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Comparison of three cooling methods for burn patients: A randomized clinical trial

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ABSTRACT

Tap water may not be readily available in numerous places as a first aid for burns and, therefore, tea tree oil products are recommended alternatives. Our aim in this study was to compare the cooling effects of three burn-cooling methodologies, running tap water, Burnshield®, and Burn Cool Spray®, and suggest indications for each cooling method.

This randomized, controlled, study enrolled patients with burns who used the emergency service of Seoul Bestian Hospital from June 2015 to October 2015. The allocation of the cooling methods was randomly generated using a computer. We cooled the burn wounds by applying one of the three methods and measured the skin surface temperature and pain level using a visual analog scale (VAS) scoring.

Ninety-six patients were enrolled in this study. The variability in the median(IQR) skin temperatures of the three groups was from 33.5 °C (31.5–35.0) to 28.7 °C (25.9–30.9), 33.8 °C (32.0–35.4) to 33.2 °C (30.5–35.0), and 34.0 °C (32.0–35.1) to 34.4 °C (32.7–35.6) for the tap water, Burn Cool Spray®, and Burnshield®, respectively. The variability of the mean VAS pain scores was 6.9 to 4.8 (tap water), 5.6 to 4.5 (Burn Cool Spray®), and 5.5 to 3.3 (Burnshield®). The reduction of skin surface temperature by tap water was significantly greater than that by the other two methods. All three methods reduced the VAS pain score after 20 min of treatment ($p < 0.001$). The tap water had a similar effect to that of the Burn Cool Spray® but significantly better than that of Burnshield®. There was a significant difference in the skin surface temperature and VAS pain score reduction ($p = 0.014$ and $p = 0.007$, respectively) between the groups cooled by tap water below and above 24 °C. The patients who visited the center within 30 min showed a significantly higher skin temperature than those who came after 30 min did ($p = 0.033$).

Tap water and Burn Cool Spray® reduced the skin surface temperature, but the Burnshield® slightly increased it. All three cooling methods were effective in relieving pain. The temperature of the tap water used was related to the reduction in skin surface temperature and VAS pain score. The patients who visited the hospital within 30 min of their burn accident needed a longer cooling time to attain a comparable skin surface temperature to those who visited after 30 min.

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1. Introduction

Cooling is a well-known initial treatment to relieve pain and minimize ongoing tissue damage in patients with burns [1–4]. The British Burn Association recommends the use of ordinary tap water as the treatment of choice for the first aid management of burns. The Australian and New Zealand Burn Association recommends the removal of all clothing from the burn area and application of cool running tap water for 20 min [5]. However, there are numerous locations where tap water may not be readily available such as cars, airplanes, and fields. Furthermore, numerous burn patients arrive at the hospital without having cooled their wounds even when tap water is available. According to our data, approximately 10% of patients with burns that visited Seoul Bestian Hospital in 2013 had not performed any first aid measures after being injured. Furthermore, the use of tap water in an ambulance is not advised because the ambulance floor could become slippery, creating further safety hazards, particularly if the use of electrical equipment such as a defibrillator is necessary.

Tea tree (*Melaleuca alternifolia*) oil products are recommended as alternative first aid treatments for burns. The Australian ambulance and paramedic services have adopted them, and they are widely used in Korean medical emergency services [6,7]. Burnaid®, Burnshield®, Burnfree®, and Water-jel® are some commercialized products containing tea tree oil, and in Korea, they are currently mostly used in the form of sterile gel soaked dressings. Burnshield is a thin layer of foam impregnated with 96% water, tea tree oil, and emulsifiers at a pH of 5.5–7. Burnshield® comes in the form of sterile sheets sealed in aluminum packets, which are available in several sizes. However, the dressing form has limitations, including for the treatment of multiple wounds or wounds on irregular or hair-covered surfaces such as the fingers or scalp. The spray formulations such as Burn Cool Spray® have an advantage over the dressing form because they can be applied to a wider variety of surfaces and they allow multiple applications.

Our aim in this study was to compare the cooling effects of three burn-cooling methodologies, running tap water, Burnshield® (dressings), and Burn Cool Spray® (spray), and suggest the indications for each cooling method.

2. Materials and methods

2.1. Patients

We carried out a randomized, controlled study, which enrolled patients with burns who attended the emergency service of Seoul Bestian Hospital from June 2015 to October 2015. The inclusion criteria were 1) $\geq$ 16 years, 2) visited the hospital visit within 3 h of burn accident (some authors have suggested that cooling may be effective up until 3 h after the accident [8]), and 3) burn area covered less than 5% of the total body surface area (TBSA). We excluded patients with the following characteristics: (1) chemical burn, (2) hypothermia, (3) received analgesics prior to the cooling treatment, and (4) patients who were uncooperative or with neurologic or psychiatric disorders or both. Patients who fulfilled the inclusion criteria and agreed to participate in the study signed an informed consent form prior to enrolment.

2.2. *Wound treatment and measurement of skin surface temperature and pain score*

We cooled the burn wounds by applying one of three methods, running tap water, Burn Cool Spray® (T&L Co. Ltd., Korea), and Burnshield® (Levtrade International, South Africa). We did not use any analgesics during the cooling treatment. The allocation of the cooling method was randomly generated using a computer. The research coordinator applied the respective cooling procedure for 20 min and measured the skin surface temperature every 5 min (five times in total from 0 to 20 min) using an infrared camera (FLIR T420, FLIR Systems Inc., Danderyd, Sweden). During the temperature measurements, we used a 50-cm long plastic ruler to keep a constant distance (approximately 50 cm) between the wound and the infrared camera. The pain score was assessed using a 10-cm visual analog scale (VAS) where 10 cm reflects worst pain [9]. The VAS was a straight horizontal line of 10 cm. We measured the initial VAS scores prior to every application. The specific cooling procedures are described below.

Cooling with tap water was carried out for 20 min in the shower mode. We used the tap water after setting the temperature to the coolest point. The temperature of the tap water ranged from 23.9 °C to 27.3 °C. The Burn Cool Spray® was sprayed on the burn wound covering the whole surface every 5 min, just after measuring the surface temperature. The Burnshield® was applied to the burn wound, and the surface temperature was measured after partially removing the Burnshield® dressing, which was replaced once the measurement was performed. All the skin surface temperatures were measured leaving a 50-cm distance between the infrared camera and the burn wound. FLIR Tools (version 4.1) was used to analyze the images. The wound temperature was defined as the hottest point of the wound (Fig. 1).

Because of the nature of this study, the patients and research coordinator who applied the cooling procedure and measured the surface temperature or recorded the pain scores but not the treating physician were allowed to know the cooling methods used.

2.3. *Statistical analysis*

All the analyses were performed using the statistical package for the social sciences (SPSS) software program for Windows (version 14.0, SPSS Inc., Chicago, IL, USA). Nominal variables are presented as frequencies and percentages. We used the Shapiro–Wilk test to assess the normality of the continuous variables, which are presented as the means $\pm$ standard deviations (SD) for normally distributed data, and medians and interquartile ranges for non-normally distributed variables. Analysis of variance (ANOVA) tests were used to assess differences between the three independently sampled groups. The Kruskal-Wallis test was used to assess the differences between the three independently sampled groups of non-normally distributed continuous variables. For the nominal variables, the Chi-squared (X^2) test was used to identify differences between the groups. When the expected

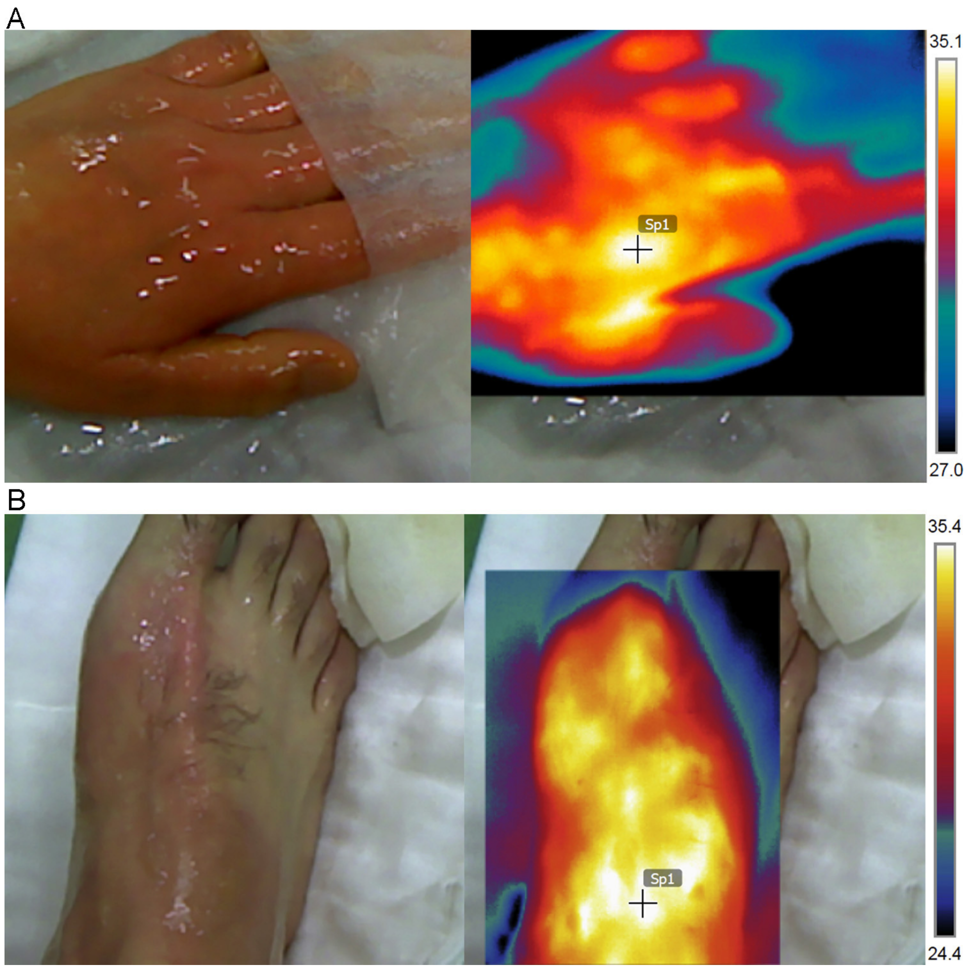

Fig. 1 – Measurement of skin surface temperature with infrared camera (FLIR T420®). Burn wound temperature was defined by the hottest point in the wound (Sp1). (A) Burn cool spray®. (B) Burnshield®.

frequencies were <5, we used the Fisher's exact test. We used a repeated measures ANOVA to assess the changes in means over three or more time points and the differences in means between three or more different groups. We used Tukey's b test to perform the post hoc analysis. P-values <0.05 were considered statistically significant.

3. Results

During the study period, 1,739 patients with burns visited the hospital emergency service, and 97 of them were included in our study. One patient with chemical burns and two who refused to complete the cooling procedure were excluded from the study (Fig. 2). Table 1 shows the demographic and clinical characteristics of the 94 patients who were ultimately enrolled and divided into the three treatment groups. The mean ages of the tap water, Burn Cool Spray®, and Burnshield® groups were 40.2, 42.7, and 42.3 years, respectively. Scalding was the most common cause of burns in all three groups. The upper extremities were the most common burn sites, followed by the lower extremities. The mean TBSA of all the three groups was 1%. The healing time was 2 days shorter in patients treated with the Burnshield® than it was in the other patients. However, this difference was not statistically significant ($p < 0.101$). The variability in the median(IQR) skin temperatures of each of the three groups was from 33.5 °C (31.5–35.0) to 28.7 °C (25.9–30.9), 33.8 °C (32.0–35.4) to 33.2 °C (30.5–35.0), and 34.0 °C (32.0–35.1) to 34.4 °C (32.7–35.6) in the tap water, Burn Cool Spray®, and Burnshield® groups, respectively. The variability of the mean VAS pain scores was 6.9 to 4.8 (tap water), 5.6 to 4.5 (Burn Cool Spray®), and 5.5 to 3.3 (Burnshield®). The tap water group showed significantly higher VAS pain scores than the other two groups did. Fig. 3 shows the difference in skin surface temperature reduction in the three groups, which was statistically significant ($p < 0.001$). The post hoc analysis revealed no significant difference between the use of the Burn Cool Spray® and Burnshield®. However, the reduction of skin surface temperature by tap water was significantly greater than that by the other two methods (Fig. 3A). All three methods reduced the VAS pain score after 20 min of treatment ($p < 0.001$, Fig. 3B). The difference in the reduction of the VAS pain score of the three groups was statistically significant ($p = 0.043$). The post hoc analysis revealed that tap water had a similar effect to that of Burn Cool Spray®, which was significantly better than that of the Burnshield®. The Burn Cool Spray® had a similar effect on pain reduction to that of the Burnshield®.

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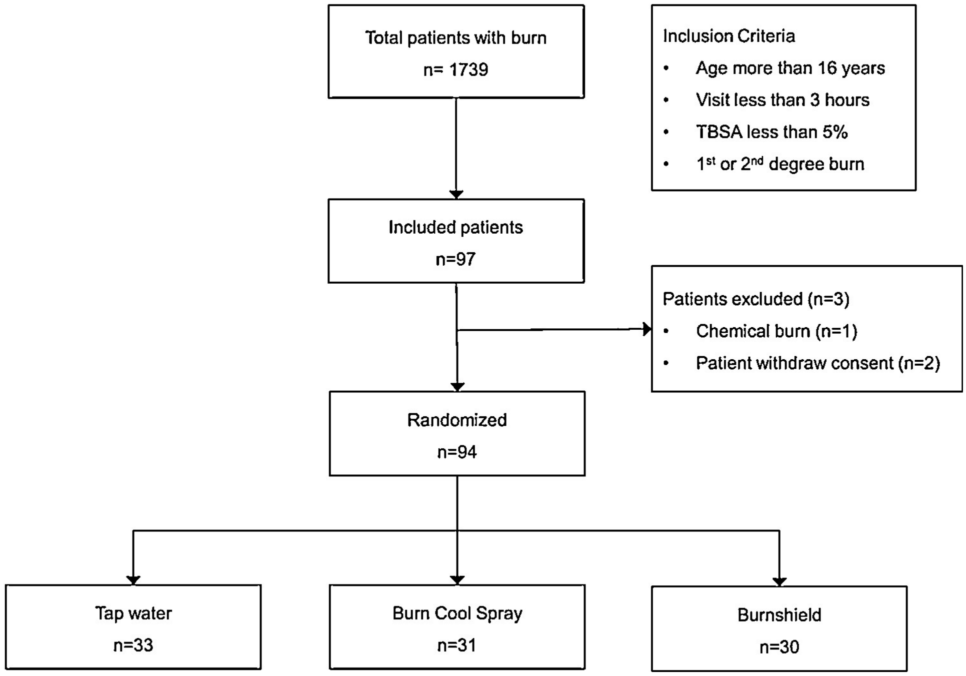

Fig. 2 – Patients' enrolment flow diagram.

Fig. 4 shows the effect of the tap water temperature on the skin surface temperature and VAS pain score reduction. There was a significant difference in skin surface temperature and VAS pain score reduction ($p = 0.014$ and $p = 0.007$) between the groups cooled by tap water below and above 24 °C. Furthermore, Fig. 5 shows the reduction in skin surface temperature and VAS pain score of patients who visited the emergency service within and after 30 min of the injury. The patients who visited within 30 min had a significantly higher skin temperature than those who came after 30 min did

Table 1 – General patient characteristics.

Variables	Tap water (*n* = 33)		Burn cool spray® (*n* = 31)		Burnshield® (*n* = 30)		P value
Male, *n* (%)	16	(48.5)	9	(29.5)	9	(30.0)	0.188
Age, y	40.2	(12.0)	42.7	(13.8)	42.3	(12.5)	0.706
Admission, *n* (%)	4	(12.1)	2	(6.5)	3	(10.0)	0.831
Accident to hospital interval, min	45.0	(22.0–99.0)	40.0	(20.0–60.0)	51.5	(25.0–72.2)	0.378
Depth of burn, *n* (%)							0.982
First degree	7	(21.2)	6	(19.4)	7	(23.3)	
Superficial second degree	22	(66.7)	22	(71.0)	21	(70.0)	
Deep second degree	4	(12.1)	3	(9.7)	2	(6.7)	
Type of burn, *n* (%)							0.944
Scald	24	(72.7)	18	(58.1)	22	(73.3)	
Contact	5	(15.2)	7	(22.6)	4	(13. 3	
Flame	1	(3.0)	2	(6.5)	2	(6.7)	
Steam	2	(6.1)	2	(6.5)	1	(3.3)	
Spark	1	(3.0)	2	(6.5)	1	(3.3)	
Site of burn, *n* (%)							0.243
Face	0	(0)	1	(3.2)	4	(13.3)	
Trunk	0	(0)	2	(6.5)	1	(3.3)	
Upper extremity	22	(66.7)	19	(61.3)	18	(60.0)	
Lower extremity	11	(33.3)	9	(29.0)	7	(23.3)	
TBSA of burn, %	1.0	(1.0–2.0)	1.0	(0.5–2.0)	1.0	(1.0–2.0)	0.696
Healing time, day	10.8	(6.1)	10.0	(6.6)	7.4	(4.7)	0.101
Initial wound temperature, °C	33.5	(31.5–35.0)	33.8	(32.0–35.4)	34.0	(32.0–35.1)	0.842
Initial VAS pain score	6.9	(2.4)	5.6	(1.9)	5.5	(2.5)	0.028

TBSA, total body surface area; VAS, visual analogue scale. Continuous variables are presented as means and standard deviations for data with a normal distribution. Data are presented as medians and interquartile ranges for variables that did not follow a normal distribution.

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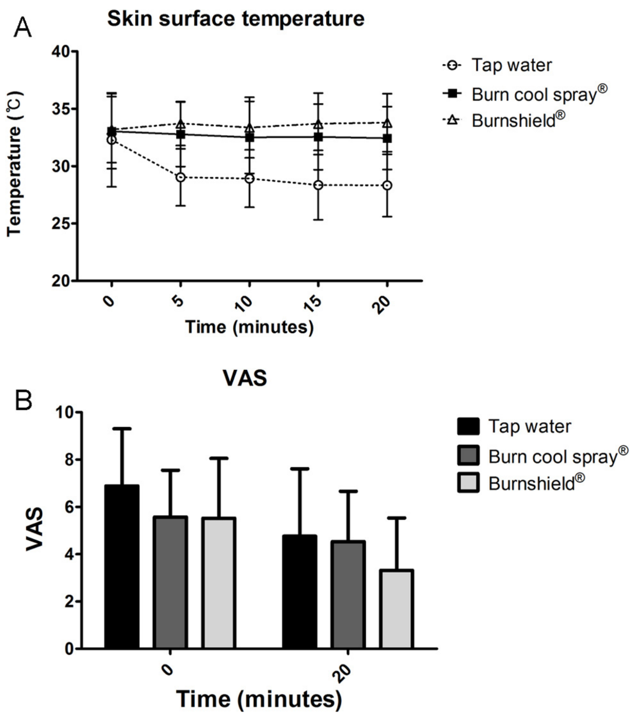

Fig. 3 – Skin surface temperature vs time (A) and pain score (B) in all three treatment groups (tap water, Burn cool spray®, and Burnshield®). (A) Skin surface temperature. (B) Pain score assessed by visual analogue score (VAS).

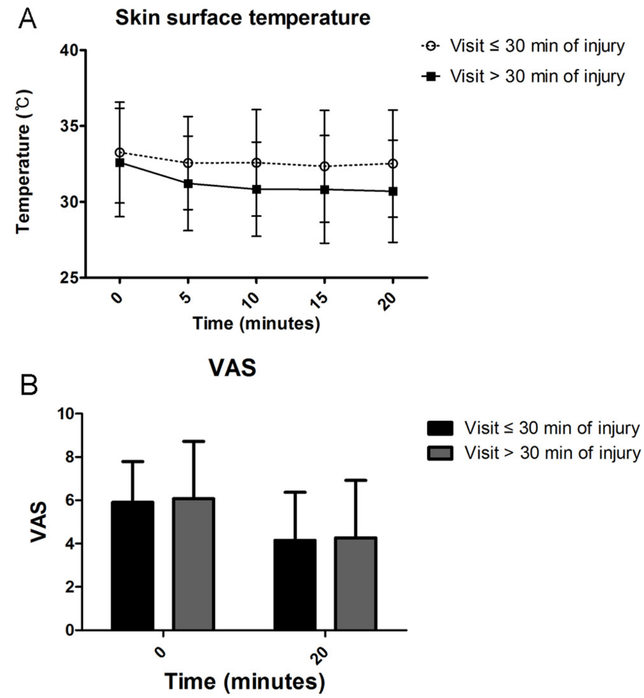

Fig. 5 – Skin surface temperature vs time (A) and pain score (B) in patients treatment procedure ≤30 min and >30 min after accident. (A) Skin surface temperature. (B) Pain score assessed by visual analogue score (VAS).

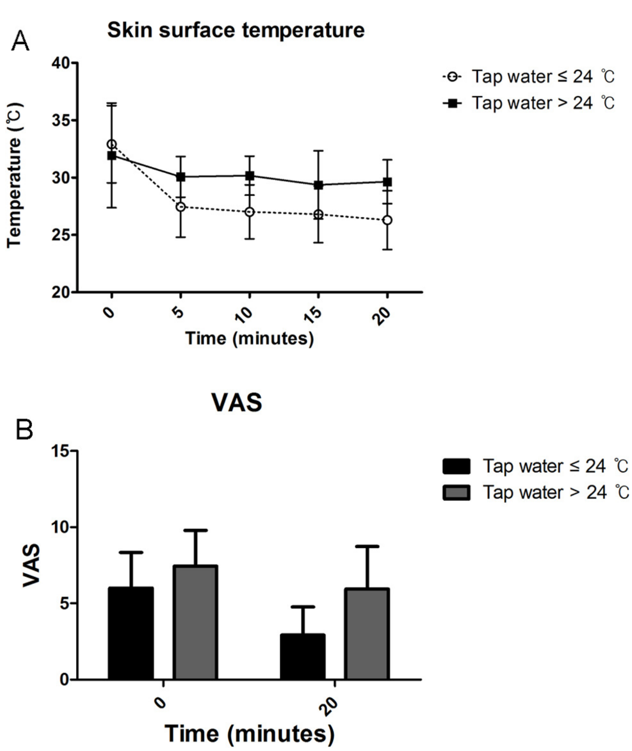

Fig. 4 – Skin surface temperature vs time (A) and pain score (B) in the tap water group subdivided in tap water temperature ≤ 24 °C and > 24 °C. (A) Skin surface temperature. (B) Pain score assessed by visual analogue score (VAS).

($p = 0.033$). However, there was no significant difference in VAS pain score ($p = 0.715$) between the two groups.

4. Discussion

The most effective first aid treatment for burn wounds is the application of cold water [10–13]. However, there are some limitations to the use of cold water in practice. First, as stated in the introduction, it is not convenient or safe to use cold water in vehicles including ambulances and airplanes. Second, it is cumbersome to use water in cases when there are multiple wounds and difficult to take a 20-min shower. Third, since tap water temperatures depend on the surrounding environment, the temperature may not be appropriate as a coolant. The temperature in Seoul started to rise from the third week of July, which partially overlapped with our study period and, therefore, the temperature of the hospital tap water increased. The temperature of the tap water in our hospital fluctuated between 23.6 °C and 27.3 °C during the study period and was at 5–8 °C in January when our study was completed. The fourth limitation of using tap water is that the volume required for a burn wound cooling procedure is high. In this study, we used 6–12 L water per minute, with a total of 120–240 L of water after 20 min of treatment. Cuttle et al. [14] used 1.6 L water per minute in their porcine study, but in clinical practice, a considerably larger amount of water is needed. In countries with water shortages, an alternative cooling method should be used when possible.

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Currently, the most commonly used burn cooling products contain tea tree oil. However, although there is a lack of clinical evidence to support their use, they are known to be effective as antibacterial, antifungal, and anti-inflammatory agents [15,16]. Australian ambulance and paramedic services [6,7], as well as numerous emergency medical service personnel and physicians in Korea use tea tree oil products. However, it is still under debate whether cooling with tea tree oil products has any influence on wound healing and scar formation [17,18], and there is no clinical evidence to support their skin soothing and pain controlling effects. We aimed to compare the clinical effects of three different cooling methods (tap water, Burn Cool Spray®, and Burnshield®) on skin surface cooling and pain control.

The skin cooling effect is generally evaluated by measuring dermal temperature [8]; however, this is not possible in humans because the technique is invasive. We hypothesized that skin surface temperature indirectly reflects dermal temperature. Therefore, the changing pattern of skin surface temperature may be more important than the absolute temperature value. The skin surface temperature in the tap water and Burn Cool Spray® groups decreased by 4 °C and 0.6 °C, respectively while in the Burnshield® group it increased by 0.6 °C. The decrease in skin surface temperature in the tap water group was significantly greater than it was in the other two groups. The VAS pain score of all three groups significantly decreased after 20 min of cooling. The tap water but not the Burn Cool Spray® was more significantly effective in reducing the pain than the Burnshield® was in the post hoc analysis; however, a tendency towards a higher efficacy was observed. One explanation for the superior performance of the Burn Cool Spray® over that of the Burnshield® may be that it was applied repeatedly to the wound. Clinically, we used Burn Cool spray® and Burnshield® in the same manner. Another reason may be that the temperature of the Burn Cool Spray® (15 °C) was lower than that of the Burnshield® (21 °C) was. The temperature of the Burn Cool Spray® at 15 °C is close to the ideal tap water cooling temperature suggested in previous studies (12–22 °C) [18,19]. However, the tap water was more effective in reducing the skin surface temperature than the other two methods were. This could be because the temperature of the Burn Cool Spray® and Burnshield® increased following their extended exposure to the burn wound while that of the running tap water was kept constant during the procedure. A remarkable fact in controlling pain is numerous patients is that significant pain scores were still observed after the burn cooling. Therefore, it is necessary to administer an additional pain reducing treatment such as analgesics with the cooling. During the study period, the lowest and highest temperature of the tap water was 23.9 °C and 27.3 °C, respectively. This temperature range was higher than that suggested in some animal studies [18,19]. We did not control the temperature of the tap water because it is difficult for burn victims to do so in actual real life situations.

The temperature of the tap water remained below 24 °C until the second week of July but suddenly started to rise to 27.3 °C. Then, the analgesic effect of the tap water decreased with an increase in the temperature of the tap water. Based on this clinical experience, we divided the subjects into two groups based on the tap water temperature 24 °C and compared the cooling effect between both groups. Fig. 4 shows the different effects of tap water at a temperature below and above 24 °C on the skin surface temperature and pain. The below 24 °C group had a significantly greater reduction in the skin surface temperature and pain than the above 24 °C group did.

Additionally, we measured the temperature of the tap water after the study was completed. The outside temperature was constantly below zero during the following month of January and, therefore, the tap water in the emergency room was at 6–9 °C. This range corresponds to the temperature of ice-cold water (1–8 °C). According to the study of Venter et al. [19], cooling with water at this temperature range could be harmful to the tissues [19].

Fig. 5 shows that the patients who visited the emergency services department within 30 min of their burn accident had a slower rate of skin surface temperature reduction than those who attended after 30 min did. Therefore, patients who visited the emergency services center within 30 min of the burn accident needed cooling for longer than 20 min to attain a comparable skin surface temperature to those who were treated after 30 min. The skin surface temperature does not directly reflect the dermal temperature, but we could infer that these temperatures might be related to each other and the potential tissue damage. This phenomenon may be due to a higher latent heat in the skin at an early than at a later stage. This is consistent with the results of Venter et al. [19] who found that immediate cooling took longer to lower the dermal temperature than delayed cooling (commenced after 30 min) did due to the presence of more latent heat in the skin at an early than at a later stage. Venter et al. [19] also reported that delayed cooling was more effective in limiting tissue damage than immediate cooling was in the same study.

This present study has several limitations that are worth mentioning. First, we measured the temperature of the skin surface and not the dermis and, therefore, it was not possible to determine the direct effect of the cooling methods on the temperature reduction. Second, since the tap water group showed a significantly higher initial VAS pain score than other groups did, it is difficult to compare objectively the analgesic effect between the groups. It may be more difficult to reduce the pain of patients with relatively low VAS pain score than it is to reduce that of patients with a high VAS pain score or vice versa. We could not identify the exact cause of the significantly higher VAS in the tap water group. One possible explanation is that significantly smaller numbers of patients in the tap water group received the prehospital cooling with ice or ice water than in the other two groups. Ice or ice water is more effective for reducing pain than tap water is. Furthermore, 30.3%, 48.3%, and 53.3% (10/33, 15/31, and 16/30) of patients in the tap water, Burn Cool Spray®, and Burnshield® groups, respectively received prehospital cooling with ice or ice water. Third, 90% of the patients in our study had superficial burns (first and superficial second degree). Therefore, patients with more severe burns (deeper than superficial second degree) might display different results. In addition, we could not investigate the influence of cooling methods on wound healing. The healing time was

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2 days shorter in patients treated with the Burnshield® than it was in patients treated with the other methods (Table 1). However, this was not statistically significant ($p < 0.101$) possibly due to the small sample size. Fourth, we could not find any studies that were similar to this one and, so, we could not calculate an appropriate sample size. Therefore, the sample size was too small to detect a potentially clinically significant difference in healing time. Fifth, the nature of this study did not allow us to incorporate double blinding and, therefore, the patients as well as the research coordinator who applied the cooling procedure and measured the surface temperature or recorded pain scores were aware of the cooling methods. However, the treating physician was unaware of the cooling methods for each group. Finally, we did not include an untreated control group in this study because of the ethical considerations and, therefore, we could not evaluate the change in the VAS in the absence of treatment.

5. Conclusion

Tap water and Burn Cool Spray® reduced the skin surface temperature while the Burnshield® slightly increased it. All three cooling methods were effective in relieving pain. The temperature of the tap water correlated with the reduction in the skin surface temperature and VAS pain score. The patients who visited the emergency services center within 30 min of the burn accident needed cooling for longer than 20 min to attain a comparable skin surface temperature to those who arrived after 30 min. This might be due to the latent heat in the skin at an early stage.

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Conflict of interest

Regencare Co., Ltd., provided the coolants (Burn Cool Spray®) used in this study. However, Regencare Co., Ltd was in no way involved in the study design or the data collection, analysis, and interpretation.

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