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Use of Subcutaneous Local Anaesthetic in Venous Catheters Channelling For Reducing Pain

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Abstract

Venous catheters channeling is one of the most widely used techniques, described by patients as stressful and painful. Nurses have at their disposal measures to reduce pain, such as the use of local anaesthetic both in topical or subdermal format. Objectives: To analyse the use of intradermal local anaesthetic (Lidocaine 1%) against the use of saline solution 0.9% in venous catheters channelling and their effectiveness for reducing the pain of venipuncture. Methods: This randomized double-blind controlled clinical trial includes a total of 24 randomly-chosen patients scheduled for surgery. They have been chosen after meeting the inclusion criteria and treated with either Lidocaine 2% or saline solution 0.9% before the peripheral venous cannulation. Immediately after the procedure, participants have taken a questionnaire to assess their discomfort level and other adverse symptoms related to the procedure by using a Visual Analogue Scale (VAS) of 10 points. Results: The Mann-Whitney U test was carried out in order to know possible significant differences between the medians of both groups. There were significant differences in the VAS ($p < 0.001$). Conclusions: Comparing to the subcutaneous administration of saline solution 0.9%, the use of Lidocaine 2% subcutaneously administered to these patients is effective for pain control.

Keywords: Pain Perception, Catheterization, Peripheral Catheters, Local Anaesthesia.

1. Background and Current Situation

Venous access channelling is one of the most used techniques in Nursing, being the channelling technique, phlebitis prevention and postpuncture care under continuous study. Nowadays nursing care must be focused on the quality and patient's comfort (Fetzer, 1999). One of the most emphasised negative perceptions of patients is the pain during the venepunctures carried out by nurses. Therefore, due to the continuous progress and development of the nursing knowledge, the uses of different measures to relieve pain in venepunctures have been an issue of the utmost interest for researchers. However, there is not yet a unique efficient technique method for channelling the peripheral venous accesses in an adult.

The cannulation of peripheral venous accesses in an adult is a standardised procedure made through the Modified Seldinger Technique linked to the use of the commercialised catheters. Nowadays it does not offer the possibility to change such technique for preventing puncture pain, as the use of anaesthetic agents for reducing this pain. Such anaesthetic agents are also fairly spread in peripheral access cannulation with a calibre smaller than 16G, even though there are studies which show the efficacy in the smallest catheters (Harrison et al., 1992). The most used current anaesthetic agents for preventing pain in venepunctures are the followings: EMLA topical cream (Fetzer, 2002), which needs administration 2 hours before for a better efficacy; Lidocaine 1 %(Soliman et al., 1988), which is subcutaneously administered; and, saline solution 0.9%, also subcutaneously administered.

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Several scientific studies show that EMLA cream, being efficient when preventing pain in venous channelling, needs to be applied 2 hours before carrying out the technique (Joly et al., 1998). For this reason and due to the workload it requires, it is not viable a daily use in nursing. Moreover, it is possible not to achieve the cannulation of the selected vein and it may require a new application on another vein.

Regarding subcutaneous medicine administration, it is important to mention that there are professionals opposed to the use of it as the appearance of a postpuncture bleb may complicate the venous channelling technique; whereas several studies refuse this situation, declaring themselves in favour of such medicine (Dennis et al., 1995). The use of intradermal Lidocaine 1% (Ong et al., 2000) stands out for pain prevention, whose detractors show that the pain caused by the medicine when administering it is the same or higher than the one by the direct catheter insertion. On the other hand, it has been showed that it is also important the choice of needle for the administration of Lidocaine for reducing the anaesthetic pain (Steinbrook et al., 1993). And secondly, the use of saline solution 0.9% has been spread, so there is controversy regarding its efficacy (Brown et al., 2004).

In conclusion, peripheral venous channelling is a common technique in nursing where we look for the patient's comfort, whose collaboration would be essential for improving the results at the puncture moment. The pain perceived by the patient may complicate his collaboration and even increase the haemodynamic damages due to the blood pressure and heart rate rise as a consequence of the perceived pain by the patient (Langham & Harrison, 1993), so it is more possible to fail the puncture.

The objective of this study is to compare the efficacy of the use of Lidocaine 2% (Langham & Harrison, 1992) against saline solution 0.9% for preventing pain in the peripheral venous cannulation in an adult and, in this way, create a line of research which contributes to the clinical decision making based on scientific evidence (Brown & Larson,1999).

Both medicines are easy to access to for any nursing professional in every work area. Despite its efficacy, the use of EMLA cream (García et al., 2007) has been omitted in this study.

2. Hypothesis

The use of Lidocaine 2% local anaesthetic subcutaneously administered on the puncture point is more effective than the use of saline solution 0.9% subcutaneously administered for reducing the pain prior to the catheter cannulation in hospitalised patients who are scheduled for a neurosurgery intervention.

2.1 Objectives.

General Objective:

Determine the efficacy of Lidocaine 2% subcutaneously administered against the administration of saline solution 0.9% for preventing the pain associated to venous catheter channelling.

Specific Objectives:

Determine the VAS value of patients receiving subcutaneous Lidocaine 2% before a venepuncture.

Determine the VAS value of patients receiving subcutaneous saline solution 0.9% before a venepuncture.

Analyse the relationship between the existing pain perceived by the patient on the VAS and the use of Lidocaine 2%.

Analyse the relationship between the existing pain perceived by the patient on the VAS and the calibre of the peripheral venous catheter.

3. Methods

3.1 Design.

Randomized double-blind controlled clinical trial.

3.1.1 Sample and Field of Study.

The study sample is formed by hospitalised patients in the Hospital Universitario Insular de Gran Canaria who have been scheduled for a surgical intervention by the Neurosurgery Service from the 1st June 2013 to the 15th June 2013.

The study inclusion criteria are as follows: 14 to 100-year-old patients with a 15 points GCS scale, no sensitive pathology in the upper limbs with normal vascularisation. They have been informed about the study participation and have signed the informed consent. Those patients who showed difficulties with the language and with cognitive damage were excluded.

3.1.2 Sample Design.

In this section we are going to calculate the minimum sample size for comparing the mean of two different groups and considering that the standard deviation is different in both groups:
Applying the formula

$$n = \frac{\left(s_a^2 + s_b^2\right)\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{d^2}$$

Then the sample size would be:

$$n = \frac{(s_a^2 + s_b^2)(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{d^2} = \frac{(0{,}45^2 + 1{,}05^2) * (1{,}96 + 0{,}84)^2}{1^2} \approx 11$$ patients per group

A probability consecutive sampling is done from the 1st June 2013 to the 15th June 2013. A simple random assignment for both groups of study.

3.2 Information sources.

The information sources we have used in this study are the questionnaires given to the patients after doing the venepuncture technique where we got a total of eight variables (Appendix 2).

3.3 Variables and measurement method.

3.3.1Randomization

The neurosurgery operating theatre staff of the Hospital Universitario de Gran Canaria, previously taught for the study, has chosen the method. For this, after randomly distributing the selected patients, nurse no. 1 chooses the appropriate vein for cannulation. On the other hand, nurse no. 2 will randomly open an envelope where it is stated the medicine they must use in each case. This step will be done with each patient to guarantee the randomization. After that, nurse no. 2 will charge the medicine under study –Lidocaine 2% or saline solution 0.9%– without telling it to nurse no. 1. The patient is told that they will be administered a medicine for anaesthetising the puncture area, without saying which one is. It is important that the nurse administering the local anaesthetic may be always the same, because the technique will be applied in a similar way to every patient and so we avoid a possible bias. In this study, nurses no. 1 and 2 will be always the same.

4. Method

The channelling procedure is carried out through the Modified Seldinger Technique. Nurse no. 2 will administer 0.2ml of the subcutaneous chosen medicine with a BD insulin syringe with a Micro-Fine needle 1ml. The patient would be informed before this and a minute later we will proceed to the cannulation of the chosen vein. Finally, the catheter is fixed. After that, nurse no. 1 will replenish the report of the variables collected (Appendix 2) during the clinical trial.

4.1 Variables:

Sociodemographics: age and sex.

Patient: previous negative experiences and pain perceived by the patient according to the VAS pain scale (Appendix 1), being such scale the most appropriate for this study due to the understanding easiness by the patient and its fast achievement (Serrano et al., 2002).

VAS lies in a 100mm line which represents the continuous spectre of the painful experience. Descriptions are at both ends –'no pain' at one of them and 'the worst imaginable' at the other one. This variable was collected when finishing the venepuncture.

Technique: amount of attempts for the venous channelling, chosen medicine and cannulated arm.

4.2 Data collection.

Once the selection criteria were verified, we requested the informed consent to each patient of the study. The data collection was carried out through a data collection questionnaire (Appendix 2), after the endorsement of the study protocol by the Research Committee of the Complejo Hospitalario Materno Insular de Gran Canaria and respecting the ethical principles of the Declaration of Helsinki.

5. Data analysis.

The statistical analysis was carried out with the R commander 2.15.2 software. All the statistical tests were bilateral and considered significant with a $\alpha = 0.05$ value. A value of $p < 0.05$ was considered statistically significant.

The mean, standard deviation, median and quartiles were summarized for the continuous variables, as well as the patient amount and percentage for the categorical variables.

The Mann-Whitney U test was used for comparing the medians of the quantitative variables.

6. Ethical considerations.

Firstly, considering the hypothesis that the medicine under study (Lidocaine 2%) is equal or more effective than the saline solution 0.9%, we would not harm the patient with the medicine under study. Moreover, the randomization of the medicine administration guarantees us that all the patients are under the same possibilities to take either of the drugs.

Regarding the patient selection, they have been informed about all the procedures from the beginning of their inclusion in the study. The informed consent will be given, offering them the option of undergoing a peripheral venous cannulation without using the anaesthetic in the first puncture or the consecutive ones.

7. Results

In this section we carry out the variable descriptive statistic of the 24 patients of this study. 24 patients were studied, 50% of them were males (12) and 50% females (12). The minimum age is 19 and the maximum 88 (rank 69), being the mean 49.75 years old (CI 95%: 42.52 – 56.98), the median is 51.5 and the standard deviation is 17.12. The asymmetry is 0.278 and the kurtosis is -0.298. The quartile values are 36.25, 51.5 and 60.75. The minimum attempts for venous channelling are 1 and the maximum are 3 (rank 2), being the mean 1.33 attempts (CI 95%: 1.09 – 1.57), the median is 1 and the standard deviation is 0.56. The asymmetry is 1.522 and the kurtosis is 1.626. The quartile values are 1, 1 and 2. 45.8 % (11) of the patients were treated with medicine A (Lidocaine 2%) and 54.2% (13) were treated with medicine B (saline solution 0.9%). 41.7% (10) of the patients suffered negative experiences against 58.3% (14) who did not suffer any negative experience. The minimum VAS value is 0 and the maximum is 6 (rank 6), being the mean 2.48 (CI 95%: 1.80 – 3.16), the median is 2.75 and the standard deviation is 1.61. The asymmetry is 0.474 and the kurtosis is -0.627. The quartile values were 1, 2.75 and 3.75. The minimum calibre is 14 and the maximum is 18 (rank 4), being the mean 16.67 (IC 95%: 16.07 – 17.26), the median is 16 and the standard deviation is 1.40. The asymmetry is -0.579 and the kurtosis is -0.696. The quartile values were 16, 16 and 18.

On the following table the variable descriptive statistics is described (Table 1).

Variable	Mean (SD)	Median
Sex, n (%)		
Male	12 (50%)	-
Female	12 (50%)	-
Age	49.75 (17.12)	51.5
Amount of attempts	1.33 (0.56)	1
Medicine, n (%)		
Medicine A– Lidocaine	11 (45.8%)	-
Medicine B – Saline solution	13 (52.4%)	-
Negative experiences		
YES	10 (41.7%)	-
NO	14 (58.3%)	-
VAS	2.48 (1.61)	2.75
Catheter calibre	16.67 (1.40%)	16

Table 1 Descriptive Statistics

Then, the inferential statistics is carried out for verifying whether there is significant differences among both groups and the VAS.

Variable	VAS	p
Medicine		
Lidocaine (median)	1	< 0.001
Saline solution (median)	3	
Sex		
Male (median)	2.25	0.997
Female (median)	2.75	
Age (correlation)	0.157	0.467
Catheter calibre (correlation)	0.083	0.699

Table 2 Inferential Statistics

The minimum VAS value of the patients treated with Lidocaine is 0 and the maximum is 1.5 (rank 1.5), being the mean 1 (CI 95%: 0.70 – 1.30), the median is 1 and the deviation is 0.45 (n=11).

The minimum VAS of the patients treated with saline solution is 2.5 and the maximum is 6 (rank 3.5), being the mean 3.73 (CI 95%: 3.09 – 4.37), the median is 3 and the deviation is 1.05 (n=13). The Mann-Whitney U test was used to verify whether there were significant differences between the medians of both groups. Significant differences were found in the VAS between both groups ($p < 0.001$) (Table 2).

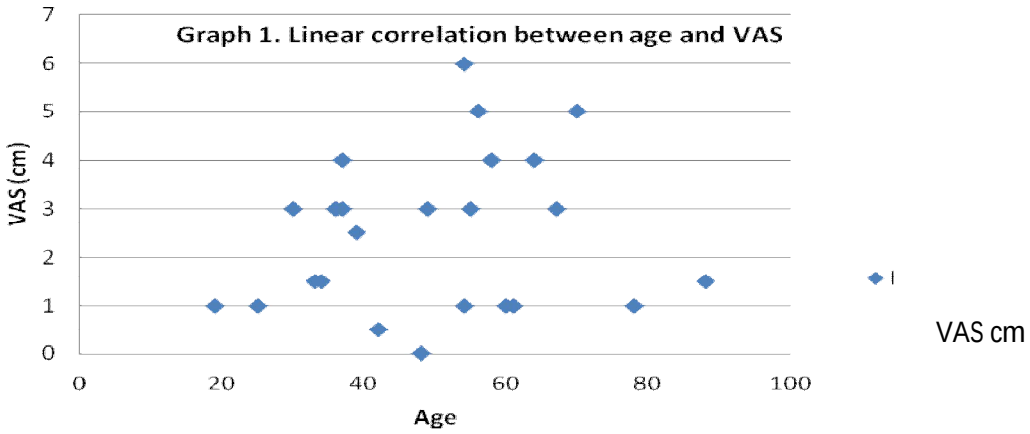
The minimum VAS value in males is 0 and the maximum is 6 (rank 6), being the mean 2.54 (CI 95%: 1.33 – 3.75), the median is 2.25 and the deviation is 1.90 (n=12).

The minimum VAS value in females is 0.5 and the maximum is 5 (rank 4.5), being the mean 2.42 (CI 95%: 1.56 – 3.27), the median is 2.75 and the deviation is 1.35 (n=12) (Table 1).

The Mann-Whitney U test was used to verify whether there were significant differences between the medians of both groups. There were not any significant difference in the VAS between both groups ($p=0.977$).

In order to verify the linear association between age and the VAS, the Pearson linear correlation coefficient was calculated, where we obtained a value of $r=0.157$ ($p=0.463$), so there is not a correlation between both variables. The Spearman correlation coefficient was also calculated, where we obtained a value of $r=0.185$ ($p=0.388$).

In order to test the linear association between the catheter calibre and the VAS, the Pearson linear correlation coefficient was calculated, where we obtained a value of r=0.083 (p=0.699, so there is not a correlation between both variables. The Spearman correlation coefficient was also calculated, where we obtained a value of r=0.021 (p=0.924) (Graph 1).



Discussion / Conclusions

This study shows that the use of Lidocaine 2% subcutaneously administered in patients scheduled for undergoing neurosurgery is effective for pain control in comparison with the saline solution 0.9% subcutaneous administration –in this case, used as a placebo. The first one showed a reduction of pain stated as the value on the VAS, being the mean value 1 (CI 95%: 0.70 – 1.30), the median is 1 and the deviation is 0.45 (n=11). In the case of the patients treated with saline solution 0.9%, the mean is 3.73 (CI 95%: 3.09 – 4.37), the median is 3 and the deviation is 1.05 (n=13). The Mann-Whitney U test was carried out to verify whether there were significant differences between the medians of both groups. Significant differences were found in the VAS between both groups ($p < 0.001$), verifying the initial hypothesis: the use of Lidocaine 2% local anaesthetic subcutaneously administered on the puncture point is more effective than the use of saline solution 0.9% subcutaneously administered for pain reduction before venous catheter cannulation in hospitalised patients who are scheduled for a neurosurgery intervention.

There was not any significant difference when comparing the linear association between the catheter calibre and the VAS. The Pearson linear correlation coefficient was calculated, where we obtained a value of r=0.083 (p=0.699), so there is not any correlation between both variables.There are similar studies where the effectiveness of the Lidocaine 1% application with bacteriostatic saline solution is assessed. In this study, there are not statistically significant differences between both medicines. It is worth mentioning that such study was blind and participants chose the arm with lower pain for the administration of Lidocaine 1% (Kahre et al., 2011).

In another randomized double-blind study, researchers compared the administration of Lidocaine 1% with a saline solution with preservatives and a preservative free saline solution. The result was that they show the same anaesthetic effects (Campbell, 2010). Another study carries out a randomized double-blind clinical trial in a patient sample (N=147), where the highest effectiveness result in the use of Lidocaine 1% against saline solution (p=0.007) (Burke et al.,2011) is obtained.

In summary, the current found studies keep the controversy regarding the efficacy of the use of Lidocaine as local anaesthetic before venepuncture. In our study, we have chosen a concentration of 2%, which may be higher if it is effective in pain reduction against the studies that chose a concentration of 1%. This concentration change has not showed any burning sensation on the assessed patients.

The possible limit of this study may have been the information that the patient should have received. Although the placebo was administered before the venepuncture, we told the patient that they were treated with a local anaesthetic which would reduce their pain. In this situation, they were influenced because the reaction to pain may have been lower than in the case of not having such information.

The results we have found make us recommend the use of Lidocaine 2% in the daily nursing practice to avoid the pain associated to venepunctures. Lidocaine 2% is easy to access to in hospitals and frequent in other procedures requiring local anaesthetic, improving patient's comfort and pain.

In further investigations, the comparison between the different Lidocaine concentrations available in the market should be suggested, together with the study of bigger patient samples or even a multicentre one, where it should be always chosen the same catheter for monitoring the perceived pain. As we have found in our study, the catheter size does not have any relationship with the VAS value.

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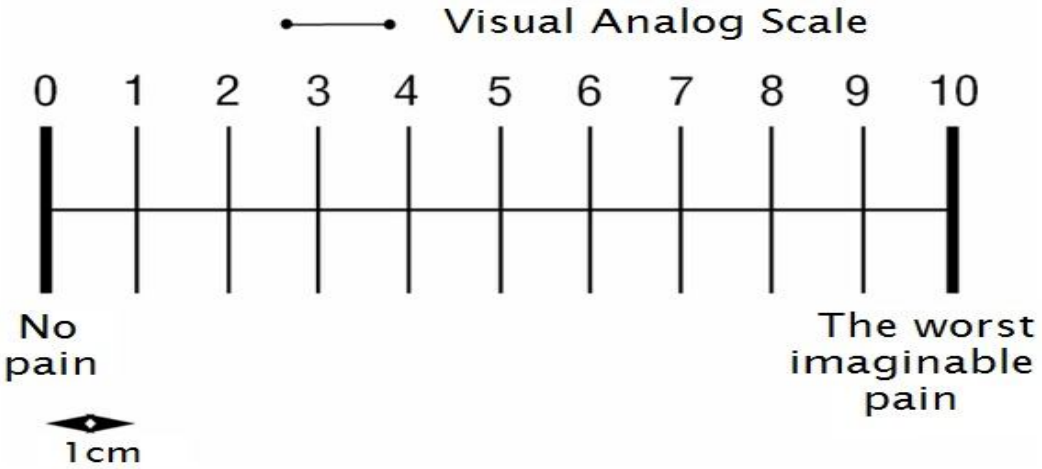
Appendix 1

VAS PAIN SCALE



Appendix 2

Data collection table:
Patient no:
Sex:
Age:
Cannulated limb: Left Right
Frch catheter calibre:
Amount of attempts:
Chosen medicine: Lidocaine 2% Saline solution 0.9 %
Previous negative experiences in venepunctures: YES NO
VAS perceived pain: cm