

Analysis of the Cost versus Value Associated with the Use of 5 % Lidocaine Topical Patch in Chronic Pain through Patients' Satisfaction

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Abstract

Background

Chronic pain is one of the most complex and prevalent health issues that involves peripheral and central mechanisms, justifying the need of multimodal analgesia. Since the use of oral medications most of the times is limited by side effects, drugs interaction and patient compliance, topical agents could provide an alternative or additional therapy. Topical capsaicin, and lidocaine patch has been studied in the literature in managing neuropathic pain conditions, however these topical agents might represent an additional healthcare cost, hence their use must be justified. The aim of this study was to assess the cost effectiveness versus the value of the use of the topical 5% Lidocaine Patch (LP) medicated plaster in chronic pain patients (CPP) through patients' satisfaction.

Methods

In this descriptive cross-sectional survey-based design a convenience sampling technique was used from the outpatient chronic pain clinic for patients with localized pain. The patients were instructed to apply the (LP) directly to intact skin to cover the most painful area for up to 12 hours within a 24-hour period.

Results

61.9% of the patients were satisfied with the use of the LP, 64.4% of the patients experienced pain relief within less than 2 hours. Only 6.7% experienced side effects, which included itching and only one patient experienced redness with burning. 64.7% of the patients reported that they will continue the use of the LP, 56.3% reported that they will recommend the use of the LP to others.

Conclusion

We concluded that the use of the 5% lidocaine topical patch is a cost-effective pain management option in chronic pain patients through patients' centered approach.

Keywords: Neuropathic, Topical, Lidocaine Patch, Localized Pain.

1. Introduction

Chronic pain is one of the most complex and prevalent health issues that has a significant social, financial, and societal impact. It can be localized or generalized and may require multimodal approach [1]. Pain physicians usually combine different therapeutic modalities that include pharmacological and non-pharmacological techniques. Hence, the oral analgesia is limited

by many factors such as adverse effects, patient's co-morbidities, and compliance to the treatment, as an alternative, many topical agents have been increasingly used with demonstrable benefits. For instance, capsaicin and topical diclofenac have been used in the treatment of soft-tissue pain, capsaicin and (LP) has been used for chronic neuropathic pain such as postherpetic neuralgia (PHN) and diabetic peripheral neuropathy (DN) [2]. Topical agents have

the advantage of being well tolerated, sidestepping the first-pass metabolism with site-specific drug delivery, offering less systemic adverse effects with minimal systemic drug interactions [3].

LP 5% has been used in different chronic pain conditions including (PHN), painful (DN), Low back pain (LBP) complex regional pain syndrome (CRPS) and has shown to be well tolerated and useful in reducing pain intensity, with minimal side effects and no serious adverse drug interactions [4,5]. However, its use represents an additional financial burden on the healthcare system, as it costs around 500 SAR (\$133) per month per patient, and thus the cost versus benefit should be taken in consideration when prescribing the LP.

Assessing the patients' satisfaction with a treatment modality is an essential tool for quality improvement, ensuring patient-centered approach, and justifying the cost versus value of its use [6]. Different studies have evaluated the cost effectiveness of the LP 5 %, with comparison to other oral medications such as gabapentin, pregabalin, and tricyclic antidepressants (TCA), in patients with PHN, Others compared the LP to other topical placebo patch, and demonstrated more effectiveness of the LP Most of these studies, were based on a core Markov model and, to our knowledge, no previous study evaluated the cost effectiveness of LP 5 % in CPP through patients satisfaction approach [7-18].

The aim of our study was to assess the cost effectiveness versus the value of the use of the LP 5% in CPP through patients' satisfaction.

2. Methods

2.1 Ethics, Study Design, and Population

This is a descriptive, cross-sectional survey that used a convenience sampling technique to select patients from the outpatient chronic pain clinic in a tertiary care center over one year period. Ethical approval for this study was provided by the local institute ethics committee, with the number [Blinded], The cohort comprised both genders with the age ranged between 18-80 years with localized pain either neuropathic, musculoskeletal, arthritic or mixed pain condition, the participation was completely voluntary, written

informed consent was obtained from each participant, and they were informed about their right to withdraw at any time of the study with no consequences. The demographic data, age, gender, marital status, education status, and comorbidity, along with the pain diagnosis, duration of pain, prior pharmacologic treatment, and the current medications were collected from the patients' charts. A self-administered questionnaire was constructed and validated by the research team, in a form of Likert type scale. It contained three parts, the first part consisted of the demographic data, the second part contained information about the disease, pain score, and drug history of the patients, the third part measured the patient general satisfaction of the LP, presence of adverse events, and the convenience of the use of the LP.

Patients were prescribed topical LP 5% (Versatis®), which is manufactured by Teikoku Pharma, located at (567 Sanbonmatsu, Higashikagawa, Kagawa 769-2601, Japan) along with their current medications without any changes throughout the study period. The patients were instructed to apply the LP directly to an intact skin to cover the most painful area. Apply up to three patches, only once for up to 12 hours within a 24-hour period. After the patches use for at least one month period the patients were interviewed either in person during the clinic follow up visit or via telephone interview, the patients were asked to rate their pain on the verbal pain scales from 0- no pain, to 10- worst pain, prior to and after the use of the LP for at least one month, and the other data were collected according to the questionnaire items.

3. Results

A total of 119 patients fulfilling the inclusion criteria were included. Patients ages were from 18 years and above with mean age of 46.9 ± 11.8 years old. A total of 79 (66.4%) patients were females and 96 (80.7%) were married. As for body mass index (BMI), 25 (26.9%) patients had normal body weight, 29 (24.4%) were overweight, while 65 (54.6%) were obese. A total of 32 (26.9%) patients were non-educated, 45 (37.8%) were at high school, and 24 (20.2%) had university level of education or above. A total of 72 (60.5%) patients had other co-morbidity (table 1).

Bio-demographic data	No	%
Age in years		
18-40	29	24.4%
41-60	55	46.2%
> 60	35	29.4%
Gender		
Male	40	33.6%
Female	79	66.4%
Marital status		
Married	96	80.7%
Single	23	19.3%

Body mass index		
Normal	25	21.0%
Overweight	29	24.4%
Obese	65	54.6%
Education level		
Non- educated	32	26.9%
High School	45	37.8%
Diploma	18	15.1%
Bachelor degree	19	16.0%
Post graduate university degree	5	4.2%
Co- Morbidities		
Yes	72	60.5%
No	47	39.5%

Table 1: Bio-demographic data of patients with chronic pain

Pain-related clinical data are shown in (table 2). The most reported type of pain was musculoskeletal (55.5%), followed by neuropathic pain (18.5%), mixed pain (18.5%), and arthritic pain (7.6%). A total of 42 (35.3%) of patients had pain for less than 30 days, 36 (30.3%) had pain for 30-60 days and 41 (34.5%) had pain for more than 60 days. A total of 80 (67.2%) patients had

high pain intensity before the treatment with LP while none had low pain intensity before the treatment, compared to 28 (23.5%) who had high pain intensity after the treatment with LP and 53 (44.5%) had low pain intensity, the mean score before treatment was 8.0 ± 1.4 (5-10) compared to 5.2 ± 2.4 (0-10) after treatment with statistically significance difference ($P=.001$) **Figure 1**.

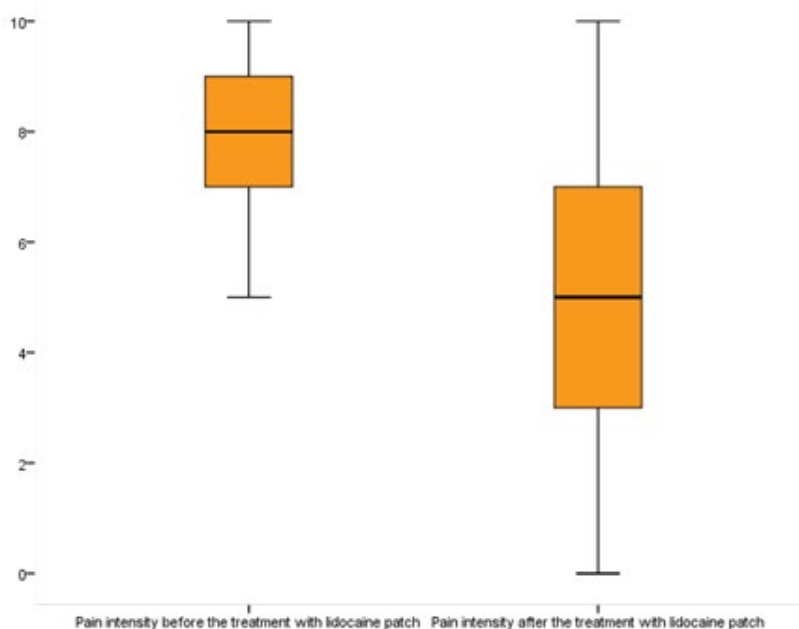


Figure 1: Pain intensity before and after treatment with lidocaine patch among study cases

Pain data	No	%
Pain diagnosis		
Musculoskeletal	66	55.5%
Arthritic	9	7.6%
Neuropathic	22	18.5%
Mixed	22	18.5%
Duration of current pain		
< 30	42	35.3%
30-60	36	30.3%
> 60	41	34.5%
Pain intensity before the treatment with lidocaine patch		
Moderate	39	32.8%
High	80	67.2%
Pain intensity after the treatment with lidocaine patch		
Low	53	44.5%
Moderate	38	31.9%
High	28	23.5%

Table 2. Pain-related clinical data among patients with chronic pain

Systematic and local analgesics consumption are shown in Figure 2. As for systemic analgesics, 75.6% had adjuvant therapy, 51.3% had Acetaminophen, 42.9% had NSAIDs, and only 16% had narcotics. A total of 52.1% had topical NSAIDs, and 2.5% had other topical analgesics.

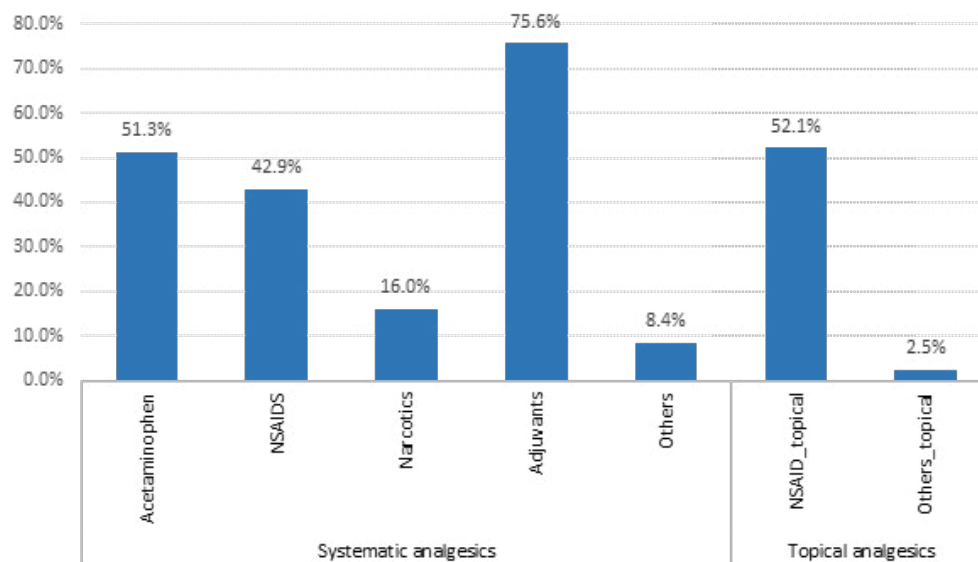


Figure 2: Received systematic and local analgesics by study patients with chronic pain

Outcome of the application of the LP is shown in (Table 3). 61.9% of the patients were satisfied with the use of LP, and 31.3% were satisfied with its adhesiveness. 64.4% of the patients experienced pain relief within less than 2 hours. Only 6.7% (8 cases) experienced side effects which included itching in 37.5% and only one patient experienced redness with burning. 5.9% of the patients reported that LP was bothersome. On the other hand, 64.7% of the patients reported that they will continue the use of LP, 56.3% reported that they will recommend it to others.

Outcome		No	%
Satisfaction with the use of 5% lidocaine patch	Very Satisfied	9	7.6%
	Satisfied	67	56.3%
	Neutral	17	14.3%
	Dissatisfied	24	20.2%
	Very dissatisfied	2	1.7%
How satisfied or dissatisfied are you with the adhesiveness (the way it sticks) of the lidocaine patch?	Very Satisfied	2	1.7%
	Satisfied	35	29.4%
	Neutral	20	16.8%
	Dissatisfied	59	49.6%
	Very dissatisfied	3	2.5%
How long does the relief of pain last after the application of the lidocaine patch?	< 2 hours	76	64.4%
	2-6	18	15.3%
	7-12	11	9.3%
	> 12 hours	13	11.0%
Are there any reported side effect as a result of the use of the patch?	Yes	8	6.7%
	No	111	93.3%
	Itching	3	37.5%
	Other	4	50.0%
	Redness with burning	1	12.5%
The side effects of the lidocaine patch were very bothersome	Agree	5	4.2%
	Neutral	2	1.7%
	Disagree	25	21.0%
	Strongly disagree	87	73.1%
How likely will you continue the use of Lidocaine patch?	Very likely	14	11.8%
	Likely	63	52.9%
	Neutral	17	14.3%
	Unlikely	21	17.6%
	Very unlikely	4	3.4%
How likely will you recommend the use of Lidocaine patch to others?	Very likely	11	9.2%
	Likely	56	47.1%
	Neutral	31	26.1%
	Unlikely	17	14.3%
	Very unlikely	4	3.4%
In general, how satisfied or dissatisfied are you with the lidocaine patch?	Very Satisfied	11	9.2%
	Satisfied	63	52.9%
	Neutral	21	17.6%
	Dissatisfied	20	16.8%
	Very dissatisfied	4	3.4%

Table 3. Outcome of the application of the lidocaine patch among patients with chronic pain

Pain reduction among study patients by their bi-demographic data, used medications, and compliance is shown in (Table 4). There was a significant pain reduction among narcotic users than among non-users (3.72 vs. 2.67 points; $P=.048$). Also, compliant patients showed a score of pain reduction of 3.72 points compared to 2.83 points for less compliant ones, and 2.24 points for non-compliant patients with recorded statistical significance ($P=.049$). Other factors showed non-significant pain score reduction ($P> 0.05$ for all).

Factors	Pain score change		p-value
	Mean	SD	
Age in years			
18-40	2.24	1.6	
41-60	2.96	2.3	.228
> 60	3.09	2.1	
Gender			
Male	2.90	2.3	.781#
Female	2.78	2.0	
Body mass index			
Normal	2.28	2.3	.337
Overweight	2.86	1.8	
Obese	3.02	2.2	
Co- Morbidities			
Yes	3.01	2.1	.185#
No	2.53	2.1	
Pain diagnosis			
Musculoskeletal	2.89	2.0	.327
Arthritic	2.33	2.1	
Neuropathic	2.45	2.5	
Mixed	3.18	2.1	
Duration of current pain			
< 30	2.93	2.1	.233
30-60	3.19	2.2	
> 60	2.39	2.0	
Acetaminophen			
Yes	2.57	1.9	.188#
No	3.09	2.3	
NSAIDS			
Yes	2.92	1.9	.664#
No	2.75	2.3	
Narcotics			
Yes	3.63	2.4	.048*#
No	2.67	2.0	

Table 4. Pain reduction among study patients by their bi-demographic data, used medications, and compliance

4. Discussion

Chronic pain management is still a health challenge, however with the current available modalities approximately a 30% pain reduction could be achieved which has a significant impact on patients' function and quality of life [19-21]. Optimal treatment of chronic pain includes physical, psychological, and pharmacological therapies [22]. Systemic medications include, but not limited to, gabapentin, pregabalin, fentanyl, oxycodone, and tramadol [23]. Main topically used agents in chronic pain are LP and capsaicin [24]. Chronic pain has significant impacts on the economy due to its effects on rates of absenteeism and reduced

levels of productivity [25]. A study conducted in Latin America on patients aged 50 years and older showed that the direct cost of PHN is 1,227 USD, the indirect cost is 773 USD, and the total cost is 2,001 USD [26]. Another study carried out in Italy calculated a mean direct medical cost per patient of €153 from the payer perspective and €297 from a societal perspective [27].

This survey draws a cost-effectiveness analysis of the use of LP in chronic pain patients through patients' satisfaction. To our knowledge, this is the first study to evaluate the cost effectiveness of LP in CPP through patients' satisfaction which was shown to

be essential for mitigating the cost versus the value of its usage [6,7]. Previous studies evaluated the cost effectiveness of the LP, in comparison to other oral medications in patients with PHN, and to other topical placebo patch, or as add-on therapy and showed it to be more effective, less costly and with better patients' satisfaction versus comparators [11,28-32]. Also, it was shown that the treatment of PHN and (DN) with LP in monotherapy and in combination therapy plus pregabalin, results in highly cost effective strategy [33]. Likewise, in a recent study from China, a Markov model was established based on earlier European studies to investigate cost-effectiveness analysis in PHN patients getting different doses of LP and Pregabalin [28,34-36]. The quality-adjusted life years (QALYs) and medical expenses were appraised, and then the incremental cost-effectiveness ratio (ICER) was calculated and, finally, sensitivity analysis was carried out. They concluded that LP reduced the economic burden of patients with PHN as they are cost-effective and more efficient compared to pregabalin. They attributed this improvement in efficacy due to more acceptable prices of LP. Our study provides an updated appraisal to the several published clinical experiences-, systematic reviews and international guidelines evaluating cost-effectiveness of LP in chronic pain, through a patient- centeredness approach to care, which is currently under focus of many institutes world-wide with the ambition to improve healthcare quality [6,26,29,37-43]. Assessment of patients' satisfaction is a vital part of this approach and provides a real-world example, however, this approach is sometimes criticized by its subjective nature [44]. Nonetheless, pain is also an inherently subjective experience, knowable only to the sufferer, so assessment of patients' satisfaction in chronic pain perhaps is more relevant compared to other non-subjective medical or surgical conditions [45]. Additionally, it is also important for patients to have their opinions and experiences into perspective and to involve them in health care decision making [46]. Patient satisfaction can be affected by some demographic factors, education, employment, and health literacy but, our results showed no significant differences in age, gender, marital status, BMI, educational level or associated co-morbidities [47-49].

Our study included different pain conditions where LP proved to be effective; Musculoskeletal, Arthritic, Neuropathic and Mixed pain conditions with either recent onset (< 30 days) or longer durations (30-60 & > 60 days) with no significant differences detected between studied factors [48,5-54]. This diversity in pain causes and duration among studied patients gives more credibility to our research.

There are some limitations of this study, as this is a single center study, multicenter studies are recommended to generalize the results, moreover the study was not placebo-controlled as we thought applying a placebo patch might be unethical in pain sufferers [55]. Also, patients' expectations were not assessed, as comparing patients' expectations to patient's satisfaction could be worth exploring in future research.

5. Conclusion

In conclusion, this study showed that the use of the 5% lidocaine topical patch is a cost-effective pain management option in chronic pain patients reflected through patients- centered approach.

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