







Comparison of the Effects of Hegu Point Ice Massage and 2% Lidocaine Gel on Arteriovenous Fistula Puncture-Related Pain in Hemodialysis Patients: A Randomized Controlled Trial

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ABSTRACT

Introduction: There is a paucity of information on the effects of Hegu point ice massage and 2% lidocaine gel on fistula puncture-related pain in hemodialysis patients. The aim of the present research was compare the two methods in terms of their effectiveness.

Methods: This study is a randomized controlled trial. Seventy hemodialysis patients were divided into two groups. The fistula puncture-related pain in the two groups was measured in the first session of hemodialysis without any intervention. During a hemodialysis session, 2% lidocaine gel was applied on the patient's arteriovenous fistula site in one group. Also, for the other group, an ice cube was used to massage on the Hegu point in the hand without fistula in the other hemodialysis session. The pain score was recorded, using the Visual Analogue Scale. The data were analyzed using SPSS ver 13

Results: No significant differences were observed in the mean pain scores of the two groups in the preintervention phase. The comparison of the pain score before and after interventions of the lidocaine gel and ice massage groups was found to bear significant differences. Moreover, the comparison of the mean changes of the pain score before and after the intervention of the Hegu point ice massage groups revealed a further reduction for Hegu point than of lidocaine gel groups.

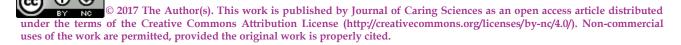
Conclusion: Lidocaine gel and Hegu point ice massage affect the intensity of fistula puncture related pain in hemodialysis patients. Given the higher effectiveness of Hegu point ice massage, this method is recommended to be used for fast and safe pain reduction in hemodialysis patients.

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Introduction

Nowadays, Hemodialysis is the major kidney function replacement in patients with endstage renal diseases (ESRD) before proceeding with the transplant. Hemodialysis is used to treat more than 60% of ESRD patients in the USA.² A very high annual growth of 6.22% is observed in cases of kidney failure in Iran, as approximately 4000 new patients are added to the previous cases every year.³ A successful hemodialysis requires access to safe, durable and reliable vessels.⁴ Fistula is the best way to access the blood stream.⁵ Hemodialysis

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patients normally undergo 2-3 hemodialysis sessions per week.6 The patients are, therefore, exposed to frequent stress and pain caused by approximately 300 arteriovenous punctures per year. This recurrent pain can lead to depression and reduction of quality of life in these patients. However, the reduction of the pain results in an improvement in the patients' quality of life and compliance with hemodialysis.7 Fifty-eight and a half percent of hemodialysis patients were found to be pain moderate and 30% were found to be going through intense pain during needles arteriovenous fistula.8 Pain relief emphasized in the literature as an important part of ESRD treatment.9 Fistula puncturerelated pain tends to decrease in patients within the first three months of their starting hemodialysis, however this might not be very significant.10

A review of literature reveals various pharmacological and nonpharmacological interventions for reducing fistula puncture-related pain, including the use of lidocaine spray¹¹, EMLA topical anesthetic cream⁷, lidocaine gel 2%¹², rhythmic breathing¹³, fistula cryotherapy¹⁴⁻¹⁶, aromatherapy with lavender^{17,18}, ethyl chloride spray¹⁹ and buttonhole cannulation technique.²⁰

The human skin is protected by a horny layer called the stratum corneum and is therefore highly permeable topical anesthesia.7 Lidocaine gel is a topical anesthetic that blocks active and inactive sodium channels and thereby contributes to conduction block, eliminating stimulation and reducing the transmission of pain.²¹ Lidocaine is a reliable rapid-acting topical anesthetic with an intermediate duration and a low systemic toxicity.22

Various studies have confirmed the effectiveness of lidocaine gel for pain relief, including the pain caused by benzathine penicillin, skin testing²¹ reducing chest tube site pain after CABG²³ and fistula puncture-related pain in hemodialysis patients.¹²

Acupressure is a holistic approach dating back to 5000 years ago.²⁴ The Hegu point or LI-IV or 4 is an important point in the large

intestine meridian, located on the dorsum of the hand, between the first and second metacarpal bones.²⁵ According to the gate control theory of pain, stimulating the skin by massage, needle insertion or scratching stimulates large fibers and transmits neural impulses to the spinal cord; if this stimulus is constant, then it keeps the pain gates closed and consequently suppresses the sensation of pain. 16,25 Another hypothesis based on neuroendocrinology theory holds that acupressure reduces pain by causing the secretion of enkephalins such as endorphins and serotonin.²⁶ Moreover, research suggests that cold effectively slows nerve conduction rate and blocks the nerve impulses and communication in the sensory fibers.²⁷ Studies have confirmed the effectiveness of Hegu point ice massage on reducing labor pain²⁸ venipuncture children pain in with thalassemia²⁹ and arteriovenous fistula puncture-related pain in hemodialysis patients¹⁴⁻¹⁶ There is no single proper method of relieving arteriovenous fistula puncturerelated pain in hemodialysis patients.³⁰ Since the pharmacological methods have many side effects, including their slow absorption,7 and skin rashes, scarring, allergic reaction and burning sensation when used frequently,27 Hegu point ice massage might be an easy and cost-effective substitute of pain reduction for the patients as it easily lends itself to the nurses use and is associated with few side effects.²⁹ In view of these obvious advantages, the researcher has designed this method for the patients. The aim of this study was to compare the effectiveness of the two methods in relieving arteriovenous fistula puncturerelated pain in hemodialysis patients.

Materials and methods

This study is the product of a Master's dissertation on Critical Care Nursing approved under 1736, and registered as IRCT: 20150831749N15 in the Iranian Registry of Clinical Trials with the ethical code of IR.MAZUMS.REC.94-1736. The sample size was determined based on a similar study

which was conducted on the effect of lidocaine spray on pain with standard deviation and mean pain score of SD₁= 2.30 and $X_0 = 1.91$ after the intervention¹¹ with $\alpha = 0.05$ and power of 0.80, and in the case of Hegu point ice massage with an estimated reduction of at least one score in pain relief, a mean pain score of $X_1 = 1.3$ and standard deviation of $SD_2 = 0.9$, ¹⁴ the sample size was calculated to be 34. A total of 37 participants were assigned to each group so as to account for 10% dropout rate. Out of 154 patients who were assessed, 74 patients met the inclusion criteria. Out of these 74 patients, in %2 lidocaine gel group 2 patients, because of using analgesics, and 2 patients in Hegu point ice massage group, because of retrying needle insertion, were excluded from the study. The data ultimately analyzed pertained to 35 patients (Figure 1). Seventy patients undergoing hemodialysis in the hemodialysis departments of Fatima al-Zahra and Imam Khomeini hospitals in Sari, Iran, were randomly assigned to each of the two groups.

The study's inclusion criteria consisted of a minimum age of 18, being capable of verbal and visual communication, being conscious Arterio-venose fistula having hemodialysis for at least three months. The exclusion criteria included a history of allergy to 2% lidocaine gel, having required more than one attempt to puncture the fistula, having cognitive disorders or skin problems on the massage site, having used analgesic drugs in the past 3 hours, the acute pain in other parts of the body, neuropathic disorders or peripheral vascular diseases, depression, anxiety and other known severe mental disorders.

The data collection tools used included the demographic information and the VAS. The demographic information consisted of items regarding age, gender, level of education, marital status, occupation, place of residence, duration of dialysis and duration of fistula and other underlying diseases (diabetes, hypertension, glomerulonephritis and cardiovascular diseases). The VAS consisted of

a horizontal scale from 0 to 100 for measuring and recording the intensity of pain by the researcher based on participants' statements.

The VAS has been used extensively in literature and its validity and reliability have thus been confirmed.^{8,11,17,31}

After obtaining written permission from the Ethics Committee of Mazandaran University of Medical Sciences, the researcher introduced herself to the officials of hospitals and also to the patients and then she explained the procedures of study to them. The eligible hemodialysis patients signed written consent forms and demographic data. The intervention was performed in two consecutively sessions.

In the first session of hemodialysis, the researcher helped the patients complete the VAS after they had undergone a fistula puncture. Before needle insertion in the second session of hemodialysis, the lidocaine group received 2 gr or 2 cc.7 of 2% lidocaine gel (productive company sina-medicine, Tehran) and were weighed on a digital scale in the laboratory. A 2 cc. of the 2% lidocaine gel was used in an area of 5 cm² over the fistula¹² 12 minutes before the fistula needle insertion. The skin was then cleared off from the gel and disinfected then needle number 16 (produced by pharmed-supa, Tehran) was inserted in fistula with all patients. The researcher measured and recorded the intensity of pain on the VAS immediately after the needle insertion. Furthermore, in the second sessions of hemodialysis for the ice massage group, a 2×2×2 cm ice cube was put in a plastic glove and covered with a single-layer cotton cloth, which was used to provide a rotational massage on the Hegu points. The researcher adjusted the pressure applied on the Hegu point by her thumb to the extent that it changed her nail color. The ice massage began minutes before the insertion arteriovenous fistula needle and continued for about 2 minutes into the cannulation of the fistula between the thumb and the index finger (Hegu point LI-4) in the hand without fistula.14

The 12-minute massage was performed periodically for a maximum of 2 minutes, followed by a 15-second pause.³² The

researcher recorded the post-intervention pain intensity after the fistula needle insertion process, using the VAS.

For data analysis, the normality of data was assessed by the Kolmogorov-Smirnov test. As the data were not normal, non-parametric tests were used in this study. The results are expressed mean (SD), frequency (percentage). The comparison of demographic between and clinical characteristics participants in the two groups was performed by using Student's t-test, chi-squared test. Spearmans correlation, wilcoxon sign ranks test and Mann-Whitney U-test was used for skewed data. All data were analyzed by using the statistical software package, SPSS version 13. P-values less than 0.05 were considered significant.

Results

The study samples in the two groups had no statistically significant differences in terms of demographic and clinical characteristics of hemodialysis patients. The demographic and clinical characteristics of the patients are provided in Table 1. The most common causes

of chronic renal failure were, lidocaine gel and Hegu point ice massage groups hypertension (28.57%) and comorbid hypertension and diabetes (28.57%), respectively.

Table 2 compares the pain score intensity caused by the arteriovenous fistula needle insertion before the intervention in the two groups after the intervention in Hegu point ice massage and lidocaine gel 2% groups.

The statistical analysis found no significant differences between the two groups in terms mean pain intensity of the pre-intervention phase. The comparison of the pain severity score before and after interventions of 2% lidocaine gel (P<0.001) and Hegu point ice massage (P<0.001) groups yielded significant differences. The mean change of the pain score before and after the intervention of the two groups revealed more effectiveness Hegu point ice massage compared to lidocaine gel on puncture-related pain in hemodialysis patients (P=0.03).

Table 3 also shows that the changes in pain severity didn't correlate with factors such as gender, age, duration of hemodialysis and duration of fistula (P<0.05).

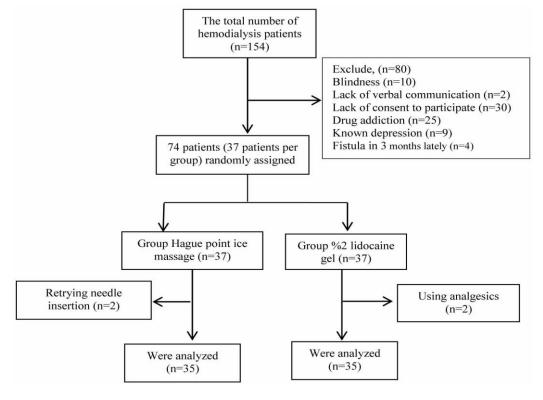


Figure 1. Flowchart of the study

Table 1. Comparison of demographic and clinical characteristics in each group of hemodialysis patients (n=35)

Variables	Lidocaine gel 2% N (%)	Hague point ice massage N (%)	Statistical indicator
Gender			$P = 0.80, x^2 = 0.059$ §
Male	20(57.1)	21(60)	
Female	15(42.8)	14(40)	
Place of residence			$P = 0.803, x^2 = 0.062$ §
City	22(62.85)	23(65.71)	
Village	13(37.14)	12(34.28)	
Education			P = 0.46, t = 2.57§
Elementary	21(60)	15(42.5)	
Junior high school	12(34.2)	16(45.7)	
High school	1(2.8)	1(2.8)	
College	1(2.8)	3(8.5)	
Married	35(100)	33(94.2)	P =0.49, Exact test=2.05
Age (years)*	64.9 (10.9)	65.31(9.8)	P = 0.88, t = 0.149§
Duration of hemodialysis (month)*	45.6(38.9)	46.4(31.7)	P = 0.65, z = 0.44§
Duration of fistula (month)*	49.5(52.4)	45.03(33.17)	P = 0.77, z = 0.77§

^{*}Values are presented as Mean (Standard Deviation), \$x^2= chi-squared test, t= t-test, z= Mann–Whitney U-test

Table 2. Comparison the mean score severity pain of arteriovenous fistula puncture-related before and after the intervention in both groups

	Group		Statistical
Pain	Lidocaine gel 2% Mean(SD)	Hegu point ice massage Mean(SD)	indicator [¥]
Before intervention	5.40(1.75), (CI: 4.8 - 6) $^{\epsilon}$	$5.54(1.22)$, (CI: $5.12 - 5.96$) ^{ϵ}	Z=0.81,P=0.41
After interventions	$4.57(1.57)$, (CI: $4.03 - 5.11$) ^{ϵ}	$4.11(1.47)$, (CI: $3.61 - 4.62$) ^{ϵ}	Z=-1.19, P=0.23
difference Mean changes related before and after intervention	0.828(0.92),(CI: 0.51 – 1.14) $^{\epsilon}$	$1.42(1.17)$, (CI: $1.02 - 1.83$) ^{ϵ}	Z=2.10, P=0.03
Comparison of pain before and after interventions, (Wilcoxon test)	P<0.001, Z=-3.8	P<0.001, Z=-4.6	

⁶Confidence interval 95% for mean, ⁴Mann-Whitney U test

Table 3. Relationship between fistula puncture-related pain with age, duration of hemodialysis, duration of fistula and gender

Variables	Change Pain Severity
Age [¥] (years)	R= 0.87, P= 0.47
duration of hemodialysis [¥] (month)	R = -1.35, P = 0.26
duration of fistula [¥] (month)	R = -0.08, P = 0.46
Gender [€]	Z=505, P=0.26
$Male^{\mathfrak{t}}$	1.24 (1.04)
Female [£]	0.96 (1.1)

[¥]Spearman Correlation, [€] Mann-whitney U test, [£] Mean (SD)

Discussion

The results showed that both lidocaine gel and Hegu point ice massage are effective in reducing arteriovenous fistula puncturerelated pain. However, Hegu point ice massage group was found to be more effective on reducing arteriovenous fistula puncture-related pain, considering pain severity mean.

Also, both groups of patients experienced moderate levels of pain during fistula needle insertion without any intervention. In a study conducted with the aim of comparing the effects of Hegu point

cryotherapy and placebo on reducing the pain of arteriovenous fistula cannulation among hemodialysis patients, Aghajanloo et al., reported the pain associated with fistula needle insertion without intervention in control group as 5.5 (0.82) and in cryotherapy group 5.9 (0.96). Thus, there were moderate levels of pain during fistula needle insertion,¹⁵ which is consistent with the findings of the present study. Ghods et al., reported the pain severity score during insertion of vascular needles in hemo dialysis patients without any intervention as 4.59 (2.02),¹⁸ which is similar to the findings in the present research.

In a study conducted with participating 40 hemodialysis patients to assess the pain intensity by VAS after needle insertion in AVF after 15-20 min applying lidocaine gel 2%, Aliasgharpour et al., calculated the mean pain score to be 5.54 (1.94) without intervention and 3.81 (1.46) when 2% lidocaine gel was used12, which is consistent with the findings of the present study. Lidocaine gel was found to be effective in reduction of the intensity arteriovenous fistula puncture-related pain. In another study Asgari et al., calculated the mean of pain intensity after using lidocaine spray to be 2.30 (1.91), while using a placebo spray gave a mean pain intensity score of 3.96 (2.14). These results confirm the effect of lidocaine spray on pain reduction arteriovenous fistula puncture in hemodialysis patients¹¹, which is consistent with the present study. Celik et al., also confirmed the effectiveness of vapocoolant sprav and prilocaine cream arteriovenous fistula puncture-related pain in hemodialysis patients and indicated that the amount of pain reduction caused by interventions these two was significantly different. However, topical medications such as vapocoolant or EMLA cream take effect within 45-60 minutes to be sufficiently absorbed to relieve pain⁷ and may have their own side effects, which limits their use.

In an effort to study the effects of Hegu point cryotherapy on fistula puncturerelated pain in hemodialysis patients, Sabita et al., divided 60 hemodialysis patients into two groups of control and experimental. The control group received no interventions on the first hemodialysis day and then had a Hegu point massage on the second day. The experimental group received no interventions on the first hemodialysis day but underwent a Hegu point ice massage of the hand without fistula 10 minutes before the fistula needle insertion until 2 minutes into the needle insertion process. The subject's pain score was measured on the VAS after a tape was fixed onto the fistula site. The results showed no significant differences in terms of the mean intensity of pain before and after the intervention in the control group. In the experimental group, however, the mean pain score dropped from 8.3 (0.66) before the intervention to 0.7 (0.33) after it. Therefore, the researchers concluded that Hegu point massage alone is ineffective in the pain rather than ice massage on the Hegu point wich has been confirmed to be effective¹⁴ and the results were is similar with the present study.

Golda et al., conducted their research with the aim of studying cryothrapy on AV Fistula cannulation site and its effects on reducing the intensity of pain. Sixty hemodialysis patients were divided into experimental and control groups, using simple random sampling. The experimental group applied crayotrapy by 3 ice cubes (made of 30 ml of water), wrapped by unsterile glove, on L1-4 meridian point 10, minutes prior to the insertion of the catheter. The control group received no interventions, the pain was assessed, using numerical rating scale. The mean post-test level of pain among hemodialysis patients in the experimental group was 1.53 (0.76) and the mean post-test level of pain among hemodialysis patients in the control group was 5.7 (1.79). The difference of the mean intensity of pain during venipuncture was found to be statistically significant between the two groups¹⁶, which is in line with the results of the present study.

Hypertension was the most common cause of chronic renal failure in the 2% lidocaine gel group; in the Hegu point ice massage group, comorbid hypertension and diabetes responsible for this condition. Ghorbanimoghaddam et al., in a study on the frequency of underlying conditions for chronic renal failure in patients undergoing dialysis have also reported hypertension (34.2%) and diabetes (26.9%) as the two most common causes of chronic renal failure³³, which is in line with the present study. Also, regarding the prevalence of patients with end-stage renal disease on dialysis, Snouber et al., found that the most common causes of ESRD were hypertension (11.1%) and diabetes (22.5%) and both combined (10.6%)³⁴, which is consistent literature. Furthermore, the significant differences were observed in the two groups in terms of the mean duration of fistula and duration of hemodialysis, Saeedi et al., investigated the effect of progressive muscle relaxation on insomnia severity of hemodialysis patients. The results of the study indicated than the mean duration of hemodialysis and duration of fistula were 4.97 (4.54) years.35 Also, in a study by Celik et al., the mean duration of fistula was 47.1 (4.54) months 7 which is consistent with the results of the our study.

The results of the present study also showed that there was no relationship between fistula puncture-related pain with age, gender, duration of hemodialysis and duration of fistula. In contrast to these findings, Ghods et al., found the duration of hemodialysis to be significantly associated with the intensity of pain, as the patients with a longer history of hemodialysis lower pain.18 reported levels of Furthermore, Li et al., investigated the pain perception in candidates using VAS and their pain intensity was measured. Based on the results obtained in this experiment, older people experience lower level of pain in comparison to the younger individuals.³⁶ The relationship between the intensity of pain with the duration of hemodialysis appears to be caused by the tendency to gradually adapt to the pain. Pain is a multifaceted issue with great complexity and is affected not only by age and gender, but also by factors such as culture and genetics.⁶

Therefore, these contradictory research findings are justifiable. In contrast to the results of the present study, Sabita et al., also revealed fistula puncture-related pain to have a significant relationship with older age and female gender¹⁴ Also in another experiment, Bahrami et al., noted that and women younger individuals experienced higher pain in EMG needling compared to the men and the older people. The higher pain sensed by women might have been caused by the fact that women comprised 61.7% of the patients while men constituted 38.3% of the study population.³⁷ Another study reported a higher intensity of pain perceived by women immediately after a surgery.³⁸ Chia et al., observed that men suffered from greater postoperative pain and required higher doses of morphine³⁹ inconsistent with the former study. Taenzer et al., found no significant differences between men and women in terms of the perception of pain immediately after surgery. 40 In another study conducted by Celik et al., being female or old, were not found to be associated with a higher intensity of pain,7 which is consistent with present findings. Thus, further descriptive-analytical studies with larger sample sizes are required to understand these relationships.

The present study found a significant difference in the mean pain score of arteriovenous fistula puncture-related pain between the lidocaine group and the Hegu point ice massage group. Hegu point massage was found to be more effective in pain reduction than lidocaine gel. Since there are no other studies which compare the effects of lidocaine gel and Hegu point

massage on the intensity of pain, further studies on this subject are therefore necessary. Although the present study as well as other studies confirm the effectiveness of lidocaine gel and Hegu point ice massage in pain reduction, more studies should be conducted to examine the effect of different doses of the gel and its duration of application as well as the duration and method of Hegu point massage on arteriovenous fistula puncture-related pain.

The limitations of this study include the patients 'exhaustion and distress which may have affected the study results. Another limitation was our inability to assign uniformed nursing staff for all needle insertion procedures, which could or have influenced on the results.

Conclusion

The results of the present study suggest that both lidocaine gel and Hegu point ice massage are effective in reducing arteriovenous fistula puncture-related pain. Given that Hegu point ice massage is more effective, this method is recommended to be used of pain relief in hemodialysis patients.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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