

The effect of the rapid injection technique without aspiration on pain level in intramuscular vaccination-a single-blind randomized-controlled trial

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Abstract

Aim: This experimental, single-blind, randomized controlled trial study was conducted to compare the effect of the rapid injection technique without aspiration on pain level in the vaccination for the young adult students.

Material and Methods: This was an experimental, single-blind, randomized controlled trial. The population of the study consisted of the nursing students who had to be tetanus vaccinated as a protective measure before the clinical practice. The students were divided into two groups, as the rapid injection technique without aspiration and control group with standard vaccination technique. The distribution of the students in the groups were made by using simple random method. The Numerical Rating Scale was used to determine the perceived pain level. In order to score the fear levels, the students were requested to choose the closest number, related to their fear, among the numbers between 0-10.

Results: In the study, it was determined that the pain mean scores of the students in the intervention group were lower compared to the students in the control group ($p=0.000$). A statistically positive correlation was determined between the fear mean score and the pain mean score ($r=0.323$) and the pain score increased with increasing fear score.

Conclusion: It was concluded that the rapid injection technique without aspiration was effective and useful in eliminating the vaccination-related pain in the young adult students. Based on these results, it is recommended for nurses to use this method, which is simple, rapid and does not require any preparation, in vaccination in adult individuals.

Keywords: Needle aspiration; pain control; vaccination

INTRODUCTION

Developing and managing vaccines is among the major public health successes of the 20th century. Hundreds of millions of diseases and millions of deaths have been prevented by vaccines (1). According to the World Health Organization (WHO), it is estimated that approximately 16 million injection administrations are made for the purpose of vaccination and treatment (2). Vaccines are accepted as one of health gains with the lowest cost by WHO and Disease Control Centers (3,4).

Despite many proven benefits of vaccines, vaccination-related pain may be a major source of worry and distress (1). Although the vaccination-related acute pain relieves in minutes, hours or days, the emotional sequelae like fear of

needle due to this may cause longer-term effects (5). The fear of needle may affect health negatively by causing the avoidance of the preventive and therapeutic care services and unwillingness towards being vaccinated, which is a worldwide public health anxiety. It is stated that the vaccine injections are considered as painful interventions and the associated fear is one of the most important factors for the lowness of the adulthood vaccination rates (4,6). In the literature, it has been stated that one of every 12 children and adults avoids being vaccinated and about 8% of the people with influenza risk in the USA reject being vaccinated due to the associated pain (4,7,8). It has been stated that a pain management, that is effective in vaccinations, will increase the immunity of the public by decreasing the number of the people, who reject being

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immunized, and in this way, the epidemic illnesses, that can be prevented by vaccination, may be eliminated (4). In the report prepared by WHO (2015) on reducing pain in vaccinations, the effective pain reducing interventions for adolescents and adults are among the primary research fields (9).

In order to reduce the pain and the distress experienced during vaccination, many various methods have been tried for many years including pharmacological, non-pharmacological and injection techniques (10,11). It is recommended that the method to be used is recommended to be an easy and rapid application that requires no preparation (12). In the literature, there are practices like manual pressure/massage, cold application, the use of topical anesthetics, using a proper injection technique as examples for these applications (13-18). While there are many studies on practices such as using manual pressure/massage practice, the use of topical anesthetics, performing cold application in eliminating the vaccination-related pain in adults, there is no study examining the effectiveness of the rapid injection technique without aspiration on the vaccination-related pain in adults. In the rapid injection technique without aspiration, the injector is held at 90 degrees, it is pricked into the tissue with a single movement rapidly; after the drug is injected in 1-2 seconds without aspiration, the injector is drawn back rapidly. In this technique; the pain is expected to reduce as the stay time of the injector in tissue and the movement of the injector reduce (19,20). Aspiration through withdrawing the plunger slightly soon after a needle is inserted into muscle is a common practice. However, there is no evidence for the necessity of aspiration (19,21-24). Because vaccines are usually injected to body parts deprived of large blood vessels, aspiration is considered unnecessary (19). Pain is expected to decrease in rapid injection without aspiration because the time a needle spends in tissues is shorter and because the needle is less mobile. Therefore, vaccination guidelines recommending the use of this technique in different countries of the world are presented below;

- Australian: Administration of Vaccines, Immunise. 10th ed. The Australian Immunisation Handbook 2009,(25)
- Taddio et.al. (2010) "The Pain of Childhood Vaccination: An Evidence- Based Clinical Practice Guideline", (19)
- Centers for Disease Control and Prevention. "General Recommendations on Immunization." Recommendations of The Advisory Committee on Immunization Practices (ACIP) 2011,(26)
- Public Health England. "Immunisation Procedures: The Green Book" 2013, (27)
- Public Health Agency Of Canada. "Canadian Immunization Guide" 2013,(28)
- Taddio et al. (2015) "Reducing Pain During Vaccine Injections: Clinical Practice Guideline", (20)
- World Health Organization: "Reducing Pain At The Time Of Vaccination: WHO Position Paper" 2015 (9).

The process of aspiration has been ingrained in the intramuscular injection procedure, and whilst many policies no longer recommend this practice, it often continues to be taught and practiced. The result is a variation in this procedure not always consistent with an evidence based approach (25).

This study was needed to be conducted to present evidential data for this method, which can be applied by nurses independently, and to support the current study results. This study is thought to be a source for nurses and to contribute the evidence that is required to put the rapid injection technique without aspiration into practice in the vaccinations.

Aim

The aim of this study is to assess the efficiency of the rapid injection technique without aspiration in reducing the pain that develops during the vaccination on the young adult students and to compare with the standard vaccination technique.

Research Hypotheses

(H₁) The pain scores of the students in the group of rapid injection without aspiration are lower than the scores of the students in the control group

MATERIAL and METHODS

Study Design

This was an experimental, single-blind, randomized controlled trial.

Setting and Sample

The study was conducted in Turkey, in a family health center in Central Anatolia Region. The population of the study consisted of the nursing students (n: 125) of the faculty of health sciences who had to be tetanus-vaccinated as a protective measure before the clinical practice. Sample selection was not performed in the study and the whole population was tried to be reached. However, as 53 students were vaccinated before and 2 students used a painkiller before the vaccination, the sample of the study consisted of a total of 70 students.

- **Inclusion criteria;** Healthy students who did not take any painkiller before the vaccination, agreed to participate in the study and gave verbal consent were included in the study.

- **Exclusion criteria;** the individuals with pain and/or acute pyretic disease, who underwent topical anesthesia and/or used any painkillers were excluded from the study.

The distributions of the students, who came to the family health center for the vaccination and were in accordance with the inclusion criteria, to the intervention group in which the rapid injection technique without aspiration was applied and the control group in which no intervention was applied by the simple randomized method. The papers with the same color and folding shape that represented the intervention and control groups were put into a cloth bag. In order to provide the randomized distribution and reduce all the negative effects, the required explanation

was made to the individuals to be vaccinated and they were requested to pull a paper randomly from the bag. In this way, the groups were balanced and totally 35 students were included in each group.

Instruments

Personal Information Form

The "Personal Information Form", developed by the researcher, included totally 5 questions about the gender, age, injection-related experience and the fear of injection of the individual. In order to score the fear levels, the students were requested to choose the closest number, related to their fear, among the numbers between 0-10.

The Numerical Pain Rating Scale

The numerical pain rating scale (NPRS) is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line. Similar to the VAS, the NPRS is anchored by terms describing pain severity extremes (29,30). The scale is composed of numbers between 0 and 10. The pain scoring is performed in the way that the individual chooses the closest point related to his/her pain. "0 point" signifies no pain and "10 points" signify worst pain.

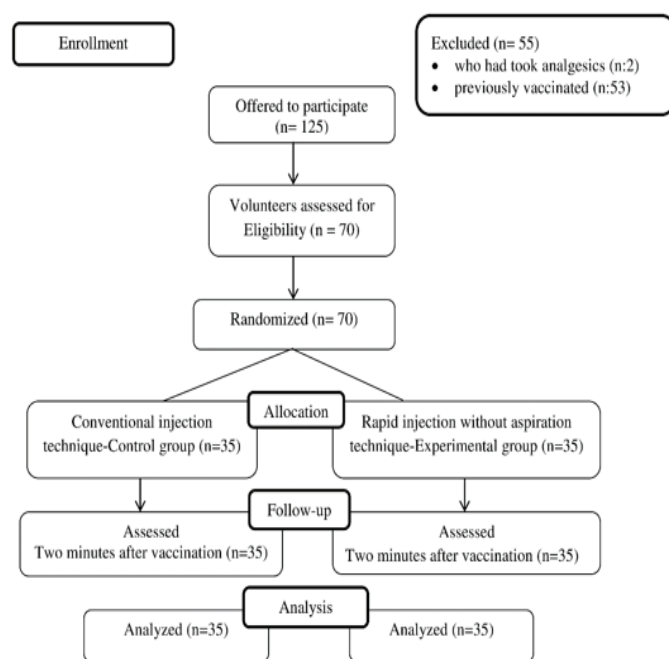


Figure 1. Diagram showing the flow of participants

Outcome Measures

Pain Level; As the study was a single-blind trial, the pain assessment was performed by another nurse, in the second minute after the injection, using the numerical rating scale, in order to provide neutrality. The nurse was informed by the researcher about the use of the scale. The nurses had no conflict of interest.

Figure 1 shows a flowchart of the study procedure. This was done according to the CONSORT statement.

Procedure

The personal information form was filled for each individual, who came to the FHC for the vaccination and agreed to participate in the study, before the procedure. The tetanus vaccine was applied into the deltoid muscle of the left arm in the sitting position in both the intervention and the control groups in the vaccination room. All the vaccines were made by a single researcher in order to eliminate the vaccination differences.

The Rapid Injection Group Without Aspiration; After filling in the personal information form, then the tetanus vaccine was administered by using rapid injection without aspiration technique (the injector was held at 90 degrees, it was pricked into tissue rapidly, and the drug was given in 1-2 seconds without performing aspiration).

The Control Group; After filling in the personal information form, the tetanus vaccine was made in accordance with the standard injection technique included in the application (the injector was held at 90 degrees, it was pricked into tissue, and the drug was given in 5-10 seconds after performing aspiration).

Two days after the vaccination, the researcher got in contact with the students in the intervention and the control groups in order to ask whether a local side effect developed in the vaccination site or not.

Data Analysis

The SPSS (Statistical Package for Social Sciences) 20.0 program was used in the data analysis. The compliance of the data of the study group to the normal distribution was examined by Shapiro-Wilk's test and it was observed that they did not conform to the normal distribution. The number and percentage distributions were used in order to assess the descriptive characteristics, Kruskal Wallis H test was conducted to examine the homogeneity of the students in both groups in terms of descriptive characteristics, Mann Whitney U test was used in the comparison of the pain scores, and t-test was used in the comparison of the mean scores of the fear scores. In the study, the significance level was accepted as 0.05.

Ethical Considerations

The study was approved by the ethics committee of a State University in Turkey (21.03.2018, 2018/9). Permission was obtained from the institutions to be conducted by the research. After providing the required information to the students to be included in the study, their verbal consents were received. Also, the study was registered under the number: NCT03723421

RESULTS

Comparison of the Groups

It was determined that 62.9% of totally 70 students in the intervention and control groups were female and their age averages were 21.47 ± 1.59 . The fear of injections was 80% among the students in the intervention group. Total fear mean score was determined as 4.87 ± 1.53 . It was found

that both groups were homogeneous in terms of the descriptive characteristics ($P>0.05$) (Table 1).

The first three reasons for fear, which were stated by those who stated that they felt fear about the injection application, were the previous painful injection experience (44.3%), school vaccines (38.6%) and the pain experienced during the venous blood sampling (27.1%) (Table 2).

Comparison of the Groups in Terms of Pain Levels

Table 3 shows the pain mean scores of the students in the intervention and control groups. When examining the table, it is observed that the pain mean scores of the students in the control group (3.71 ± 1.6) were higher than the students in the intervention group (0.77 ± 0.87) and the difference was statistically highly significant ($P=0.000$).

No statistically significant difference was determined between the age and gender values of the students and their pain mean scores ($P>0.05$). However, a statistically significant positive correlation was determined between the fear mean score and the pain mean score ($r=0.323$, $p\leq0.05$) and the pain score increased with increasing fear score (Table 4).

When the local side effect in the injection site was questioned, 34.2% of the student's stated that pain and swelling developed. When the existence of side effect was examined between the groups, it was determined that although the existence of local side effect in the injection site in the control group (37%) was higher than the individuals in the intervention group (31.4%) and the difference was not statistically significant ($P>0.05$).

Table 1. Comparison of the individuals' descriptive characteristics in terms of the groups (n=70)

Descriptive Characteristics	Group						X ² *	p
	Rapid Injection without Aspiration		Control		Total			
	n	%	n	%	n	%		
Female	22	62.9	20	57.1	42	60	0.238	0.626
Male	13	37.1	15	22.9	28	40		
	Rapid Injection without Aspiration		Control		Total		U**	P
	n	$\overline{X} \pm SD$	n	$\overline{X} \pm SD$	n	$\overline{X} \pm SD$		
Age	35	21.48±1.72	35	21.45±1.48	70	21.47±1.59	66.500	0.774
Fear	29	4.79±1.8	27	4.96±1.22	56	4.87±1.53	430.00	0.519
*Kruskal–Wallis H test, **Mann Whitney U								

Table 2. The reasons for the fear of injection of the individuals, who participated in the study, with their own statements (n=70)

	Rapid injection without aspiration		Control		Total		χ^2	p
	n*	%	n*	%	n*	%		
The previous painful injection experience	14	48.2	17	62.96	31	44.3	1.220	0.296
School-age vaccines	13	44.82	14	51.85	27	38.6	0.276	0.789
The pain experienced during the venous blood sampling	5	17.24	14	51.85	19	27.1	7.472	0.010
The pain caused by drugs	9	31.3	4	14.81	13	18.6	2.064	0.131

*Kruskal–Wallis H test, **Mann Whitney U

Table 3. Comparison of the pain mean scores of the individuals in the intervention and control groups (n=70)

	Pain Score			Test	
	$\bar{X} \pm SD$	Min	Max	Mean rank	U
Rapid injection	0.77±0.87	0	3	19.64	57.500
without aspiration					
Control	3.71±1.6	1	7	51.36	0.000
Total	2.24±1.95	0	7		

DISCUSSION

In accordance with the results of this study conducted to assess the efficiency of the rapid injection technique without aspiration in reducing the pain experienced by the young adult nursing students during the vaccination, it was determined that the rapid injection technique without aspiration was effective in relieving the pain in the young adults who were tetanus-vaccinated. During the injection, it is recommended to perform aspiration by drawing the piston back slowly just after the insertion of injector into the muscle. However, there is no data showing the necessity of such a practice in the literature. It has been stated that there is no need for aspiration in the injections in the vastus lateralis and deltoid muscles and ventrogluteal region and aspiration may only be applied in the injection applications in the dorsal gluteal region as it is close to the gluteal artery (10,21-24). Generally, it is accepted that the aspiration is not necessary as the regions used for vaccine injection do not have large blood vessels (19,20). In the studies conducted with the infants who were vaccinated, in Canada, India, and Turkey, it has been stated that the rapid injection technique without aspiration is effective on the pain related to the IM vaccinations (21,31,32). In the literature, no study was found in which the effect of the rapid injection technique without aspiration in eliminating the pain in adults during the vaccinations was examined. This study supports that the rapid injection technique without aspiration may be effective in reducing pain in every age group.

Anxiety and fear are important factors in perceiving the pain. According to the gate control theory, the anxiety and fear open the gate and they increase the perception of the pain (33). For this reason, it is stated that high level of fear may cause a higher level of pain reaction (34,35). The result that the pain score increases with increasing fear score supports the literature. 80% of the students participating in the study had fear of injection. Several studies have reported that the adult prevalence rates of some degree of needle fear range from 14% to 38% (36,37,38). 27.2% of the tetanus-vaccinated adult individuals in Turkey, 30% of the adult individuals who applied to a clinic for travel vaccines in USA, 37.2% of the young patients aged between 14 and 25 years in the study of Khan et al. (2015), 39% of the adult individuals in the study of Noble et al., (2013) and

1/3 of the adults in the study of Taddio et al., (2012) stated their fear of needle, all of which indicated that the fear of injection is common among adults (6,38-40). It is stated that the painful injection experiences in childhood have an important role in the development of this fear (5,19). It is estimated that 25% of the adults in Canada have a fear of needle that has developed in childhood (19). It is stated that the fear of needle develops in one of every ten adults due to the experience of painful vaccination experienced in childhood (6). Also in the current study, the school-age vaccines were stated to be one of the most important reasons for the fear of injection and this result supports the literature. When it is taken into consideration that the negative injection experiences in childhood have an important role in the development of the fear of needle and this causes an important obstacle for the immunization services and also fear and avoidance in receiving medical care, the importance of managing the pain in the injection applications effectively starting from childhood becomes apparent.

CONCLUSION

It was determined that the rapid injection technique without aspiration decreased significantly the pain mean scores in the young adult nursing students compared to the control group. It was concluded that the rapid injection technique without aspiration was effective and useful in reducing the vaccination-related pain in adults.

According to the results of this study; by considering that the rapid injection technique without aspiration decreases the vaccination-related pain, it is recommended for the midwives and nurses to use this simple and rapid method that does not require preparation for vaccinations. Also, it is recommended to determine the knowledge and practices of the midwives and nurses related to the importance of and reducing the pain experienced by the individuals in vaccinations, to conduct the studies on eliminating the barriers by determining the difficulties and needs in putting a new method, which has been proven to be effective in reducing pain, into routine use, and to study the effect of the rapid injection technique without aspiration in different vaccines and the other intramuscular injection administrations apart from vaccines.

LIMITATION

There are two significant limitations of this study. The first, the study was conducted with only a group of young adults. Second, Although there are frequently used instruments in pain studies, the use of self-reporting instruments in the study may be a second limitation of the study.

Financial Disclosure: There are no financial supports.

Ethical approval: The study was approved by the ethics committee of a State University (Çankırı Karatekin University) in Turkey (21.03.2018, 2018/9).

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