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Subcutaneous Lidocaine Infusion for Chronic Widespread Pain: A Chart Review and Survey Examining the Safety and Tolerability of Treatment

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Abstract: Chronic widespread pain (CWP) is characterized by persistent pain across multiple body regions, often accompanied by fatigue, cognitive difficulties, and psychological distress. **Background/Objectives:** Affecting approximately 10% of the general population, CWP disproportionately impacts women, individuals from lower socioeconomic backgrounds, immigrants, and those with a family history of chronic pain. Standard treatments, including cognitive-behavioral therapy, exercise, and pharmacotherapy, often provide insufficient relief. This study explores a novel approach to treating treatment-resistant CWP: high-dose subcutaneous lidocaine infusions administered over extended periods. **Methods:** The research included a retrospective chart review and patient survey to evaluate safety and tolerability. The protocol started with a dose of 10-12 mg/kg of adjusted body weight, increasing by 10-15% per month, with a maximum dose of 2000 mg. **Results:** The chart review of 27 patients revealed mild to moderate side effects in seven patients, with no severe adverse events. A survey of 15 patients indicated a higher incidence of side effects; however, all patients reported that the benefits outweighed the negatives. On average, patients experienced 61% pain relief, lasting 19 days per infusion. **Conclusions:** This study demonstrates that subcutaneous lidocaine infusions are a well-tolerated treatment for CWP, offering significant pain relief and improving patients' quality of life.

Keywords: lidocaine; pain management; patient survey; chronic widespread pain

1. Introduction

Chronic widespread pain (CWP) is a debilitating condition characterized by persistent pain across multiple body regions, often accompanied by fatigue, cognitive impairments, and psychological distress [1,2]. Affecting approximately 10% of the population, CWP disproportionately impacts women and is linked to factors such as low social support, immigrant status, family history of chronic pain, manual labor, and low socioeconomic status [1,3–5]. Obesity, sleep disturbances, and chronic disease further increase its persistence [2]. Those meeting WP2019 criteria for CWP face an increased mortality risk, particularly among marginalized groups, highlighting the need for accessible, affordable, and effective treatments [6,7].

Determining the proportion of individuals with CWP who do not respond to treatment is challenging and inconsistently documented in large-scale epidemiological studies [8]. Clinical trials indicate that there can be high rates of treatment failure, suggesting real-world outcomes may be even more challenging [9]. Evidence of treatment failure often comes from controlled trials, such as those investigating gabapentin for neuropathic pain, where treatment may reduce pain intensity for some individuals by up to 50% [10], which suggests there is a substantial population suffering from treatment-resistant pain for whom effective pain management solutions are yet to be discovered [8].

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CWP is typically best managed through a multidisciplinary stepped approach [11]. First-line interventions such as cognitive-behavioral therapy (CBT), exercise, and patient education have shown success in reducing pain sensitivity, psychological distress, and reversing deconditioning [12,13]. However, when these non-pharmacological treatments prove insufficient, pharmacotherapy is introduced. In Canada, only a limited number of medications are approved for CWP and are typically reserved for severe cases [14]. Pharmacotherapy also presents challenges, including analgesic failure, polypharmacy, side effects, and addiction risks [9,15].

Lidocaine, first used for neuropathic pain in 1943, blocks sodium channels to reduce nociceptor sensitization and hyperexcitability [16]. Its anti-inflammatory effects reduce cytokines involved in secondary hyperalgesia and central sensitization [17,18]. Lidocaine infusions offer a minimally invasive option for chronic pain, with studies demonstrating the efficacy of intravenous lidocaine and patches for chronic and neuropathic pain [19–21]. Subcutaneous lidocaine has shown promise for cancer-related pain, though a meta-analysis found intravenous lidocaine provides only short-term relief [22,23]. While safe and cost-effective, research on subcutaneous lidocaine for CWP remains limited [24,25]. Patient expectations and clinician relationships influence outcomes, emphasizing the need for patient perspectives in future research [26].

This study evaluates subcutaneous lidocaine for CWP by assessing safety and tolerability through a retrospective chart review and efficacy via a patient survey. Unlike previous studies on low-dose intravenous lidocaine (1-5 mg/kg) over short periods, this research explores higher subcutaneous doses (12-20 mg/kg) administered over longer periods (up to 24 hours at 50 mg/hr) [23]. The findings aim to inform clinical guidelines and optimize treatment strategies for CWP. One of the authors (WFL) has been involved in providing this form of pain management safely since 2002, out of hospital ambulatory care units in BC, Canada, with no serious adverse effects reported in this time.

2. Materials and Methods

Patients with treatment-resistant CWP, including those with fibromyalgia, were referred to the lidocaine program after failing at least two mainstream interventions such as nortriptyline, duloxetine (Cymbalta), physiotherapy, or targeted injections (e.g., trigger point, facet, or nerve blocks). Needle-phobic patients were also considered candidates.

Prior to treatment, all patients required an electrocardiogram (ECG) to rule out arrhythmias or prolonged QT intervals, and they were screened for contraindications such as allergies to lidocaine, frailty, significant renal (GFR < 30 mL/min) or liver dysfunction (ALT/AST > 2.5x normal), and cardiac pathology (e.g., heart failure, arrhythmias). Patients on medications that suppress the central nervous system (e.g., high-dose gabapentin, benzodiazepines) were given careful consideration.

At the first visit, patients were weighed to calculate an adjusted body weight, chosen to reduce overdose risk in those with obesity. Lidocaine doses were set at 10-12 mg/kg based on this adjusted weight, calculated via an online tool [27]. Patients received a detailed handout explaining the procedure, potential side effects, and post-treatment instructions. After discussing any questions, informed consent was obtained.

Dose increases occurred at no more than 10-15% per month if pain symptoms were not adequately treated. The ceiling dose was 20 mg per kilogram of adjusted body weight, and regardless of weight, no patient was administered more than 2000 mg lidocaine (100 mL of 2% lidocaine) per infusion. Saline (or 5% dextrose/D5W) was added in a 1:1 ratio to the 2% lidocaine. For doses less than 1500 mg (up to 75 ml 2% lidocaine), a 125 ml Avanos elastomeric pump was used with 2% lidocaine infused at a rate of 5 mL/hr. For doses exceeding 1500 mg, a 270ml Avanos elastomeric pump was used with 2% lidocaine in a 1:1 ratio with Saline or D5W to be infused at a rate of 5 mL/hr (50 mg lidocaine/hr). The subcutaneous line was placed in the patient's abdominal or pectoral area and clamped off so that the patient could return home. On average, the course of infusion lasted approximately 24 hours. When the infusion was complete, the patient was instructed to remove the catheter and discard the materials.

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Table 1. Standard classification of side effects and patient instructions.

Level	Symptoms	Instructions
Mild	Slight drowsiness or slight metallic taste	Continue infusion.
Moderate	Marked sleepiness, strong metallic taste, dizziness, ringing in the ears, numbness around mouth and tongue, vomiting	Stop the infusion for 45 minutes by clamping the line and reevaluating.
Severe	Moderate symptoms that persist after clamping the line **or** any of the following: Change in blood pressure, irregular heart rate (heart arrhythmias), allergic reaction (hives, shortness of breath, swelling of lips or tongue), confusion, seizures	For persistent moderate symptoms, call the clinic or attend the emergency department. For all other severe symptoms, go directly to the emergency department.

Participants had to be diagnosed with CWP and have received at least three subcutaneous lidocaine infusions. All participants were over 18 years of age. There were no exclusion criteria. Ethics approval was obtained to review 27 patient electronic medical records (EMRs). For patients who had more than three infusions, only the most recent three were analyzed. Chart reviews occurred from February 26 to March 1, 2024.

Participants were recruited by using filtered EMRs. Eligible participants were then further filtered into those who consented to be emailed a survey about their treatment. Of the 27 who met the criteria, 21 participants indicated in their medical records that they would be interested in receiving emails to participate in future research hosted by the clinic. Those who agreed were emailed a letter of initial contact and a Qualtrics link to the consent form and survey. Of those who were contacted for the survey, 15 individuals completed it.

A clinic medical office assistant filtered EMRs based on inclusion criteria. The first author then collected data on the patient's age, sex, number of lidocaine infusions, and adverse events experienced during the three most recent treatments. Patients may have seen one or a combination of clinicians at the facility.

Participants were contacted via email and asked to complete a brief (i.e., approximately 10 minutes) online survey (Appendix 1). Specifically, participants were asked to recall their experiences with their three most recent subcutaneous lidocaine infusions. The survey aimed to comprehensively understand their personal experiences with, and perspectives on, this treatment.

The retrospective chart review and survey data were compiled into a de-identified dataset. Survey responses were summarized using descriptive statistics (i.e., frequencies and percentages for categorical variables and means and ranges for continuous variables). All analyses were performed in SPSS v27. Responses to the final open-ended question were analyzed using conceptual content analysis to identify the impact of the treatment on participants' lives that may not have been captured in the closed-ended questions or chart review [28,29]. Preliminary codes were derived inductively by the first author and then expanded and contracted to best fit the data.

3. Results

3.1. Chart Review

The chart review sample consisted of seven males and 20 females. The average age of the sample was 53, ranging from 25 to 73 years old. On average, patients had undergone 17 total infusion treatments, ranging from three to 29 treatments.

Seven of the 27 patients reported adverse events to their physician at their subsequent treatment session. In two cases, patients called into the clinic to report acute nasal congestion, one of which also reported difficulty breathing. In both cases, the congestion was resolved. Other events recorded were mild in nature and included headache, nausea, fatigue, restlessness, an initial increase in pain (x2),

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low mood, and itchy eyes. When considering the number of events per patient, of the seven who reported side effects, four reported two side effects of treatment (e.g., headache and nausea), and three reported one side effect over the course of their three most recent treatments. The remaining 20 patients did not report any side effects to their treatment provider.

3.2. Survey

The survey sample consisted of five self-reported men and ten self-reported women. The average age of the sample was 51, ranging from 25 to 73 years. The survey had a 100% completion rate, with all participants answering both closed- and open-ended questions. Of the 15 respondents, 14 were still undergoing treatment, while one had discontinued trying a new, insurance-covered medication to reduce costs and time. In the open-ended section, two participants mentioned financial challenges, and one cited time barriers related to the treatment.

Of the 15 participants, eight reported no side effects, and seven reported experiencing one or more side effects (see Table 2). When asked if the benefits of the medication outweighed its side effects, all seven who experienced side effects indicated that the benefits did indeed outweigh the side effects. These findings mapped onto the open-ended survey portion, where 5 participants elaborated on their side effects. Specifically, one reported physical and psychological side effects (e.g., fatigue and annoyance). Likewise, four patients described having minor, manageable physical side effects (e.g., fatigue and itching, which were reduced by clamping the line) associated with treatment. The following is a representative quote from this content: "I typically fall asleep for a few hours after the start of the infusion and am somewhat tired and groggy for six to eight hours post-infusion. This is not a negative effect and is something easily managed." When asked about their comfort level during the treatment on a scale of 0 (not at all comfortable) to 100 (completely comfortable), respondents rated their comfort at 84, with scores ranging from 41-100.

3.3. Treatment Outcomes

All participants reported experiencing pain relief from the treatment. On average, they rated their pain reduction at 61%, with individual responses ranging from 13% to 93% (0 indicating no relief and 100 indicating maximal relief). These results were consistent with the open-ended responses, where ten patients elaborated on their pain reductions. For instance, one patient noted, "[Lidocaine] reduces the daily pain by about 30%, which may not sound significant, but considering my usual pain level is 8/10 all day, it's a welcome relief." In addition to pain reduction, five patients reported overall life improvements, three mentioned enhanced physical function and activity, two highlighted better sleep, and two described improvements in social functioning (e.g., work and family responsibilities). On average, participants reported that the relief lasted 19 days, with a range of five to 44 days.

Table 2. List of side effects endorsed and the number of occurrences.

Side Effect	# of Times Endorsed
Drowsy	6
Rash/Skin Irritation	4
Nausea w/o vomiting	3
Lightheaded	2
Metallic Taste	2
Swelling	2
Redness	2
Allergic Reaction	1
Confusion	1

Note. Participants could endorse more than one side effect.

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4. Discussion

This study builds on existing evidence that lidocaine is a safe and effective treatment for various types of chronic pain [18,20–22]. It also extends the literature in two key ways: first, by evaluating the safety and tolerability of a novel approach involving high-dose subcutaneous lidocaine infusions over prolonged periods, and second, by capturing patient-reported experiences and perspectives. The findings indicate that the treatment is generally well-tolerated, with participants reporting high levels of comfort during administration. Despite the occurrence of mild side effects in about half of the surveyed patients, all who experienced them affirmed that the benefits outweighed the negatives. Most notably, the treatment provided substantial pain relief, with participants highlighting improvements in quality of life, physical function, sleep, and social responsibilities. While a small number of participants raised challenges related to cost and time, the overall effectiveness of the treatment and the willingness of patients to continue underscores its positive impact on managing treatment-resistant chronic widespread pain (CWP).

The study revealed notable discrepancies between the chart review and the follow-up survey, particularly regarding the incidence of side effects. The survey indicated a higher frequency of side effects compared to the chart documentation, which may be attributed to several factors. First, patients might have considered the side effects too mild to mention during clinical visits, deeming them insignificant. Second, healthcare providers may not have explicitly asked about certain symptoms, leading to their omission in the chart reviews.

Although the survey did not capture follow-up information on severe side effects, it is inferred that any allergic reactions were likely minor, as no patients required hospital visits, urgent care, or clinic follow-ups for serious reactions. Patients may have also failed to mention these symptoms during appointments, either because they felt the issues were trivial or simply forgot by the time of their next session.

This discrepancy underscores the value of direct patient reporting in capturing a complete picture of treatment experiences and highlights the potential underreporting of side effects in routine clinical documentation. The survey, conducted virtually at the patients' convenience, may have given them more time to reflect and provide detailed responses, further contributing to the discrepancy.

Strengths of this study include a naturalistic examination of the population of interest (i.e., those living with CWP) via retrospective chart review followed by an in-depth examination of their perceptions of treatment. This approach provides considerable insight into this novel procedure for both clinicians treating those with CWP and persons with lived experience. Although the sample size was small, these findings, in conjunction with previous studies and common clinical practice, provide evidence that this treatment may be useful for those experiencing CWP, including those who have experienced previous treatment failure. High completion rates among participants in the survey portion enhance the reliability of the data. Further, the combination of chart reviews and follow-up surveys provides a comprehensive understanding of both clinical outcomes and patient perspectives, offering valuable insights into their opinions and experiences. However, the study also has limitations. The small sample size, dictated by the unique nature of the population, restricts the generalizability of the results. Additionally, the absence of a clinical trial design limits the ability to establish causality, and the insufficient number of patients precludes the use of advanced experimental statistics, reducing the robustness of the findings.

The implications of this research are both multifaceted and significant for clinical practice and future studies. First, the findings demonstrate that subcutaneous lidocaine infusions provide substantial pain relief and improve quality of life, offering healthcare providers a viable option to recommend for chronic pain management. The high patient-reported comfort and manageable side effects further reinforce its practicality. Second, the variability in individual responses and relief duration underscores the need for personalized treatment plans and deeper exploration of factors influencing treatment efficacy. Moreover, challenges related to cost and time barriers suggest a need to enhance accessibility, possibly through better financial support from provincial funders and insurance companies. Addressing these barriers could improve patient adherence and satisfaction. Ultimately,

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this research highlights the importance of integrating both clinical outcomes and patient experiences in the development and implementation of effective chronic pain treatments.

For people with treatment-resistant CWP, this approach may offer much-needed relief. Unfortunately, the supply fee for this treatment is approximately CAD 150.00 per session, and this fee is not covered by insurance. With patient relief lasting an average of 19 days per session, this translates to an annual out-of-pocket expense of approximately CAD 2,850.00 for the average patient, assuming they receive treatments consistently throughout the year. However, this calculation only accounts for the direct costs of the treatment sessions themselves. Additional indirect costs, such as taking time off work to attend appointments, arranging childcare, and expenses related to travel and transportation, further increase the financial burden on patients. These factors can significantly impact access to treatment for an already vulnerable population [2,6,7].

Future research should prioritize longitudinal studies to evaluate the long-term efficacy and safety of this treatment. Comparative effectiveness research, including trials against other pain management therapies, would be valuable for determining both efficacy and cost-benefit outcomes [30]. Investigating individual variability through personalized medicine approaches, alongside comprehensive cost-benefit analyses, is essential for improving accessibility. Mechanistic studies exploring the biological underpinnings of the treatment, paired with expanded patient-reported outcomes and qualitative data, will provide deeper insights into patient experiences. Implementation research can identify optimal strategies for integrating this treatment into diverse healthcare settings, while studies on combination therapies could enhance pain relief and mitigate side effects, offering a more holistic approach to pain management.

5. Conclusions

This study, although small-scale, demonstrates that high-dose subcutaneous lidocaine infusions are generally a safe and well-tolerated method to reduce pain for individuals with treatment-resistant chronic widespread pain (CWP). Participants reported significant pain relief, with improvements in quality of life, physical functioning, sleep, and social responsibilities. While some mild side effects were noted, they were manageable, and all patients indicated that the benefits of treatment outweighed the negatives. The high levels of comfort reported during the infusions and the substantial pain reduction experienced underscore the treatment's viability as a practical option for chronic pain management. However, challenges related to cost and accessibility highlight the need for systemic changes, such as increased financial coverage, to improve patient access. Future research should focus on larger, longitudinal studies and explore ways to optimize treatment efficacy and accessibility, ultimately ensuring that this promising intervention reaches a broader population of patients with CWP.

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Institutional Review Board Statement: The survey study was approved by the Behavioural Research Ethics Board at UBC Okanagan under certificate number H2302985. The chart review was approved by the Clinical Research Ethics Board at UBC Okanagan under certificate number H232558.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: The authors wish to disclose that A.N. and W.F.L are both practicing physicians at the clinic where the study was conducted. While their clinical roles may present a perceived conflict of interest, all efforts were made to ensure that the research was conducted impartially and that data collection, analysis, and interpretation of results were carried out independently of clinical practice. The study was designed with rigorous methods to minimize bias, and the clinical involvement of the authors did not influence the outcomes or

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conclusions of this study. Specifically, the first author compiled the data, and the analysis was completed by the first and second authors. Using this approach ensured unbiased results.

Appendix A

Appendix A.1

1) Are you still receiving subcutaneous lidocaine infusions? Y/N
1a) If No, why: (check all) cost, time, travel, no longer effective, too many side effects, pain better managed by another medication, I had a surgical intervention, I had a nonsurgical intervention, I've recovered, other:____?
2) Have you experienced any negative side effects from lidocaine treatment? (Yes or No)
2a) If Yes: Check all that apply:

Minor: Numbness around the lips, fingers, and/or toes;
drowsiness; lightheadedness; tinnitus (ringing ears);
metallic taste, swelling; redness; rash; skin irritation.
Moderate: Nausea with vomiting, severe dizziness, tremors,
mild confusion.
Serious: Change in blood pressure; heart arrhythmias; allergic
reaction; confusion; seizures

2b) If Yes: Did the benefits outweigh the side effects of the medication? (Yes or No)
3) How much pain relief do you experience on average from the infusion? (None to Maximal; 0%-100% Visual Analogue Scale (VAS))
3a) How comfortable were you during your treatment session? (Not at all to Extremely; 0-100 VAS)
4) How long does the relief typically last? (____ days)
4a) Is there anything you'd like to tell us about the relief you experienced? _____
5) Would you recommend this treatment to others with chronic pain? (4-Point Likert: Definitely not, Probably not, Probably would, Definitely would).
6) Please describe in your own words how this treatment affected your life (the effects may be negative, positive, or neutral) _____.

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