

Efficacy and safety of capsaicin 8% patches: The experience of a rheumatology department

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Abstract

Background: Capsaicin 8% patches are recommended for the treatment of localized neuropathic pain, which is a frequent reason for rheumatology consultations.

Objectives: This study aimed to evaluate the efficacy and safety of capsaicin 8% used in our Rheumatology Department.

Design: Single-center retrospective study.

Methods: Patients treated by capsaicin 8% between October 03, 2019 and December 31, 2023 were included. Their age, sex, pain duration, DN4 score, pain intensity, and the cause of the neuropathic pain were collected. Patch safety was assessed on the day of application and after 15 days. The patient was asked about improvement, pain intensity, and the occurrence of burning sensations.

Results: One hundred twelve patients (mean age 62, 70% female) were included. The causes of neuropathic pain were especially scar ($n=31$), digital osteoarthritis ($n=26$), or radiculalgia ($n=22$). Sixty patients reported improvement (54%) at day 15, with a mean percentage of improvement of 59%. Mean pain intensity decreased from 6.4 ± 1.9 to 4.5 ± 2.7 ($p < 0.001$). This improvement in pain was significant regardless of etiology. There was no difference in age, sex, and pain duration between improved and unimproved patients. Fifty-eight patients (58/106: 54.7%) experienced burning sensations after patching, mainly of moderate to high intensity (32/52: 61.5%), with an average duration of 2 days. Of the eight unimproved after the first patch, six reported a 50% improvement after the second patch.

Conclusion: Capsaicin 8% appeared to be an effective treatment in localized neuropathic pain, whatever the cause. It seemed beneficial to repeat the application after the 1st one had failed. Burning sensations after placement were fairly frequent, usually moderate to high, but lasting only a short time.

Keywords

8% capsaicin patches, neuropathic pain, rheumatologic diseases, efficacy, safety

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Introduction

Capsaicin, the active component of chili peppers, recognized for its ability to produce a burning sensation when applied to the skin, have gained increasing attention, particularly in the files of pain management. Its mechanism of action involves the activation of Transient Receptor Potential Vanilloid 1 receptors of nerve fibers, leading to depletion of neuropeptides such as substance P, and inducing prolonged desensitization of neuronal pathways responsible for pain transmission.¹ Transdermal capsaicin patches have been proved to decrease localized neuropathic pain (NP) in different conditions.^{2–4}

Moreover, French guidelines and the Special Interest Group on Neuropathic Pain (NeuPSIG) distinguish between local and diffuse NP. In local NP, antidepressants and antiepileptics are not recommended in first line especially because of

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significant side effects, lidocaine patches and transcutaneous electrical nerve stimulation (TENS) (i.e., local treatments) are Moisset et al.,⁵ Biesbroeck et al.,⁶ and Finnerup et al.⁷ Therefore, Bates et al.⁸ recommended topical patches as a first-line treatment of localized NP.

In rheumatology, chronic pain and inflammation are key symptoms in several diseases, and NP is often therefore found not only in radiculopathy but also in osteoarthritis or rheumatic diseases.^{9,10} Exploring capsaicin's analgesic properties offers a promising avenue for pain relief in rheumatology without systemic analgesic treatment. Campbell et al.¹¹ provided a comprehensive review of capsaicin's application in rheumatology, focusing on its effects in pain modulation and the potential of intra-articular injections for managing osteoarthritis pain.¹ However, the use of intra-articular injection of capsaicin is more linked to clinical research than routine care. In rheumatology, Deal et al.¹² or McCarthy and McCarty¹³ assessed the effects of a low-dose capsaicin cream (0.025% or 0.075%) in osteoarthritis and concluded to positive but weak and irrelevant analgesic effects. International Societies of Rheumatology do not recommend the use of low-dose capsaicin^{14–17} but their recommendations concern only low-dose capsaicin and not the 8% capsaicin used in the management of NP. Transdermal 8% capsaicin is used in everyday life in Pain Assessment and Treatment Centers for localized NP linked to neuropathy caused by diabetes, chemotherapy, or linked to scar.^{18–20} Preliminary studies suggest that 8% capsaicin may reduce NP in osteoarthritis and rheumatoid arthritis.²¹ The routine use of 8% capsaicin in rheumatology centers is rare because it requires a specific training in the treatment use and in its application. The aim of this study was to assess the efficacy and safety of transdermal 8% capsaicin in patients with NP treated in routine care in a Rheumatology Department.

Materials and methods

Ethics statement

Ethical approval for this study was obtained from the local Ethics Committee (IRB00013412, "CHU de Clermont Ferrand IRB #1," IRB number 2024-CF288).

Informed consent

Patients were informed about the objectives of the study, the modalities of anonymization of their personal data using the RedCap secure web platform. Written informed consent was obtained for each included patient.

Study design

This single-center retrospective study involved an analysis of medical files of patients who received transdermal 8%

capsaicin in the Rheumatology Department of the University Hospital of Clermont-Ferrand. All the patients treated by 8% topical capsaicin between the October 30, 2019 and December 30, 2023 were included.

Patients

Inclusion criteria were as follows: adult patient with a localized NP characterized by the DN4 questionnaire when the score was $\geq 4/10$, whatever the disease causing the pain and treated by 8% capsaicin patch. Concomitant NP treatments or analgesic treatments were allowed and not changed during the study period. Exclusion criteria were refusal to participate.

Demographic and clinical data collection

The following parameters were collected:

- Age and sex.
- Pain duration.
- DN4 questionnaire to define the presence of NP with a score ≥ 4 .²²
- The disease causing NP: radiculopathy, osteoarthritis, scar, peripheral neuropathy.
- Numeric rating scale (NRS) for pain the day of the capsaicin application. NRS pain score was expressed by the patient itself. Patients rated the degree of pain they feel on a 11-point scale. Zero is no pain, the 1–3 level is mild pain, the 4–6 level is moderate pain, and the 7–10 level is high pain. Ten corresponded to the highest pain intensity.²³
- Patient reported pain intensity was also collected using NRS scale during a phone call, 15 days after the capsaicin pose.
- During the phone call, 15 days after the capsaicin pose, we asked the patient if there was an improvement or not and the percentage of improvement. Count of 0% corresponded to no improvement and 100% to a total improvement.
- Burning sensations during or immediately after the pose. During the phone, we asked the patient if there was burning sensations after the pose, the intensity of burning feeling (mild, moderate, or high) and for how long in days. According to the procedure we systematically follow in our department during 8% capsaicin application, all patients had cold packs application.

For each patient, we collected the total number of capsaicin applications over the study and the time in months between two poses.

Table 1. Characteristics of the 112 included patients.

Characteristics	Causes of neuropathic pain					
	All	Radicular pain	Operative scar	Hand osteoarthritis	Neuropathy	Other
Number of patients	112	22	31	26	9	30
Mean age, years	61.7 ± 13.4	69.2 ± 14.5	56.4 ± 14.8	61.4 ± 6.4	65.2 ± 9.1	58.5 ± 13.5
Women	78/111, 69.6%	14/22, 64.6%	22/31, 71%	23/26, 88.5%	7/9, 77.8%	22/30, 73.3%
Pain duration, years	5.4 ± 7.1	4.4 ± 5.5	5.5 ± 10.0	8.9 ± 5.1	3.2 ± 2.4	2.8 ± 4.0
Baseline NRS pain	6.4 ± 1.9	6.1 ± 2.2	5.9 ± 1.8	6.3 ± 1.7	7.7 ± 1.5	6.9 ± 1.7
NRS pain after capsaicin	4.5 ± 2.7	4.4 ± 2.6	4.4 ± 2.5	3.4 ± 2.5	4.8 ± 1.8	5.7 ± 3.0
Comparison of pain intensity before and after capsaicin	$p < 0.001$	$p = 0.02$	$p = 0.006$	$p < 0.001$	$p = 0.002$	$p = 0.03$
Number of improved patients	60/111, 54.0%	10/22, 45.5%	15/31, 48.4%	19/26, 73.1%	5/9, 55.6%	14/30
Percentage of improvement by the patient, % (min–max)	59% (20–100)	57.9% (25–100)	52.5% (20–80)	67.9% (20–100)	46.3% (25–75)	56.7% (20–90)
Number of patients with burning sensations after capsaicin pose	58/106, 54.7%	10/21, 47.6%	13/28, 46.4%	19/25, 76.0%	3/9, 33.3%	17/29, 58.6%
Number of patients with moderate to intense burning sensations	32/52, 61.5%	5/10, 50.0%	6/10, 60.0%	12/17, 70.6%	3/3, 100.0%	8/17
Duration of burning sensations, days	1.7 ± 1.9	1.6 ± 0.9	1.2 ± 0.4	2.1 ± 0.8	5.3 ± 0.6	1.5 ± 0.5
Number of patients with at least 2 capsaicin poses	31	3	9	9	3	10
Delay between 2 poses, months	4.8 ± 3.6	6.8 ± 5.8	4.2 ± 2.4	6.0 ± 5.2	2.9 ± 0.5	4.3 ± 2.9

VAS: visual analogic scale.

Statistical analysis

Statistical analysis was performed using Stata software (version 13, StataCorp, College Station, TX, USA). Continuous variables were presented as mean and standard deviation. Cases of nonnormality were presented as medians, quartiles, and extreme values. Categorical variables were expressed as numbers and associated percentages. The NRS pain intensity between baseline and day15 was compared using paired *t*-test. We used a one-way analysis of variance test to compare the mean decrease of NRS pain between D14 and baseline between the five groups (radicular pain, scar, hand osteoarthritis, neuropathy, and other). We compared the characteristics of patients in whom the patch was effective to those in whom it did not improve pain using *t*-test for continuous variables and Chi² test for categorical data. The relation between the variation of NRS pain between baseline and day 15 or the percentage of improved patients and the parameters (age, male gender, pain duration, burning sensation) was assessed using Spearman's correlation test for continuous variables and logistic regression for categorical variables. A two-tailed $p < 0.05$ was considered to be statistically significant.

Results

One hundred and twelve patients had at least one capsaicin 8% patch applied in our Rheumatology Department between October 30, 2019 and December 30, 2023. Most of them were women (70%) with a mean age of 62 years (Table 1).

NP had existed for an average of 5 years. The causes of this pain were scar ($n=31$), hand osteoarthritis ($n=26$),

radiculargia ($n=22$), neuropathy ($n=9$) or another, sometimes unknown, cause ($n=30$). All the participants had a DN4 score ≥ 4 . The mean NRS pain intensity significantly decreased from 6.4 ± 1.9 to 4.5 ± 2.7 ($p < 0.001$). This improvement in pain was significant regardless of etiology. We found no difference in the comparison of the decrease of pain intensity in the five groups ($p=0.15$). Sixty patients (54%) reported a pain improvement during the phone call 15 days after the patch application, with an average percentage of improvement of 59%.

Fifty-eight patients (58/106: 54.7%) experienced burning sensations following capsaicin pose, mainly of moderate to high intensity (32/52: 61.5%) with an average duration of 2 days (Table 1).

There were no significant differences between improved and unimproved patients in age (61.2 ± 1.7 vs 62.4 ± 1.9 years; $p=0.32$), sex (female: 76.7% vs 62.8%; $p=0.11$) or pain duration (5.0 ± 0.7 vs 5.2 ± 1.2 years; $p=0.46$). There was no relationship between the presence of burning sensations during or after the pose and patch efficacy (Table 2). No parameter was significantly associated with the NRS pain improvement after capsaicin pose (Table 3). The percentage of improved patients in pain intensity was not associated with age (OR=0.99; 95% CI: 0.97–1.02), male sex (OR=0.51; 95% CI: 0.22–1.16), pain duration (OR=1.0; 95% CI: 0.94–1.06), or presence of burning sensations after or during the pose (OR=1.67; 95% CI: 0.77–3.62).

Thirty-one patients had a second 8% capsaicin patch applied (Figure 1). The mean delay between the two poses was 5.3 months (min–max: 2.2–16.8) for the 23 patients improved after the first application and 3.2 months (min–max: 2.0–6.0) for the 8 patients unimproved. Of these eight

Table 2. Comparison of the patients' characteristics between those improved and unimproved after one capsaicin 8% pose.

Characteristics	No improvement (<i>n</i> = 51)	Improvement (<i>n</i> = 60)	<i>p</i> -Value
Mean age, years	62.4 ± 1.9	61.2 ± 1.7	0.32
Female, <i>n</i> (%)	32/51 (62.8%)	46/60 (76.7%)	0.11
Pain duration, years	5.2 ± 1.2	5.0 ± 0.7	0.46
Occurrence of burning sensations after capsaicin pose, <i>n</i> (%)	24/50 (48.0%)	34/56 (60.7%)	0.19

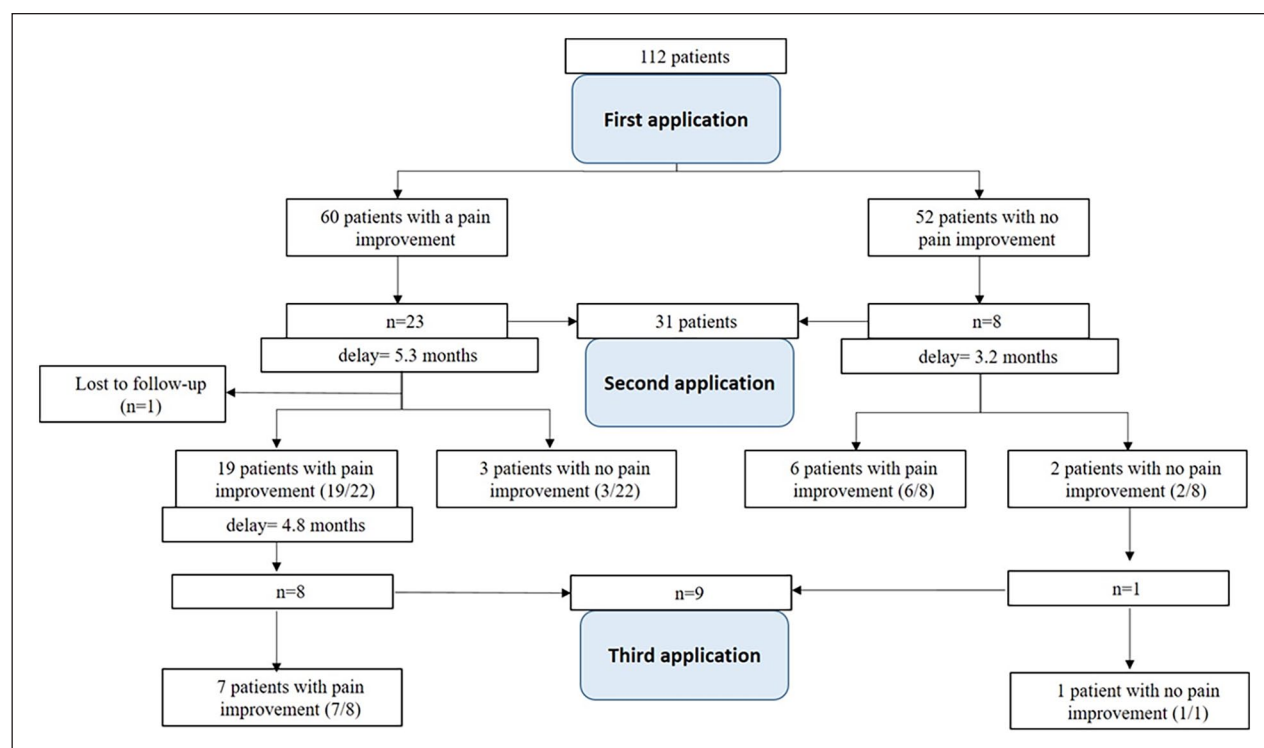
n: number of patients.

Table 3. Associations between patients' characteristics and VAS pain variation or percentages of improved patients.

Characteristics	VAS pain variation after capsaicin pose versus baseline	Percentage of improved patients
Age, years	<i>r</i> = 0.004, <i>p</i> = 0.97	OR = 0.99 (0.97–1.02)
Male	OR = 0.52 (0.13–2.11)	OR = 0.51 (0.22–1.16)
Pain duration	OR = 0.96 (0.89–1.03)	OR = 1.0 (0.94–1.06)
Occurrence of burning sensations	OR = 0.51 (0.12–2.17)	OR = 1.67 (0.77–3.62)

Values in brackets are 95% confidence interval.

OR: odds ratio; *r*: correlation coefficient.

**Figure 1.** Capsaicin 8% application in data collection period.

n: number of patients.

unimproved after the 1st patch, six reported an improvement after the 2nd patch of around 50%. One patient who was unimproved after the 1st and 2nd patches attempted a 3rd patch, without further success. Of the 23 patients who improved after the first procedure, 19/22 (86.4%) improved after the second procedure, 7/8 (87.5%) after the third one, and 4/4 (100%) after the 4th. The average time between

applications was 4.8, 7.2, and 7.4 months, respectively. In the same way, 16 on 22 patients had burning sensations after the 1st application, including 9/14 (64.3%) of moderate to high intensity. They were 12/22 (54.5%) after the 2nd application, 8/12 (66.7%) of moderate to high intensity. After the 3rd application, 2/8 (25%) reported a mild burning sensation lasting 48 h.

Discussion

We found that 8% capsaicin patch could be an interesting treatment in Rheumatology for localized NP observed in scars, radicular pain, neuropathy, or other causes like osteoarthritis. NRS pain was significantly decreased 15 days after the pose and safety was quite good, except burning sensations, sometimes intense but always short-time, less than 2 days. More than 50% of treated patients reported an improvement in pain intensity whatever the cause. Initially, we were wondering that there might be a different effect of capsaicin 8 depending the cause of the NP. But our results confirmed that all causes of NP can be significantly improved by 8% capsaicin patch. Improvement of painful radiculopathies, chemotherapy-induced, or diabetic peripheral neuropathy and of NP associated with surgery with 8% capsaicin has already been reported.^{19,24–26} But, to our knowledge, use of 8% capsaicin in a Rheumatology Department and especially in the treatment of NP caused by specific rheumatologic diseases, such as hand osteoarthritis for example, has not been widely reported in the literature.

A clear distinction must therefore be made between low-dose capsaicin, which offers no real improvement in pain and is not one of the treatments recommended by rheumatology associations, and capsaicin 8%, which is effective in treating localized NP. The recommendations for the nonsurgical management of hip and knee OA differs from one to another concerning topical capsaicin.²⁷ The 2019 American College of Rheumatology concluded to a conditional recommendation for the use of topical capsaicin in knee OA. The recommendation was weak for the 2020 Veterans Affairs and Department of Defense (VA/DoD) treatment guidelines and the conditional recommendation was against the use of topical capsaicin for the 2019 Osteoarthritis Research Society International.^{14,17,28} In these three guidelines, it concerned low-dose topical capsaicin in knee OA pain without NP. When the OA pain is neuropathic, 8% capsaicin can be used. The most important point before using 8% capsaicin patch is indeed to be sure that pain is a neuropathic one.

The average time between the application of 2 patches was 5.3 and 3.2 months, respectively, for the groups of patients improved and unimproved after the first capsaicin application. This delay is perfectly acceptable if the pain has improved. It is not necessary to systematically pose another capsaicin patch after 2 or 3 months if the patient is still improved on pain. However, if the patient has not improved after the first patch, don't hesitate to schedule a second or a third patch fairly quickly, with a minimum delay of 2 months, as reported in summary of product characteristics. In our study, a patient who was not improved on NP with 2 capsaicin patches 2–3 months apart did not seem to benefit from a third patch. But the need to use two or even three or more patches of 8% capsaicin to achieve a significant improvement has already been reported, in particular in a recent narrative review.²⁹ Freynhagen et al.³⁰ found that in STRIDE (nondiabetic NP) and PACE (painful diabetic peripheral neuropathy),

respectively, 306 and 313 received the capsaicin patch. Sixty and 96 had, respectively, a pain improvement after the first application; 33 and 68 after the second, and 11 and 43 after the third.

Our study has some limitations. First, it was a retrospective design of patient's medical files analysis with an assessment of the patient only 15 days after capsaicin pose by phone call. No regular medical reevaluation was planned which could have informed about lasting pain relief effects. It would have been interesting to have a pain assessment 1 month or 6 weeks after the capsaicin application, since late pain relief has been described with capsaicin patches. But unfortunately, this data were not available in the patients' medical files. Second, it was an open study with no control group, which limits the comparison and prevents from drawing strong conclusions. However, we found that occurrence of burning sensations was not associated with the patch efficacy. Patients with no burning sensations can be improved in pain intensity with no difference with those experienced burning sensations. This lack of difference minimized the limitation due to the placebo effect, the absence of blind and control group. The main strength of our study was to assess the everyday life 8% capsaicin application in a Rheumatology Department, that is, outside a pain center, where capsaicin is usually administered. Third, we did not calculate a sample size for this study. Therefore, we cannot be sure that the sample of patients analyzed in this study is sufficient to draw strong conclusion. However, we had efficacy and safety data for more than 100 patients treated by 8% capsaicin, which is still relevant. Concomitant NP treatments or analgesics were allowed. Unfortunately, the data of what kind of analgesic treatments the patients used when they were applying 8% capsaicin patch were missing in almost the medical files. It would have been interesting to know these treatments because they may have influenced the outcome. However, these treatments were insufficient to improve pain before capsaicin application and were not changed during the study period.

Conclusion

Our study shows that 8% capsaicin patch can be administered in a Rheumatology Department, provided that the entire nursing team is trained in its application, with interesting efficacy for patients suffering from localized NP whatever the cause, and with correct safety.

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We would like to thank all the nurses of our Rheumatology Department who realize each week the poses of 8% capsaicin patches and contact 15 days after the patients who had 8% capsaicin to ask them for efficacy and safety.

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Statements and declarations

Ethical considerations

Ethical approval for this study was obtained from the local Ethics Committee (IRB00013412, “CHU de Clermont Ferrand IRB #1,” IRB number 2024-CF288).

Consent to participate

Patients were informed about the objectives of the study, the modalities of anonymization of their personal data using the RedCap secure web platform. Written informed consent was obtained for each included patient.

Author contributions/CRedit

Study conception and design: Sylvain Mathieu, Anne Tournadre, and Martin Soubrier. Acquisition of data: Sylvain Mathieu. Statistical analysis: Sylvain Mathieu. Interpretation of the data, manuscript writing and revision: Marine Beauger, Marion Couderc, Sandrine Malochet-Guinamand, Marie-Eva Pickering, Martin Soubrier, and Anne Tournadre. All authors were involved in the drafting of this manuscript or critically revising it for important intellectual content, and all authors approved the final version to be submitted for publication. Sylvain Mathieu has full access to all of the study data and takes responsibility for the data integrity and the accuracy of the data analysis.

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Conflicting interests

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Data availability

Data are available from the corresponding author upon reasonable request.

Supplemental material

Supplemental material for this article is available online.

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