ORIGINAL ARTICLE

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Effect of coolant spray on rib fracture pain of geriatric blunt thoracic trauma patients: a randomized controlled trial

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SUMMARY

OBJECTIVE: This study aimed to evaluate the effectiveness of cryotherapy in elderly patients with rib fractures due to blunt thoracic trauma.

METHODS: In this prospective randomized controlled study, geriatric patients were assigned to groups to receive either coolant spray (n=51) or placebo spray (n=50). The visual analog scale scores of all patients were recorded before starting spray application (V0), as well as at 10th (V1), 20th (V2), 30th (V3), 60th (V4), 120th (V5), and 360th (V6) minute. The mean decreases in the visual analog scale scores were calculated.

RESULTS: The differences between V0 and V1, V0 and V2, V0 and V3, and V0 and V4 mean visual analog scale scores measured in the coolant spray group were found to be significantly higher ($p<0.001$). In V1, V2, V3, and V4 measurements, the incidence of "clinical effectiveness" in the coolant spray group was significantly higher than in the placebo group ($p=0.001$).

CONCLUSIONS: Coolant spray therapy can be used as a component of multimodal therapy to provide adequate analgesia due to rib fractures in geriatric patients.

KEYWORDS: Acute pain, coolant spray, cryotherapy, geriatric, rib fracture, trauma

INTRODUCTION

Rapid growth in the geriatric population and their efforts to lead an independent and active life has led to a significant increase in the number of geriatric cases admitted to trauma units of emergency departments (ED)[1]. For these vulnerable patients, "pain" due to trauma is a complicated situation that affects the quality of life and behavior, impairs cognitive function, worsens the course of comorbid diseases, and can lead to death.

In the geriatric population, thoracic injuries are the second most common injury after head injuries[2]. In older patients, thoracic injuries may occur even with low-energy mechanisms due to lower bone density and reduced chest wall elasticity[3]. The most common injury due to blunt thoracic trauma in this population is the fracture of the rib(s)[4]. The pain caused by rib fractures is a serious symptom, and it is challenging to manage[5].

In daily practice, both pharmacological and invasive methods (e.g., epidural catheters, intercostal, paravertebral, and interpleural blocks) are used to ensure adequate analgesia in rib fractures[6]. Cryotherapy application is frequently used to treat acute pain due to musculoskeletal trauma. The primary mechanism in cryotherapy is to reduce the perception of both local and systemic pain by reducing nociceptive input. Although there are many different studies on the analgesic efficacy of coolant sprays, there is no study in the literature about their use in blunt thoracic trauma. This study aimed to evaluate the effectiveness of cryotherapy in the early pain treatment of elderly patients with rib fractures due to blunt thoracic trauma. The cooling spray treatment was preferred for cryotherapy because of its nonpharmacological nature and ease of use by health care workers.

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METHODS

This is a prospective, randomized, controlled, double-blind, multicenter clinical trial. Patients admitted to EDs of three hospitals between January 10, 2019, and January 10, 2020, were evaluated for eligibility. The study was approved by the Ethics Committee at Atatürk University Faculty of Medicine.

Patient selection

Patients aged 65 years and over who were referred to the EDs due to falls from the patient's own height and whose treatment and discharge was completed in ED were examined. Among these patients, those diagnosed with rib fractures due to isolated blunt thoracic trauma after radiologic imaging (e.g., chest x-ray or computed tomography) were evaluated for the study.

Inclusion criteria

1. Trauma history in 24 h.
2. Patients with fractures in less than three ribs and limited to a single hemithorax.
3. Having a visual analog scale (VAS) score of ≥5.

Exclusion criteria

1. Inability to provide informed consent.
2. Chest injury scores >11 (insufficiency of this treatment)[7].
3. Having additional trauma-related injuries, skin lesions, and/or trauma in multiple regions of the thorax.
4. Patients with fractures in ribs 1 and 2 (risk of serious injury).
5. History of regular analgesic usage, antiaggregant and anticoagulant drug usage, and/or allergy to nonsteroidal anti-inflammatory drugs (NSAIDs) and narcotic analgesics.
6. Having coagulation disorders, hematologic disease, gastrointestinal bleeding, uncontrolled heart failure, renal failure, liver failure, and chronic lung disease.
7. Patients in whom trauma-related complications developed during the ED follow-up, and patients who needed to be hospitalized.

Informed consent was obtained from patients who met the eligibility criteria. The study coordinator randomized the patients into two treatment groups using a formal randomization protocol (www.random.org/integers).

Intervention

Application of the sprays and measurement of the VAS scores were performed by ED physicians who were blinded for the study. For the placebo group, a standard saline solution refrigerated at 4°C was prepared. In the coolant spray group, Cryos® Spray (Phyto Performance, Italy) was applied at a distance of 20 cm from the injured area for 5–10 s. The first spray application was performed after the initial assessment, and the second spray application was performed at the end of the 30th minute. All patients were given intravenous (IV) dexketoprofen (50 mg in 50 mL standard saline solution) in 5 min simultaneously with the first spray application. The rescue analgesic treatment was IV fentanyl at a dose of 1 μg/kg.

Outcomes

Patients' demographics, vital signs, pain levels, chest injury scale scores, and local side effects associated with spray treatment were recorded. The VAS was used to measure the pain levels of the patients. Patients were asked to rate the pain level with a value from 0 to 10[8]. The VAS scores were recorded at admission (V0), as well as at 10th (V1), 20th (V2), 30th (V3), 60th (V4), 120th (V5), and 360th (V6) minute. The mean VAS decreases and the mean percentage VAS reductions for each measurement time were calculated. The primary outcome variable of this study was determined as a ≥50% reduction (clinical effectiveness) according to the V0. The secondary outcome variable was the frequency of patients who needed at least one dose of rescue treatment.

Statistical Analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows, version 20.0 (IBM Corp., Armonk, NY, USA). Efficacy analyses were performed in the per-protocol (PP) population. Safety analysis was performed on the intention-to-treat (ITT) population. Comparisons between the treatment groups were made with the unpaired t-test and the Mann-Whitney U test. The incidences of adverse events were compared using the chi-square test. The confidence interval (CI) was 95%, and a p-value of <0.05 was accepted as statistically significant.

RESULTS

Patients

There were 108 patients in the ITT population, of whom 53 were given placebo spray, and 55 were given coolant spray (Figure 1). A total of seven patients (three in the placebo spray group and four in the coolant spray group) were excluded from the study during the 6-h follow-up period of the study. Notably, 50 and 51 patients remained in the placebo and coolant spray groups for the PP population, respectively.

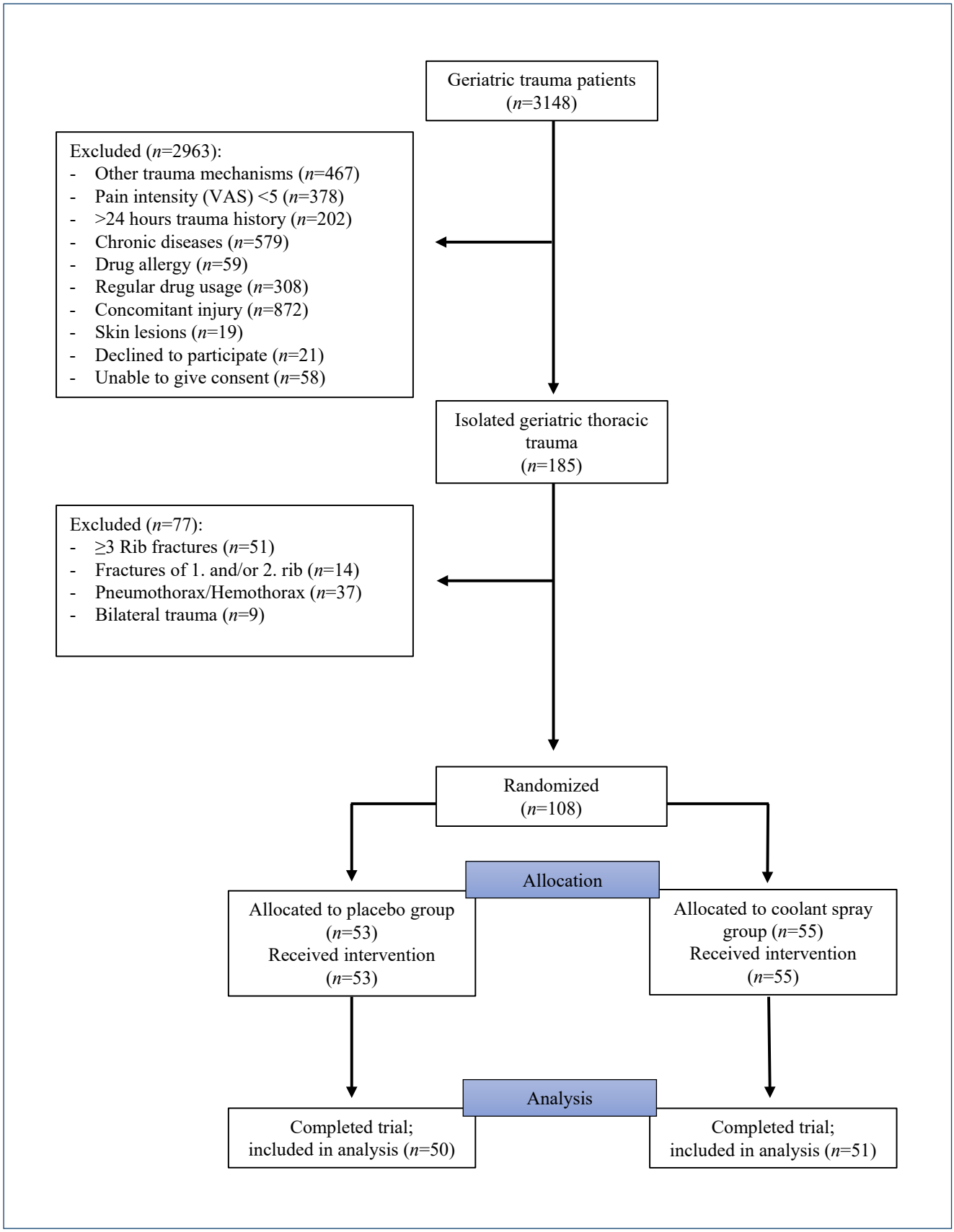


Figure 1. CONSORT diagram of the study.

Of the 108 patients, 54 (53.3%) were male, and the mean age was 71.7±4.2. Demographics and baseline variables are shown in Table 1; no significant differences were determined between the two treatment groups.

Efficacy

The mean V0 values of the groups were 7.38 (placebo spray) and 7.49 (coolant spray), and this difference was not statistically significant (p>0.05). The mean VAS values at each measurement time and the changes over time are presented in Figure 2. The differences between V0 and V1, V0 and V2, V0 and V3, and V0 and V4 mean delta VAS values of the coolant spray group were found to be significantly higher. These scores were as follows: V0–V1: 1.04, 95%CI 0.56–1.51 (p<0.001); V0–V2: 1.88, 95%CI 1.25–2.52 (p<0.001); V0–V3: 2.16, 95%CI 1.51–2.81 (p<0.001); V0–V4: 2.49, 95%CI 1.82–3.14 (p<0.001). However, measurements between V0 and V5 and between V0 and V6 showed no significant difference between the two treatment groups (p>0.05). The mean percentage reduction in the V0 and V1, V0 and V2, V0 and V3, and V0 and V4 scores in the coolant spray group was significantly higher than that in the placebo spray group. These values were as follows: % mean for V0–V1: 14.2, 95%CI 7.6–20.5 (p<0.001); % mean for V0–V2: 24.6, 95%CI 16.8–32.3 (p<0.001); % mean for V0–V3: 28.0, 95%CI 20.3–35.7 (p<0.001); and % mean for V0–V4: 32.7, 95%CI 25.1–40.3 (p<0.001). There was no significant difference between the two treatment groups in the % mean difference measurements for V0 and V5, and V0 and V6 (p>0.05).

The frequency of "clinical effectiveness" was also shown in Figure 3. In V1, V2, V3, and V4 measurements, the incidence of "clinical effectiveness" in the coolant spray group was significantly higher than in the placebo group. In terms of the proportions of patients with "clinical effectiveness," placebo/coolant spray were 0 of 11 patients at V1 (p=0.001), 4 of 31 patients at V2 (p<0.001), 14 of 42 patients at V3 (p<0.001), 31 of 48 patients at V4 (p<0.001), 38 of 38 patients at V5 (p=0.862), and 36 of 40 patients at V6 (p=0.454).

Rescue analgesic medication was needed in 15 (14.9%) patients. There was no significant difference between the treatment groups in terms of rescue analgesic medication need (p=0.425). None of the patients described side effects that could be associated with coolant spray (e.g., frostbite, urticaria, and nerve damage).

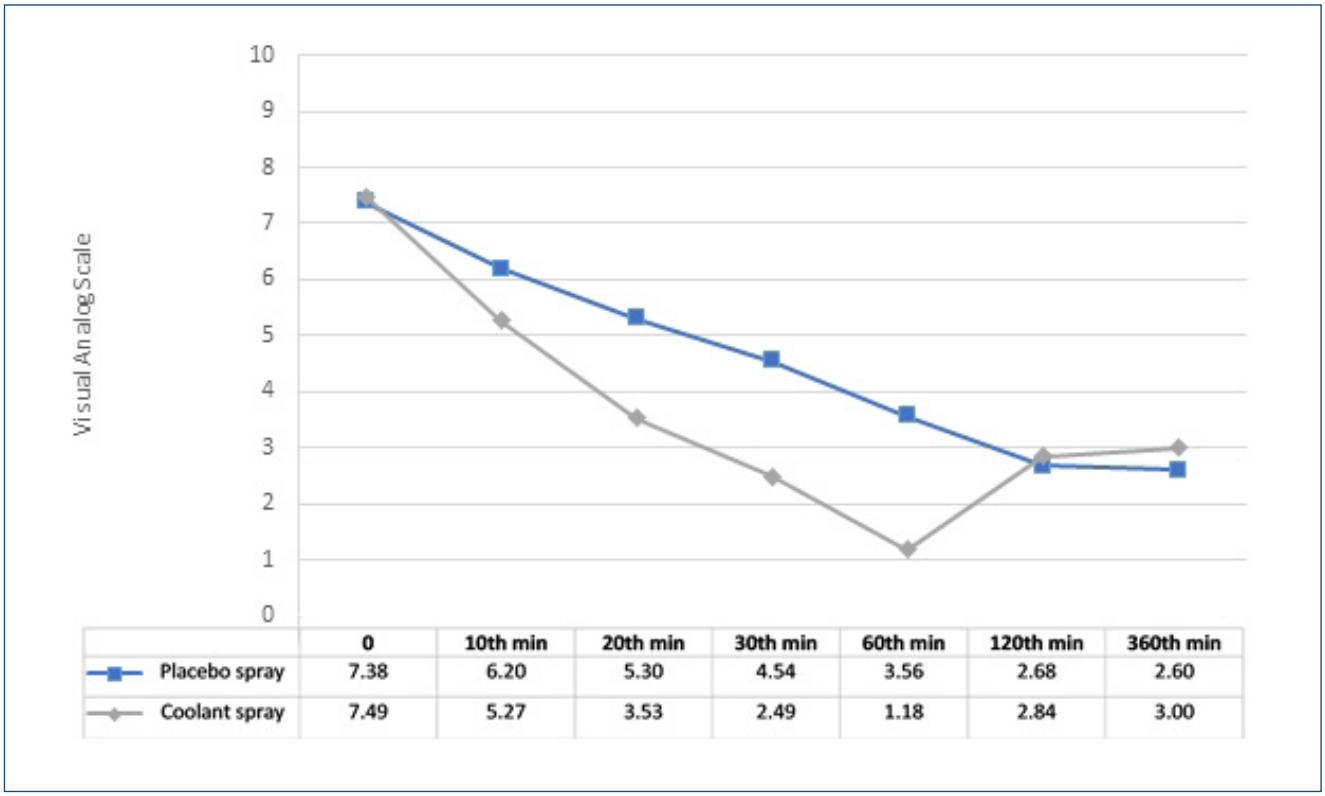
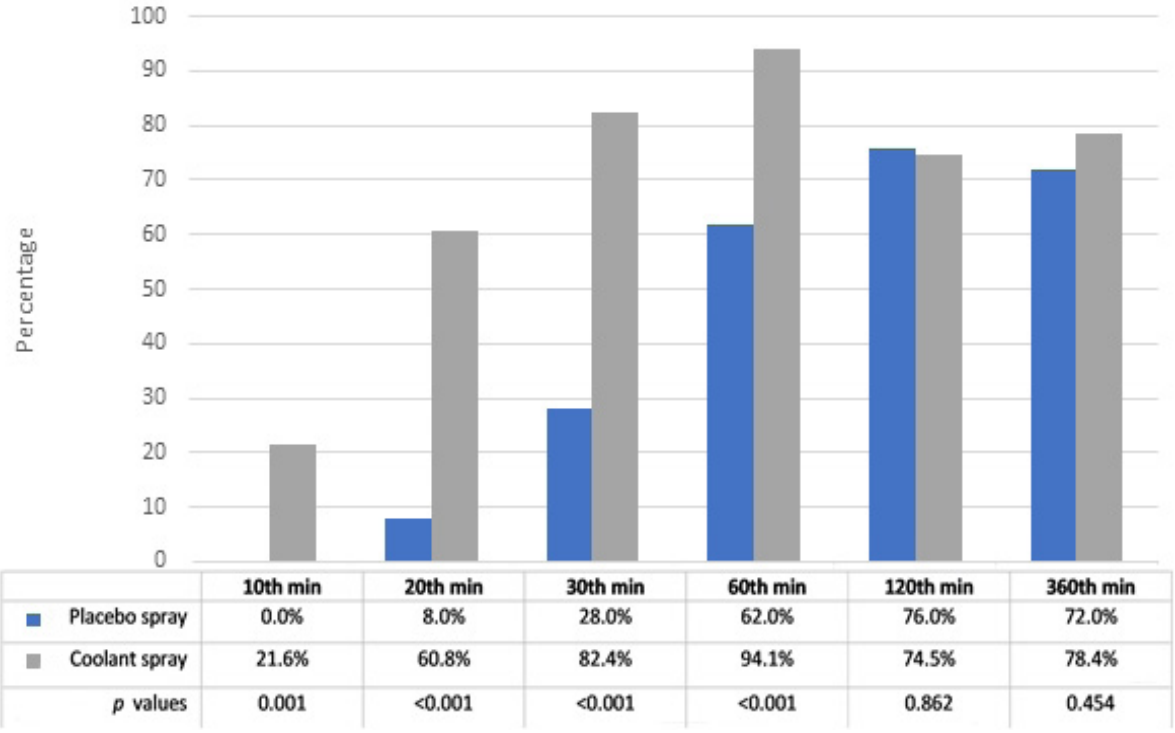


Figure 2. Efficacy of placebo spray versus coolant spray on mean VAS scores.



	10th min	20th min	30th min	60th min	120th min	360th min
Placebo spray	0.0%	8.0%	28.0%	62.0%	76.0%	72.0%
Coolant spray	21.6%	60.8%	82.4%	94.1%	74.5%	78.4%
p values	0.001	<0.001	<0.001	<0.001	0.862	0.454

Figure 3. At the time of each measurement, the frequency of detection (shown as percentage) of clinical effectiveness (decrease in VAS score by ≥50% compared to the beginning).

Retrospective power analysis

The mean VAS values were examined when 20 patients were present in both treatment groups. We found a statistically significant difference between delta VAS values at the 30th minute (mean difference: 2.85, 95%CI 1.78–3.92, p<0.001). In our power analysis based on these mean values and SDs, the power of the test was estimated at 0.91, while type I error was 0.01.

DISCUSSION

The coolant spray was preferred for cryotherapy because of its nonpharmacological nature and ease of use by health care workers. In our study, the primary outcome of "clinical effectiveness" was determined as the situation in which a reduction of ≥50% was achieved according to the initial VAS score.

Rib fractures constitute a significant proportion of thoracic trauma-related injuries[9]. An early and multimodal analgesic treatment approach applied from the moment of the first application allows these patients to breathe deeply, cough, and expectorate their secretions[5]. The effectiveness of analgesic therapies applied in treating pain due to rib fractures has been discussed in the literature for many years. The most commonly studied analgesic methods were interventional ones [10,11]. Since the physical characteristics of each traumatized patient will not be the same, it may be necessary to develop special treatment protocols for different populations. Different from the literature, we examined geriatric patients who are a trauma-sensitive and vulnerable group.

Geriatric patients become more vulnerable to falls and related injuries[12]. Kara and his colleagues found that "low-energy fall" was the most common cause of trauma-related referrals in the population aged 65 years and over[13]. In the literature, it is stated that NSAID and opioid analgesics are frequently preferred treatments for analgesia in young adults with rib fracture that develops as a result of such traumas[14]. However, age-related changes in the pharmacokinetic and pharmacodynamic properties of these drugs increase the incidence of unexpected side effects[3]. This has led us to suggest the need for new methods that are not systemic and have a low risk of side effects in providing analgesia to geriatric patients.

Cryotherapy decreases the tissue temperature in the application area, resulting in slowing the conduction velocity in peripheral sensory nerve endings. It also provides topical analgesia and anesthesia by

slowing down metabolism and suppressing inflammation[15,16]. Studies in the literature show that coolant spray is successfully applied for analgesia and topical anesthesia before injection or minor interventional procedures[15,17]. We found a significant decrease in the scores of the patients who were applied coolant spray compared to placebo. In addition, the number of patients who achieved "clinical efficacy" during the four measurement times during this period was significantly higher in the coolant spray group. In EDs, the first 60 min usually involves uncomfortable procedures such as physical examination and transfer for radiologwical examination. We believe that coolant spray application can be added to treatment as a method that can increase the comfort of both the patient and the ED doctor by reducing VAS from the first moment patients step into ED or even from triage.

It was stated that there were no serious side effects associated with the treatment in the studies in which coolant spray was applied in literature[18,19]. Similar to the literature, we did not encounter any side effects related to treatment application. Topical coolant spray application provides the possibility of use in repetitive doses thanks to its reliability and nonpharmacological structure.

Limitations

We evaluated the effectiveness of the treatment during our study by applying two doses of spray to patients in the coolant spray group. However, we think that a study in which repetitive coolant spray is used more frequently and longer term VAS measurements are monitored can contribute to the literature.

CONCLUSION

The geriatric population is a special group of patients who need alternative analgesic methods due to aging-related effects, additional diseases, and multiple drug use. Coolant spray therapy can be safely used in geriatric patients as a recovery option to reduce the uncomfortable moments that pain can cause during their time in ED.

AUTHORS' CONTRIBUTION

İA: Conceptualization, Formal analysis, Data curation, Methodology, Investigation, Resources, Validation, Writing – review & editing, Writing – original draft, Visualization, Project administration. **SD:** Conceptualization, Formal Analysis, Methodology, Validation, Writing – review & editing, Writing – original draft, Visualization. **AOK:** Formal analysis, Data curation, Investigation, Project administration, Resources, Writing – original draft, Writing – review & editing. **TD:** Conceptualization, Formal analysis, Methodology, Validation, Visualization, Writing – review & editing. **MBK:** Conceptualization, Formal analysis, Methodology, Validation, Visualization, Writing – review & editing. **STAG:** Data curation, Formal analysis, Investigation, Project administration, Resources, Writing – original draft, Writing – review & editing. **ZC:** Formal analysis, Methodology, Validation, Project administration, Supervision, Writing – review & editing.

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