

The effect of a stress ball on pain and anxiety during sharp debridement in patients with diabetic foot ulcers: A randomized controlled, single-blind study

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ABSTRACT

Objective: The aim of this study was to investigate the effect of using a stress ball during sharp debridement on the pain and anxiety in patients with diabetic foot ulcers.

Methods: This study with a randomized, controlled and single-blind design was conducted at a single-center on patients diagnosed with diabetic foot ulcers who were being treated at the endocrinology and metabolic diseases clinic of a university hospital. Patients in the intervention group started using a stress ball before the debridement procedure and continued to use it until the procedure ended. No intervention was made to the patients in the control group. Data were collected by using the Descriptive Information Form, Diabetic Foot Meggit-Wagner Classification, Visual Analogue Scale (VAS), and State Anxiety Inventory (STAI).

Results: The study was completed with a total of 76 patients, 38 each in the intervention and control groups. The use of stress balls led to a reduction in anxiety and pain symptoms in the intervention group. The anxiety score of the patients in the intervention group was also found to be statistically significantly lower than those in the control group after the procedure ($p = 0.008$; $\eta^2 = 0,091$). The VAS scores of the patients in the intervention group were found to be statistically significantly lower than those in the control group both during ($p < 0.001$; $\eta^2 = 0.348$) and after ($p < 0.001$; $\eta^2 = 0.438$) the procedure.

Conclusions: The use of a stress ball was found to be an effective method of reducing the level of pain and anxiety that occurs during the sharp debridement procedure. Stress ball application is a practical, easy, and cost-effective non-pharmacological method.

Clinical trial number: The study was recorded in the ClinicalTrials.gov website with the number NCT06316115.

1. Introduction

Diabetes is one of the fastest-progressing global health problems of the 21st century and affects approximately half a billion people around the world [1]. According to the current data of the World Health Organization, diabetes has been diagnosed in 422 million people and has been found to be related to the cause of death of 1.6 million people every year [2] Approximately half of the diabetic population is at risk for developing foot ulcers [3]. The result of a prevalence study conducted in

our country has reported that more than 1 million of the 7 million patients with diabetes had developed diabetic foot ulcer (DAU) and nearly 500,000 patients had diabetic foot infection [4]. Diabetic foot ulcers cause deterioration of the patient's quality of life, significantly increase treatment costs, and result in lower extremity amputations and increased mortality. Diabetic foot patients make up 50–70 % of non-traumatic foot amputations [5].

Diabetic foot ulcer management includes various practices such as wound debridement, infection control, and monitoring ulcer healing.

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Wound debridement is considered an important intervention in the treatment of diabetic foot ulcers as it accelerates ulcer healing and decreases the risk of complications. Various debridement approaches including sharp, surgical, hydro surgery, and biological debridement are available [6]. Sharp debridement is a procedure in which trained healthcare professionals use sterile instruments to remove nonviable tissue, crust, callus, and other contaminants from the wound bed [7,8]. This intervention helps stimulate the formation of healthy granulation tissue, decreases bacterial load, and facilitates wound healing but it is a painful procedure [7]. Guidelines issued by the International Diabetic Foot Working Group (IWGDF) in May 2023 emphasize that no debridement method can completely replace sharp instrument debridement as the gold standard approach [9]. The most important problems during wound care of patients diagnosed with diabetic foot ulcers are “pain” and “anxiety”, and these are nursing diagnoses that nurses should manage [10]. The pain and anxiety felt during sharp debridement make it difficult to perform the debridement procedure effectively and delays wound healing. Methods such as massage, behavioral and cognitive therapies, interventional nerve blocks, electro-acupuncture, transcutaneous electrical nerve stimulation, ultrasound therapy, cold saline application, and topical local analgesics are reported to reduce the pain and anxiety associated with the debridement procedure [10–13]. The method of diverting attention, which is among cognitive therapies, is known as a technique that aims to reduce and control the perception of pain by drawing the relevant receptors of the brain to another point faster than the painful stimulus impulses. A stress ball is one of the non-pharmacological methods used to divert the attention of individuals when they consciously focus on a stimulus [14].

Stress balls have recently been used to reduce stress, tension, and anxiety in certain studies [15–17]. By squeezing the ball, the nerves in the hands are stimulated and signals are sent to the limbic region of the brain, providing an acupressure effect. It is also the easiest and cheapest method to get rid of stress and maintain the person’s mental wellbeing [14]. When we examined the literature, using a stress ball during the endoscopy procedure was reported to have positive effects on pain and anxiety reduction, and patient satisfaction [18]. The use of a stress ball has been found to positively affect the vital signs and decrease the pain during a transrectal prostate biopsy procedure [19], and also have a positive effect on anxiety during skin cancer excision [17]. To our knowledge, there is no study in the literature regarding the use of a stress ball to prevent the pain and anxiety during sharp debridement. In line with this information, the current study investigated the effect of using a stress ball on the pain and anxiety levels of patients with diabetic foot ulcers during wound debridement.

1.1. Study hypotheses

H11. The use of a stress ball in patients with diabetic foot ulcers has an effect on reducing the severity of the patients’ pain during the sharp debridement procedure.

H12. The use of stress ball in patients with diabetic foot ulcers has an effect on reducing the patients’ state anxiety level during the sharp debridement procedure.

2. Methods

2.1. Study design

This study was conducted with a randomized, controlled, single-blind (evaluator-blind) design. The results were reported based on the CONSORT and TIDier Checklist.

2.2. Setting and participants

This study included patients who were treated at the endocrinology and metabolic diseases clinic of a university hospital in Turkey between December 2023 and March 2024. Inclusion criteria were receiving inpatient treatment at the department; aged 18 years and over; diagnosed with diabetic foot ulcer; the physician’s decision to perform sharp debridement for the first time; pain ≥ 1 according to the Visual Analogue Scale (VAS) before the procedure; no hand/arm problem that would prevent using the stress ball; able to communicate in Turkish; no disorder that would prevent communication (psychological or related to hearing and understanding, etc.); and volunteering to participate in the study. Patients for whom an intervention to reduce pain was decided on before sharp debridement (local anesthesia, nerve blockade, opioid analgesics, etc.) and patients who applied non-pharmacological methods to reduce the pain before the procedure were not included in the study.

2.3. Study sample

This study was conducted at the endocrinology and metabolic diseases clinic of a university hospital. The annual number of patients hospitalized with diabetic foot ulcer treatment was 543, and the sample calculation of the study was determined by using the G*Power program. A study that investigated the effect of a stress ball on pain in invasive procedures was taken as the reference in the calculation of the sample since there was no previous study conducted in the same study group [19]. Predicting that the difference between pain intensities would be evaluated with t test, and that the effect value would be 0.70 with a 95 % confidence interval and 80 % power, it was calculated that 34 participants would be sufficient for the sample. Considering possible losses from the study (hospitalization, death, changing treatment center, etc.), a total of 76 patients, with 38 in each group, was included in the study.

2.4. Data collection tools

2.4.1. Descriptive information form

The descriptive information form was created by evaluating the studies conducted with patients diagnosed with diabetic foot ulcer [10, 20–22]. A total of 13 questions were asked about the patient’s year of birth, education level, employment status, income level, place of residence, year of diabetes diagnosis, etc. in the descriptive information form.

2.4.2. Diabetic Foot Meggit-Wagner Classification

The Meggitt-Wagner classification was developed in 1976 by Meggitt and was edited in 1981 by Wagner. This classification system, which is based on the depth of the wound and graded in six categories from stage 0 to stage 5 according to the presence of osteomyelitis and gangrene is evaluated with observational findings, excluding ulcer depth [23]. Signs of ischemia and infection are limited and do not include the presence of neuropathy. However, it is known that evaluating these factors has positive effects during the healing process of diabetic foot ulcers [24]. Wound classification was evaluated by a physician specialized in endocrinology and metabolic diseases and recorded by a nurse independent of the study.

2.4.3. Visual analogue scale

The Turkish validity and reliability of the scale, which was developed by Price et al. (1994) to evaluate the severity of the pain, was conducted by Eti Aslan (2004) by evaluating the presence of pain in the post-operative period. 0 means “I have no pain” and 10 means “I have unbearable pain” on the scale graded from 0 to 10. Written permission for the use of the scale was received via an e-mail from Eti Aslan. The intensity of the pain before, during (10 min after debridement started), and after debridement was recorded by a nurse independent of the study. A total of 3 VAS values were obtained [25].

2.4.4. State anxiety scale (STAI)

The State Anxiety Scale (STAI-I) was developed in 1970 by Spielberger, and the Turkish form was adapted and a validity-reliability study conducted by Öner N et al. [26]. The anxiety level is scored as "(1) not at all, (2) a little, (3) a lot, and (4) completely" in STAI-I. The highest score is 80 and the lowest score is 20. Higher total anxiety scores indicate higher anxiety levels. The Cronbach Alpha internal consistency coefficient of the scale was found to be between 0.94 and 0.96 [26]. Cronbach's Alpha coefficient was found to be 0.91 and the interclass correlation coefficient (ICC) to be 0.91 in the first measurement in this study. The anxiety level of the patients was evaluated twice in total, before and during the debridement procedure (at the 10th minute following the start of debridement) by a nurse independent of the research.

2.5. Data collection

The data were collected from the patients after their written consent for participation in the study was obtained. The descriptive information form of the patients who met the study criteria was filled out in the patient room 30–60 min before the debridement procedure, without hindering the treatment and care provided, without interfering with the routine of the healthcare personnel, and without causing a change in the sharp debridement procedure. The state anxiety scale was evaluated before and during debridement and recorded by a nurse independent of the study.

2.5.1. Intervention

A stress ball, one of the nonpharmacological methods, was used in the study. Squeezing a stress ball activates the muscles in the hand and arm, stimulates the release of endorphins, helps clear the mind, improves concentration, and serves as a simple technique for managing pain and anxiety [15]. The literature indicates that the use of a stress ball during endoscopy procedures positively impacts pain, anxiety, and patient satisfaction [18], as well as pain and vital signs during transrectal prostate biopsy procedures [19], and reduces anxiety during skin cancer excisions [17]. The stress ball used (with a diameter of 3 cm) was round in shape and made of medium hardness high-quality silicone. It was obtained by the researchers and given to the patients.

2.5.2. Before the sharp debridement procedure

- Patients in the intervention group were informed about the intervention.
- Before starting the study, the patients were provided a theoretical explanation and a practical demonstration on how to use the stress ball.
- The pain of the patients was evaluated and recorded by a nurse independent of the study.
- The anxiety was evaluated and recorded by the same person before and after the debridement procedure.
- The patient was asked to use the ball and correct use was confirmed.
- Patients were asked to count to three, squeeze the ball once and then release it, inhaling each time they squeezed the ball and exhaling each time they released it [14,16].
- A nurse independent of the study gave the patients a stress ball 5 min before the debridement procedure and asked them to start using it.

2.5.3. During the sharp debridement procedure

- The debridement procedure was performed by the same person on each patient.
- Each debridement took approximately 20–30 min and the patient continued to use the ball.

- Patients were instructed to count to three as previously taught, squeezing the ball once and then releasing it. They inhaled with each squeeze and exhaled with each release.
- The pain of the patients was evaluated and recorded by a nurse independent of the study during the procedure (at the 10th minute following the start of debridement).
- The anxiety was evaluated and recorded by the same person during the debridement procedure.

2.5.4. After the debridement procedure

- The patient stopped using the ball immediately after the debridement procedure was completed.
- The patient did not use a ball after debridement while the wounds were being covered with dressing material.
- The pain of the patients was evaluated and recorded by a nurse independent of the study and immediately after the procedure was completed.

2.5.5. Control group

The routine debridement procedure was applied to the patients in the control group by the same person. Apart from this, no additional intervention was implemented. Each patient's pain was evaluated and recorded by a nurse independent of the study before, during (at the 10th minute following the start of debridement), and after the debridement procedure. Similarly, the patient's anxiety was evaluated and recorded before and during the debridement procedure (at the 10th minute following the start of debridement) by a nurse independent of the study.

2.5.6. Randomization and blinding

The patients were assigned into the experimental and control groups using the [random.org](https://www.random.org) program (<https://www.random.org>). Even numbers were assigned to the experimental group and odd numbers to the control group, so that equal assignments were made to both groups. The intervention was carried out at the department by the researcher, who was a specialist nurse. Classification of the wound area and sharp debridement were performed by a trained endocrinology and metabolic diseases specialist physician independent of the study. The tests before and after the procedure in the study were performed by a clinical nurse independent of the study. Thus, the subjects were not informed about which group they were in and the data was blinded to the researchers. The data were entered into the statistical program by an independent researcher, and the analyses were carried out by another independent researcher (Fig. 1).

2.6. Data analysis

IBM SPSS Statistics for Windows, version 23.0, was used for data analysis, with frequency distribution (number and percentage) for categorical variables and descriptive statistics (mean, standard deviation, median, and interquartile range). The normal distribution of the numerical variables was assessed with the Kolmogorov–Smirnov and Shapiro–Wilk tests. One-way analysis of variance was used to determine the differences between the two groups for variables with a normal distribution. Categorical variables were analyzed with the chi-squared test. Variables without normal distributions were evaluated with the Mann–Whitney U test (assessment of the differences between two groups). Eta squared values were used to represent the measure of effect size, where 0.01 indicates a small effect size, 0.06 a medium effect size, and 0.14 or higher a large effect size. Reliability analyses were evaluated with Cronbach's Alpha coefficient and the interclass correlation coefficient (ICC).

2.7. Ethical approval and informed consent statements

Data were collected after obtaining written permission from the XXX

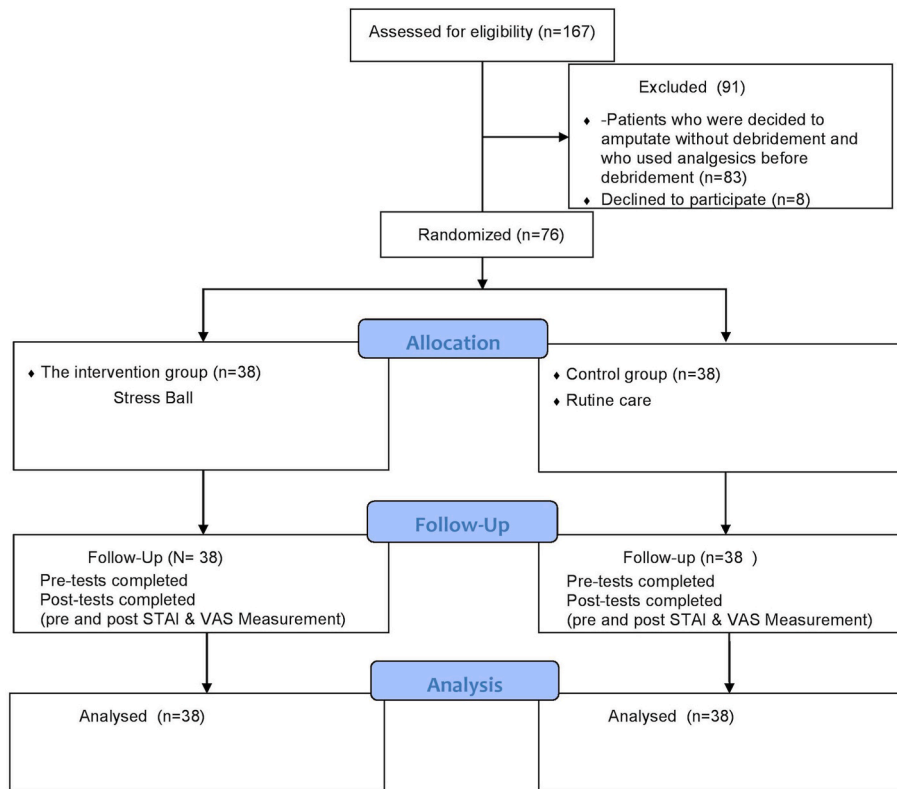


Fig. 1. CONSORT study follow diagram.

University Health Sciences Ethics Committee (Decision No: XXX), the institution where the study was conducted, and from the researchers and the patients participating in the study for the scales to be able to conduct the study. The Declaration of Helsinki was applied at every stage of the research. The purpose of the study was explained to each patient participating in the study, and they were informed that it was voluntary and that the data collected for the study would be used for scientific purposes.

3. Results

The study was completed with a total of 76 patients, 38 in the intervention group and 38 in the control group. No difference was present between the intervention and control groups in terms of socio-demographic and clinical variables ($p > 0.05$) (Table 1).

After the procedure, the State Anxiety Scale (STAI) scores of the patients in the control group were found to be statistically significantly higher than those in the intervention group ($p = 0.008$; $\eta^2 = 0.091$) (Table 2, Fig. 2). The pain intensity scores of the intervention group were found to be statistically significantly lower than the control group both during ($p < 0.001$, $\eta^2 = 0.348$) and after ($p < 0.001$, $\eta^2 = 0.438$) the procedure (Table 2, Fig. 3). No participants reported any discomfort related to stress ball use.

4. Discussion

This study, which is the first known study to investigate the effect of using a stress ball on the pain and anxiety during the sharp debridement procedure, found diverting patients' attention by using a stress ball to be an effective method to reduce the level of pain and anxiety that occurred during the procedure.

Increased pain occurs during the sharp debridement procedure due to cell damage and neural stimulation [10,27]. There are a limited number of studies on the use of non-pharmacological methods to reduce

pain during debridement [12]. The patients in the intervention group, where the stress ball was used, were found to feel less pain during and after sharp debridement in this study. The effect size of the difference between the groups regarding pain intensity was high. When the literature was examined, the use of a stress ball was found to decrease the pain felt by the patients undergoing transrectal prostate biopsy [19], and decrease the pain felt by hemodialysis patients during vascular access cannulation [28]. The hand nerves are stimulated by squeezing the ball, and the stimuli are sent to the limbic region of the brain. The effect stimulates the nervous system and reduces the amount of stress hormones. Stimulating certain points of the palms with pressure causes the release of endorphins that fight cortisol in the body. Besides, cortisol leads to vasodilation in blood vessels and an increase in tissue oxygenation. The pain may be reduced as a result of these changes [16].

The anxiety that occurs with increased pain during the sharp debridement procedure is one of the most important problems that patients with diabetic foot ulcers face during wound care. In the current study, the anxiety levels felt by the intervention group during the procedure were found to be lower than in the control group. The effect size of the anxiety level difference between the groups during the procedure was moderate to high. When we examine the literature, some other studies also support this finding. The study of Özen et al. (2023) [16], has found using a stress ball for four weeks to be an effective method in reducing anxiety levels in hemodialysis patients. Other studies have also reported that using a stress ball reduces the level of anxiety perceived by hemodialysis patients [15], and is effective in reducing the level of anxiety felt during endoscopy [18]. Anxiety is a strong emotional response that occurs due to beliefs about danger and uncontrollability. It is an emotion that can be affected by individuals' expectations, interpretations, perception of danger, and cognitive distortions [29]. We can conclude in this study that the relaxation provided by hand movements while using a stress ball and drawing attention to a different stimulus helps patients relax mentally and reduces their anxiety levels.

Table 1
Baseline demographics and clinical characteristics of the intervention and control groups (n = 76).

Variables	Intervention Group	Control Group	p
Age	59.02 ± 9.96	56.39 ± 8.51	0.22
DM diagnosis duration (year)	19 [10.75–26.25]	13 [5.75–23.5]	0.08
Diabetic foot duration (day)	25 [17.75–45]	22 [15–30]	0.13
Gender			
Male	27 (71)	23 (60.5)	0.46
Female	11 (29)	15 (39.5)	
Place of Residence			
Village	9 (24)	13 (34)	0.351
County	11 (29)	13 (34)	
Province	18 (47)	12 (32)	
Educational Status			
Illiterate	17 (45)	11 (29)	0.34
Primary School	12 (32)	15 (40)	
Middle School	7 (18)	12 (31)	
High School	2 (5)	–	
Working Status			
Working	5 (13)	11 (29)	0.79
Not Working	33 (87)	27 (71)	
Income Status			
Less than expenses	3 (8)	3 (8)	0.69
Equals expenses	33 (87)	31 (82)	
Exceeds expenses	2 (5)	4 (10)	
Marital Status			
Married	30 (79)	28 (74)	0.394
Single	8 (21)	10 (26)	
Co-morbidity			
None	12 (32)	11 (29)	0.791
Hypertension	25 (65)	25 (65)	
Cardiac problems	1 (3)	1 (3)	
Chronic renal failure	–	1 (3)	
Previous History of Diabetic Foot			
Yes	15 (40)	20 (53)	0.179
No	23 (60)	18 (47)	
Smoking			
Yes	12 (32)	17 (45)	0.173
No	26 (68)	21 (55)	
Alcohol use			
Yes	3 (8)	–	0.12
No	35 (92)	38 (100)	
Diabetic Foot Ulcer Stage			
Extending into subcutaneous tissue	17 (45)	19 (50)	0.89
Deep ulcer	19 (50)	17 (45)	
Limited ulcer	2 (5)	2 (5)	

Data were presented as median [IQR], mean ± SD, or n (%).

A: One-Way Anova, C: Chi-Square, a: Mann-Whitney U.

Table 2
Anxiety and pain scores differences between intervention and control groups (n = 76).

Time	Intervention N = 38	Control N = 38	p	Effect Size (η ²)
STAI –I Anxiety Scores				
Pre-intervention	40.5 [38–42]	41 [40–42]	0.144	0.028
During intervention	41 [40–43]	42 [41–44]	0.008^a	0.091
VAS Pain Scores				
Pre-intervention	6 [4–8]	5 [4–6]	0.224	0.019
During intervention	5 [4–6]	8 [6.75–10]	<0.001^a	0.348
Post-intervention	4 [2.75–5]	8 [7–9.25]	<0.001^a	0.438

Data was presented as median [IQR].

Bold values are statistically significant, p < 0.05.

a: Mann-Whitney U test.

^a Difference: **Control > Intervention.**

4.1. Strengths and limitations

The study had several strengths. Firstly, it is the first known randomized controlled study in the literature to evaluate the effect of using a stress ball during sharp debridement. Another strong aspect of the

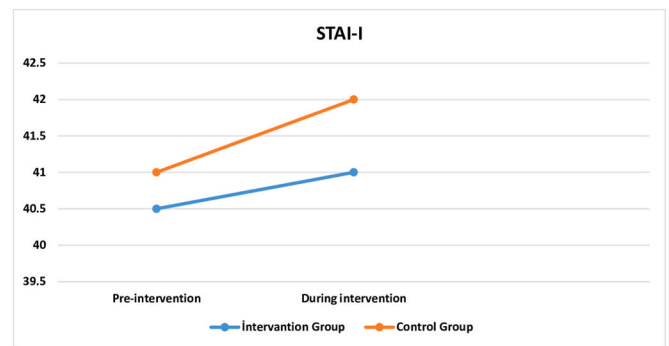


Fig. 2. The state anxiety levels of the patients before and during the debridement procedure.

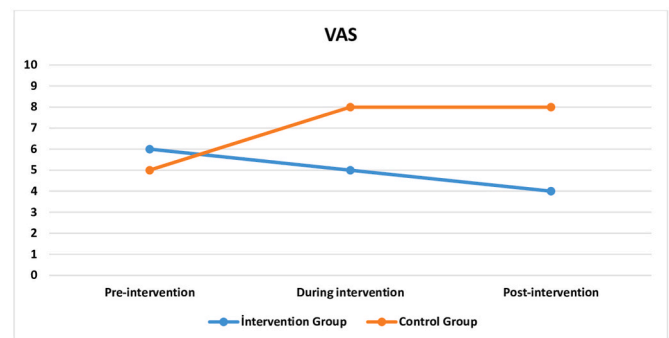


Fig. 3. The pain levels of the patients before, during, and after the debridement procedure.

study is that it demonstrates that the patient’s pain can be reduced with a stress ball, which is an easily accessible, cost-effective, and non-pharmacological method, instead of relying on pharmacological treatment. Finally, the evaluator was blinded in the study, increasing the methodological integrity.

The study also had some limitations. The efficiency of the stress ball was evaluated during a single debridement session for each patient in this study. New studies can be conducted in which patients use stress balls during multiple debridement applications and where pain, anxiety, and other parameters are monitored. Blinding was not performed for the patients as it was not feasible for the intervention procedures. We used stress balls for only one session and did not evaluate their long-term effects. We did not record the potential confounding variables such as overall health status or concurrent treatments. Lastly, the results cannot be generalized to all patients undergoing sharp debridement because the current study was conducted at a single center.

5. Conclusion

Using a stress ball is a practical, easy, economical, and non-pharmacological method. It can be employed routinely to reduce the level of pain and anxiety that occurs during the debridement procedure. Future studies could be conducted to compare it with different non-pharmacological methods to reduce pain and anxiety. It can also be used together with pharmacological methods in order to reduce the use of the latter methods to decrease pain. Additional studies examining the effects on wound healing and patient satisfaction are also necessary.

In conclusion, the use of a stress ball was found to be effective in reducing the level of pain and anxiety during sharp debridement.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethical approval and informed consent statements

Data were collected after obtaining written permission from the Hasan Kalyoncu University Health Sciences Ethics Committee (Decision No: 2023/87), the institution where the study was conducted, and from the researchers and the patients participating in the study for the scales to be able to conduct the study. The Declaration of Helsinki was applied at every stage of the research. The purpose of the study was explained to each patient participating in the study, and they were informed that it was voluntary and that the data collected for the study would be used for scientific purposes.

Author contributions

Conception and design of the study, drafting the article writing: Fatma Aslan, Nurten Ozen. Acquisition of data, analysis of data, supervision, reviewing: Betül Tosun. Conception and design of the study, drafting the article writing, supervision, reviewing: Nurten Özen. Analysis of data, drafting the article writing, reviewing: Neşe Altınok Ersoy

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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