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# Evaluation of the Impact of Therapeutic Patient Education on Compliance and Efficacy of Lidocaine 5% Medicated Plaster on Allodynic Symptoms in Postoperative Localized Neuropathic Pain

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## Summary

**Objective:** To evaluate the impact of therapeutic patient education (TPE) on compliance and efficacy of lidocaine 5% medicated plaster (LMP5) on allodynic symptoms in patients with post-operative localized neuropathic pain (LNP) and in treatment failure.

**Materials and methods:** Retrospective study involving 69 patients. All patients received therapeutic education and had standardized efficacy and safety data collection. Pain induced by touch, pressure, hot and cold stimuli was collected at baseline and after 3 and 6 months of follow-up.

**Results:** TPE had a positive impact on compliance: 100% and 94.5% of patients were still in the program after 3 and 6 months. LMP5 confirmed its long-term efficacy and good tolerance. It provided substantial pain relief that improved over the 6 months of follow-up. LMP5 reduced all allodynic symptoms including a complete and rapid improvement of mechanical allodynic symptoms induced by touch and pressure. Allodynic symptom induced by hot stimulus improved over the first 3 months while that induced by cold stimulus improved over the 6 months of treatment. These different efficacy kinetics of LMP5 may be due to lidocaine exerting different pharmacological activity on the Aβ, Aδ and C fibres involved in pain transmission.

**Conclusion:** This retrospective study demonstrates the usefulness of TPE and confirms the efficacy of LMP5 in the management of LNP.

**Keywords:** Lidocaine 5% medicated plaster; Therapeutic education; Allodynia; Efficacy; Tolerance; Compliance

## Introduction

Neuropathic pain (NP), frequently encountered in clinical practice (7% of the general population and around a quarter of patients with chronic pain [1]) is secondary to a peripheral or central lesion or disease affecting the somatosensory system. Neuropathic pain, more common in patients aged over 50 years, is often of higher intensity and longer duration than nociceptive pain [2].

Given its very high frequency and its impact on quality of life [3], it is vital, during the first assessment of a patient suffering from pain, to look out for the characteristic symptoms of NP such as spontaneous pain (electric shocks, burning sensations, shooting pain, etc.) and evoked pain such as allodynia or hyperalgesia confirmed by clinical examination [4]. Using the area of an A4 sheet of paper (21x29.7 cm) to define localized NP (LNP), one study showed that, in a population of patients with chronic NP, 60% had LNP [5]. Diagnosis of the localized nature of NP influences the therapy that is subsequently proposed. An allodynic or hyperalgesic area may derive benefit from systemic treatments such as antiepileptics or tricyclic antidepressants or from topical treatments such as capsaicin 8% patch or lidocaine 5% medicated plaster (LMP5) [6].

Despite the availability of these different treatments, management of NP remains difficult and no treatment is effective on all types and all symptoms of NP [7]. The effective doses of systemic treatments are often difficult to find, necessitating

long titration periods and they are frequently associated with adverse events [8]. In Europe and in France, LMP5 "is indicated for the symptomatic treatment of postherpetic neuralgia (PHN) in adults" [9] and, because of its pharmaceutical form (medicated plaster), LMP5 is an alternative to systemic treatments. LMP5 is well tolerated [10] and as effective as pregabalin but without the systemic side effects in PHN [11]. This efficacy is maintained over the long term [12]. Furthermore, LMP5 physically protects allodynic and hyperalgesic areas from external stimuli [9].

LMP5 has also demonstrated its efficacy on other types of LNP [13,14]. The SFETD (French Society for Pain Research and Treatment - *Société Française d'Etude et de Traitement de la Douleur*) recommends LMP5 as "first-line therapy in patients with allodynia for whom systemic treatments are not advisable or are contraindicated" [15]. In international recommendations, LMP5 is recommended for the management of NP caused by several pathologies. Thus "LMP5, owing to its excellent tolerance, can be used as a first-line option in elderly patients, especially those who experience central nervous system-related adverse events with oral treatments" (EFNS) [16]. "LMP5 is recommended as a second-line option for peripheral NP" (NeuPSIG) [17] and "as a first-line option for NP" (Mayo Foundation) [18].

Furthermore, the difficulties in managing NP are compounded by compliance problems common to all treatments prescribed over the long term for chronic diseases. The incidence of adverse events and the sometimes-difficult titration explain the low compliance, estimated to be 43% with antiepileptics and antidepressants, observed in people with NP [19].

These results are consistent with the estimated compliance of around 50% found in studies performed in patients with chronic diseases in developed countries [20]. Furthermore, if the communication between the prescriber and the patient is not adapted and/or insufficiently informative, engendering misunderstanding about the proposed therapy, the patient is more likely to terminate the therapy prematurely [21]. Implementation of therapeutic patient education (TPE) increases the quality and efficacy of therapy in chronic diseases [22]. By improving communication and promoting a better understanding of underlying pathophysiological mechanisms, TPE could improve compliance among patients with NP.

The aim of the present study is to evaluate the impact of TPE on the compliance and efficacy of LMP5 in patients suffering from post-surgical LNP and in treatment failure.

## Method

### Study design

Retrospective study based on data collected from medical records of patients who attended the *Centre de Traitement de la Douleur – Site Morvan de Brest* in France between 2011 and 2014. These patients benefited from TPE and planned follow-up duration was at least 6 months. Standardized clinical data were collected during the inclusion visit and after 3 and 6 months of follow-up.

### Patients

All patients, old of at least 18 years, with post-surgical LNP, in treatment failure, who were prescribed LMP5, benefited from a TPE.

### Data collected during the inclusion visit

Sex, age and aetiology of pain as well as current analgesic treatments were collected.

Pain intensities over the previous week and at the inclusion visit were evaluated using an 11-point (0-10) numerical scale (NS) in which 0 corresponds to "no pain" and 10 to "maximum imaginable pain".

Diagnosis of NP was confirmed by using DN4, a questionnaire containing 10 items grouped into 4 questions. The neuropathic nature of pain was confirmed if the overall score was ≥4/10 [23].

The clinical examination sought to determine the localized or diffuse nature of the NP. The localized nature of NP was determined by the presence of allodynic symptoms characterized by pain induced by touch (using a brush - limited area - and a hand – large area), pressure (von Frey test [24]), hot and cold (thermo rollers) stimuli.

### Follow-up data

All patients underwent a full clinical examination after 3 and 6 months to evaluate the presence or absence of allodynic symptoms induced by touch (using a brush - limited area- and a hand - large area), pressure (von Frey test), hot and cold (thermo rollers) stimuli.

Pain relief, subjective experience, tolerance, cognitive barriers to correctly use treatment, ease of treatment use and compliance were collected using 11-point (0-10) numerical scales (NS) in which the scores 0 and 10 corresponded, respectively, to: for pain relief, no pain relief to complete pain relief; for subjective experience, very negative to very positive; for tolerance, poor tolerance to good tolerance; for cognitive barriers to correct use of treatment, no cognitive barriers to maximum cognitive barriers; for ease of use, difficult to use to very easy to use; for compliance, poor compliance to good compliance.

### Therapeutic patient education

TPE was initiated with the aid of different parties (doctor, psychologist, pharmacist, nurse, patient, patient's family...) and consisted of a coordinated journey punctuated by regular visits, and phone calls and emails.

As soon as the presence of post-surgical LNP was demonstrated, the strategy consisted in offering a therapeutic


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test with an anaesthetic cream. The cream was applied to the allodynic area and the patient invited to seek out the different sensations induced by the treatment. The patient received then a prescription for an 8-day trial period so the test could be done every day and was asked to keep a diary of the pain intensity and to perform a DN4 questionnaire every day. Then the patient was invited to attend a TPE session with a psychologist so that they could look over the provided explanations together and the psychologist could answer any questions the patient might have. This strategy elicited cooperation and placed the patient in a dynamic change.

The discussion on words, sensations, subjective experiences and questions would culminate in more technical exchanges. These covered the notion of nerves, their roles in human anatomy, their functions (central/peripheral nervous system) and their dysfunctions (whether related to disease, surgery, etc.). The concept of nerve conduction provided the link between electrical and chemical functions and targets of specific treatments for NP. After the explanations had been provided in everyday, the patient could ask for clarifications according to his/her understanding. A background paperwas handed to the patient so that he could talk about it with his family and refer to it as necessary. The care contract part provided the opportunity to frame the process in terms of milestones and realistic achievable goals. Medications were integrated into a set of actions including psychosocial activities and close follow-up too. The medications were presented as a vital part of the process to help the patient regain a good quality of life.

The following medical appointment reviewed progress and checked whether the patient adhered to the program, notably by judging the quality of information provided in the diary. After the clinical examination and evaluations, LMP5 treatment was instituted. A placebo was used to demonstrate the recommended way of applying and using the treatment. The application zone and duration, possible trimming, skin care, removal, regularity of care, adaptation to everyday activities were covered individually. A sheet summarizing all these points was given to the patient.

Interviews were held regularly over the first three months, then at less regular intervals. All healthcare professionals were informed about the program so that they would not provide discordant information, which the patient would be able to exploit to his advantage.

### Treatments

To cover the allodynic zone to be treated, patients could receive a maximum of three LMP5. The duration of application was supposed to be 12 hours every 24 hours (12 hours with and 12 hours without LMP5)

### Statistics

**Generalities:** Qualitative variables were described in terms of numbers and percentages of the different response modalities. 95% confidence intervals were calculated if necessary. The number of missing data was specified. Quantitative variables were described in terms of numbers, means, standard deviations and medians. All statistical tests were bilateral with a type 1 risk of 5%, with the exception of normality which was tested with a 1% cut-off point. Statistical analyses were performed with the software program SAS version 9.4.

### Analysis of data collected at the first appointment

Data from the first appointment were described in global terms and by aetiology (orthopaedic surgery vs other surgery). The two groups were compared as follows:

A. For comparing qualitative variables between the two groups, Chi-2 test or Fisher's exact test, depending on the numbers,

B. For comparing quantitative variables between the two groups, *Student's* test for independent series or the Mann-Whitney non-parametric test if the conditions for the parametric test were not fulfilled.

### Analysis of allodynic data

Each symptom was described with a 95% confidence interval for absence of the symptom. Given that all patients had all symptoms at the inclusion visit, evolution was tested using a Chi-2 test for equal distributions. The number of signs present was also calculated at each time point and compared to the number of signs at the inclusion visit (5 signs). The evolution of the number of symptoms was evaluated using Student's test for paired series or the Mann-Whitney non-parametric test if the conditions for parametric testing were not fulfilled.

### Analysis of follow-up data

Data were described at 3 and 6 months.

## Results

Seventy-three patients received this therapy and participated in the TPE program. Of the 73 records, 69 (94.5%) were usable and hence constitute the analysed population.

### Patient characteristics at the first appointment

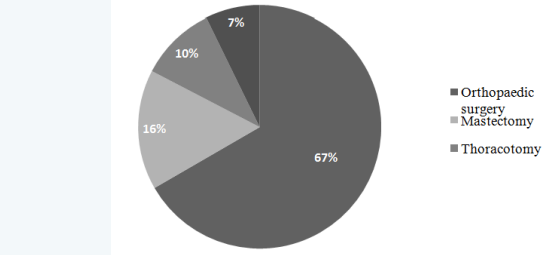


**Figure 1:** Aetiology of localized neuropathic pain (n=69).

Patients, in treatment failure and attending the Brest site, had post-surgical NP, after orthopaedic surgery for the majority


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of then (67%) (Figure 1). The majority were women (68.1%) aged 61.1±10.3 years (Table 1). Current analgesic treatments consisted almost exclusively of those indicated for nociceptive pain management: WHO ladder step 1 (82.5%) and 2 (58.0%) analgesics, NSAIDs (29.0%) and step 3 (21.7%) analgesics, while treatment indicated for NP (antiepileptics and antidepressants) were only prescribed for one patient (Table 1). All patients had a positive DN4 (≥4) and NP with a well-circumscribed allodynic area and spontaneous pain very frequently diffusing beyond the allodynic zone (97.1%) (Table 1). Pain intensity over the previous week (5.8±1.1) and during the inclusion visit (4.1±1.5) was moderate to severe, in spite of the ongoing analgesic treatments (Table 1). Finally, the "orthopaedic surgery" subgroup contained more women (p=0.0176), was older (p<0.0001), was taking more step 1 (p=0.0150), 2 (p=0.0011) and 3 (p=0.0133) analgesics and had experienced more intense pain in the previous week (p=0.0496) (Table 1).

**Table 1:** Patient characteristics collected at the inclusion visit (n=69).

| Data collected at the inclusion visit | | All patients | Orthopaedic surgery | Other surgery | p |
|---|---|---|---|---|---|
| Patient characteristics | | | | | |
| Gender n (%) | | | | | |
| | Male | 22 (31.9) | 19 (41.3) | 3 (13.0) | 0.0176 |
| | Female | 47 (68.1) | 27 (58.7) | 20 (87.0) | |
| | Age (years) | | | | |
| | Mean (SD) | 61.1 (10.3) | 66.3 (5.3) | 50.7 (10.0) | < 0.0001 |
| | Median | 63.0 | 67.0 | 52.0 | |
| Treatments n (%) | | | | | |
| | Anti-inflammatories | 20 (29.0) | 15 (32.6) | 5 (21.7) | 0.3482 |
| | Step 1 analgesics | 57 (82.5) | 42 (91.3) | 15 (65.2) | 0.0150 |
| | Step 2 analgesics | 40 (58.0) | 33 (71.7) | 7 (30.4) | 0.0011 |
| | Step 3 analgesics | 15 (21.7) | 14 (30.4) | 1 (4.3) | 0.0133 |
| | Topical treatments* | 3 (4.3) | 3 (6.5) | 0 (0) | 0.5457 |
| | Antiepileptics | 1 (1.4) | 1 (2.2) | 0 (0) | 1.0000 |
| | Antidepressants | 1(1.4) | 1 (2.2) | 0 (0) | 1.0000 |
| DN4>4n (%) | 69(100) | 46 (100)) | 23 (100) | - | |
| Pain characteristics | | | | | |
| | Localized pain. n (%) | 69 (100) | 46 (100) | 23 (100) | - |
| | Diffuse pain. n (%) | 67 (97.1) | 46 (100) | 21 (91.3) | 0.1078 |
| Pain intensity | | | | | |
| | Over the previous week | | | | |
| | Mean (SD) | 5.8 (1.1) | 6.0 (1.2) | 5.5 (0.8) | 0.0496 |
| | Median | 5.5 | 6.0 | 5.5 | |
| At the inclusion visit | | | | | |
| | Mean (SD) | 4.1 (1.5) | 4.3 (1.6) | 3.7 (1.3) | 0.0993 |
| | Median | 3.5 | 4.0 | 3.0 | |

* Other than lidocaine 5% compress (LMP5)

## Treatments

Throughout the follow-up period, all patients received one LMP5 per day except 3 patients (4.3%) who received two LMP5s. Nonepatient received three LMP5s.

## Impact of TPE on treatment compliance

In practice, this approach was never declined by any patients to whom it was offered. By converting patients into agents of their own pain management, this therapeutic education improved follow-up. Thus 69 patients (100%) were still in the program at the 3rd month and 65 (94.2%) at 6 months. Two patients terminated the treatment due to lack of efficacy, one patient moved far away from the centre and one patient was lost to follow-up.

## Evolution of allodynic symptoms

At the inclusion visit, all patients had all of the 5 allodynic symptoms under evaluation. Quantitatively, the mean number of allodynic symptoms had fallen to 1.0±1.5 (p<0.0001) after 3 months and 0.4±0.7 (p<0.0001) after 6 months (Table 2).


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Similarly, the percentage of patients with allodynic symptoms was significantly lower after 3 and 6 months of treatment (Figure 2). Qualitatively, after 3 months of treatment, there were significantly fewer patients with mechanical allodynic symptoms induced by touch (using a hand or brush) and by pressure or with thermal allodynic symptom induced by hot stimulus (reduction ranges from 85.5% to 90.0%: p<0.0001); however 47.8% of patients still had thermal allodynic symptom induced by cold stimulus (Table 3). After 6 months of treatment, no patients had mechanical allodynic symptoms induced by touch and pressure (p<0.0001), 15.4% still had thermal allodynic symptom induced by hot stimulus (p<0.0001) and 23.1% by cold (p<0.0001) (Table 3).

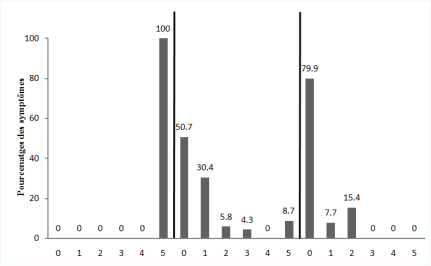


**Figure 2:** Percentage of patients with allodynic symptoms (n=0 to 5) at the inclusion visit and after 3 and 6 months of follow-up.

**Table 2:** Mean number of allodynic symptoms per patient after 3 and 6 months of follow-up.

| Number of allodynic symptoms | | Difference Inclusion visit / 3rd or 6th Month | P [95% CI] |
|---|---|---|---|
| Inclusion visit (n = 69) | 5.0 (0.0)<br>(5.0) | | |
| 3rd month (n = 69) | 1.0 (1.5)<br>0.0 | -4.0 (1.5)<br>(-5.0) | < 0.0001<br>[-4.4 - -3.7] |
| 6th month (n = 63) | 0.4 (0.7)<br>(0.0) | -4.6 (0.7)<br>(-5.0) | < 0.0001<br>[-4.8 - -4.4] |

**Table 3:** Number of patients with each of the allodynic symptoms (touch, pressure, hot and cold) at the inclusion visit and after 3 and 6 months of follow-up.

| Allodynic symptoms n (%) | Inclusion visit n = 69 | 3rd month n = 69 | p [95% CI] | 6th month n = 65 | p [95% CI] |
|---|---|---|---|---|---|
| Touch (friction with hand - extended area) | 69 (100) | 8 (11.6) | < 0.0001<br>[80.9; 96.0] | 0 (0) | < 0.0001<br>[100; 100] |
| Touch (friction with brush - limited area) | 69 (100) | 10 (14.5) | < 0.0001<br>[77.2; 93.8] | 0 (0) | < 0.0001<br>[100; 100] |
| Pressure (von Frey test) | 69 (100) | 7 (10.1) | < 0.0001<br>[82.7; 97.0] | 0 (0) | < 0.0001<br>[100; 100] |
| Hot stimulus (thermal roller) | 69 (100) | 10 (14.5) | < 0.0001<br>[77.2; 93.8] | 10 (15.4) | < 0.0001<br>[75.8 - 93.4] |
| Cold stimulus (thermal roller) | 69 (100) | 33 (47.8) | 0.7180<br>[40.4; 64.0] | 15 (23.1) | < 0.0001<br>[66.7 - 87.2] |

## Follow-up data

After 3 months of follow-up, pain relief was very high (6.5±1.7) and at 6 months had further increased to 7.5±2.1. The patients' subjective experience with regard to the therapy was favourable, with mean scores higher than 7 at the 3rd and 6th month; at the same time, cognitive barriers that could potentially limit the therapy were weak. The ease of use of LMP5 encouraged compliance (mean scores of 10 at each evaluation time point). Finally, LMP5 was well tolerated with mean scores of around 9 at each evaluation time point (Table 4).

**Table 4:** Follow-up data after 3 and 6 months of therapeutic management.

| Follow-up data Mean (SD) Median | 3rd month n = 68* | 6th month n = 65 |
|---|---|---|
| Relief | 6.5 (1.7)<br>6.5 | 7.5 (2.1)<br>9.0 |


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| | | |
|---|---|---|
| Subjective experience | 9.0 (0.0)<br>9.0 | 8.9 (0.3)<br>9.0 |
| Ease of use of treatment | 8.5 (0.5)<br>8.5 | 8.6 (0.6)<br>9.0 |
| Cognitive barriers to correct use of treatment | 2.0 (1.3)<br>1.0 | 2.2 (2.0)<br>1.0 |
| Compliance | 10 (0.0)<br>0 | 10 (0.0)<br>0 |

*Missing datum: n = 1.

## Discussion

A neuropathic component must be systematically sought for in every patient presenting with chronic pain, because of its impact on quality of life [3,25] as well as the availability of specific therapeutic strategies to manage it [5]. In addition to establishing the diagnosis of NP, there is the added impact of compliance among patients with chronic pain. Du Pen et al. [26] showed that between 62% and 72% of patients with cancer pain were compliant. However the rate of compliance varies according to how the prescribed analgesic is administered. The rate is between 22% and 27% for on-demand administration and between 85% and 90% for administration at fixed times [27]. In a recent study carried out in France [28] compliance with analgesic treatments increased with pain intensity but remained low: 27% in cases of mild pain and 44% in cases of severe pain. Forgetfulness, negligence and feeling well or poorly were the most common reasons provided to explain non-respect of prescriptions [28]. In NP, an estimated 43% of patients treated with antiepileptics or antidepressants are compliant [19]. Finally, non-relieved pain imposes a major economic burden on health systems and constitutes a major public health problem in Europe [29,30] and in France [31].

TPE has a positive effect on compliance of patients with chronic diseases [32,33] including pain [34]. According to the WHO [35], TPE is designed to help patients acquire or maintain the skills they need to manage life with a chronic disease as well as possible. TPE should be an integral part of the management of chronic pain patients. Consequently, by following the recommendations of the French National Authority for Health (HAS) [36] and implementing a multidisciplinary approach, this study showed that a TPE program to patients with LNP led to improvements in compliance rate, with 100% patients still in the program after 3 months and 94.2% after 6 months.

Optimization of therapeutic compliance also leads to improvements in the quality of therapeutic management. The follow-up confirmed the good tolerance and efficacy of LMP5 over the long term [12] as well as its ease of use. LMP5 provided significant pain relief that improved over the 6 months of follow-up. Only two patients terminated the therapy for lack of efficacy. By regularly evaluating all allodynic symptoms, this study was also able to confirm the efficacy of LMP5 against localized symptomatology of NP [37,38]. LMP5 led to a reduction in all allodynic symptoms but the efficacy was variable over time. LMP5 led to rapid and complete elimination of mechanical allodynia evoked by touch and pressure. Thermal allodynic symptom induced by hot stimulus improved over the first 3 months while that induced by cold stimulus improved over the 6 months of treatment. These results confirm those found in patients with NP who experienced substantial improvement in allodynia symptoms [37,30,40]. The observed kinetics of the efficacy may be due to lidocaine exerting different pharmacological activity on the Aβ, Aδ and C fibres involved in pain transmission. Confirming this hypothesis a differentiated action of lidocaine on Aδ and C sensory fibres has already been shown in healthy volunteers [42].

## Conclusion

This retrospective study demonstrated the usefulness of TPE in the management of LNP. By improving compliance, TPE optimizes therapeutic management. Data collected on the evolution of allodynic signs showed that LMP5 is rapidly effective on the most incapacitating mechanical allodynia, that evoked by touch and pressure. Long-term treatment, promoted by TPE, leads to an improvement in the efficacy of LMP5 on thermal allodynic symptoms induced by hot and cold stimuli.

These findings showing the effect of TPE in the management of LNP need to be confirmed by a prospective study, in order to evaluate its real impact. Similarly, the kinetics of LMP5's efficacy on allodynic symptoms need to be confirmed in patients with LNP. The present retrospective study conducted in a high number of patients confirmed the usefulness of long-term prescription of LMP5 in the management of LNP.

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