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Effect of addition of distraction to cryotherapy on arteriovenous cannulation-associated pain: A randomized controlled trial

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Abstract

Introduction: Pain associated with the arteriovenous fistula needle is considered one of the major challenges faced by nurses and patients. This study evaluates the effectiveness of using two different approaches in combination to alleviate pain associated with arteriovenous fistula needle cannulation, and patients' satisfaction level with this method.

Methods: A randomized clinical trial was conducted on hemodialysis patients who were allocated to one to two groups: intervention (distraction plus cryotherapy) (n = 25) or control group (receiving cryotherapy alone) (n = 25). The pain level was assessed before and at the end of applying cryotherapy and distraction techniques. Patients' satisfaction level was assessed at the end of the trial.

Findings: After the application of cryotherapy and distraction techniques for the intervention group, the mean value of pain level was 2.12 (0.9) compared with 3.92 (0.16) for the control group. Independent t tests showed a significant difference between groups regarding the pain level with p value less than 0.05. The mean satisfaction level for the participants receiving only cryotherapy was 4.6 out of 10, compared with 5.9 for the patients who received cryotherapy and distraction techniques.

Discussion: The findings revealed that using two different approaches in combination to control pain associated with AV fistula cannulation was more effective than using a single strategy. The technique can be used in clinical settings to reduce pain and improve patients' satisfaction level.

KEYWORDS

arteriovenous fistula, cryotherapy and distraction technique, hemodialysis, pain

INTRODUCTION

Pain associated with arteriovenous (AV) fistula needle insertion is considered a major challenge for more than 57% of patients treated with hemodialysis.[1] Further, pain is considered one of the leading causes of hemodialysis noncompliance to a therapeutic regimen, as many patients tend to skip hemodialysis sessions to avoid feeling pain.[2] Nonadherence to recommended treatment leads to cardiovascular and respiratory complications, resulting in death if not managed immediately.[3]

Despite recent advances in pain management, pain is still recognized as a serious problem.[4] The side effects make patients dissatisfied with the traditional pain

management approach based on pharmacological intervention. They therefore seek pain relief through alternative which, although gaining in popularity among patients and healthcare providers for managing acute and chronic pain, have not been fully adopted by healthcare providers and policymakers.[5]

Therapeutic touch, acupuncture, transcutaneous electrical stimulation,[6] aromatherapy,[7] and heat and cold therapy [4,8] are among the therapeutic treatments suggested in the literature to manage acute pain the patients with CKD. Two of the alternative therapies considered specifically for managing pain associated with AV fistula cannulation are cryotherapy[4,8–10] and distraction.[11,12] However, no studies have assessed the effectiveness of using two approaches in combination therapies at the same time to achieve more pain relief effects. Therefore, this randomized trial aims to assess the effectiveness of using cryotherapy and distraction to alleviate this pain, and to assess patient satisfaction with these pain management strategies.

METHODS

A randomized clinical trial was performed. Patients were included in the study if they met the following criteria: age 18 and above, diagnosed with ESRD, receiving hemodialysis on a regular basis, using AV fistula or AVG as access for hemodialysis, and able to self-report pain. Patients with other conditions like sensitivity to cryotherapy were excluded from the study, as were those who underwent two hemodialysis sessions in less than 24 h or more than 72 h because this timing affects pain sensation[8]; and patients who had received analgesic medication within the preceding 12 h. Based on Cohen's power analysis technique,[13] and using G power 3 software, the sample was calculated using medium effect size (0.2), power of 0.80 and an alpha level of 0.05, and a paired t test. The results indicated a required sample of 42 participants. However, 15% was added to overcome any attrition during the study, as recommended by Polit and Beck.[14] Accordingly, the estimated sample size was 50 participants. The study participants were chosen by simple random sampling from the hemodialysis unit of a government hospital in Amman, Jordan. All the patients who matched the inclusion criteria were placed on a list and each was assigned a specific number. Random number generator software was then used to produce select potential participants. The author then contacted these individuals to seek their approval for participation in the study. Those who agreed and submitted informed consent were allocated to one of two groups, again using a random number generator: (1) group receiving cryotherapy alone (control group) and (2) group receiving both cryotherapy and distraction. Institutional Review Board approval was obtained from the University of Jordan and the Jordanian Ministry of Health, and ethical approval from the selected hospital.

Measures

Pain was measured using a numerical rating scale (NRS), with three pain levels: scores from 1–3 indicate mild pain, 4–6 moderate pain, and 7–10 severe pain (Hawker et al., 2011). The patient satisfaction level was measured using the Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R).[15] This scale comprises 11 items ranging from zero (extremely dissatisfied) to 10 (extremely satisfied).

Data collection

Initially, pain levels were measured over two consecutive hemodialysis sessions, and the mean level of the two measures was calculated to serve as a baseline information about the pain intensity. Before commencing the intervention, sensitivity test to cryotherapy in the hemodialysis units was done 15 min before the intervention. It was performed by applying ice to the hugo point, located in the web between the thumb and index of the hand that is contralateral of the cannulation site and held it for 1 min. For group one, the researcher applied an ice bag containing ice cubes wrapped in a towel to prevent skin injury to Hegu points and held it for 10 min. For group two (distraction plus cryotherapy), the patients received the same treatment, but were also given a stopwatch and asked to observe it and start counting at the sixth minute for up to 4 min. The ice was kept during the needle insertion for both groups. The AV fistula needle was then inserted while the ice was removed; pain intensity was measured within 30 s of the cannulation process. Next, the patients were also asked to rate their satisfaction level immediately after measuring the pain level post-intervention. Two hemodialysis technicians used the area puncture technique during the study, one for the control group and the other for the intervention group.

Ethical considerations

This study was designed to consider human rights, potential risks, and benefits. Patients were assured that their participation was entirely voluntary, and they had the right not to participate or to withdraw from the study at

any time. The details of the study were fully disclosed in the informed consent. The researchers were available at the time of consent and to answer questions from the participants throughout the study.

RESULTS

Participants' characteristics

The study sample consisted of 50 participants diagnosed with ESRD and treated with maintenance hemodialysis. All participants who met the inclusion criteria and participated in the baseline measurement completed all the study phases, representing a 100% response rate. As reported in Table 1, both groups' baseline data were similar; the mean age for group 1 was 31 (SD = 10.1) and for group 2 29.9 (SD = 8.6). In group 1, a majority of the participants were male (n = 15; 60%), with 10 female participants (40%). Similarly, in group 2, 17 (68%) were male and only 8 (32%) female. In the first group, the mean years the patients had been on hemodialysis was 5 (SD = 7.1), with 3.8 (SD = 4.2) for the second group. A majority of patients used arteriovenous fistula as vascular access: 18 (72%) in group 1 and 22 (88%) in group 2; the rest used an arteriovenous graft. The frequency of hemodialysis sessions was three times per week for 15 members (60%) of group 1, and for 21 (84%) members of group 2; the remaining participants received hemodialysis two times per week. Finally, concerning vascular access placement duration, the mean was almost 15 months for group 1 and 16.3 for group 2.

Before the application of the intervention, AV fistula cannulation-related pain level was measured over two consecutive Hemodialysis session during which cryotherapy alone was used as described in Methods. As shown in Table 2, the mean value of pain for group 1 was 5.3 (SD = 1), reflecting a moderate pain level, and 5.1 (SD = 1.1) for group 2; there was no significant difference between the groups (t [48] = 0.47, p = 0.63). At the individual level, members of both groups reported pain as a moderate level (n = 20; 82% for group 1) and (n = 21; 84% for group 2). Only five (18%) participants reported severe pain in group 1 and 4 (16%) in group 2; none of the participants in either group reported feeling mild pain.

Table 3 shows that the mean pain level after only cryotherapy (group 1) was 3.92 (SD = 0.16), reported individually as moderate or mild (n = 14, 66% and n = 11, 44%, respectively). When cryotherapy and distraction techniques were applied for group 2 (distraction plus cryotherapy), the pain level mean was 2.12 (SD = 0.9), and reported as mild by all participants (n = 25, 100%). Independent t test showed a significant

TABLE 2 Cannulation pain levels during two hemodialysis sessions pre-randomization using cryotherapy only (n = 50)

	Group 1 n (%)	Group 2 n (%)	*p*-value
Pain levels, mean (SD)	5.34 (1)	5.20 (1.1)	0.63
Pain categories			
Mild	0	0	
Moderate	20 (82)	21 (84)	
Severe	5 (18)	4 (16)	

TABLE 1 Characteristics of the study participants (n = 50)

Variables	Group 1 cryotherapy (n = 25)	Group 2 cryotherapy and distraction (n = 25)	*p*-value
Age (years), mean (SD)	31.1 (10.1)	29.9 (8.6)	0.65
Gender *N* (%)			0.56
Male	15 (60)	17 (68)	
Female	10 (40)	8 (32)	
Years on hemodialysis 17, mean, (SD)	5 (7.1)	3.8 (4.2)	0.47
Type of vascular access *N* (%)			0.15
Arteriovenous fistula	18 (72)	22 (88)	
Arteriovenous graft	7 (28)	3 (12)	
Frequency of hemodialysis *N* (%)			0.06
2 times	10 (40)	4 (16)	
3 times	15 (60)	21 (84)	
Duration of vascular access (months), mean (SD)	14.9 (6.9)	16.3 (8.6)	0.52

TABLE 3 Cannulation pain levels after addition (or not) of distraction to cryotherapy (group 2) vs. cryotherapy alone (group 1). Patients also receiving cryotherapy

	Mean value				
Groups	**Group 1**	**Group 2**	**Mean difference**	***t***	**df**
Pre-intervention Group 1 vs. Group 2	5.34	5.20	0.14	0.47[a]	48
Post intervention Group 1 vs. Group 2	3.92	2.12	1.8	9.8[a]	48

[a]Significant at $\alpha = 0.05$.

TABLE 4 Difference in pain levels after addition (or not) of distraction in patients also receiving cryotherapy among the same group

	Mean value			
Pairs	**Pre**	**Post**	**Mean difference**	***p* value**
Group 1 pre vs. Group 1 post	5.34	3.92	−1.42	0.01
Group 2 pre vs. Group 2 post	5.20	2.12	−3.08	0.01

TABLE 5 Patient satisfaction with pain management

	Group 1	**Group 2**	***p*-value**
Satisfaction mean (SD)	4.6 (1.0)	5.9 (1.52)	0.01

difference between the groups regarding the pain level: $t\,(48) = 9.84$, $p = 0.00$.

Further analysis using a paired t test revealed a significant difference in the mean value of pain level pre- and postintervention: $t\,(24)=19$, $p = 0.00$ for group 1; and $t\,(24)=26$, $p = 0.00$ for group 2 (distraction plus cryotherapy). Findings confirmed that using two techniques (cryotherapy and distraction) was more effective than using one technique to alleviate pain associated with AV fistula needle insertion (Table 4).

The results presented in Table 5 showed that the mean satisfaction level for members of group 1, only cryotherapy, was 4.6 out of 10. On the other hand, the patients who received both cryotherapy and distraction reported a higher satisfaction level with a mean value of 5.9 out of 10. There was a significant difference between the groups, $t\,(48) = 3.64$, $p = 0.01$.

Discussion

The present paper may be the first experimental study to assess the effectiveness of using two different approaches in combination in controlling pain during the insertion of AV fistula.

The current study revealed that the average baseline level of pain felt in inserting the AVF fistula needle was moderate. This was expected, as no clear policy or nursing intervention exists concerning specifically the pain associated with AV fistula cannulation. Moreover, previous studies have shown insufficient knowledge or training toward pain management among nurses.[16] For instance, Jordanian nurses reported a low level of knowledge and attitude toward pain management.[16–18] There are many reasons for ineffective pain management, such as nurses' heavy workload, their lack of time,[19] the limited authority given to them, and nurse–patient relationships.[20] Locally, patients' hesitance or fear, and nurses' reluctance to contact physicians for analgesic orders, are significant barriers to pain management and intervention implemented by Jordanian nurses.[17]

The findings of the present study are consistent with several previous studies[2,7,9,10] that reported a moderate pain level among more than 60% of patients receiving hemodialysis. Our findings also confirm the use of cryotherapy as an effective strategy in reducing the pain associated with AV fistula cannulation as reported by many previous researchers.[8,21–24]

Additionally, the intervention used with group 2 (distraction plus cryotherapy) was found to be effective in mitigating the pain associated with AV fistula cannulation; indeed, the amount of pain reduction was higher than for cryotherapy alone. As no studies to date have assessed the use of cryotherapy and distraction as a pain management intervention to control fistula cannulation pain, it is impossible to compare our findings with others.

The results of this study revealed that the patients were more satisfied with distraction plus cryotherapy than cryotherapy alone with mean satisfaction level of 5.9\10 vs. 4.6\10. This was an expected result as the satisfaction level is associated with pain reduction level. However, no studies have measured patients' satisfaction with cryotherapy alone or combined with other pain management intervention to control fistula cannulation pain; therefore, discussing our finding with other studies was

not possible. This highlights the need to conduct more studies that address patient's satisfaction with dual strategies to mitigate pain because the high level of satisfaction is considered the optimum outcome that may affect the patient decision to seek health care and adhere to prescribed treatment. We also believe that using the dual strategy, distraction and cryotherapy, could improve the nurse–patient relationship, reported elsewhere as a barrier to pain management.

Finally, a crossover between the control and intervention groups is recommended in future studies, to identify any differences. Furthermore, future study is recommended to compare the intensity of pain by gender.

CONFLICT OF INTEREST

The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

ETHICS STATEMENT

Hereby, Hamzeh Abunab consciously assure that for the manuscript "Effect of addition of distraction to cryotherapy on arteriovenous cannulation-associated pain: a randomized controlled trial," the following is fulfilled:

1. This material is the authors' own original work, which has not been previously published elsewhere.
2. The paper is not currently being considered for publication elsewhere.
3. The paper reflects the authors' own research and analysis in a truthful and complete manner.
4. The paper properly credits the meaningful contributions of coauthors and coresearchers.
5. The results are appropriately placed in the context of prior and existing research.
6. All sources used are properly disclosed.
7. All authors have been personally and actively involved in substantial work leading to the paper and will take public responsibility for its content.

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article and can be provided in detail upon request.

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