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Effectiveness of Lidocaine Cream for Reducing Pain Sensation of Pre Injection of Subcutaneous Lidocaine in Lumbal Puncture Diagnostic and Therapeutic Procedures

T. Christin,[1] A. Okparasta,[1]* and R. W. Susilaningrum[2]

[1] Neurology Department, Medical Faculty of Sriwijaya University/Mohammad Hoesin Hospital, Palembang
[2]Resident of Neurology Departement, Medical Faculty of Sriwijaya University/Mohammad Hoesin Hospital, Palembang

Email: andikaazizah@gmail.com
jendraja.chris@gmail.com

Abstract

Lumbar puncture is one of the methods that is quite often performed for various purposes. There is no global agreement regarding the use of local anesthesia in subcutaneous or topical infiltration prior to LP. Topical anesthesia injection in lumbar puncture still cause pain, there should be needing additional topical anesthesia. The aim of the study is comparing the effectiveness between lidocaine cream and placebo cream prior lidocaine subcutaneous injection to reduce pain sensation in LP procedures. The study was conducted in July-October 2019, randomized and clinical trial (RCT) by sampling technique using block randomization method. Sample was divided into two group. Pain scale was assessed when the needle touched the skin, subcutaneously and overall in both groups. Data analysis using SPSS ver 22 for windows. The average age of subjects is 38.50±14.43 years and majority are women (57.9%). There is significance difference of pain scale between groups when needle touched the skin (p=0,035), meanwhile, there is not significance difference when needle subcutaneously (p=0,061) and overall (p=0,182) in both groups. Lidocaine cream has been shown to be significantly more effective in reducing pain pre lidocaine subcutaneous injection compare to placebo cream when needle touched the skin.

1. Introduction

Lumbar puncture (LP) is one of the methods in Neurology that is quite often performed for various purposes, one of which is for taking Liquor Cerebrospinal (LCS).[1] Lumbar puncture is useful as a diagnostic and therapeutic method in diseases involving the central nervous system. Lumbar puncture procedures include subarachnoid space pricking through the L3-L4 or L4-L5 intervertebral.[2] Lumbar puncture is a painful procedure. In a study that measured the pain scale on lumbar puncture from a total of 463 respondents, 40% of patients experienced severe degree of pain with a median score of 7 (verbal rating score (VRS) between 5-8). The average patient (85%) feels insufficient to get topical anesthesia using subcutaneous lidocaine.[3] Lumbar puncture can cause muscle spasms or movement of the patient, both of which can increase the difficulty and duration of the procedure.[4] Giving topical anesthesia in the form of injection is important in lumbar puncture, but it is said that the injection of topical anesthesia is far more painful than lumbar puncture itself,[5] so that additional topical anesthesia is needed to minimize the scale of pain caused by injecting subcutaneous as a local anesthetic.[6]

Lidocaine is one of the anesthetic drugs recommended for use on the skin both subcutaneous and topical infiltration.[7] Lidocaine is a local anesthetic that is often used during LP treatment by subcutaneous infiltration. According to Day et al (2008) in the Randomized controlled trial (RCT) use of topical lidocaine 5% compared with placebo applied for 30 minutes before the lumbosacral

block action showed topical lidocaine 5% effectively reduced pain in the skin when the needle was inserted, but did not reduce pain when the needle is inside the muscle and does not reduce overall pain.[4] While studies according to Massoth et al. (2018) comparing the use of topical anesthesia with 5% lidocaine-procaine cream compared with subcutaneous prilocaine and placebo before LP treatment showed no significant pain differences in the lidocaine-procaine group 5% compared with subcutaneous prilocaine.[6]

Therefore additional research is needed regarding the administration of topical lidocaine before injection. So based on previous studies researchers wanted to find out more about the effectiveness comparison between the use of lidocaine cream followed by subcutaneous lidocaine compared with placebo cream with subcutaneous lidocaine on the level of pain when the spinal needle touches the skin, penetrates subcutaneous tissue and pain measures as a whole.

2. Methods and Material

This is a blinded, randomized, clinical trial study using primary data from questionnaire of patients undergoing lumbar puncture. The study was conducted in the period of July 1st until October 31th 2019. Sampling technique using block allocation or block randomization based on internet. Subjects were divided randomly into two groups.

The population in this study were all patients that undergoing lumbar puncture in Mohammad Hoesin Hospital Palembang. Inclusion criteria in this study were indicated diagnostically or therapeutically for LP, conscious, do not have difficulties in language or cognitive function, have already signed informed consent, stable, do not have contraindicative criteria for LP. Exclusion criteria in this study were had allergic of lidocaine cream, consumed anticoagulant in the least 72 hours, had neurological impairment i.e hypesthesia, had analgesic drug before the procedure.

Minimum sample amount was calculated using formula two numeric. 38 patients then divided into two group. One with lidocaine cream 10.56% and lidocaine subcutaneous injection, another with placebo cream and lidocaine subcutaneous injection. There is no interaction between operator and respondent, also operator had no information regarding the cream they applied to patients. There is only one operator who did all of the lumbar puncture in 38 patients. The cream (both lidocaine cream dan placebo) then applied to patients prior to lidocaine subcutaneous injection. Pain scale assessed using numerical rating scale (NRS) when spinal needle inserted to the skin, inserted to subcutaneous and when overall pain observed. Data was collected and then analyzed using SPSS ver 22 for windows. The analysis in this study with Mann Whitney, Chi-Square, and Fischer exact test.

3. Results

In the period of July 1st to October 31th 2019 there were 38 patients who met inclusion criteria, 19 people each were placed in the treatment and control groups. The mean age in this study was 38.50±14.43 years with the most of the patients were in the age group between 18-30 years (36.8%), followed by age group 31-45 years (31.6%), 46-60 years (23.7%) and >60 years old (7.9%). Majority of sample was women (57.9%) compare to men (42.1%). The level of education in most of them is senior high school (47.4%). Most of the participants include in this study were jobless or retiring with percentage 50%, followed by private sector worker (26.7%) and laborers/farmers (23.7%). Majority of subjects did not have a history of hypertension (65.8%), nor previous DM (86.8%). This is the first LP procedure for most patients (71.1%). The LP procedures had indicated for identifying disease mostly rather than therapy (81.6% and 18.4%).

The distribution of disease diagnoses varies from infectious diseases (bacterial meningitis, tuberculosis meningitis or mengingoencephalitis), autoimmune diseases (autoimmune encephalitis, guillain barre syndrome, NMO), genetic diseases (ALL, periodic hypokalemia paralysis, epilepsy). Most patients had a periodic hypokalemia paralysis diagnosis (21.1%), then followed by ALL (18.4%), TB meningitis (15.8%), guillain barre syndrome (13.2%), bacterial meningitis (10.5%), NMO (7.9%), and each with meningoencephalitis and autoimmune encephalitis (5.3%), and also with a diagnosis of epilepsy (2.6%).

The direct LP trial was successful at the first time (86.8%) more than it had to repeat in the second trial (13.2%). The average duration of time needed for the cream to have anesthetic effect is 58.42±7.17 minutes. Most of the patients did not suffer from complication post LP (89.5%) and only 4 person (10.5%) did suffer from headache right after the procedure.

Table 1. Characteristics of Patients

Variables	Total N (%)	Lidocaine cream + Subcutaneous Injection N (%)	Placebo cream + Subcutaneous Injection N (%)
Age (Mean ± SD)	38.50±14.43	37.63±15.98	39.37±13.09
Age categories			
- 18-30 years	14 (36.8)	8 (42.1)	6 (31.6)
- 31-45 years	12 (31.6)	5 (26.3)	7 (36.8)
- 46-60 years	9 (23.7)	4 (21.1)	5 (26.3)
- >60 years	3 (7.9)	2 (10.5)	1 (5.3)
Gender			
- Women	22 (57.9)	11 (57.9)	11 (57.9)
- Men	16 (42.1)	8 (42.1)	8 (42.1)
Level of education			
- Elementary	7 (18.4)	2 (10.5)	5 (26.3)
- Junior High	5 (13.2)	3 (15.8)	2 (10.5)
- Senior High	18 (47.4)	9 (47.4)	9 (47.4)
- Academy	2 (5.3)	1 (5.3)	1 (5.3)
- Do not school	6 (15.8)	4 (21.1)	2 (10.5)
Type of Job			
- Private sector	10 (26.3)	7 (36.8)	3 (15.8)
- Farmers/laborers	9 (23.7)	4 (21.1)	5 (26.3)
- Jobless/retiring	19 (50.0)	8 (42.1)	11 (57.9)
Hypertension History			
- Yes	13 (34.2)	7 (36.8)	6 (31.6)
- No	25 (65.8)	12 (63.2)	13 (68.4)
Diabetes History			
- Yes	5 (13.2)	3 (15.8)	2 (10.5)
- No	33 (86.8)	16 (84.2)	17 (89.5)
LP History			
- Yes	11 (28.9)	3 (15.8)	8 (42.1)
- No	27 (71.1)	16 (84.2)	11 (57.9)
LP Indication			
- Diagnostic	31 (81.6)	17 (89.5)	14 (73.7)
- Therapy	7 (18.4)	2 (10.5)	5 (26.3)

Diagnosis			
- Meningitis Bacterial	4 (10.5)	1 (5.3)	3 (15.8)
- Meningitis Tuberculosis	6 (15.8)	4 (21.1)	2 (10.5)
- Meningoencephalitis	2 (5.3)	1 (5.3)	1 (5.3)
- Autoimmune Encephalitis	2 (5.3)	2 (10.5)	0 (0.0)
- Guillain Barre Syndrom	5 (13.2)	2 (10.5)	3 (15.8)
- NMO	3 (7.9)	2 (10.5)	1 (5.3)
- ALL	7 (18.4)	2 (10.5)	5 (26.3)
- Periodic Hypokalemia Paralysis	8 (21.1)	4 (21.1)	4 (21.1)
- Epilepsy	1 (2.6)	1 (5.3)	0 (0.0)
LP trial			
- 1st trial	33 (86.8)	15 (78.9)	18 (94.7)
- 2nd trial	5 (13.2)	4 (21.1)	1 (5.3)
Duration of Anesthesia	58.42±7.17	58.95±6.57	57.89±7.87
Complications			
- Yes	4 (10.5)	3 (15.8)	1 (5.3)
- No	34 (89.5)	16 (84.2)	18 (94.7)

Table 2 shows the distribution of subjects based on numeric rating scale (NRS), were divided into mild (scale 1-3), moderate (scale 4-6) and severe (7-10) pain. When the puncture needle touches the skin, almost all patient suffers mild pain (92.1%), while only a small proportion feels moderate pain (7.9%). When the needles were subcutaneous, 81.6% were found with mild pain, and only 15.8% experienced moderate pain, while another 2.6% with severe pain . When the NRS measured as whole, a majority of 92.1% experienced mild pain, and only 7.9% had moderate pain.

Table 2 Characteristics of Pain Assessed by Numeric Rating Scale

Variables	**Total N (%)**	**Lidocaine cream + Subcutaneous Injection N (%)**	**Placebo cream + Subcutaneous Injection N (%)**
Inserted to skin			
- Mild pain	35 (92.1)	18 (94.7)	17 (89.5)
- Moderate pain	3 (7.9)	1 (5.3)	2 (10.5)
Subcutaneously			
- Mild pain	31 (81.6)	18 (94.7)	13 (68.3)
- Moderate pain	6 (15.8)	1 (5.3)	5 (26.3)
- Severe pain	1 (2.6)	0 (0.0)	1 (5.3)
Overall			
- Mild pain	35 (92.1)	19 (100.0)	16 (84.2)
- Moderate pain	3 (7.9)	0 (0.0)	3 (15.8)
Total	**38 (100.0)**	**19 (100.0)**	**19 (100.0)**

In the comparison of the effectiveness of lidocaine cream with placebo based on NRS when the needle touches the skin, the p value <0.05 (p = 0.035), which means that there is a significant difference between the two creams. Analysis of NRS values when the needle inserted subcutaneously, no significant difference was found with a value of p> 0.05 (p = 0.061). Similarly, when assessing overall pain, which had a value of p> 0.05 (p = 0.182)

also found no significant difference in pain reduction in the lidocaine cream group.

Table 3. Comparison of the Effectiveness of Lidocaine Cream with Placebo Cream

Variables	Lidocaine cream + Subcutaneous Injection N (%)	Placebo cream + Subcutaneous Injection N (%)	P Value
Inserted to skin	1.00 (0-3)	2.00 (0-5)	0.035[a]
Subcutaneously	2.00 (0-4)	2.00 (0-7)	0.061
Overall	1.00 (0-3)	2.00 (0-5)	0.182

[a]*Mann Whitney*

4. Discussion

Aim of this study to look at the effectiveness of reducing pain sensation pre subcutaneous lidocaine injection in patients who received lidocaine cream before undergoing lumbar puncture. This study compared the effectiveness between the use of lidocaine cream and subcutaneous lidocaine injection with placebo cream and subcutaneous lidocaine injection. The study population was 38 research subjects, with 19 each placed in the treatment group and placebo. The division of groups is done randomly, using the internet-based randomization allocation method.

The mean age of the subjects in this study was 38.50 ± 14.43. The majority of patients were in the age group of 18-30 years (36.8%). This differs from previous studies which also assessed pain scale in lumbar puncture procedures, where the average age of participants was ± 65.67 years.[6] Another study by Page-Wilson et al. (2016) who assessed pain in 47 participants who underwent lumbar puncture procedures showed an average age of 33 ± 7.8 years.[8]

In this study more women (57.9%) than men (42.1%) were found. In accordance with previous studies by Page-Wilson et al. (2016) where there were more female participants (55.3%) compared to men (44.7%).[8] Gender does not play a role in the prevalence of lumbar puncture, because this action itself is carried out according to its indications, but women have a higher sensitivity related to pain than men.[9]

The study subjects mostly did not have a history of hypertension (65.8%) and diabetes mellitus (86.8%). Whereas 71.1% of patients underwent LP for the first time, while another 28.9% had undergone previous procedures related to the indications of LP itself, of which 28.9% with a history of LP were around 18.4% with therapeutic indications to enter injection of chemotherapy drugs for ALL. Most of the LPs were successful in the first try (86.8%). Complications after lumbar puncture in only 10.5% of patients are headache. The duration of time needed for the cream to cause anesthetic effects is an average of 58.42 ± 7.17 minutes.

This study showed a significant decrease in pain in the use of lidocaine cream compared with placebo cream pre-injection of subcutaneous lidocaine when the puncture inserted to the skin during the lumbar puncture procedure. In addition, there was no significant difference in pain between the lidocaine cream group and placebo cream when the needle was below the subcutaneous and overall pain assessment. These results are in accordance with the findings of a previous study by Day IJ et al. (2008) which showed differences in pain reduction in lumbar puncture procedures with the use of a 5% liposomal lidocaine cream when the needle was penetrated into the skin compared to placebo (p value 0.003). Then it became insignificant when the needle entered into the

subcutaneous and when the overall pain assessment ($p = 0.901$ and $p = 0.368$).[4]

Topical anesthesia works by blocking nerve conduction reversibly close to where it is administered by targeting free nerve endings of the dermis or mucosa, thereby eliminating the sensation of pain in a limited area. The depth of the anesthetized area depends on the duration of contact with topical anesthesia. In the use of EMLA creams, with the time required 60 minutes after the application of the cream obtained the maximum anesthetic effect reaches a depth of 3 mm.[10]

There were limitations in this study include the sample size and objective measurement of pain scale. This study still did not represent a whole population regarding its small sample sizes. The measurement to assess pain scale in the patient still using the subjective method, so that's why there will be needed further investigation in the future studies.

5. Conclusion

The conclusion of this study that there was a significant decrease in pain when the needle inserted to the skin in the lidocaine cream group compared to the placebo group. However, there was no significant difference in pain between the two groups when the needle was below subcutaneously or as a whole, this proves that the penetration of lidocaine cream into the skin only reached ± 3 mm so that a significant difference in pain reduction was only seen when the needle was still just touching the skin.

References

1. Alsuwailem MH, Alkhatem AH, Alshabib AA, Aldraisi MH, Khalid A, Jughiman A, et al. 2018. Lumbar Puncture : Indications , Complications , Technique and CSF Analysis in Pediatric Patients. Egypt J Hosp Med.70(January):638–43.
2. Johnson, S. Kimberly dan Daniel J. S. 2018. Lumbar puncture: Technique, indications, contraindications, and complicaions in adults. Wolters kluwer.
3. Scotton, J William, Susan P. Mollan, Thomas W, Sandra D, Hannah B, Keira M, Andreas Y, Shelley W, Alexandra J S. 2018. Characterising the patient experience of diagnostic lumbar puncture in idiopathic hypertension: a cross sectional online survey. BMJ Open; 8:e020445.
4. Day IJ, Kent CF, Burnham RS. 2008. Can Topical Anesthetic Reduce the Pain Associated with Diagnostic Blocks of the Lumbosacral Spine ? Pain Med. 9(6):675–9.
5. Hudgins PA, Fountain AJ, Chapman PR, Shah LM. 2017. Difficult Lumbar Puncture : Pitfalls and Tips from the Trenches. Am J Neuroradiol. 1–8.
6. Massoth C, Weidlich S, Pöpping DM, Gurlit S, Möllmann M, Wenk M. 2018. Effects of Local Skin Anaesthesia on Pain During Lumbar Puncture. Journalof Anaesthesiol Crit Care. 1(1):1–5.
7. Kouba DJ, Lopiccolo MC, Alam M, Maibach HI, Tanner JW, Vashi N, et al. 2016. Guidelines for the use of local anesthesia in office-based dermatologic surgery. J Am Dermatology [Internet]. 1–19. Available from: http://dx.doi.org/10.1016/j.jaad.2016.01.022
8. Page-Wilson G, Wardlaw SL, Nguyen KT, Smiley RM. Evaluation Of Pain And Stress In Healthy Volunteers Undergoing Research Lumbar Punctures. Neurology 87 July 26, 2016.
9. Wandner LD, Scipio CD, Hirsh AT, Torres CA, and Robinson ME. The Perception of Pain in Others: How Gender, Race, and Age Influence Pain Expectations. The Journal of Pain, Vol 13, No 3 (March), 2012: pp 220-227
10. Kumar M, Chawla R and Goyal M. Topical Anesthesia. J Anaesthesiol Clin Pharmacol. 2015; 31(4): 450-456. Doi: 10.4103/0970-9185.169049. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4676230/