Original Article

Effects of ShotBlocker on Relief of Pain Due to Hepatitis B Vaccine Injection into Deltoid Muscle

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Abstract

Backround: Different techniques have been used to reduce pain due to intramuscular injections, one of the nursing functions. ShotBlocker is one of the techniques used for reduction of pain.
Aim: This study was performed to examine effects of ShotBlocker on relief of pain due to hepatitis B vaccination into deltoid muscle in adults.
Methodology: The study has a randomized-controlled and single-blind design and was conducted between September and November in 2015. It consisted of two groups; i.e. experimental and control groups, and 242 participants aged 18-31 years old. While ShotBlocker was used in the experimental group during vaccination, routine vaccination was performed in the control group. Pain severity was evaluated by using Visual Analog Scale (VAS) at the end of vaccination. Data were analyzed with t-test, mean, numbers and percentages.
Results: There was not a significant difference in pain severity between the experimental and control groups. The women in both groups had more severe pain. Body-mass index was found to affect pain severity in both groups. In fact, as body-mass index increased, pain severity decreased.
Conclusions: Using ShotBlocker does not affect severity of pain caused by vaccination of Hepatitis B into deltoid muscle. However, irrespective of use of ShootBlocker, body mass-index affects pain and women with a low body mass index can have more severe pain.

Key words: Injection Pain, Intramuscular, ShotBlocker, Nursing

Introduction

One of the most frequent complications encountered during intramuscular injections, one of the basic nursing functions, is pain. Most patients complain about pain during and after injections. There are several mechanisms of pain due to intramuscular injections, including mechanical trauma caused by needles, types of medicine, speed of injections, injection sites, age and gender (Carter & McCoy, 2008; Kusumadevi et al., 2011) Nurses use some non-pharmacological techniques to reduce pain due to intramuscular injections. Of all these techniques, distraction of patients' attention (Rodger & King, 2000), pressure application by hands onto injection sites (Chung et al., 2002) and cold compression on injection sites before injections (Hasanpour et al.,2006) have been found to reduce pain.

Another technique is to apply ShotBlocker on injection sites to reduce pain due to intramuscular injections. ShotBlocker is a small, flat plastic device applied to skin and has a horseshoe-shape (U-shaped). It has short and blunt rounded nubs on the underside (Figure 1-2). The underside of the device is placed onto injection sites just before injections. There is an opening in the middle of the device leaving the

injection site open. ShotBlocker is pressed on the surface of skin during injections. It is thought to reduce pain by stimulating nerve endings faster with pressure of rounded nubs on the device. This stimulation decreases pain by blocking pain signals temporarily during injections and by inhibiting the central nervous system (Cobb & Cohen, 2009).

Figure 1. ShotBlocker, underside with rounded nubs

Figure 2. ShotBlocker, upside

Studies directed towards showing whether ShotBlocker is effective in reducing pain during injections have generally been conducted on children. Drago et al. (2009) used ShotBlocker on children during intramuscular injections. Although their observations of nurses and caregivers revealed that ShotBlocker was effective in reduction of pain, the children's pain evaluations did not show that it was effective (Drago et al., 2009) Cobb and Cohen (2009) found that ShotBlocker was not effective in relief of pain and anxiety due to injections in children (Cobb & Cohen, 2009). Besides, Celik and Khorshid (2015) in their study on adult patients reported that ShotBlocker reduced pain but did not reduce anxiety during intramuscular injections (Celik & Khorshıd, 2015).

Research Question

Does ShotBlocker effect on relief of pain due to hepatitis B vaccination into deltoid muscle in adults?

Methodology

This is a randomized, controlled, single-blind study and was carried out on the first-grade students studying at a school of health in nursing and midwifery departments of a university between September and November in 2015.

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Table 1. The distribution of age, height, weight and body mass index of the participants in the experimental and control groups (n=242)

	Experimental Group (n=121)	Control Group (n=121)
	X±SD	X±SD
Age (year)	19±1.69	19±1.35
Height (cm)	165.0±7.17	166.6±7.66
Weight (kg)	59.8±1021	59.8±10.23
BMI (kg/m^2)	21.5±3.26	21.4±2.93
Gender Female Male	 100 (82.6%) 21 (17.4%)	 100 (82.6%) 21 (17.4%)

Table 2. The Comparison of VAS Scores between the Experimental and Control Groups (n=242)

Group	VAS Scores			
	n	X±SD	t	p
Experimental Group	121	33.8±26.05	0.259	0.796
Control Group	121	33.0±23.87		

Table 3. Differences in VAS Scores between the Females and the Males in the Control and Experimental Groups (n=121)

Gender	n	VAS Scores in the Experimental Group			VAS Scores in the Control Group		
		X±SD	t	p	X±SD	t	p
Female	21	37.95 ± 25.46	4.01	0.00	36.0± 25.01	3.10	0.00
Male	100	14.28 ± 19.38	4.79		18.80 ± 8.04	5.62	

The study population consisted of 292 individuals aged 18-31 years old. The simple randomization method was used for sampling. Fifty individuals vaccinated against Hepatitis B before and having sustaining effects of immunization with this vaccine were not included in the study. Thus, the study sample included 242 individuals, who were randomly divided into experimental and control groups.

Randomization was performed by drawing lot and 121 individuals were assigned into the experimental group and 121 individuals were assigned into the control group.

Data were gathered with a questionnaire created by the researchers. It consisted of two sections; Section I included questions about demographic features such as age, gender, height and weight, and section II was composed of Visual Analog Scale (VAS).

Before vaccine injections, height and weight of the participants were measured and recorded in the questionnaire. The rest of the questions were also completed. Then, the injections were performed. Hepatitis B vaccine is administered into deltoid muscle, located on the outer side of the upper arm. It is a suitable site for injecting little and non-irritating medicine (Gray & Miller, 2008). Drug absorption is fast in this muscle because it has a good blood flow (Carter & McCoy, 2008; Rodger & King, 2000). Twenty-four-gauge needles are used and injections are performed at a 90-degree angle. One-millimeter medicine can be administered into deltoid muscle at most (Potter & Perry 2013; Small, 2004). In this study, all the injections were administered into the muscle by the same researcher. Euvax B vaccine 1ml was used and 0.5ml of Euvax B vaccine was composed of 10 ug vaccine. Hepatitis B vaccine was administered via a 25X25 gauge needle and a syringe with 1 ml-volume.

In the experimental group, before injections, rounded nubs of ShotBlocker were placed on deltoid muscle in a way that they could touch the skin and that the injection site would be open. Then, Hepatitis B vaccine was administered. At the end of injections, injection syringes were removed, insertion sites were pressed with a piece of dry cotton, and ShotBlocker was removed from the sites. No massage or firm pressure was applied to the injection sites. After the injections, pain severity was evaluated by another researcher by using VAS. As for the control group, the same vaccine dose, the same type of needles, and the same size of syringes were used by the same researcher. The same vaccination technique was utilized as in the experimental group except for the use of ShotBlocker. After the injections, pain severity was evaluated by using VAS and recorded.

Ethical approval was obtained from the ethical committee of Medical School, the Directorate of Health School and the Public Health Directorate. In addition, written and oral informed consent was obtained from the participants.

Results

A total of 242 individuals, of whom 121 were in the control group and 121 were in the experimental group, were included in the study. In the experimental group, the mean age, was 9±1.69 years (range: 18-31 years), the mean height was 165.0±7.17 cm (range: 150-185cm), the mean weight was 59.8±10.2 kg (range: 42-110kg) and the mean body mass index (BMI) 8±3.26kg/ m^2 (range: 16- 37.5kg/m^2). Of all the participants in the experimental group, 82.6% were female and 17.4 % were male. In the control group, the mean age was 19±1.35 years (range: 18-25 years), the mean height was 166.0±7.6 cm (range: 150-187 cm), the mean weight was 59.8±10.2 kg (range: 35-88 kg) and the mean BMI was 21.4±2.93 kg/m^2 (range: 14.2-30.4 kg/m^2) (Table 1).

The mean VAS score of the individuals was 33.8 ± 26.0 (range: 0.0- 100.0) in the experimental group and 33.0±23.8 (range: 0.0-100.0) in the control group with a statistically significant difference (t= 0.259; p= 0.796>0.05) (Table 2). In the ShotBlocker group, the mean VAS score was 37.95±25.46 in the females and 14.28±19.38 in the males with a statistically significant difference (p=0.00< 0.05).

In fact, the women exposed to ShotBlocker had more severe pain than the men exposed to Shot Blocker. In the control group, the mean VAS score was 36.0±25.01 in the females and 18.80±8.04 in the males with a statistically significant difference (p=0.00< 0.05). The women felt more severe pain than the men in the

group not exposed to ShotBlocker (Table 3).

Discussion

The present study showed no significant difference in pain severity between the group in which ShotBlocker was used and the one in which ShotBlocker was not utilized during injections of Hepatitis B vaccine (p=0.796> 0.05; Table 2). Therefore, ShotBlocker was considered as ineffective in reducing pain due to vaccine injections, which is consistent with the literature. In a study by Drago et al. on children aged between 2 months and 17 years (2009), although nurses thought ShotBlocker helped to decrease pain, there was not a decrease in pain severity (Drago et al., 2009).

Another study examining effects of ShotBlocker on pain in children aged between 4 and 12 years during vaccination revealed that ShotBlocker was not effective in reducing pain and anxiety (Mennutı, 2007). Foster et al. found in their study on 171 children aged between 3 months and 17 years that ShotBlocker was ineffective in lowering pain during vaccination (Foster et al., 2005).

Susilawati et al. (2010) examined effects of ShotBlocker on 66 neonates to whom Hepatitis B vaccine was administered. In contrast to findings of abovementioned studies, they determined that injection pain in the experimental group was lower than that of the control group (Susilawati, Arhana, Subanada, 2010).

The age of the study group ranges from neonatal period to 17 years in the forgoing studies examining effects of ShotBlocker. The current study was carried out on individuals aged 18 - 31 years. Considering that most of the studies reported in the literature including the present study did not reveal a significant difference in pain severity between individuals exposed to ShotBlocker and those not exposed to this pain-relieving apparatus, it can be concluded that ShotBlocker does not affect pain severity. However, it has been known that the density of deltoid muscle into which intramuscular injection is applied varies with age. As deltoid muscle is small, the area available on this muscle for injection is limited. It has been reported that the muscle sometimes may not completely develop even in adults. In addition, individual differences affect the muscle size and density. It has been stated that the distance between the midpoint of deltoid muscle and the axillary nerve is 2 cm on average in children and 5 cm in adults based on measurements made on the front side of the muscle. This distance may vary depending on individual differences and gender. Proximity of the muscle to the nerve also affects pain severity and duration (Chung et. al., 2002; Hasanpour et. al., 2006; Kontakis et. al., 1999; Loukas et. al., 2009). This can explain conflicting findings from studies about effects of ShotBlocker on injection related pain. Celik and Khorshid (2015) used the ventrogluteal site for intramuscular injections in their study on adults and found that ShotBlocker reduced pain. The injection site can also be responsible for conflicting findings in the literature (Celik & Khorshıd, 2015).

In the present study, gender differences were found to affect pain severity significantly both in the individuals exposed to ShotBlocker and those not exposed to this apparatus (p<0,05; Chart 3). In fact, the women in both groups had more severe pain than the men. Mitchell and Whitney (2010) examined effects of injection speed on pain during intramuscular Hepatitis B vaccinations in adults and reported that women felt more pain than men (Celik & Khorshıd, 2015).

Kusumadevi et al. (2010) in their study on perceived pain in men and women during intramuscular injections examined pain severity in 300 individuals aged between 15 and 45 years during injections given to the gluteal site. They determined that women felt much more pain than men. They attributed the difference to the fact that plasma estrogen levels might cause a variety of changes in neurotransmitters such as serotonin, ß endorphin, acetylcholine and dopamine (Kusumadevi et al., 2011). In a study by Wadner et al. (2012) using The Gender Role Expectation of Pain Questionnaire (GREP) to evaluate effects of gender on pain, women were found to be more susceptible to pain [19]. Similarly, Harris et al. in their study on adults aged 14-45 years found that women experienced much more pain after administration of HPV vaccine into deltoid muscle (Wandner et al., 2012).

Racine et al. (2012) reviewed studies on gender

differences in pain published over the past decade. They classified factors affecting pain into biological, physiological, psychological, and social factors, and past experiences. They showed that hormonal factors, considered as biological factors, (gonadal steroid hormone, hormones released during menstrual cycle and stress hormone) were effective. Physiological factors affecting pain severity were found to be blood pressure, heart rate, peripheral sensitivity of the nervous system and pain mechanisms. Psychological factors including depression, anxiety, and stress and personal factors were also reported to play a role in perceived pain (Racine et.al., 2012). These factors, not examined in the current study, could have explained the reasons why women felt much more pain than men. Shankara et al. (2014) measured the distance between the deltoid site and bone tissue and subcutaneous tissue during intramuscular injections in 200 adults. They found that subcutaneous tissue was thicker and that muscle tissue was thinner in women than in men (Shankara et. al., 2014). Ozdemir et al. determined pain severity 10 and 30 minutes after intramuscular injections into the dorsogluteal site. They reported that men and individuals aged over 40 years had more severe pain 10 minutes after the injections. Results of the abovementioned studies suggest that many factors can affect pain in men and women and that physiological differences can get involved in pain severity (Ozdemir et.al.,2010).

In the present study, BMI significantly affected pain severity in both control and experimental groups ($p<0.05$). A study in which deltoid muscle tissue was scanned with ultrasound showed a positive correlation between thickness of deltoid fatty tissue and BMI (Shankara et. al., 2014). Consistent with the present study, Ozdemir et al. (2010) reported that normal-weight and thin (BMI under 24.9) individuals had more severe pain 30 minutes after intramuscular injections than others (Ozdemir et.al., 2010). It seems that as weight increases, thickness of deltoid tissue increases, and consequently, pain severity decreases.

During intramuscular injections into deltoid muscle, it is important to grasp the muscle tissue in thin and normal-weight individuals. In fact, it is necessary to grasp the muscle tissue and to hold the ShotBlocker with one hand and to perform aspiration with the other.

Therefore, while administering injections into deltoid muscle, nurses using ShotBlocker need to have good manual skills.

Conclusions

In light of the results of this study, it seems that ShotBlocker utilized during Hepatitis B vaccine administrations into deltoid muscle does not affect pain. Besides, women can experience more severe pain during hepatitis B vaccine injections regardless of usage of ShotBlocker. In addition, as body mass index increases, pain severity can decrease. It can be suggested that the study should be replicated in different age groups and in larger samples.

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