina Gritsenko: design, conduct, manuscript writing. Jacob Hascalovici: design, manuscript writing. Amaresh Vydyanathan: design, planning, conduct. Camille Fontaine: planning, conduct. Kathryn Breidenbach: conduct, manuscript writing. Sarang S. Koushik: design, planning, manuscript writing. Omar Viswanath: design, data analysis, manuscript writing. Naum Shaparin: design, planning, conduct, manuscript writing. Blaze T. Borowski: manuscript writing.

CONFLICT OF INTEREST

Dr. Shaparin receives funding for his institution from AcelRx Pharmaceuticals, Averitas Pharma, and Heron Therapeutics. Dr. Grisenko is a consultant to Pacira Pharmaceuticals and Averitas. I have disclosed these interests fully. No other potential competing interest was reported by the rest of the authors.

FUNDING

None.

ACKNOWLEDGEMENTS

We acknowledge the support of the patient's primary care physician, Dr. Joel Posner

Submitted: April 28, 2025 EST. Accepted: April 28, 2025 EST.
Published: June 16, 2025 EST.

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