MCBU SBED
MANİSA CELAL BAYAR ÜNİVERSİTESİ SAĞLIK BİLİMLERİ ENSTİTÜSÜ DERGİSİ
MANISA CELAL BAYAR UNIVERSITY JOURNAL OF INSTITUTE OF HEALTH SCIENCE
ISSN: 2147-9607

ARAŞTIRMA MAKALESİ
RESEARCH ARTICLE
CBU-SBED, 2024, 11(3): 462-473

The Effect of Helfer Skin Tap Technique on Pain Reduction and Hemodynamic Parameters after Tetanus Injection in Pregnant Women

Helfer Skin Tap Tekniğinin Gebe Kadınlarda Tetanoz Aşı Enjeksiyonu Sonrası Ağrıyı Azaltma ve Hemodinamik Parametreler Üzerine Etkisi

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Gönderim Tarihi / Received: 24.06.2024
Kabul Tarihi / Accepted: 10.09.2024
DOI:10.34087/cbusbed.1502612

Öz

Giriş ve Amaç: Araştırmanın amacı gebe kadınlarda tetanoz enjeksiyonu sonrasında Helfer skin tap tekniğinin ağrının azalması ve hemodinamik değişkenler üzerine etkisini belirlemektir.
Gereç ve Yöntemler: Bu karşılaştırılmalı ve körlenmemiş randomize kontrollü deneysel bir çalışmadır. Ağustos 2021-Mart 2022 tarihleri arasında bir Aile Sağlığı Merkezinde tetanoz aşısı olan 65 gebe kadın ile yürütüldü. Tetanoz aşısı gebelerin 33'üne Helfer skin tap tekniği, 32 kadına ise standart kas içi enjeksiyon tekniği kullanılarak deltoid bölgeye uygulandı. Gebe kadınlarda ağrı şiddeti aşı sonrası Sayı Derecelendirme Ölçeği ile değerlendirildi. Hemodinamik değişkenleri ise aşı yapılmadan önce ve aşı yapıldıktan hemen sonra ölçüldü.
Bulgular: Helfer skin tap grubu ile standart uygulama grubu arasında müdahale sonrası ortalama ağrı şiddeti açısından istatistiksel olarak anlamlı fark olduğu belirlendi. Helfer skin tap grubundaki örneklemin çoğunluğu (%69,7) hafif düzeyde ağrı (2.00±1.80) algılarken, standart uygulama grubundaki katılımcıların çoğunluğu (%46,9) müdahale sonrasında orta şiddette ağrı (3.43±1.99) hissetti. Helfer skin tap grubundaki örneklemin çoğunluğu (%69.7) hafif düzeyde ağrı algılarken, standart uygulama grubundaki katılımcıların çoğunluğu (%46.9) müdahale sonrasında orta şiddette ağrı hissetti.
Sonuç: Helfer skin tap tekniğinin intramüsküler tetanoz aşısı uygulaması sırasında ağrıyı azaltmada etkili bir yöntem olduğu sonucuna varıldı.

Anahtar kelimeler: İntramüsküler enjeksiyon, ağrı, Helfer skin tap tekniği, hemodinamik değişkenler

Abstract

Aim: The study was aimed at determining the effect of the Helfer skin tap technique on pain reduction and hemodynamic variables in pregnant women after tetanus injection.
Method: It was a comparative and non-blinded randomized control experimental study. It was conducted with 65 pregnant women who got tetanus vaccine in a Family Health Center between August 2021, and March 2022. The tetanus vaccine was administered to the deltoid side using the Helfer skin tap technique to 33 pregnant women

and the standard intramuscular injection technique to 32 pregnant women. The pain intensity was evaluated on the Number Rating Scale after vaccination in pregnant women. The hemodynamic variables of the pregnant women were examined before and immediately after the vaccine administration.
Results: It was determined that there was a statistically significant difference between the Helfer skin tap groups and the standard application group in terms of mean pain intensity in the post-injection. The majority of the sample (69.7%) in the Helfer skin tap group perceived mild pain (2.00±1.80) and most of the participants (46.9%) in the standard application group had moderate pain (3.43±1.99) in the post-injection
Conclusion; It was concluded that the Helfer skin tap technique is an effective method to reduce pain after intramuscular tetanus vaccine administration.

Keywords: Intramuscular injection, pain, Helfer skin tap technique, hemodynamic variables

1. Introduction

According to the 2015 guidelines of the World Health Organization (WHO), a minimum of 16 billion injections are made each year throughout the world. Vaccination comprises approximately 5% of all injections [1]. Although maternal and neonatal tetanus is a disease that can be prevented by vaccination, it is still a serious health condition affecting maternal and infant morbidity and mortality in developing countries. Thus, it is extremely important that women at fertility age are vaccinated against tetanus to protect both the mother and the baby from the disease. According to the literature, 26.0% of pregnant women took at least two doses of the tetanus toxoid vaccine [2]. The most common side effect of tetanus vaccine is temperature (2.4%-6.5%) and pain at the injection site [3]. Pain is a subjective experience, which is a multidimensional phenomenon that is hard to define [4]. One's response to pain is influenced by many factors such as race, age, gender, anxiety, sociocultural variables, and pain tolerance [5]. It is reported that vaccine-related pain causes fear and anxiety in some individuals, which in turn leads to avoidance of protective and curative healthcare services and reluctance to get vaccinated [6,7]. Moreover, pain could cause many short and long-term complications. The physiologic reaction to acute pain is initially adaptive, as it allows for an immediate fight or flight response via the sympathetic nervous system and the neuroendocrine system [8]. Since acute pain stimulates the sympathetic system, such short-term complications may develop as increased respiratory rate, heart rate and blood pressure and decreased saturation (SPO_2) levels [9].

Intramuscular (IM) vaccination administered using the right injection technique is known to cause less pain and injury [10]. Nurses employ different approaches like applying pressure, tapping the skin, cold and hot applications to reduce the pain caused by the IM vaccine administration. Helfer skin tap is among the techniques that relax muscles [11]. In 1988, Joanne Helfer developed the "Helfer Skin Tap Technique (HSTT)" which is applied by touching the skin over the injection site and attempting to reduce the IM injection-related pain. In this technique, after determining the injection site, nearly 15 strokes are made on the skin for almost five seconds using the fingertips of the dominant hand in order to soften the muscles. Later, the skin is cleaned with alcohol, the non-dominant hand is put in a V shape and the skin is hit three times. During the third stroke, the syringe is pricked into the muscle at a 90-degree angle at the same time [12]. Making a few taps relaxes the muscles and counting to three helps synchronize the muscle tap and injection and standardizes the technique [13]. Mechanical stimulation of muscle fibers of larger diameters decreases the effect of smaller, pain generating fibers [14]. According to the gate control theory suggested by Roger Metzack and Past Wall (1965), in addition to mechanical stimulation during an IM injection, this technique also causes distraction, which, in turn, helps reduce pain [15].

Studies carried out on adults [10,16,17] and newborn patients [13,18-20] show that HSTT, compared with the standard injection method (SIM), is effective in reducing patients' pain when administering an IM injection. In the randomized controlled study conducted by Güven and colleagues (2020) with 100 adults who got Diclofenac injections, patients who were injected using the HSTT were found to have significantly lower levels of pain [17]. The results of this study are significant for showing that nurses can use the HSTT to control the pain generated by IM injection and that the method is a simple, cost-effective and reliable one. Only one study has been found on the effect of using the HSTT when administering IM tetanus vaccines to pregnant women in the literature [21]. Rautela and colleagues, (2020) conducted the study with pregnant women who got IM tetanus vaccines and found that 33.3% of the pregnant women who were vaccinated using the HSTT had no pain, 60% had little pain and 6.6% had moderate pain. In the control group, in which the SIM was used, on the other hand, it was seen that 30% of the women had little pain, 50% had moderate pain while 20% had severe pain. As a result, the study concluded that HSTT was more effective than the SIM in reducing pain during IM tetanus vaccination [21]. There are a limited number of studies on the effects of IM injection-generated pain on hemodynamic variables [22]. The study conducted by Therese and Devi (2014) found

that in adult patients who were given IM injections using the HSTT and SIM, systolic and diastolic blood pressure and heart rates did not differ significantly before and after the administration [22]. When the related literature was reviewed, it was seen that the effect of acute pain on hemodynamic variables varied in different sample groups [23-26]. These conflicting findings suggest that patients' vital signs are not specific to pain when they are exposed to painful procedures. However, we think that the change in hemodynamic variables caused by acute pain due to IM injection in high-risk conditions such as pregnant women is important. In the literature, there is no study evaluating the effect of HSTT use on pain intensity and hemodynamic variables in pregnant women who had tetanus vaccine. In this sense, we believe that our study will contribute to the literature. Also, SIM should be compared with the HSTT in order to reduce the pain that occurs due to IM injections and to reveal the most reliable IM injection technique. This study aimed to determine the effect of HSTT on pain reduction and hemodynamic variables in pregnant women after tetanus injection.

The hypotheses of this research were as follows.

Hypothesis 1. The HSTT in the administration IM Tetanus vaccine has effect on the pain intensity associated with the vaccination.

Hypothesis 2. The pain intensity vaccinated with the HSTT in the administration IM Tetanus vaccine is less than vaccinated with the standard application group (SAG).

Hypothesis 3. The HSTT in the administration IM Tetanus vaccine has effect on hemodynamic parameters.

2. Methods

2.1. Study Design

It was a comparative and non-blinded randomized control experimental study that was carried out at a Family Health Center in Turkey between August 2021, and March 2022.

2.2. Participants

This study was conducted on pregnant women who applied to the Family Health Center to get a tetanus vaccine. Inclusion criteria were being over the age of 18, being pregnant, applying for tetanus vaccine, speaking Turkish, and participate in the study voluntarily. Exclusion criteria were having a vaccination other than tetanus, having pain or a local infection scar tissue, wound, burn, incision at the IM injection site before vaccination, receiving parenteral treatment in their injection area, having a circulatory disorder, peripheral vascular disease, cognitive and psychological problems, using painkillers at least 6 hours before the procedure.

2.3. Sample Size and Statistical Power Considerations

The sample of the research was calculated by the G. Power-3.1.9.2 program at an 80% confidence level before data collection. The study's sample size was calculated using Cohen's effect size values, as there were no relevant studies [27]. The power was calculated based on pain intensity using repeated-measures ANOVA (between factors). As a result, the effect size of the study was 0.50, based on an alpha level of .05 and a power of 0.80, and the minimum sample size was calculated as 26 pregnant women, 13 in the Helfer skin tap group (HSTG) and 13 in the SAG. In clinical trials, more than 10-20% of the sample size calculated in the power analysis hould be taken so that factors such as drop outs or missing data do not reduce statistical power.

Pregnant women were randomly assigned to one of two groups: A total of 96 pregnant women applied for tetanus vaccine at the Family Health Center. 22 pregnant women were excluded from the study out of 96 because using pain relievers at least 6 hours before the procedure (n=7) or refused to participate (n=15). As a result, the research began with 74 pregnant women. A total of nine pregnant women, four from the HSTG and five from the SAG, voluntarily dropped out of the study. Thus, 65 participants completed it. HSTG and SAG each included 33 and 32 pregnant women, respectively. Data were analyzed with the Intent-to-treat analysis (ITT) principle and drop-outs were included in the analysis. It was 0.89 for HSTG and 0.86 for SAG. The Consolidated Standards of Reporting Trials flow chart detailing pregnant women recruitment is shown in Figure 1.

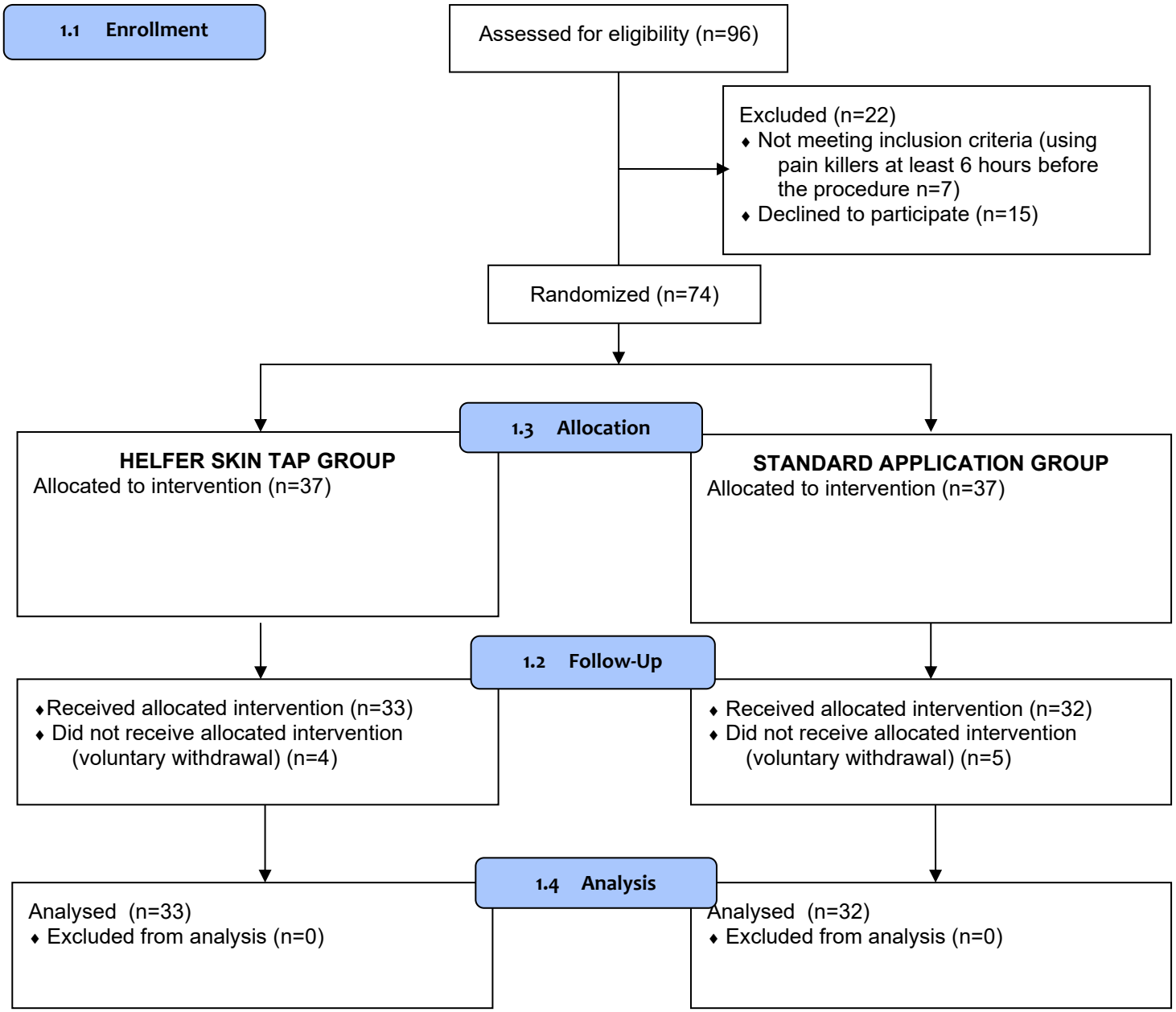

Figure 1. CONSORT flow diagram of study participants

2.4. Randomization

Computer-generated random numbers were used for simple randomization of subjects. The inclusion criteria were assigned to the HSTG and SAG by a computer-based random number generator. The numbers in set 1 were taken to the HSTG and the numbers in set 2 to the SAG by lottery method. The lottery was made by the third researcher working in a family health center as a nurse.

2.5. Outcome Measures

Primer outcome was the pain intensity after the tetanus vaccine based on the Number rating scale (NRS). Seconder outcome included the change in hemodynamic variables (Systolic and diastolic blood pressure, heart rate, SpO_2 and respiratory rate) before and immediately after tetanus vaccine administration.

2.6. Instruments

2.6.1. The Questionnaire of Descriptive Characteristics of Pregnant Women

The first form had 10 questions intended to elicit information about the pregnant women's descriptive features such as age, weight, smoking, education and employment status, number of children and pregnancy, having IM injection and any problem after IM injection, and number of tetanus injection.

2.6.2. Pain and Hemodynamic Parameters Follow-up Form

This form also included hemodynamic variables which were evaluated by the third researcher working in a family health center as a nurse before and after the tetanus vaccine. The researchers developed these questions in accordance with the literature [17,21-26]. Data were collected directly by measuring systolic and diastolic blood pressures with the same sphygmomanometer in a comfortable sitting position. The heart rate was determined by palpating the radial pulse for one minute. The respiratory rate was calculated by counting the number of breaths for one minute. A pulse oximeter as used to measure SpO_2 levels. A pulseoximeter is a compact, non-invasive device that clips on to the finger of a pregnant woman to detect the level of oxygen saturation in her blood. The same devices were used for all pregnant women. The Family Health Center owns these devices and all devices are calibrated regularly by a firm in May of each year at the Family Health Center.

2.6.3. Number Rating Scale (NRS)

The second part of the questionnaire was NRS. NRS is a useful and easy-to-use tool to assess the severity of IM injection pain. NRS is a valid and reliable measurement tool in the evaluation of pain in IM injections, and it has been widely used in the evaluation of pain in IM injections in adults in many studies [14,16,21]. It is a scale in which 0 is defined as no pain and 10 as maximum pain. It asks pregnant women to rate their pain on a scale of 0 to 10, with 0 representing no pain, 1-3 mild pain, 4-6 moderate pain, and 7-10 severe pain.

2.7. Data collection

2.7.1. Helfer Skin Tap Group (HSTG)

The HSTG filled "The questionnaire of descriptive characteristics of pregnant women" and hemodynamic variables of the pregnant women were measured and recorded by the third researcher before the tetanus vaccine. Pregnant women in this group were vaccinated against tetanus with the HSTT by the same researcher. The pain and hemodynamic variables were evaluated immediately after the vaccine. A total of 33 pregnant women completed the study in the HSTG.

2.7.1.1. Helfer Skin Tap Injection Procedure

1. Place the pregnant woman in a seated position and open her right arm to inject into the deltoid muscle.
2. After selecting the injection site, use the tips of the dominant hand fingers to tap the skin (approximately 15 strokes) for about five seconds to soften the muscles.
3. Remove the syringe cover from the dominant hand after using alcohol to clean the skin. The non-dominant hand should form a V and strike the skin three times.
4. Prick the syringe into the muscle simultaneously with the third stroke at a 90-degree angle.
5. Following aspiration, keep hitting the skin with the tips of the fingers of the non-dominant hand while injecting the medication (total 0.5 ml) at 5 seconds with the dominant hand.
6. After administering the drug, form the non-dominant hand into a V and strike the skin three times. Take the syringe needle out simultaneously during the third stroke [12].

2.7.2. Standard Application Group (SAG)

The SAG filled "The questionnaire of descriptive characteristics of pregnant women", and hemodynamic variables of the pregnant women were measured and recorded by the third researcher before the tetanus vaccine. Pregnant women in this group had tetanus vaccine with the SIM by the same researcher. The pain and hemodynamic variables were evaluated immediately after the vaccine. A total of 32 pregnant women completed the study in the SAG.

2.7.2.1. Standard Injection Procedure

1. Place the pregnant woman in a seated position and open her right arm to inject into the deltoid muscle area.

2. Choose the injection site, then use alcohol to prepare the skin.
3. Prick the needle into the muscle at a 90-degree angle while holding the skin firmly between your non-dominant hand's thumb and index finger.
4. After aspiration, administer the medication (total 0.5 ml) by injecting 5 seconds with the dominant hand.
5. Remove the syringe needle 10 seconds after the drug is consumed [17-28].

2.8. Statistical analysis

The descriptive characteristics of pregnant women were compared in the groups by chi-square and Fisher's exact test with the SPSS 20.0 software. Distribution and association between the pain intensity and descriptive characteristics were examined by chi-square, Fisher's exact test, and one-way ANOVA. Normality was tested using Skewness and Kurtosis. According to Skewness and Kurtosis values for normality, it was determined that the distribution of the pain intensity conformed to normal and hemodynamic variables were concluded with non-parametric distribution. Pain intensity was evaluated with parametric tests (independent t-test) in post-injection among groups. Wilcoxon and Mann-Whitney U tests were used for the comparison of the hemodynamic variables between groups and within groups, respectively. A p-level of <0.05 was considered as statistically significant.

2.9. Ethical Considerations

Ethical approval was obtained from the Ethical Committee of Manisa Celal Bayar University (date: 19.08.2020 number: 20.478.486/489), and informed consent was obtained from all pregnant women. Permission was received from Manisa Local Health Authority after one year from ethical committee approval due to the COVID-19 pandemic (Date: 16.08.2021 Number: 49654233-604.02-02-810). All pregnant women provided written consent after being informed about the study's aim and procedures. This study was registered at the clinicaltrials.gov (Clinical Trial registration number: NCT05761340).

3. Results

A total of 65 participants completed the study (HSTG=33 and SAG =32). When the descriptive characteristics of the groupswere compared, there was no statistically significant difference between HSTG and SAG regarding socio-demographic variables (p>0.05) (Table 1).

Table 1: Comparison of descriptivecharacteristics in Helfer Skin Tap Group and Standard Application Group

Descriptive characteristics	Helfer Skin Tap Group (n=33)		Standard Application Group (n=32)		Total (n=65)		Test
	n	%	n	%	n	%	
Education							
Primary school	9	27.3	4	12.5	13	20.0	*X^2=2.216 df=2 p=0.33
Secondary+High school	18	54.5	21	65.6	39	60.0	
University+Graduate education	6	18.2	7	21.9	13	20.0	
Employment status							
Employed	8	24.2	6	18.8	14	21.5	**p=0.76
Unemployed	25	75.8	26	81.3	51	78.5	
Smoking							
Yes	7	21.2	5	15.6	12	18.5	**p=0.75
No	26	78.8	27	84.4	53	81.5	
Number of children							
No children	10	30.3	12	37.5	22	33.8	*X^2=0.976 df=3 p=0.80
1 child	15	45.5	15	46.9	30	46.2	
2 children	4	12.1	3	9.4	7	10.8	
3 or more children	4	12.1	2	6.3	6	9.2	
Number of pregnency							
1 pregnancy	10	30.3	11	34.4	21	32.3	*X^2=1.309 df=2 p=0.52
2 pregnancy	14	42.4	16	50.0	30	46.2	
3 ormorepregnancy	9	27.3	5	15.6	14	21.5	
Number of tetanus injection							
First dose	23	69.7	21	65.6	44	67.7	**p=0.76

Second dose	10	30.3	11	34.4	21	32.3	
Having intramuscular injection							
Yes	30	90.9	27	84.4	57	87.7	**p=0.47
No	3	9.1	5	15.6	8	12.3	
Having any problem after intramuscular injection							
Yes	9	27.3	3	9.4	12	18.5	**p=0.108
No	24	72.7	29	90.6	53	81.5	
The average of weight (Mean±SD**)**	69.50±11.96		75.26±15.12		72.33±13.81		***t=-1.707 df=63 p= 0.093
Mean age (Mean±SD**)**	30.51±5.02		28.43±5.51		29.49±5.33		***t=-1.589 df=63 p=0.11

*X^2= Chi-Square test,**Fisher'sexact test,*** t test, ****SD=Standard Deviation

The mean pain intensity of the participants was statistically significantly different between the HSTG (2.00±1.80) and SAG (3.43±1.99) in the post-injection ($p<0.01$). Pre- injection was not performed because pregnant women who had pain before the procedure were excluded from the study. The majority of the sample (69.7%) in the HSTG perceived mild pain and most of the participants (46.9%) in the SAG had moderate pain in post-injection. It was found that there was a significant difference between the pain intensity in post-injection among groups ($p<0.01$) (Table 2).

Table 2: Comparison of the pain intensity in post injection among groups

	Helfer Skin Tap Group (n=33)		**Standard Application Group (n=32)**		**Test**
Pain intensity after injection	n	%	n	%	
None	6	18.2	3	9.4	*X^2=12.778 df=3 **p=0.00**
Mild	23	69.7	12	37.5	
Moderate	3	9.1	15	46.9	
Severe	1	3.0	2	6.3	
Pain intensity after injection (Mean±SD***)	2.00±1.80		3.43±1.99		**t=-3.047 df=63 **p=0.00**

*X^2= Chi-Square test, **Independent t test, ***SD=Standard Deviation

When the hemodynamic variables of the pregnant women in the HSTG were compared before and after the vaccination, no statistically significant change was found in their systolic and diastolic blood pressure, heart rate, and SPO_2 levels ($p>0.05$). On the other hand, pregnant women's respiratory rate was seen to decrease at a statistically significant level after the vaccination ($p<0.01$). Hemodynamic variables of the pregnant women in the SAG showed no statistically significant difference before and after the vaccination ($p>0.05$). When the hemodynamic variables of the pregnant women in both groups were compared after the injection, heart rates of the HSTG pregnant women were found to be significantly lower than those of the SAG ($p<0.05$) whereas their SPO_2 levels were significantly higher compared with pregnant women in the SAG ($p<0.01$). When the change in the hemodynamic variables of the groups before and after the injection was examined, there were no significant differences between the changes in the hemodynamicvariablesof the groups (Table 3).

Pain intensity of the pregnant women in the HSTG and SAG after the administration were compared in terms of some sociodemographic variables and it was seen that they did not vary significantly by previous experience of IM injection, having problems after previous IM injections and age ($p>0.05$) (Table 4).

Table 3: Comparison of the hemodynamic variables in groups pre and post injection

HemodynamicVariables	Times	Helfer Skin Tap Group (n=33)	Standard Application Group (n=32)	Test
		(Mean±SD*)	(Mean±SD*)	
Systolic Blood Pressure (mm Hg)	**Pre-injection**	106.66±12.16	100.31±10.77	***Z=340.500 **p=0.01**
	Post- injection	105.75±8.48	101.56±10.42	*** Z=388.000 p=0.05
	[a]Difference of systolic blood pressure	0.90±11.48	-1.25±6.95	*** Z=459.500 p=0.35
Test		**z=-0.505 p=0.61	**z=-1.231 p=0.21	
Diastolic Blood Pressure (mm Hg)	**Pre- injection**	64.09±7.95	62.34±9.58	*** Z=464.000 p=0.38
	Post- injection	62.72±7.19	62.75±9.37	*** Z=522.000 p=0.93
	[b]Difference of diastolic blood pressure	1.36±9.29	-0.40±7.17	*** Z=457.000 p=0.32
Test		**z=-0.908 p=0.36	**z=0.000 p=1.00	
Heart Rate (pulse/minute)	**Pre- injection**	85.51±10.20	89.53±9.83	*** Z=399.000 p=0.09
	Post- injection	85.03±9.77	89.34±16.39	*** Z=361.000 **p=0.02**
	[c]Difference of heart rate	0.48±9.78	0.18±16.01	***MU=504.000 p= 0.75
Test		**z=-0.652 p=0.95	**z=-0.195 p=0.84	
SpO_2 (%)	**Pre- injection**	98.33±0.81	98.06±0.75	*** Z=414.500 p= 0.10
	Post- injection	98.48±0.66	98.00±0.80	*** Z=349.500 **p=0.01**
	[d]Difference of SpO_2	-0.15±0.61	0.06±0.75	*** Z=443.500 p=0.18
Test		**z=-1.406 p=0.16	**z=-0.471 p=0.63	
Respiration Rate (per minute)	**Pre- injection**	25.21±2.34	23.68±2.03	*** Z=323.000 **p=0.00**
	Post- injection	24.12±2.23	26.03±18.29	*** Z=402.000 p=0.09
	[e]Difference of respiration rate	1.09±1.87	-2.34±17.83	*** Z=476.000 p=0.47
Test		**z=-2.925 **p=0.00**	**z=-1.030 p=0.30	

*SD=Standard Deviation, **Wilcoxon test, ***Z=Mann-Whitney U test

[a]Difference of systolic blood pressure: Pre-injection minus post-injection

[b]Difference of diastolic blood pressure: Pre-injection minus post-injection

[c]Difference of heart rate Pre-injection minus post-injection

[d]Difference of SpO_2: Pre-injection minus post-injection

[e]Difference of respiration rate: Pre-injection minus post-injection

Table 4: Distribution and association between the pain intensity and Descriptive characteristics

	The pain intensity after injection in Helfer skin tap group (n=33)				Test	The pain intensity after injection in Standard Application Group (n=32)				Test
	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe	
Having intramuscular injection										
Yes	5 (16.7)	21 (70.0)	3 (10.0)	1 (3.3)	**p=0.77	3 (11.1)	9 (33.3)	14 (51.9)	1 (3.7)	**p=0.24
No	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)		0 (0.0)	3 (60.0)	1 (20.0)	1 (20.0)	
Havingany problem after intramuscular injection										
Yes	1 (11.1)	6 (66.7)	1 (11.1)	1 (11.1)	**p=0.38	0 (0.0)	1 (33.3)	2 (66.7)	0 (0.0)	**p=0.74
No	5 (20.8)	17 (70.8)	2 (8.3)	0 (0.0)		3 (10.3)	11 (37.9)	13 (44.8)	2 (6.9)	
Mean age (mean±SD)	29.66±4.63	30.86±5.52	30.33±2.88	28.00±0.0	***F=0.166 p=0.91	25.33±6.65	29.50±6.34	28.13±5.09	29.0±1.41	***F=0.463 p=0.71

*X^2= Chi-Square test**Fisher'sexact test*** OneWayAnova

4. Discussion

IM injections are invasive interventions that frequently cause pain [22]. IM administration on the deltoid region leads to greater pain due to the small size of the area [29]. Helping the patient to relax by using the best approach to prevent and relieve pain is among the primary responsibilities of a nurse [22]. Reducing IM injection-related pain is reported to increase the quality of nursing care [30]. Therefore, evidence-based procedures that are effective in pain management should be determined. Physical interventions and injection techniques that minimize pain during injection have an advantage over other techniques since they can be involved in clinical practice without requiring additional cost or time [31]. This study was conducted to determine the effect of HSTT on pain reduction and hemodynamic variables after tetanus injection in pregnant women. Our study found that the mean pain intensity of the pregnant women whose IM tetanus vaccine was administered using the HSTT were significantly lower than those of SAG. Moreover, it was seen that the number of pregnant women who experienced moderate and severe pain was high among the SAG. Studies conducted with adults [17,22,28] and infant patients [20,30] show that HSTT appears to be more effective in pain relief compared with the SIM. The HSTT is an easy and time-saving procedure that provides mechanical stimulation through rhythmic tapping and helps pain control [32]. Studies using the HSTT in pregnant women who are given IM tetanus shots are scarce in number. In the study carried out by Rautela and colleagues (2020), it was seen that 33.3% of the pregnant women who were vaccinated using the HSTT had no pain, 60% had little pain and 6.6% had moderate pain. Of the pregnant women who were given their IM tetanus shots using the SIM, on the other hand, 30% had little pain, 50% moderate pain and 20% had severe pain. In this respect, our findings seem to be compatible with the study of Reutela and colleagues (2020) [21]. In another study, the HSTT was found to be effective in reducing pain associated with tetanus intramuscular vaccination among pregnant women [33]. The literature includes studies reporting results that support our findings concerning IM injection with the HSTT. In the study conducted by Karabey and Karagozoglu (2021) with patients who were vaccinated with Hepatitis B, the HSTT was found to be more effective in reducing pain than the standard technique [34]. In another study conducted by Kaur and colleagues (2019) with 110 adult patients receiving IM Diclofenac treatment due to orthopedic problems, the patient's pain was evaluated with 3 different pain scales and the HSTT was compared with the SIM. The study found that the pain intensity of patients who were given IM injections with the HSTT were low in all [16]. Jyoti and colleagues (2018) carried out a study with 60 adult patients and concluded that the pain intensity of patients whose IM injections were administered using the HSTT were significantly lower than those of the patients who received SIM [35].

It is agreed that acute pain causes sympathetic stimulation [36] and some physiological changes occur in individuals as a response to the pain [37]. Therefore, in order to confirm the pain reported by patients, clinicians use some other clinical data like heart rate and blood pressure [36]. Some studies revealed that heart rate, blood pressure and respiratory rate increased due to pain [38], but the size of the changes seen in these hemodynamic variables was proportional to stimulus intensity [39]. There is little evidence proving that pain severity is strongly and coherently related to the patient's hemodynamic variables [23]. When the change in

the hemodynamic variables of both groups before and after vaccination was examined, it was seen that only the respiratory rates of the HSTG pregnant women decreased significantly after vaccination, but no significant change occurred in other hemodynamic variables. In addition, the heart rates of the HSTG pregnant women were significantly lower than those of the SAG while their SPO_2 levels were higher. The literature includes a limited number of studies examining the effect of pain during IM injection on hemodynamic variables [22]. In the study conducted by Pio and his colleagues on pregnant women who received tetanus vaccination, the HSTG exhibited lower mean heart rate and respiratory rate compared to the control group and there was no significant difference was found in blood pressure between the two groups [33]. Therese & Devi (2014) reported that systolic and diastolic blood pressure and heart rates of patients who received injections with the HSTT and SIM did not change before and after the intervention [22]. In the literature review, it was seen that the effect of acute pain on hemodynamic variables varied among different sample groups. While some study results show hemodynamic variables do not change significantly after painful interventions [23-25], some others report that blood pressure, heart rate [26] and respiratory rate [26] increase with pain. Roatta et al. (2011) found that acute stressors like pinprick caused increases in vasoconstriction and blood pressure in rabbits. The study also showed that no response was made to painful nasopharyngeal stimulation [40]. Different pain areas and modalities are reported to possibly cause varying autonomic responses [41]. This could explain the variance in the pain-related hemodynamic variables in all these studies conducted with different sample groups.

Pain is a subjective experience that is shaped by age, emotional state, sociocultural factors, previous experiences of pain, and the patient's knowledge of pain and the meaning of the pain [42]. In the present study, pregnant women's age, previous IM injection experiences and problems experienced during previous IM injections were seen to have no effect on their pain intensity. The literature reports varying findings concerning the effect of these variables on pain intensity.

The present study has some limitations. First, blind review was not possible since the pregnant women's pain intensity were measured by the researcher. In future studies, pain evaluation could be performed by a nurse outside the study. The second limitation is that the study was conducted with pregnant women who got tetanus vaccine. Pain following IM injection may differ according to the drug content. Thus, the study should be repeated with different drug groups. Another limitation of the study is that pregnant women were not asked about their satisfaction with the HST injection. Since pain experience is influenced by individuals' anxiety levels, failure to evaluate the participants' anxiety levels is another limitation of the study

5. Conclusion

Mean pain intensity of pregnant women who got IM tetanus vaccines with the HSTT were found to be lower than the pregnant women group who received SIM. Respiratory rates of the pregnant women in the HSTG fell significantly after the administration while the change in the other hemodynamic variables was not significant. When the hemodynamic variables of both groups were compared following vaccination, heart rates of the HSTG pregnant women were found to be significantly lower than the pregnant women who received SIM whereas their SPO_2 levels were significantly higher. Based on these findings, it may be recommended that the HSTT technique be preferred in tetanus vaccination to pregnant women, because the HSTT is an effective method in reducing pain after IM injection when compared with the SIM.

Since the HSTT is an effective and practical method to use safely for reducing the pain caused by the tetanus vaccine, it is recommended that nurses are informed about the method and it should be used more widely. Moreover, it would be beneficial to teach IM injections administration using the HSTT by including it in the nursing education curriculum. It is recommended to test the efficacy of HSTT in different vaccine IM injection.

6. Acknowledgments

The research team would like to thank all the pregnant women who took part in the study.

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