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Original Article

Application of ice and vapocoolant spray to reduce tetanus vaccine pain: A prospective, randomized, controlled, clinical study

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Abstract

Aim: Tetanus is one of the vaccine-preventable diseases, that threatens human health in our country and the world, and one of the most common symptoms after vaccination is localized pain. In this study, we aimed to compare the effectiveness of vapocoolant spray with ice application and control group in reducing the pain during vaccination.

Material and Method: This prospective randomized controlled trial included 292 patients who received tetanus vaccination between January 1st, 2017 and April 1st, 2017 and who agreed to participate in the study. Patients were assigned to 3 groups. Before vaccination, vapocoolant spray was applied to Group 1 and ice was applied to Group 2, and application was directly performed to Group 3 (control). The pain at the time of vaccination and at injection was noted between 0-100 using Visual Analogue Scale (VAS).

Results: Of the 315 patients included in the study, 292 fulfilled the inclusion criteria. Patients who were applied ice (5.3 ± 7.1) or vapocoolant spray (4.1 ± 5.4) at the time of intervention had statistically significantly lower VAS values than control group (8 ± 10.6) ($p = 0.002$; $p < 0.001$, respectively). The mean VAS values during injection, in control patients and ice and vapocoolant spray applied patients were found to be as 9.5 ± 8.11; 6.3 ± 7.4; 11.5 ± 10.2, respectively. VAS values at injection were statistically significantly lower in ice-applied patients than in the control group ($p = 0.039$).

Conclusions: Both ice and vapocoolant spray reduce pain occurred during tetanus vaccination compared to the control group. With easy and fast applicability, ice and vapocoolant spray can be used to reduce the pain during the tetanus vaccine.

Keywords: Vapocoolant spray; ice; tetanus; vaccine.

INTRODUCTION

Tetanus is one of the vaccine-preventable diseases, that threatens human health in our country and the world (1). One of the most common symptoms after vaccination is localized pain (2). Although topical creams, oral analgesics (acetaminophen and ibuprofen) and special anesthesia delivery systems have been used to relieve pain, a single method has not achieved universal success (3).

Ice application has been used as an analgesic since ancient time medicine (4). First, this method reduces pain by eliminating edema and muscle spasm. In addition, ice application is effective in relieving pain by slowing or blocking the conduction of peripheral nerves (5). It is a method that can be prepared cheaply and performs skin anesthesia relatively quickly. It has been previously found that application of ice to the injection site has been effective in reducing pain in adult patients who will receive tetanus vaccination (6). Similarly, vapocoolant spray is the cryotherapeutic topical agent used in short, painful procedures (7). Many studies have shown that vapocoolant spray reduces operation-related pain during emergency venous interventions, but there is no study on the use of tetanus vaccine-induced pain (8,9).

The aim of this study was to compare the efficacy of vapocoolant spray with ice application and control group in reducing the pain caused by tetanus vaccination in adults.

MATERIAL and METHODS

Local ethics committee approval was obtained in this prospective randomized controlled study. Written informed

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consent was obtained from all patients participating in the study. This study included patients aged 18 years and older who received tetanus vaccination in the emergency department between January and April 2017. Patients who were younger than 18 years of age, refused to participate in the study, unstable patients, those who had painkiller within 24 hours before the procedure, patients with acute or chronic pain to suppress the injection pain were not included in the study. Patients' age, sex, pain experienced by the patients during vaccination were recorded using Visual Analogue Scale (VAS). VAS is the most commonly used method in pain scales (10). In our study, pain scores during the introduction of the needle into the skin and during the intramuscular injection of tetanus toxoid were noted. The VAS score, which was asked to be marked firstly, was the measured value for the pain that occurred when the 25 gauge injector needle used in the emergency room for this vaccination punctured the skin. Our hypothesis is that the ice and coolant spray minimizes this pain. The second VAS score that we ask from the patients to mark is to measure the tension-induced pain caused by 1 cc of tetanus toxoid injected into the deltoid muscle. Injection was made to the non-dominant arm of the patients.

Patients were given detailed information about the procedure VAS. Before vaccination, patients were randomized by the method of closed envelope. Group 1: Vaccination was performed to patients 10 seconds after the vapocoolant spray application. Group 2: Vaccination was performed to patients 30 seconds after the ice therapy. Group 3: Vaccination was performed to patients directly. Vapocoolant spray (Nexcare® Coldhot, containing ethyl chloride, fluorinated hydrocarbon and alkane mixtures (butane, propane, and pentane) was applied on the skin according to the manufacturer's instructions for 10 sec, from 10 cm above until whitening begins on the skin. Ice treatment was performed on the forearm by applying the ice cube (3x3x3 cm) placed in a latex glove for 30 sec. 30 min after the administration of the tetanus vaccine, the intervention and injection pain scores were measured using a 100 mm visual analogue scale with 'no pain' text (0 mm) at the left end of the scale and the 'worst pain possible' text (100 mm) at the right end. This scale is a validated, reliable and easy way to measure pain. In our study, VAS scores over 30 were accepted as moderate pain, above 54 mm as severe pain (10).

Statistical analysis

Descriptive statistics used in the study were frequency, percentage, mean, interval and standard deviation. Two-way comparisons between the vapocoolant group and the other groups were performed using chi-square test. VAS scores during intervention and injection were compared with the Mann-Whitney U test. Statistical analysis was performed using Windows SPSS 18.0 (SPSS Inc, Chicago, Ill) and $p < 0.05$ was considered significant.

RESULTS

Of the 315 patients included in the study, 23 did not meet the inclusion criteria (Figure 1). Table 1 shows the differences between the three groups (control, ice and vapocoolant spray).

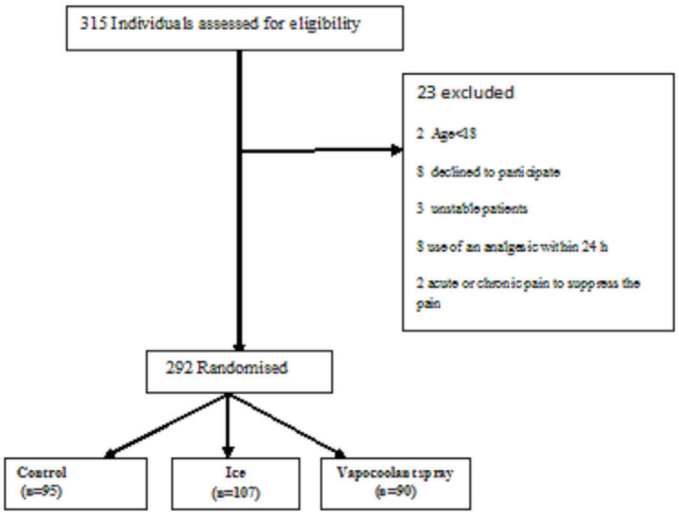

Figure 1. Flow chart of participants

Table 1. The comparison of study groups in terms of demographic status and pain scores, assessed by the visual analogue scale (VAS)

	Control (n=95)	Ice (n=107)	Vapocoolant spray (n=90)	p^1	p^2	p^3
Age (years)	37.7±16.2	38.4±15.7	40.2±17.8	NS	NS	NS
Gender (female/male)	33/62	32/75	30/60	NS	NS	NS
Administration						
VAS mm	8±10.6	5.3±7.1	4.1±5.4	0.002	<0.001	NS
Moderete pain VAS >30 mm (n)	4	2	1	NS	NS	NS
Severe pain VAS>54 mm (n)	2	0	0	NS	NS	NS
Injection						
VAS mm	9.5±11.8	6.3±7.4	11.5±10.2	0.016	0.039	<0.001
Moderate pain VAS >30 mm (n)	8	2	2	0.017	NS	NS
Severe pain VAS>54 mm (n)	1	0	1	NS	NS	NS

p^1 = comparison between control group and ice group
p^2 = comparison between control group and vapocoolant spray group
p^3 = comparison between ice group and vapocoolant spray group
Abbreviations: VAS-visual analogue scale; NS- non specific

There was no significant difference between the groups in terms of age and sex. The mean VAS values at the time of intervention in control patients, ice and vapocoolant spray applied patients were found as 8 ± 10.6, 5.3 ± 7.1, 4.1 ± 5.4, respectively (Table 1; Figure 2). Ice or vapocoolant spray applied patients had statistically significantly lower VAS values than the control group (p = 0.002; p <0.001, respectively). However, no significant difference was observed in patients with moderate or severe pain.

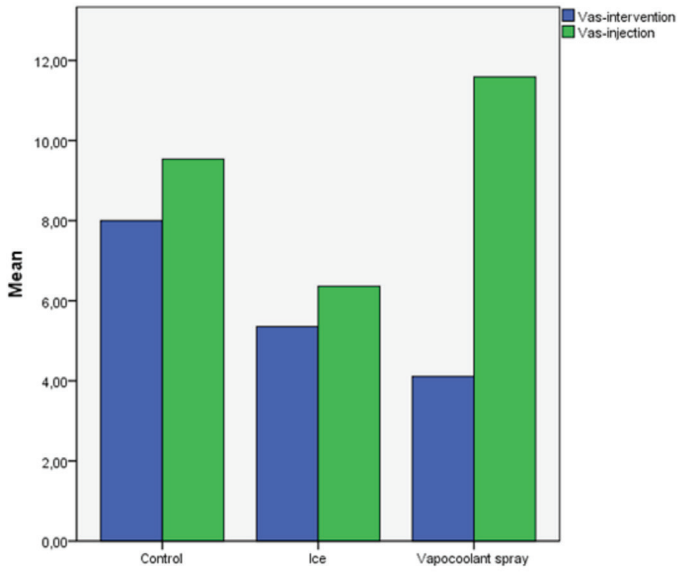

Figure 2. Histogram of patients VAS scores during the intervention and injection

The mean VAS values during injection in control patients and ice and vapocoolant spray applied patients were found to be as 9.5±11.8, 6.3±7.4, 11.5±10.2, respectively (Table 1; Figure 2). In vapocoolant spray applied patients, higher VAS values were obtained at the time of injection compared to control and ice applied patients (respectively, p = 0.016; p <0.001). VAS values at injection were statistically significantly lower in ice applied patients than in the control group (p = 0.039). In addition, in ice applied patients, those with moderate pain were statistically significantly lower than in the control group (p = 0.017). There was no significant relationship between pain scores and age and sex (p> 0.05).

DISCUSSION

Vapocoolant spray is an evaporative spray made with ethyl chloride and has been shown to provide anesthesia during injection (11). Since then, vapocoolant spray has been widely used in minor surgical procedures, sports injuries and muscle pain for pain control (12). In addition, it is cheaper than many local anesthetic agents, can be applied quickly and can act immediately (13). However, as far as we know, there is no study in the literature about the usage for pain control during the tetanus vaccine application.

It is controversial whether Vapocoolant spray reduces intravenous cannulation related pain in comparison with placebo and non-treated patients. In a prospective, randomized study conducted by Mace et al., it was reported that it reduced intravenous cannulation related pain (14). Similar results have been reported in another study with pediatric patients (14). However, Hartstein et al. did not detect any difference in adults in pain perception between Vapocoolant spray and controls (15). In our study, vapocoolant spray applied patients were found to have low pain scores at the time of tetanus intervention compared to the control group; however, VAS values were found to be higher compared to control and ice applied patients, during injection. We believe that this situation may be caused by the difference in sensitivity of the patients to perceive the pain.

It has been known for centuries that people use ice to alleviate pain (16). Both ice and vapocoolant spray reduce the temperature of the surface to which they are applied. Thus, nerve conduction rate decreases, causing a decrease in pain sensation (17). In their study, Goel et al. used ice cubes as analgesic preparations and found a significant reduction in pain during minor surgery (18). In another study, they reported that the pain during lidocaine and epinephrine injection decreased with ice application (19). Yoon et al. compared vapocoolant spray with ice in intradermal skin test and found that ice was more effective in reducing pain (8). In our study, ice application was significantly lower in the tetanus vaccine compared to the control group both during the intervention and at the injection. In addition, in ice applied patients, those with moderate pain were statistically significantly lower than in the control group (p = 0.017). Despite these effects, it is a disadvantage that the ice cannot always be at hand and that its life is short due to the ambient temperature. It can also be an important indicator in terms of comfort for the patients to indicate that their hands are cold when they hold the ice on the area to be injected. However, coolant sprays can be easily and reliably used in any environment.

Patient characteristics that may affect the perception of pain were examined in many studies and they stated that sex was the most important factor affecting the perception of pain and that women were more sensitive to pain than men (20). In their study Alsantali et al. found that women who applied ice had significantly higher pain scores than men (4). In this study, the pain score was assessed over 10, and this score was found to be 5.4 in women and 4.1 in men (p <0.001). In our study, different from the literature, no significant relationship was found between sex and VAS. As shown in Figure 2, the application of cold significantly reduces the pain at the time the needle punctures. However, they seem to feel more tension within the muscle. Considering that there are many internal and external features affecting the pain, this situation should be evaluated with a larger prospective study.

There are some limitations to our study. Firstly, the perceived pain during injection may vary depending on the depth of the needle and the injection technique. Although the practice was performed by experienced nurses in our

study, the application was not performed by a single nurse. Secondly, many different indicators and criteria were used to evaluate pain in the studies. Thirdly, the lack of a study that could be compared with our study of the efficacy of vapocoolant spray in relieving pain in tetanus vaccine pain. Finally, our study was conducted in a single center with a small number of patients. Multicenter studies with larger patient population are required.

CONCLUSION

In our study, we compared ice application, vapocoolant spray usage and control group to reduce pain during tetanus vaccination. Both ice and vapocoolant spray significantly decreased the pain compared to the control group. Both ice and vapocoolant spray can be used to reduce pain during tetanus vaccination with easy and fast applicability.

Competing interests: The authors declare that they have no competing interest.
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