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Comparison of the use of evaporative coolants and ice packs for the management of preoperative edema and pain in ankle fractures: a prospective randomized controlled trial

Young Hwan Park[1] · Jong Hyub Song[1] · Tae Jin Kim[1] · Seong Hyun Kang[1] · An Seong Chang[1] · Hak Jun Kim[1]

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Abstract

Introduction The use of evaporative coolants in the management of acute musculoskeletal injury has received increasing attention recently. However, its efficacy compared with conventional cryotherapy in treating injured human subjects remains unclear. The purpose of this study is to compare the efficacy of evaporative coolants with that of ice packs in preoperative management of edema and pain in patients with an ankle fracture.

Material and methods Sixty-three patients in need of surgical treatment for ankle fracture were randomly assigned to either an evaporative coolant group or an ice pack group. Both treatments were applied for 5 days after injury and outcomes were measured daily. The primary outcome was a reduction in edema as measured by the figure-of-eight-20 method and the secondary outcome was measured by visual analog scale (VAS) for pain.

Results Two-way analysis of variance with repeated measures showed no significant group effect and no significant group-by-time interaction in terms of reduction of edema and VAS score for pain between two groups. No adverse effects were reported in either group.

Conclusion Evaporative coolants exhibited comparable efficacy to ice packs in preoperative cryotherapy of ankle fractures without adverse effects. While evaporative coolants are more expensive than ice packs, they can present a viable option for cryotherapy.

Level of evidence Level I, prospective randomized study.

Keywords Evaporative coolant · Ice pack · Cryotherapy · Ankle fracture · Figure-of-eight-20 method · Visual analog scale (VAS)

Introduction

Although more high-quality trials are needed to provide clear, evidence-based guidelines, cryotherapy is now widely used as a standard treatment for acute musculoskeletal injuries [1–3]. The proposed explanatory mechanism is that, by decreasing tissue temperature, ice can diminish pain, metabolism, and muscle spasms, and minimize the inflammatory process and edema, thereby aiding recovery after soft-tissue trauma [4–6]. Various cooling methods have been used to apply cold to the injured area, such as ice massages, ice towels, ice packs, ethyl chloride and other vapor coolants, chemical reaction devices, and inflatable splints that use refrigerant gas [1, 7–9].

Ice packs are among the commonly used methods of delivering cryotherapy due to their simplicity and convenience. Although prolonged application should be avoided to

✉ Hak Jun Kim
hjunkimos@gmail.com

Young Hwan Park
ospark1982@gmail.com

Jong Hyub Song
jhsong0301@naver.com

Tae Jin Kim
owlrocker@gmail.com

Seong Hyun Kang
seonghyunkang@gmail.com

An Seong Chang
anseong.jang@gmail.com

[1] Department of Orthopaedic Surgery, Korea University Guro Hospital, 148 Gurodong-ro, Guro-gu, Seoul 08308, South Korea

prevent frostbite and nerve injuries, the method appears to be effective and harmless, with few complications or side effects [1, 2, 10]. However, due to differences in the mode, duration, and frequency of ice application, an optimal protocol is still lacking [2]. In addition, ice packs cannot be applied efficiently when patient compliance is low, and require periodic use of freezers. These shortcomings have prompted a search for alternative treatments.

Ethanol-based evaporative coolants employ the effects of latent heat evaporation, which draws heat out of the underlying surface. This cooling effect is thought to modify the inflammatory response, helping reduce edemas. Since they can be sprayed on a surface, the working area of coolants is larger than that of ice packs, which cool through direct external contact. In addition, coolants do not have to be refrozen periodically as do ice packs. Due to these advantages, and despite a higher price, the use of coolants has received increasing attention recently. Until now, however, no prior studies have compared the clinical effects of evaporative coolants and traditional cryotherapy such as ice packs. If evaporative coolants are to be used as an alternative treatment, evidence that they are not inferior to traditional cryotherapy will be required.

This study was designed to compare the clinical effects of evaporative coolants and ice packs for the management of preoperative swelling and pain in ankle fractures. The authors hypothesized that the clinical effect of evaporative coolants is not inferior to that of ice packs.

Materials and methods

Design

A prospective, randomized, controlled, singled-blinded, clinical trial, using a repeated-measures design was carried out at a single university hospital. The study was approved by the ethics committee of the same institution.

Patients

All skeletally mature patients (16 years old or older) with ankle fractures in need of surgical treatment and referred to the hospital's emergency unit from February 2017 to May 2018 were assessed for eligibility (Fig. 1). Exclusion criteria were bilateral ankle fractures, open fractures, pathologic fractures, concomitant tibia shaft fractures, previous

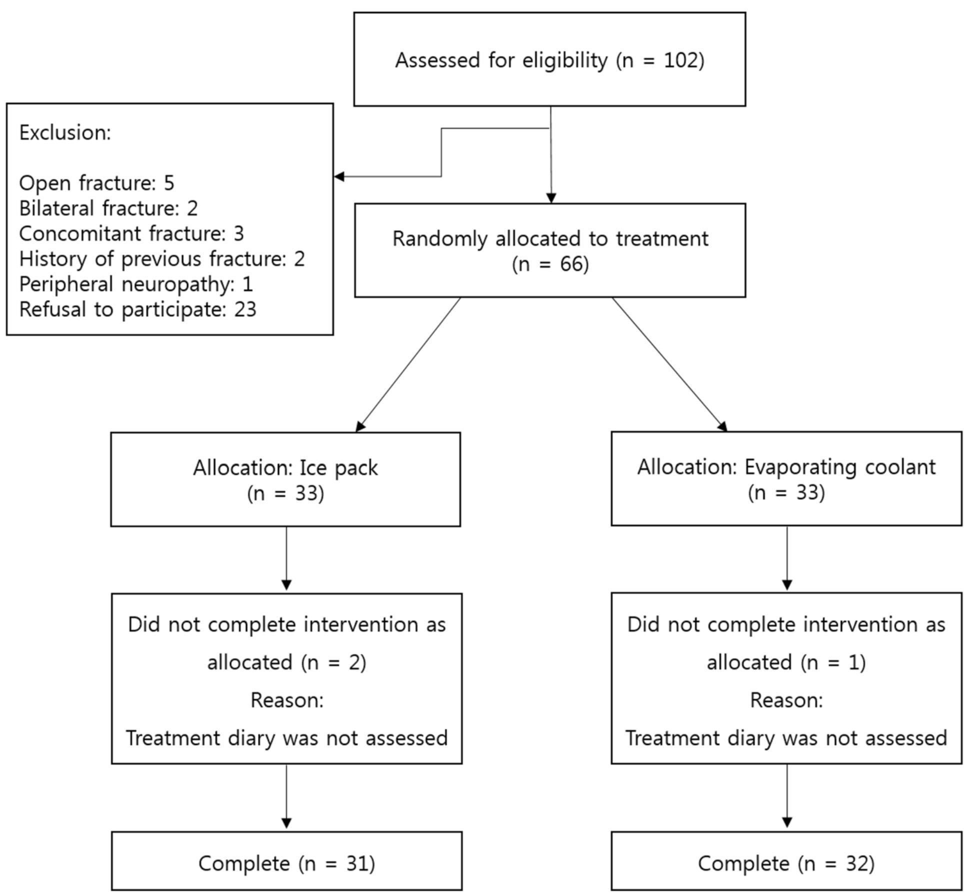

Fig. 1 CONSORT (Consolidated Standards of Reporting Trials) diagram

significant injury or a fracture of either ankle, peripheral neuropathy, peripheral vascular disease, soft tissue infection in the region on either injured ankle, or an inability to complete the study protocol. Patients meeting eligibility criteria were informed of the study. After obtaining written informed consent, the study coordinator randomized the patients into one of the two treatment groups using sequentially numbered opaque and sealed envelopes. The randomization sequence was generated by computer through an independent software specialist.

Primary and secondary outcome measures

The primary outcome in this study was a reduction of ankle edema during the preoperative period. The figure-of-eight-20 method, described and published by Rohner-Spengler et al. [11] was used to assess edemas. Using this method, ankle edema was measured in millimeters daily after the final cryotherapy of the day for the first 5 days of injury. All measurements were consistently performed by one author. As a secondary outcome measurement, a 10-cm visual analog scale (VAS) [12, 13] was used to measure pain over the same period as ankle edemas. Use of nonsteroidal anti-inflammatory drugs was allowed in both groups as a rescue medication, and any use was recorded. No analgesics other than the accepted rescue medications were used. At the end of the study, patient satisfaction was measured with a questionnaire, in which the choices (scores) were the following: no benefit or harm (0); little benefit (1); good benefit (2); and excellent benefit (3) [1].

Interventions

As a routine preoperative protocol for ankle fracture, multilayer compression bandages (two layers of cotton wool and two or three layers of short stretch bandages) with a short leg splint were applied to all patients. Multilayer compression bandages were maintained all day except during daily ankle edema measurements, each of which took less than 30 min. In a control group, ice packs were applied as the method of previous study [3]. Ice packs (20 × 20 cm) were completely filled with water, placed in a freezer, and removed when frozen. Before application, the packs were held under hot water for 30 s. After 10 min of ice pack application, each ankle was rested at room temperature for 10 min, and the ice was then reapplied for a further 10 min. This intermittent application was repeated every 2 h. In the study group, the evaporative coolant (Physicool™; Physicool Ltd., London, United Kingdom) was additionally applied to the outside of the compression bandage to allow the cooling effect of the material to affect the ankle joint, which is a modification of the method of Mumith et al. [14] (Fig. 2). Since the liquid coolant may wet the cotton wools, a thin plastic wrap was placed between the bandages and cotton wools. The compression bandage was re-soaked with spray coolant every 2 hours. Application of ice packs and evaporative coolants was performed by one author (who was not involved in edema measurements) 12 h per day over the first 5 days of injury.

Fig. 2 The evaporative coolant was applied to the outside of a compression bandage. A thin plastic wrap was placed between the bandage and the cotton wools to prevent wetting of the cotton wools by the coolant. The compression bandage was re-soaked with a spray coolant every 2 h

Sample size calculation

Although it is possible that members of the evaporative coolant group responded more positively than those in the control group, demonstrating superiority would require an impractically large study because results of a pilot study showed close mean and standard deviation between the two groups. For this reason, a noninferiority design was chosen to test the hypothesis that the control group was not inferior to the evaporative coolant group. The margin of noninferiority was set at – 8 mm because an 8 mm difference is of clinical relevance, and it is above the minimal detectable change of figure-of-eight-20 measurements [3]. It was estimated that 30 patients in each group would provide 80% power to test the hypothesis with regard to a minimal detectable change at 5 days after injury (a = 0.05, sigma = 11). Assuming a 10% dropout rate for those who would be lost to follow-up, 33 patients were required in each group for this study. A priori power analysis was performed using G*Power software, v3.01 (Franz Faul, Christian-Albrechts-Universität Kiel, Kiel, Germany).

Statistical analysis

The results were analyzed for normal distribution by a Kolmogorov–Smirnov test. The demographics and clinical characteristics of the two groups are presented as frequency for categorical variables and mean ± standard deviation (SD) for continuous variables. The Student *t* test was used to determine any significant differences between the two groups in terms of continuous variables, and Chi-square or Fisher exact tests were used to determine any significant differences in the categorical variables. The outcomes at the follow-up visits were compared using a two-way analysis of variance (ANOVA) with repeated measures for time and adjustment of *P* values by the Greenhouse–Geisser epsilon. Statistical analyses were performed using SPSS v20.0 (SPSS Inc., Chicago, Illinois), and significance was set at $P < 0.05$.

Results

Baseline characteristics

Sixty-three patients (male: female, 40:23) with a mean age 48.3 years (SD, 16.6, range 18–72) were recruited. Patient demographic characteristics and baseline variables between the two groups are presented in Table 1. No intergroup differences were found.

Edema changes

The medians and upper and lower quartiles of the changes in edema as measured with the figure-of-eight-20, in millimeters over a period of 5 days of intervention, are presented in Fig. 3. Initial edemas were 534 ± 38 mm in the ice pack group and 544 ± 45 mm in the evaporative coolant group. No intergroup difference was found ($P = 0.345$). Analysis of edema change showed no significant group effect (F [1,42] = 0.21, $p = 0.647$) and no significant group-by-time interaction (F[2.64, 118.75] = 1.29, $p = 0.279$).

Table 1 Baseline characteristics

Characteristic	Ice pack ($n = 31$)	Evaporative coolant ($n = 32$)	*P* value
Age, years	50.1 (15.8)	46.1 (18.2)	
Sex, *n*			
Female	9	14	0.338
Male	22	18	0.297
BMI, kg/m^2	23.4 (2.3)	24.3 (3.2)	0.212
Diabetes, *n*	4	2	0.426
Cause of injury			0.770
Fall	18	17	
Sports injury	7	7	
Motor vehicle accident	4	7	
Other	2	1	
Fracture type			0.531
Unimalleolar	4	6	
Bimalleolar	25	22	
Trimalleolar	2	4	

Values expressed as mean (standard deviation) or number

VAS for pain

The medians and upper and lower quartiles of the VAS scores for pain over a period of 5 days of intervention are presented in Fig. 4. Patients in the ice pack group (7.3 ± 1.0) had similar initial VAS scores for pain compared with the evaporative coolant group (7.1 ± 1.3) ($P = 0.801$). VAS analysis for pain showed no significant group effect (F[1,4] = 0.26, $p = 0.613$) and no significant group-by-time interaction (F[2.97, 124.81] = 0.84, $p = 0.473$).

Other outcomes

The use of nonsteroidal anti-inflammatory drugs during the intervention period in each group is presented in Table 2; no significant difference in the frequency of use per person between the two groups was found ($P = 0.771$). Patient satisfaction with the treatment (score from 0 to 3) at the end of the study in the ice pack group (2.2 ± 0.4) was similar to that of the evaporative coolant group (2.4 ± 0.4) ($P = 0.698$). No incidence of frostbite, nerve palsies, or any other potentially deleterious effects in either group was reported throughout the duration of the trial.

Costs

The ice packs we used cost $11.60 per unit, and two or three units were used per patient for the protocol (range of total costs, $23.20–$34.80). The evaporative coolant costs $54.24 per unit. One unit of evaporative coolant was used per patient. These costs can be varied by region or country.

Discussion

This study is the first prospective randomized controlled trial to rigorously compare the effectiveness of two cryotherapies for the preoperative management of ankle fractures. The most important finding of the present study is that the clinical effects of an evaporative coolant for the management of edema and pain did not differ from those of ice packs. These results demonstrated that an evaporative coolant can be a viable alternative to ice pack application as a preoperative cryotherapy in the ankle fractures.

Energy removed from a liquid during evaporation reduces the temperature of the liquid, resulting in evaporative cooling [15]. Among evaporative materials, ethanol-based solutions are effective at reducing surface temperatures with minimal adverse effects [16, 17], which is advantageous for

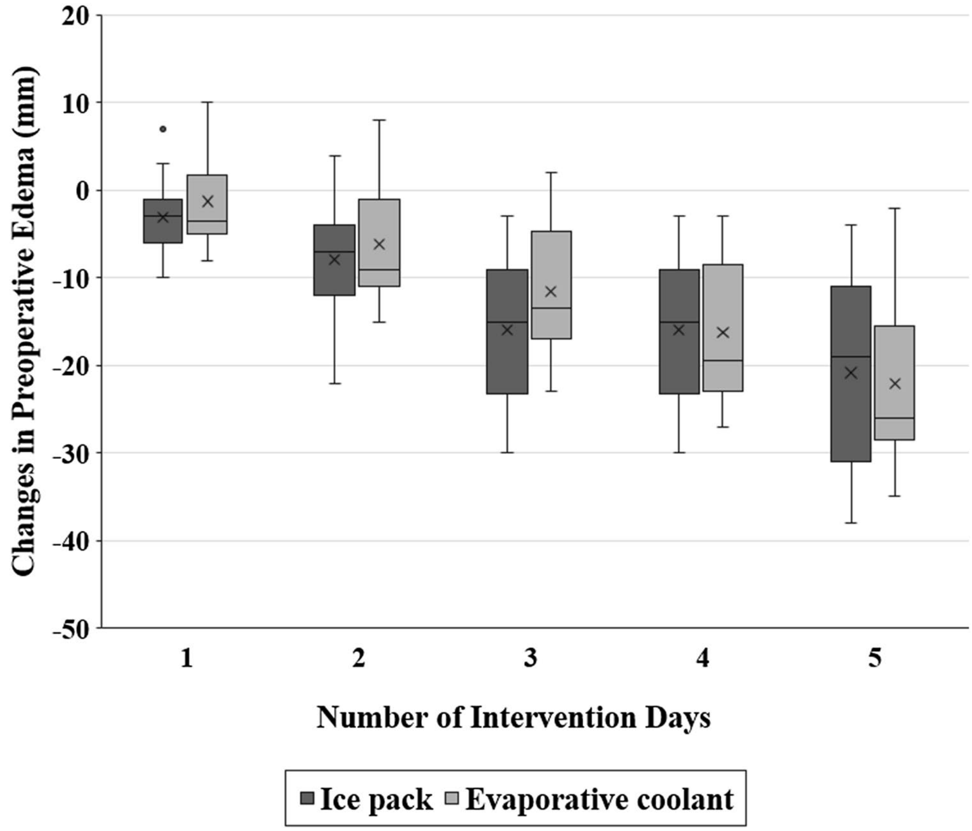

Fig. 3 A bar graph showing preoperative edema changes in each group over a period of 5 intervention days. The horizontal black line in the bar represents the median change and the X mark represents the mean change in millimeters as measured with the figure-of-eight-20 method. Error bars indicate the upper and lower quartiles. The circular symbol represents an outlier. Negative values represent the amount of edema reduction from baseline. Positive values represent an augmentation of edema. There were no significant differences between the two groups over 5 days of intervention. Two-way ANOVA with repeated measures for time with adjustment of p values by the Greenhouse–Geisser epsilon showed no significant group effect ($F[1,42]=0.21$, $p=0.647$) and no group-by-time interaction ($F[2.64, 118.75]=1.29$, $p=0.279$)

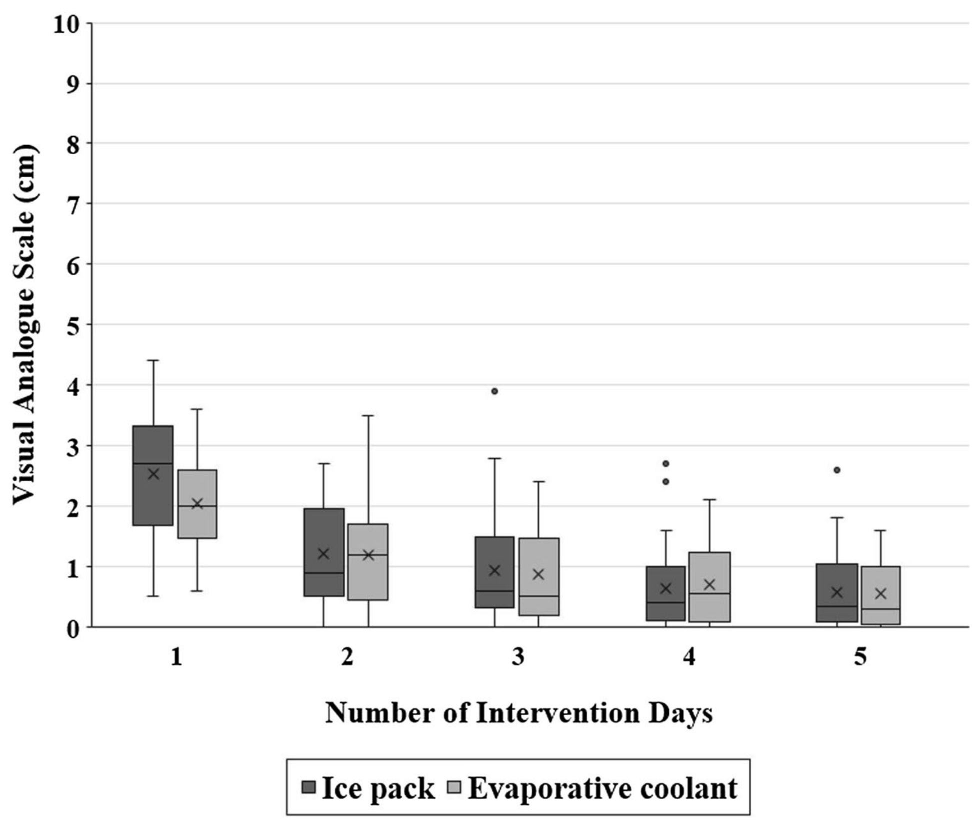

Fig. 4 A bar graph showing visual analog scales scores for pain in each group over 5 intervention days. The horizontal black line in the bar represents the median value and the X represents the mean. The error bars indicate upper and lower quartiles. The circular symbols represent outliers. No significant differences between the two groups over 5 days of intervention were reported. A two-way ANOVA with repeated measures for time with adjustment of p values by the Greenhouse–Geisser epsilon showed no significant group effect ($F[1,42]=0.26$, $p=0.613$) and no group-by-time interaction ($F[2.97\ 124.81]=0.84$, $p=0.473$)

Table 2 Use of nonsteroidal anti-inflammatory drugs during intervention days

Drug	Ice pack ($n=31$)	Evaporative coolant ($n=32$)
Ibuprofen	3	4
Naproxen	3	1
Ketorolac	3	3

application to sports injuries. In addition, in experimental studies, about 30% of surface temperature reduction from 24 °C was observed after evaporation of an ethanol/water solution [18]. Although effectiveness can differ depending on usage and methods, these studies provide a basic rationale for the clinical application of ethanol-based evaporative coolants.

Evaporative coolants have some benefits over ice packs, which offer traditional direct external cooling. First, there is no need to use a freezer to make low-temperature materials, which is perhaps the biggest drawback of conventional cryotherapy. Second, because spraying coolants does not require periodic replacement of a treatment pack, it increases convenience, which in turn improves patient compliance and maximizes the effectiveness of treatment. Third, it is hygienic because it does not repeatedly re-use cryogenic materials and leave residues after evaporation.

Drawbacks to the use of evaporative coolants include higher costs, which vary by region and country. Although evaporative coolants do not require the use of freezers, their cost-effectiveness compared with ice packs has not been proven to date. In addition, there is no definitive protocol for ideal usage capacity and frequency due to a lack of studies on evaporative coolants. For these reasons, evaporative coolants have not been considered a primary treatment method for cryotherapy.

Several studies of the systemic application of evaporative cooling effects for the treatment of exercise-induced hyperthermia have been conducted [19–21], but the single study of local application of evaporative cooling effect was limited. Mumith et al. [14] prospectively compared the effect of evaporative coolant bandages with a cryocuff in patients who underwent total knee arthroplasty. In postoperative rehabilitation, the evaporative coolant exhibited superior performance to that of a cryocuff on pain and range of motion. Based on these results, the authors concluded that an evaporative coolant can be a good option for cryotherapy after total knee arthroplasty. However, there have been no other comparable studies of the local application of evaporative coolants. Therefore, the authors believe that this study is meaningful because it makes up for insufficient clinical evidence on the use of evaporative coolants in musculoskeletal injuries.

Our study has some limitations. First, due to an ethical issue, it did not include a group of patients who received only a routine preoperative protocol consisting of multilayer compression bandages. By including this group, a comparison of the clinical effects of cryotherapy and noncryotherapy in ankle fractures would have been possible. However, the additional clinical effects of ice packs over routine protocols in preoperative edema and pain were observed in a pilot study and other recent studies showed the efficacy of cryotherapy on musculoskeletal injuries [1, 3]. Second, all interventions were consistently performed by one author to reduce bias due to differences in application methods. Therefore, despite the authors' expectation that evaporative coolants would be easy to use, the study could not assess patient compliance and convenience. Third, ankle edemas were measured by one author, raising concerns about observer reliability. However, because the reliability of the figure-of-eight-20 method was verified by previous studies [11, 22], the authors determined it would not affect the results significantly.

Conclusion

No difference in reduction of edemas and VAS pain scores between the evaporative coolant and ice pack groups in the preoperative management of ankle fractures was detected. Despite the higher costs, an evaporative coolant can be a viable option in patients who have difficulty applying conventional cryotherapy.

Author contributions YHP: lead investigator and first author, writing manuscript. JHS: performing study intervention and data analysis. TJK: outcome assessment and manuscript review. SHK: outcome assessment and data analysis. ASC: outcome assessment and data analysis. HJK: corresponding author and study coordinator, manuscript review.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the contents of this study.

Ethical approval This study was approved by the institutional review board of the authors' institutions. All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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