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Effect of stress ball use on cannulation-related invasive pain in Hemodialysis patients: a randomized controlled, single-blind study

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Abstract

Background Stress ball usage is one of the non-pharmacological methods that help reduce pain and anxiety by diverting an individual's attention elsewhere.

Purpose This study evaluates the impact of stress ball use on pain levels during cannulation in hemodialysis patients.

Methods A single-blind, randomized, controlled design was used. Sixty-four participants were divided into experimental ($n=32$) and control groups ($n=32$). The experimental group used a stress ball for 3 min before and during cannulation, while the control group received routine care without additional intervention. Pain was assessed using the Visual Analog Scale (VAS) after cannulation across 12 sessions. Statistical significance was set at $p < 0.05$.

Results The median VAS score in the intervention group was significantly lower than in the control group. The intervention group showed a significant decrease in VAS scores over 12 sessions ($p < 0.01$). Stress ball usage had an increasing effect over time ($p = 0.016$). Overall, median VAS scores differed significantly between groups ($p < 0.01$).

Conclusion Using stress balls during cannulation reduces pain intensity in hemodialysis patients, with increased effectiveness over multiple sessions. Nurses can recommend stress balls as a simple and cost-effective pain management method.

Trial registration This study was retrospectively registered at ClinicalTrials.gov (Registration No: NCT06237738) on 2024-01-12.

Keywords Hemodialysis, Arteriovenous fistula, Pain, Cannulation, Stress ball

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Background

Pain is a serious problem for hemodialysis patients; pain experienced during cannulation, in particular, may negatively affect treatment compliance and the patient's life quality [1]. Cannulation pain occurs due to the response of pain-sensitive nerve endings in the tissue when the needle is inserted into the skin. Literature indicates that the occurrence of pain during arteriovenous fistula (AVF) cannulation ranges from 12 to 80% [2, 3]. Hemodialysis patients typically undergo arteriovenous fistula cannulation procedures approximately 156 times a year, as they usually receive dialysis three times per week. For patients on more frequent dialysis schedules, this number can double, potentially reaching up to 312 procedures annually [4]. Each procedure is often associated with moderate to severe pain [5]. This may cause additional problems such as insomnia, anxiety, stress, and depression [6, 7].

There are various reports in the literature regarding the factors affecting cannulation-related pain. These include the needle tapered tip direction, cannulation method, artery needle direction, presence of stenosis in the fistula or infection in the fistula area, and the skill of the healthcare professional performing the cannulation [8, 9]. No statistically significant difference with the needle tapered tip direction in terms of pain scores was observed in the study of Akyol Durmaz et al. (2015) [10], while it was observed in other studies that the pain score was lower when the needle was placed in a downward direction than when it was placed in an upward direction [3, 11]. Similarly, the buttonhole method has been observed to be superior to the rope ladder technique in decreasing cannulation-related pain in some studies evaluating the effect of the cannulation method on pain [12]; other studies have reported the opposite [13, 14].

Various approaches, including pharmacological and non-pharmacological techniques, are employed to manage the invasive pain linked to cannulation in hemodialysis patients. Due to the risks of drug addiction and side effects associated with pharmacological methods, non-pharmacological approaches are often favored as they are more accessible, have minimal side effects, and are cost-effective [7, 15]. As a result, these methods have been increasingly adopted across various healthcare settings involving invasive procedures. For example, stress ball use has been shown to reduce pain and anxiety during procedures such as endoscopy, angiography, and outpatient gynecological interventions [16, 17]. Distraction techniques, including stress balls, virtual reality, and music therapy, have demonstrated efficacy in decreasing procedural discomfort and improving patient satisfaction in these contexts [18]. Moreover, active distraction methods have proven particularly effective in pediatric dental procedures, where managing anxiety and behavioral responses is critical [19]. These findings underscore

the versatility and effectiveness of non-pharmacological approaches in diverse invasive procedures, beyond hemodialysis.

Using a stress ball is a non-pharmacological technique that aids in alleviating pain and anxiety by redirecting the individual's focus [20–22]. Based on the gate control theory, this method adopts the principle of inhibiting pain receptors by stimulating mechanoreceptors and thus reducing pain perception. When a pain stimulus is received, the process of activating nociceptors through nerve fibers and transmitting pain messages to the brain can be prevented by mechanoreceptor stimulation. This process stimulates the activation of mechanoreceptors through distracting stimuli and allows pain reduction and increased tolerance to pain. In the end, mechanoreceptor stimulation can significantly reduce pain perception by inhibiting the transmission of pain signals [23–25].

Reports indicate that using a stress ball can decrease pain during endoscopy procedures [16] and surgeries performed with local anesthesia [26, 27], fear and pain when obtaining a nasal sample for the detection of the Coronavirus (polymerase chain reaction (rRT-PCR) test) [28], and the pain experienced while establishing peripheral vascular access [18]. This method has also been found to be effective in reducing the pain experienced during intravenous catheter insertion, especially in the pediatric population [20, 21, 29]. However, studies examining the effect of stress ball use on invasive pain during AVF cannulation are limited [1]. Existing studies point to the lack of pain management strategies based on non-pharmacological methods and indicate the need for more studies in this area [1, 30]. This study aimed to explore how using a stress ball influences the pain experienced during cannulation in hemodialysis patients.

Methods

Study design

A single-blind, randomized, controlled design was employed for this study.

Setting and participants

The study was conducted with patients receiving treatment in the hemodialysis unit of a state hospital in Turkey from October to December 2023. Participants included patients who had been undergoing hemodialysis treatment via AVF for four-hour sessions, three days a week, for at least three months. The rope-ladder technique was used for all arteriovenous fistula (AVF) cannulation in this study. This technique involves rotating the needle insertion sites within the fistula area to minimize the risk of complications such as aneurysm formation, scarring, and infection. The choice of this technique reflects the standard practice at the study site and ensures consistent methodology for all participants. These patients were

aged 18 or older, had no psychiatric disorders impeding communication, experienced pain with a VAS score of ≥ 1 during cannulation, and willingly volunteered for the study. Exclusion criteria were pregnant women, patients who had taken painkillers within the last three hours, and those with hand/arm issues affecting the use of a stress ball.

Sample size

The study population comprised 88 patients undergoing hemodialysis during the designated period. Although no previous research specifically focused on cannulation pain in adults undergoing dialysis, the sample size was estimated using data from similar studies [1, 20, 22, 26]. The use of a stress ball was found to reduce pain in participants compared to the control group, with effect sizes ranging from $d=0.62$ to $d=1.29$ across these studies [1, 20, 22, 26]. Based on these studies, the average effect size of 0.8 was used for the sample size calculation, with 95% confidence and 80% power. Using G*Power (v3.1.9), the required sample size was determined as 26 participants per group. Considering a potential 20% dropout rate, the final sample size was set at 64 participants (32 per group).

The CONSORT Flow Diagram illustrates the enrollment, randomization ($n=64$), and follow-up process. A total of 88 participants were assessed for eligibility, with 24 excluded due to not meeting inclusion criteria, declining participation, or other reasons. The intervention group used stress balls ($n=32$), while the control group received routine care ($n=32$). Both groups completed 12 VAS measurements throughout the study period (Fig. 1).

Collection of data

Participants were randomly assigned to intervention and control groups using a simple random draw method conducted by a hemodialysis unit's nurse who was not involved in the study. This approach ensured allocation concealment. Randomization software was not used in this study; instead, hemodialysis shifts were pre-assigned to patients by the hemodialysis unit based on routine scheduling practices. To ensure methodological rigor, randomization into intervention and control groups was performed independently of these shifts. The randomization process involved a simple random draw method conducted by an independent nurse who was not involved in the study's data collection or analysis.

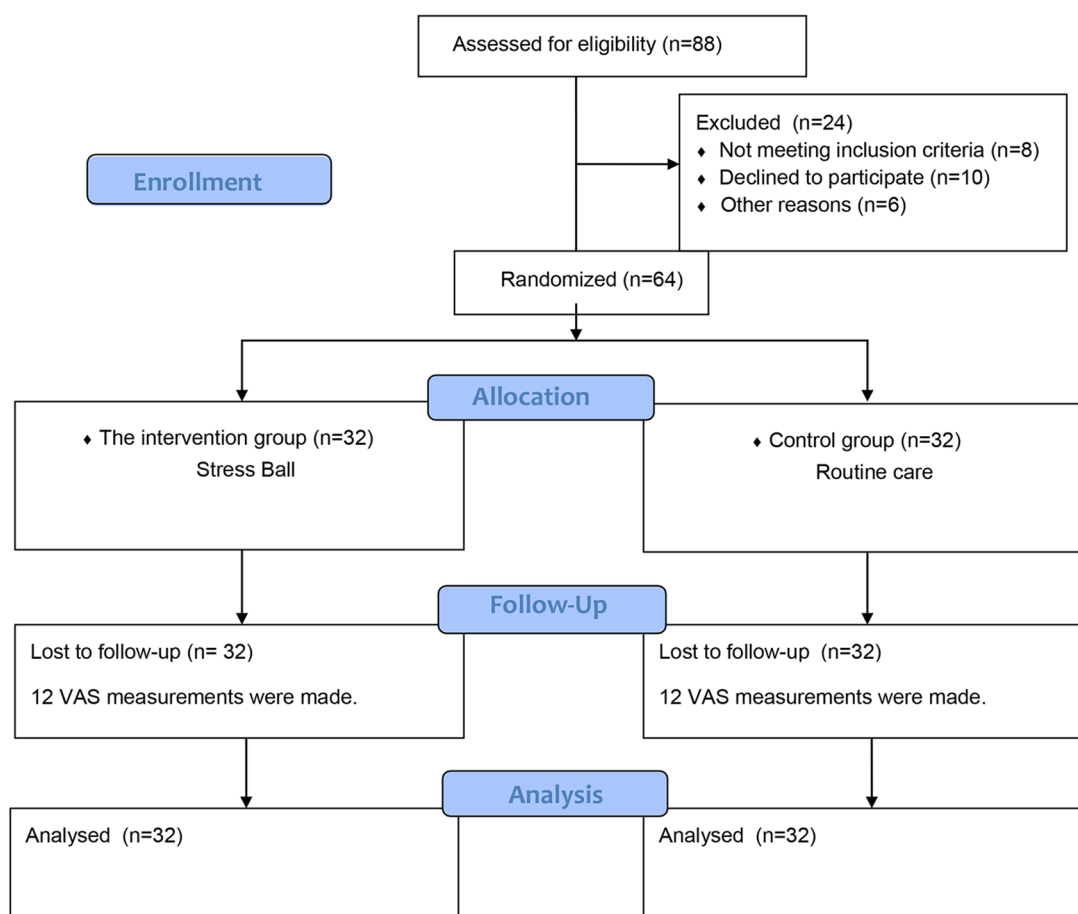


Fig. 1 CONSORT study flow diagram

This approach ensured that the allocation of patients to study groups was unbiased and unrelated to their pre-assigned shifts. Patients who attended the sessions on Mondays, Wednesdays, and Fridays were included in the intervention group, and those who attended the sessions on Tuesdays, Thursdays, and Saturdays were included in the control group. In this single-blind study, participants were informed about the general aim of evaluating pain management strategies during hemodialysis without providing specific details on the effects of stress ball use. Pain assessments were conducted by a nurse who was not involved in the intervention to ensure unbiased measurement.

Intervention group The patients participating in the study were given a stress ball and asked to use it before the cannulation process. A single nurse consistently performed the cannulation procedure for all patients throughout the study. Right after the cannulation procedure, a nurse not involved in the study assessed the patient's pain. Pain severity measurements were made 12 times during a total of 12 sessions.

Stress ball usage Before starting the study, the researchers explained to the patients how to use the stress ball both in theory and with a practical demonstration. Then, the patient was asked to use the ball, and whether he/she was using it correctly was confirmed. The patients were asked to hold the ball in the hand that did not have the fistula and to squeeze the ball for 3 min before and during the needle insertion. Patients were told to count to three, squeeze and release the ball once, breathe in when squeezing the ball, and exhale and focus only on the ball when releasing it [29, 31, 32]. The stress ball provided was made of silicone and had a medium level of hardness. A separate ball was used for each patient. The balls were provided by researchers.

Control group After the cannulation process, a nurse from the hemodialysis unit, who was not part of the study, assessed the patient's pain without any intervention. Pain severity was evaluated 12 times during a total of 12 sessions.

Data collection tools

Participant Descriptive Characteristics Questionnaire: Developed by the researchers after reviewing relevant literature [4, 18, 30, 31, 33–35], this semi-structured form includes 14 questions focusing on the socio-demographic and medical information of the participants. The researchers administered the questionnaire through face-to-face interviews, taking approximately 10 min during the second hour of hemodialysis treatment.

Visual Analogue Scale (VAS)

The scale, which was initially created by Price et al. (1994) to measure pain intensity, was validated and tested for reliability in Turkish by Eti Aslan (2004) through the assessment of postoperative pain in patients [36]. This scale was chosen for its high sensitivity and ability to detect subtle variations in pain intensity, which was essential for evaluating the effectiveness of the intervention. Furthermore, the Visual Analogue Scale (VAS) is a linear scale specifically designed for measuring severe acute pain [37].

The VAS used here was a 10-cm straight line with 'no pain at all' at one end and 'pain as bad as it could be' at the other. Respondents were asked to mark a point on the line that best represented their pain intensity. The distance (in cm) between the 'no pain at all' end and the mark indicated the VAS rating of pain intensity. This scale is a continuous line, where 0 represents 'no pain' and 10 represents 'worst imaginable pain'. Participants were asked to place a mark on the line that represented their current pain intensity, and the distance from the 0 point was measured in centimeters to quantify the pain [36, 38].

Ethical considerations

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the Non-Interventional Research Ethics Committee of Hasan Kalyoncu University (Approval Date: 24.07.2023, Approval Number: 2023/064). Additionally, institutional permission was granted by the Gaziantep Provincial Health Directorate for data collection within hemodialysis units (Approval No: E-87825162-663.08-227120911). Informed consent was obtained from all individual participants included in the study.

Patient and public involvement in research

In this study, patients were not directly involved in the conceptualization, design, or conduct of the research. However, their experiences and feedback were considered during the data collection process to ensure the relevance and applicability of the findings. The results of the study will be disseminated to the participants through informational sessions at the hemodialysis unit where the study was conducted. Future studies may include more direct involvement of patients and the public in the research process to enhance the study's impact and relevance.

Statistical analysis

The data obtained in this study was analyzed using version 2.3.21 of the JAMOV software. The Shapiro-Wilk test assessed whether the data followed a normal

Table 1 The distribution of demographic and clinical characteristics of Hemodialysis patients between groups

Variables	Control group (n=32)	Stress ball group (n=32)	Test (χ^2/t) p
Age (year)	56.06 ± 13.88	52.12 ± 13.35	1.156 ^c 0.252
Hemodialysis duration (months)	72.65 ± 32.00	61.96 ± 39.06	1.197 ^c 0.236
Fistula age (months)	55.25 ± 26.86	41.00 ± 27.19	2.108 ^c 0.036
Gender			
Female	28(87.5)	13(40.6)	15.270 ^a
Male	4(12.5)	19(59.4)	< 0.001
Education status			
Illiterate	24(75)	16(50)	4.916 ^a
Literate	7(21.9)	12(37.5)	0.178
Primary & High School	1(3.1)	4(12.5)	
Chronic disease			
Yes	24(75)	21(65.6)	0.674 ^a
No	8(25)	11(34.4)	0.412
Dialysis shift			
Morning	23(71.9)	18(56.3)	1.697 ^a
Afternoon	9(28.1)	14(43.7)	0.193
Fistula location			
Brachiocephalic	9(28.1)	13(40.6)	1.108 ^a
Radiocephalic	23(71.9)	19(59.4)	0.292
Needle rotation			
Yes	5 (15.6)	1(3.1)	2.943 ^b
No	27(84.4)	31(96.9)	0.086

^a Chi-square; ^b Fisher's exact test; ^c Student's t test. Data was presented mean ± standard deviation or n (%)

distribution. The study's main analyses included comparing the VAS scores according to group and time factors. The Robust ANOVA method via the Walrus package was preferred for these data that did not comply with a normal distribution. The Bonferroni correction was applied to control the risk of type I errors during multiple comparisons. When presenting the data, median values (minimum-maximum) were used to show the changes over time and between groups. $P < 0.05$ was accepted as the level of statistical significance. Additionally, graphs were prepared with the Graph Pad software to represent the visual changes in the VAS score over time.

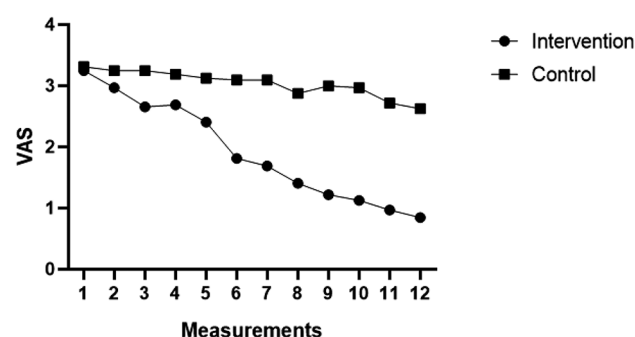
Results

The results of the group comparisons regarding the descriptive characteristics of the participants are presented in Table 1. The mean age of the patients in the control group was 56.06 ± 13.88 years; the mean hemodialysis duration was 72.65 ± 32.00 months; the mean fistula age was 55.25 ± 26.86 months; chronic disease was present in 75%, and needle rotation was being used in 3.1%. The mean age of the patients in the intervention

Table 2 Comparison of pain scores between intervention and control groups by group and time

	Test statistic (f)	p
Group	39.40	< 0.001*
Time	7.350	< 0.001*
Group * Time	23.33	0.016*

f=Robust ANOVA, The median was used as the comparison method. * $p < 0.05$ statistically significant

**Fig. 2** Changes in pain intensity over time for intervention and control groups. VAS: Visual Analog Scale

group was 52.12 ± 13.35 years, mean hemodialysis duration was 61.96 ± 39.06 months, mean fistula age was 41.00 ± 27.19 months, a chronic disease was present in 65.6%, and needle rotation was being used in 15.69%. Except for gender and fistula age ($p < 0.05$), no statistically significant differences were observed between the groups ($p > 0.05$). The effects of stress ball use on the invasive pain experienced during cannulation in hemodialysis patients were evaluated using Robust ANOVA. Regarding the group factor, the median VAS value of the study group ($n = 32$) was found to be statistically significantly lower than the median value of the control group ($n = 32$) ($p < 0.001$). Regarding the time factor, a statistically significant decrease in VAS scores was found throughout the 12 sessions ($p < 0.001$). The effect of stress ball use gradually increased with group and time interaction ($p = 0.016$) (Table 2). Pain intensity was measured using the VAS, the intervention group ($n = 32$) used stress balls, while the control group ($n = 32$) received routine care. A significant reduction in pain intensity over time was observed in the intervention group compared to the control group ($p < 0.001$). Error bars represent the standard error of the mean (Fig. 2).

When the effect of stress ball use on invasive pain in hemodialysis patients was evaluated in detail with the VAS pain scores that varied over time, the median VAS score of the intervention group in Session 1 was 3.0 (min-max=0.0–9.0). This value increased to 1.0 (min-max=0.0–7.0) in session 12, and a significant statistical difference was identified ($p < 0.001$). The median VAS values were 3.0 (min-max = 1.0–9.0) in Session 1 and Session

Table 3 Median pain scores across 12 sessions with statistical comparisons between groups and over time

Time	Group		Total	p
	Stress ball	Control		
	Median (min-max)	Median (min-max)	Median (min-max)	Between Sessions
Session 1	3.0 (0.0–9.0) A	3.0 (1.0–9.0) A	3.0 (0.0–9.0) a	Session 1 vs. 12 $p < 0.001$
Session 2	3.0 (0.0–9.0) AB	3.0 (1.0–9.0) A	3.0 (0.0–9.0) ab	Session 2 vs. 12 $p < 0.001$
Session 3	2.0 (0.0–9.0) ABC	3.0 (1.0–9.0) A	3.0 (0.0–9.0) abcd	Session 3 vs. 12 $p < 0.001$
Session 4	3.0 (0.0–9.0) AB	3.0 (1.0–9.0) A	3.0 (0.0–9.0) abc	Session 4 vs. 12 $p < 0.001$
Session 5	2.0 (0.0–9.0) BC	3.0 (1.0–9.0) AB	2.0 (0.0–9.0) abcde	Session 5 vs. 12 $p < 0.001$
Session 6	1.0 (0.0–7.0) CD	3.0 (0.0–9.0) A	2.0 (0.0–9.0) bcdef	Session 6 vs. 12 $p < 0.001$
Session 7	1.0 (0.0–7.0) CDE	3.0 (0.0–9.0) A	2.0 (0.0–9.0) cdef	Session 7 vs. 12 $p < 0.001$
Session 8	1.0 (0.0–7.0) DEF	2.0 (0.0–7.0) AB	2.0 (0.0–7.0) def	Session 8 vs. 12 $p < 0.001$
Session 9	1.0 (0.0–7.0) DEF	2.0 (0.0–9.0) AB	2.0 (0.0–9.0) def	Session 9 vs. 12 $p < 0.001$
Session 10	0.0 (0.0–7.0) EF	2.0 (0.0–9.0) AB	2.0 (0.0–9.0) ef	Session 10 vs. 12 $p < 0.001$
Session 11	1.0 (0.0–7.0) F	2.0 (0.0–9.0) AB	2.0 (0.0–9.0) f	Session 11 vs. 12 $p < 0.001$
Session 12	1.0 (0.0–7.0) F	2.0 (0.0–9.0) ABC	1.0 (0.0–9.0) f	-
Total	2.0 (0.0–9.0)	3.0 (0.0–9.0)	2.0 (0.0–9.0)	-

A-F (For stress ball and control Groups): Values with the same letter within each group (intervention or control) indicate no statistically significant difference. Different letters represent significant differences between groups or sessions

A-F (For Total): Values with the same letter in the total column indicate no statistically significant difference in the median values across sessions. Different letters signify significant changes over time

2, decreasing to 2.0 (min-max = 0.0–9.0) by Session 12 in the control group (Table 3).

Statistically significant differences were found between the study and control groups in the comparisons between sessions. VAS median values at Session 6 and Session 7 were found to be 1.0 (min-max = 0.0–7.0) in the study group and 3.0 (min-max = 0.0–9.0) in the control group. These differences between sessions were found to be significant due to additional statistical evaluations performed by applying the Bonferroni correction ($p = 0.028$ for Session 1 - Session 6; $p = 0.037$ for Session 1 - Session 7) (Table 3; Fig. 2).

Discussion

This study revealed that the stress ball effectively reduces invasive pain experienced during the cannulation procedure in hemodialysis patients.

Since hemodialysis is a tiring and long-term treatment that may be necessary two or three times a week in certain patients, the pain experienced during the cannulation process can be unnerving, may increase their fear and anxiety, and reduce compliance with the treatment process [8, 33, 39]. The current study evaluated the effect of stress ball use on invasive pain in hemodialysis patients and found the pain level in the intervention group using the stress ball to be significantly lower than in the control group. A significant reduction in pain levels was also observed over time, indicating that the effect of stress ball use increased over time in the intervention group. When the sessions were examined in detail, lower pain levels were detected in the intervention group compared to the control group as the sessions progressed. However, as this study was conducted in a single-center

setting, the generalizability of the findings may be limited. Patient populations in other settings might differ in terms of demographics, comorbidities, and treatment practices, which could influence the outcomes of stress ball use. Future multi-center studies with a more diverse patient population are needed to confirm and extend these results.

Some studies have reported that non-pharmacological methods are easier and more economical than pharmacological methods in reducing pain during hemodialysis cannulation [1, 7, 15, 32]. These methods work by reducing the perception of pain or diverting attention from its source. This diversion decreases the processing of pain signals in the brain, allowing the patient to feel less pain. By decreasing the individual's focus on the pain, non-pharmacological methods effectively reduce the intensity of pain experienced [20, 21]. Such techniques, including distraction methods like stress balls, have become increasingly popular due to their minimal risk of side effects and cost-effectiveness [26, 40]. Our findings align with prior research demonstrating the efficacy of distraction techniques, such as stress balls, in reducing pain and anxiety during invasive procedures. For instance, Dinish and Sousa (2023), in their pilot study, reported that the use of stress balls during hemodialysis cannulation significantly reduced pain compared to the control group, emphasizing the similarity in mechanisms with other non-pharmacological approaches [1]. Similarly, Karatas et al. (2023) observed significant reductions in pain and anxiety during endoscopy when stress balls were used as a distraction tool [16]. Yılmaz and Güneş (2018) further highlighted the effectiveness of distraction methods, including stress balls, during peripheral intravenous

catheterization, demonstrating their broader applicability in pain management [18]. Additionally, studies have explored the benefits of distraction techniques in diverse clinical settings. Research evaluating various distraction techniques during angiography and outpatient gynecological procedures has shown significant reductions in both anxiety and pain levels, while also improving patient satisfaction [17, 41]. Similarly, Shekhar et al. (2022) investigated the effects of active and passive distraction techniques during local anesthesia administration in pediatric dental procedures [19]. Their randomized controlled trial demonstrated that active distraction methods, such as the use of stress balls, were significantly more effective in reducing dental anxiety, improving behavioral responses, and minimizing pain levels compared to passive techniques like audiovisual glasses. These findings further highlight the versatility and effectiveness of active distraction methods in managing procedural pain and anxiety across different patient populations. In light of these findings, using a stress ball to manage pain in hemodialysis patients provides an easy and economical solution. Furthermore, the observed increase in its effectiveness over time highlights its potential as a sustainable method for pain management in both adult and pediatric populations. Future research should continue exploring its application in different clinical settings and among diverse patient populations to confirm its utility and optimize its implementation.

Strength and limitations

The most notable strength of this study is that it is the first to examine the impact of a stress ball on invasive pain over an extended period (12 sessions) within the literature. However, the study has some limitations. Firstly, the assessment of pain severity relied on self-reported, inherently subjective measures. Secondly, since the study was conducted at a single center, the findings may not be generalizable to the entire population of hemodialysis patients in Turkey. Thirdly, as the study was single-blinded, potential biases cannot be completely ruled out. While participants were blinded to the specific purpose of stress ball use, future studies could incorporate double-blind designs to minimize potential biases. Additionally, a study design where both the researchers and the statistician analyzing the data are blinded to the group allocations could be implemented. Future research should include multi-center trials with larger sample sizes and consider blinding both participants and researchers wherever possible.

Conclusion

This study indicates that using a stress ball during cannulation for hemodialysis patients may effectively reduce pain severity. Additionally, it was observed that the pain

reduction became more significant with increasing sessions. We recommend integrating active distraction methods, such as stress ball use, into routine clinical practices to reduce procedural anxiety and pain across diverse patient populations. Additionally, combining these methods with other non-pharmacological interventions, such as aromatherapy, guided imagery, or music therapy may enhance their effectiveness and offer more comprehensive management of anxiety and pain. Future research should focus on exploring these combinations and conducting multi-center, large-scale studies to validate findings across different clinical settings and patient demographics.

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Author contributions

Substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work: B.T., S.B., E.D., N.Ö. Drafting the work or revising it critically for important intellectual content: B.T., S.B., E.D., N.Ö. Final approval of the version to be published: B.T. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: B.T., S.B., E.D., N.Ö.

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Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the Non-Interventional Research Ethics Committee of Hasan Kalyoncu University (Approval Date: 24.07.2023, Approval Number: 2023/064). Additionally, institutional permission was granted by the Gaziantep Provincial Health Directorate for data collection within hemodialysis units (Approval No: E-87825162-663.08-227120911). Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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