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Research Article/Özgün Araştırma

The effect of the terumo band used for hemostasis after transradial angiography on extremity pain

Transradial anjiografi sonrası hemostazın sağlanmasında kullanılan terumo bandın ekstremite ağrısı üzerine etkisi

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Abstract

Aim: This study aimed to evaluate pain associated with the use of the Terumo band pneumatic compression device in patients undergoing transradial angiography.

Materials and Methods: This descriptive study was conducted with 100 patients between October 2022 and October 2023. Data was collected using a demographic data form, the Short Form McGill Pain Questionnaire, and a Pain Assessment Form. Descriptive statistics, independent samples t-test, and ANOVA were used for data analysis.

Results: The mean pain score was 6.74 ± 6.99 one hour after application of the Terumo band and 3.81 ± 4.63 one hour after removal (t = 6.716; p = 0.001).

Conclusion: Patients experienced pain both during and after the application of the Terumo band. As a recommendation for nursing practice, it is suggested that nurses continue pain assessment following transradial angiography and employ evidence-based interventions such as finger exercises, hot/cold application, and elevation to manage pain.

Keywords: Nursing; Pain; Terumo band; Transradial angiography.

Öz

Amaç: Araştırmada, transradyal yöntem anjiyografi yapılan hastalarda Terumo band pnömatik sıkıştırma cihazına bağlı olarak gelişen ağrıyı belirlemek amaçlanmıştır.

Gereç ve yöntem: Tanımlayıcı desende yürütülen bu çalışma Ekim 2022 ve Ekim 2023 tarihleri arasında 100 hasta ile gerçekleştirilmiştir. Veriler, demografik veri formu, McGill Ağrı Ölçeği Kısa Form ve Ağrı Değerlendirme Formu aracılığıyla toplanmıştır. Verilerin analizinde sayı, yüzde, ortalama, gruplar arası karşılaştırmada bağımsız örneklemler t-testi ve Anova testi kullanılmıştır.

Bulgular: Hastaların Genel McGill ağrı düzeyi Terumo band takılı olduğu 1. saat 6,74 ± 6,99, Terumo band çıkarıldıktan 1 saat sonra 3,81 ± 4,63 olarak belirlenmiştir (t=6,716; p=0,001).

Sonuç: Çalışmanın bulguları, hastaların Terumo band uygulamasının hem uygulandığı sırada hem de sonrasında ağrı yaşadığını ortaya koymuştur. Hemşirelik uygulamalarına yönelik öneri olarak; hemşirelerin transradiyal anjiyografi sonrasında ağrı değerlendirmesine devam etmesi ve ağrıyı yönetmek amacıyla parmak egzersizleri, sıcak/soğuk uygulama ve elevasyon gibi kanıta dayalı yöntemleri kullanması önerilmektedir.

Anahtar Kelimeler: Hemşirelik; Ağrı; Terumo band; Transradyal anjiyografi.

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Bu makale araştırma ve yayın etiğine uygun hazırlanmıştır.
intihal incelemesinden geçirilmiştir.

Introduction

In coronary angiography, the radial approach is considered a safer alternative to femoral access.[1,2] The radial artery catheterization method was first used by Radner in 1948 to visualize the aorta.[3] Stent placement in the coronary arteries of the heart with the transradial approach was first performed in 1993.[4] The European Society of Cardiology (ESC) guidelines published in 2018 reported the advantages of coronary angiography via radial artery catheterization, such as fewer complications related to the access site, increased patient comfort due to early mobilization, and a low mortality rate.[5–8] Radial artery catheterization and coronary angiography are preferred because of the fewer complications compared to the femoral artery and the anatomically safer surroundings in terms of nerves and veins compared to other access sites.[4,9] In addition, in a study, the transradial angiography method was compared with the transfemoral angiography method and it was found that the cost of the transradial approach was lower.[10,11] Despite the advantages listed above, it also carries significant risks such as the small diameter of the radial artery, the need for experience, the long duration of the procedure due to if being performed by inexperienced physicians and therefore the prolongation of radiation exposure; and the possibility of causing spasm, hematoma and radial artery stenosis in the radial artery.[12,13]

Furthermore, problems such as pain, swelling, ecchymosis, loss of hand strength and parasthesia in the puncture area are also experienced after radial angiography.[14,15]

Pain is one of the most common problems encountered by nurses regardless of the unit they work in. The North American Nursing Diagnostics Association (NANDA) has included pain relief among the goals of nursing.[16] Treatment of pain requires a multidisciplinary team approach. The nurse is the most active member in this process. The nurse has knowledge and responsibility in defining pain, its causes, characteristics, factors affecting pain, prevalence, evaluation and approaches to relieving pain.[17]

Nurses are involved in the management of the radial approach before, during and after the procedure and play an active role in preventing complications that may occur.[6] Early recognition of complications and management of hemostasis are among the critical nursing duties. Nurses should monitor vital signs, check peripheral arterial pulses, and evaluate and provide care for the extremity where the procedure was performed after the procedure in terms of skin, temperature, colour change, loss of sensation and pain.[18]

Manual compression, pneumatic compression, hemostatic dressing, and patent hemostasis methods are used by healthcare professionals to provide hemostasis after angiography.[19] Among these methods, Terumo Band (TR) is one of the frequently preferred pneumatic compression methods designed to assist in hemostasis of the radial artery after a transradial procedure.[20,21]

When the literature is investigated, there are studies on the problems experienced in the puncture area after radial angiography,[14,15] but no studies have been found to define the pain in the puncture area. During the use of TR band, healthcare personnel focus on the above-mentioned bleeding and radial artery occlusion monitoring, and it has been observed that the vital sign of pain, which is both a sign of complication and disrupts patient comfort, is ignored. The aim of this study is to determine the pain in the puncture area due to the TR band pneumatic compression device used on patients after the transradial angiography method, something which is widely used in Türkiye and the world and whose use is increasing day by day, to add to the literature and thus to increase the quality of nursing care.

Materials and Methods

Study design

The data of the study was collected cross-sectionally.

The population and sample of the study

The data of the study consists of 100 patients who underwent transradial coronary angiography for the first time in a research and practice hospital in Turkey between October 2022 and October 2023. Prior to the research,

hospital records were reviewed, which revealed that 134 patients had undergone their first angiography within the last year. Consequently, the sample size was calculated using a method for a known population, and the study was conducted with 100 patients. A post-hoc power analysis was performed using G*Power software, version 3.1.9.7. For a sample size of *n* = 100, an effect size of dz = 1.17, and a significance level of α = .05, the statistical power was found to be > .99. Therefore, the study was concluded with this sample size.

Radial artery cannulation

All procedures were performed at a single center by an interventional cardiologist with wide experience in transradial intervention. The right or left arm was positioned toward the side of the patient's body after being supported by a wooden plate from below and the wrist was hyperextended. After local anesthesia of the intervention area with 1% lidocaine in the skin and subcutaneous tissue, radial artery puncture was performed 1-1.5 cm proximal to the radial styloid process with a 21-gauge micropuncture needle and a 0.025 inch straight-tipped guidewire using standard techniques. The guidewire was left in the vessel and the short hydrophilic sheath was placed in the vessel after the needle was removed. A bolus of 5 mg verapamil and 5000 international units (IU) heparin was administered intravenously through the side puncture of the sheath. In cases where percutaneous coronary intervention (PCI) was performed, an additional dose of 2500 or 5000 IU heparin was administered through the sheath.

Hemostasis protocol

In the center where the study was conducted, TR band, one of the pneumatic compression methods, was used. According to the manufacturer's manual, before the radial catheter is withdrawn at the end of the procedure, the compression device (TR Band, Terumo, Japan) is placed on the wrist with the balloon part covering the puncture site, and simultaneously with the catheter withdrawal, 15-18 ml of air is injected into the balloon part of the TR band which presses on the puncture wound, and the catheter is withdrawn and pressure is created. Following this, the air in the TR band is released until a slight blood leakage occurs from the puncture point. At this point, the band is gently re-inflated (with 2-3 ml of air) until the blood leakage stops completely. In this way, the excess pressure is removed and sufficient pressure is provided to ensure hemostasis and at the same time prevent circulatory disorders. The removal protocol varies according to the amount of heparin administered to the patient. If 50 U/kg or less heparin is administered during the procedure, 60 minutes should pass without removing the air from the band, and a wait of 120 minutes if more than 50 U/kg heparin is administered. Following these periods, 3 cc of air is evacuated every 15 minutes, with bleeding controls. In case of bleeding, air is injected into the balloon again until bleeding stops and after waiting for 30 minutes without taking air, the bleeding status is evaluated. Then, the removal process can continue.[21]

Socio-Demographic patient information form

The socio-demographic patient information form was developed based on a review of the relevant literature and consisted of eight questions addressing age, gender, profession, marital status, educational level, presence of chronic illness, tobacco use, and alcohol use.[14,22,23]

McGill pain scale short-form

Patients' pain was assessed with the McGill Pain Questionnaire Short Form (SF-MPQ). The scale was developed by Melzack in 1987,[24] and its Turkish validity and reliability were confirmed by Biçici in 2010.[25] The main component of the SF-MPQ is a 15-item questionnaire comprised of 2 subscales: 1) a sensory subscale with 11 items and 2) an affective subscale with 4 items. Each item is rated on a Likert intensity scale with 0 = none, 1 = mild, 2 = moderate, or 3 = severe. The total SF-MPQ score was obtained by totalling the item scores (range 0–45). The sensory subscale ranges from 0–33, and the affective subscale ranges from 0–12. Descriptive adjectives in the perception of pain of the subjects are evaluated with a numerical value scale (0=none, 1=mild,

2=moderate, 3=severe). In addition, a 10 cm visual analog scale is used to measure the intensity of pain felt during the evaluation. They are asked to indicate the pain they feel during the evaluation with an "X" mark on the 10 cm scale. According to this scale, the value of "0" indicates no pain, and the value of "10" indicates the most severe pain. The distance between the marked point and the starting point is measured in cm. Finally, the patient's total pain intensity was evaluated with a 6-point Likert-type scale (0=no pain, 1=mild, 2=disturbing, 3=troubling, 4=terrible, 5=unbearable).

Pain evaluation form

The form was prepared in accordance with the relevant literature and finalized following evaluation by 10 experts.[14,22,23] The pain assessment form has 2 stages, the first stage consists of 9 questions and was directed to the patients during the first hour after the TR band was attached. With this form, the pain in the puncture area and the extremity where the procedure was performed was evaluated while the TR band was attached. The second stage form consists of 10 questions and was directed to the patients 1 hour after the TR band was removed from the patient and the pain in the puncture area and the extremity where the procedure was performed was evaluated. With this form, filled in during two different periods, the pain experienced during and after the TR band was attached, could be compared.

Data collection

The study included patients who were over 18 years of age, conscious, and undergoing radial angiography for the first time. Patients with chronic pain, rheumatoid arthritis, and those who reported using painkillers were excluded from the study. In addition, patients with ongoing chest pain after transradial angiography and those whose general condition was poor were excluded from the study. Before starting the study, the researcher met with the participants, provided information about the study, and explained the purpose of the study. Patients who agreed to participate in the study were asked to sign a written "Informed Consent Form". The patients were asked to fill out a pain assessment form 1 hour after TR band was placed and 1 hour after TR band was removed after transradial angiography. In addition, the patients were questioned about the pain they experienced with the Mcgill Pain Scale Short Form. Data collection was performed by a single researcher utilizing the same measurement tools at consistent time points to maintain standardization. Patient-reported pain outcomes were obtained through self-assessment, ensuring they were free from any investigator bias or guidance. Furthermore, to reinforce the robustness of data quality, the principal researcher underwent specific training to guarantee the accurate and consistent use of all data collection forms and assessment scales.

Data analysis

The data obtained in this study was analysed with SPSS Statistics version 26.0 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp) package program. In the first stage, frequency analyses relating to demographic findings were given. Frequency analyses, frequency (n) and percentage (%) values of the groups were calculated. Then, frequency analyses relating to scale levels, mean (Average), standard deviation (SD), minimum (Min) and maximum (Max) values of the groups were calculated. While investigating whether the variables came from a normal distribution, as well as the Kolmogorov-Smirnov test, skewness and kurtosis coefficients were used, and according to Tabachnik and Fidell (2013), if the skewness and kurtosis values are between-1.50 and +1.50, it is accepted that the variables came from a normal distribution. Levene test was used for variance homogeneity assumption. When examining the relationship between dependent continuous variables, the relationship between 2 measurement levels was tested with dependent samples t test. When interpreting the results, 0.05 was used as the significance level; it was stated that there was a significant difference when $p<0.05$, and that there was no significant difference when $p>0.05$.

Ethics committee approval

Before the study, ethics committee approval (Decision No: 2022/180) was obtained from the Non-Interventional Clinical Research Ethics Committee of Duzce University. After the patients participating in the study were informed about the study, their verbal and written consents were obtained. The study was conducted in accordance with the Declaration of Helsinki.

Results

Of the participants, 69% (n=69) were between the ages of 18-65, 68% (n=68) were male, 92% (n=92) were married and 29% (n=29) were retired. In terms of education level, 59% (n=59) were primary school graduates, 69% (n=69) had at least one chronic disease, and the rate of smoking was 44% (n=44) and the rate of alcohol consumption was 13% (n=13) (Table 1). Despite the absence of a table presentation, statistical comparisons of pain levels with age, sex, and comorbidities demonstrated no significant correlation.

Table 1. Frequency distribution table for demographic characteristics.

Characteristics	Category	n	%
Age	18-65	69	69.00
	66-74	25	25.00
	75-84	6	6.00
	85-	0	0.00
Gender	Male	68	68.00
	Female	32	32.00
Job/profession	State employee	12	12.00
	Labourer	13	13.00
	Housewife	28	28.00
	Student	0	0.00
	Free trader	13	13.00
	Retired	29	29.00
	Other	5	5.00
Marital situation	Married	92	92.00
	Single	8	8.00
Education level	Primary school	59	59.00
	Junior school	8	8.00
	High school	17	17.00
	University	9	9.00
	Other	7	7.00
Chronic illness situation	Yes	69	69.00
	No	31	31.00
Tobacco useage	Yes	44	44.00
	No	56	56.00
Alcohol useage	Yes	13	13.00
	No	87	87.00

It was determined that 68% of the participants felt pain in the treated arm and 23% of the participants felt pain in their entire arm. Those who felt numbness in the treated hand were 79%, those who felt tingling were 66%, those who stated that there was no sensation were 42%, those who felt swelling were 74% and those who felt cold were 75% (Table 2).

After the TR band was removed, 50% of the participants felt pain in the treated arm, while the rate of those who felt pain in the entire arm was determined as 18%. The rate of participants who felt numbness in their hand was 12%, tingling was 25%, swelling was 47% and coldness was 38%. In addition, the rate of those who felt relief when the air was removed from the device was 98%, and the rate of those who felt increased pain when using the treated hand was determined as 22% (Table 3).

Table 2. Findings regarding the pain assessment form at the 1st hour after TR band application.

Category	Answer	n	%
Do you feel pain in your arm where the procedure was performed?	Yes	68	68.00
	No	32	32.00
Does the pain extend to your whole arm?	Yes	23	23.00
	No	77	77.00
Do you feel pain only in the exact area the procedure was performed?	Yes	61	61.00
	No	39	39.00
Do you feel any discomfort from the device applied to stop bleeding?	Yes	51	51.00
	No	49	49.00
Do you feel any shivering in that hand?	Yes	79	79.00
	No	21	21.00
Do you feel any tingling in that hand?	Yes	66	66.00
	No	34	34.00
Is there any loss of feeling in that hand?	Yes	42	42.00
	No	58	58.00
Does your hand feel swollen?	Yes	74	74.00
	No	26	26.00
Do you feel coldness in that hand?	Yes	75	75.00
	No	25	25.00

Table 3. Findings regarding the pain assessment form 1 hour after TR tape removal.

Category	Answer	n	%
Do you feel pain in your arm where the procedure was performed?	Yes	50	50.00
	No	50	50.00
Does the pain extend to your whole arm?	Yes	18	18.00
	No	82	82.00
Do you feel pain only in the exact area the procedure was performed?	Yes	43	43.00
	No	57	57.00
Do you feel any shivering in that hand?	Yes	42	42.00
	No	58	58.00
Do you feel any tingling in that hand?	Yes	25	25.00
	No	75	75.00
Is there any loss of feeling in that hand?	Yes	12	12.00
	No	88	88.00
Does your hand feel swollen?	Yes	47	47.00
	No	53	53.00
Do you feel coldness in that hand?	Yes	38	38.00
	No	62	62.00
Did you feel relief as long as the air was removed from the device on your wrist?	Yes	98	98.00
	No	02	2.00
Does your pain increase when you use your hand on the treated side?	Yes	22	22.00
	No	78	78.00

In the comparison of the pain levels at the 1st hour after TR band was attached and 1 hour after TR band was removed with the McGill Pain Scale-Short Form, a significant decrease in post-procedure pain levels was observed for all variables ($p<0.05$) (Table 4).

Discussion

In recent years, technological developments and new methods have increased the number and variety of percutaneous coronary interventions performed for diagnostic and therapeutic purposes. In order to ensure the comfort of patients, it is of great importance to determine the risks such as catheter insertion site pain and increased anxiety level that may arise depending on the type of coronary angiography they will undergo. After transradial angiography, patients have pressure applied on the puncture site with the TR Band for approximately 2-4 hours until hemostasis is achieved.[26] This pressure on the puncture site may cause problems such as pain, hematoma, swelling, paresthesia and loss of strength in the treated area.[14,15] In this study, 68% of the patients stated that they experienced pain while the TR band was in place, and 50% of them stated that their pain continued one hour after

the TR band was removed. Similarly, Dharma et al. evaluated arm pain after transradial angiography in their study with 1706 patients in three different centers and reported that one in every 20 patients experienced pain.[22] Thakor et al., in their study examining the procedural and clinical results after transradial angiography, mentioned the pain experienced by patients in the forearm and puncture area among the radial artery complications.[27] Long-term compression of the radial artery puncture area can cause damage to the radial sensory nerve and decrease blood flow to the surrounding muscles, causing pain, weakness and dysfunction.[28,29] In this study, the majority of patients reported that they felt numbness, chill, and tingling in the puncture site and hands while the TR band was in place. One hour after the TR band was removed, a significant decrease in numbness, chill, and tingling was observed. Furthermore, in our study, a large majority of patients (75%) stated that they felt cold in their hands during the first hour of TR band pressure. It is thought that this situation is due to the effect of the compression created by the TR band used on the patients. Arm pain was associated with radial artery occlusion, multiple puncture attempts, small radial artery diameter, and prolonged compression to obtain hemostasis over 4 hours. All the above variables (with the exception of prolonged compression) can also be associated with radial artery spasm and are associated with radial artery occlusion.[22,30] Although these aforementioned effects of compression may emerge, nurses should diligently monitor the symptoms of extremity compromise (e.g., pain, pallor, paresthesia, pulselessness) during patient follow-up. This clinical vigilance is crucial since evidence in the literature indicates that 4.5% of patients followed for 30 days post-procedure still experienced pain.[31]

Table 4. Comparison of pain levels at 1 hour after TR band application and 1 hour after TR band removal.

Category	Mean	SD	t	p	Cohen's d
Sensory subscale					
Sensory hour 1	5.62	5.68	6.922	0.001*	3,580
Sensory after 1 hour.	3.13	3.77			
Affective subscale					
Affective hour 1	1.12	1.58	3.921	0.001*	1,120
Affective after 1 hour	0.68	1.12			
Numerical Rating Scale					
Pain level after applying Terumo Band	3.08	2.30	6.913	0.001*	
Pain level after removal of Terumo Band	1.68	1.65			
Pain intensity					
Pain intensity on applying Terumo Band	1.65	1.10	6.988	0.001*	
Pain intensity on removal of Terumo Band	1.01	0.83			

**p<0,05; dependent samples t test*
Mean ± standard deviation (minimum and maximum)
SD: Standard Deviation

In order to determine this damage, multidimensional scales are used by nurses in pain assessment. Barbosa et al. compared distal transradial, transradial and transfemoral methods in terms of pain intensity and reported that pain in the puncture site was most common in patients who underwent transradial intervention.[32] In this study, it was observed that approximately half of our patients continued to experience pain while the TR band was attached and after it was removed. In another study, the time to achieve hemostasis was endeavoured to be shortened with TR band and it was stated that there was no difference in arm and puncture site pain in patients in whom TR band was removed in a shorter time.[33] Although our study did not aim to shorten TR band time, studies have shown that pain persists after radial angiography as in this study and causes discomfort for the patient. In addition, pain is among the main indicators for complications such as radial artery occlusion, ischemia, and inflammatory arthritis. Failure to monitor pain after removal of the TR band may result in these complications being missed.[22] This study is an exemplary one, showing that nurses should continue to monitor pain. Pre-procedural finger exercises for patients undergoing transradial angiography can enhance radial artery blood flow and increase arterial diameter, thereby potentially improving puncture success and reducing

procedure-related pain.[34] Similarly, the application of local heat to the puncture site immediately prior to radial sheath removal is also an effective method for mitigating pain.[23] Post-procedure, the application of cold therapy and elevation of the affected arm are recommended for patients complaining of arm pain. In addition to these interventions, it is thought that protecting the procedural arm from interventions such as blood pressure monitoring and phlebotomy may also be beneficial for preserving regional circulation and preventing pain.

Limits of the study

Despite the valuable insights gained from this study, several limitations should be acknowledged. First, although the sample size was sufficient for initial statistical comparisons, it remains relatively small and obtaining data from a single hospital setting may limit the generalizability of the findings. Second, pain assessment was conducted only one day after angiography. Moreover, selection bias may have influenced the results, as only patients who voluntarily agreed to participate were included, potentially limiting the representativeness of the target population.

Conclusion

In this study, the TR band used on patients after transradial angiography was evaluated in terms of pain at two different times and drew attention to the importance of pain among the minor complications of the intervention site of transradial angiography. According to the results of the study, it is seen that patients experience pain while the TR band is attached and after it is removed. Nurses contribute to patients returning to their daily activities more quickly by providing them with more qualified care. Therefore, it is recommended that nurses continue to evaluate pain after transradial angiography intermittently and continue pain management interventions in the post-angiography period.

Data availability

The data that supports the findings of this study is available on request from the corresponding author. The data is not publicly available due to privacy or ethical restrictions.

Ethics committee approval

Before the study, ethics committee approval (Decision No: 2022/180) was obtained from the Non-Interventional Clinical Research Ethics Committee of Duzce University. After the patients participating in the study were informed about the study, their verbal and written consents were obtained. The study was conducted in accordance with the Declaration of Helsinki.

Author Contributions

A.E: contributed to the study conception and design, manuscript writing, data analysis and interpretation, and critical revisions.

İ.A: was involved in study design, data collection, literature review, manuscript writing, and manuscript preparation.

O.K: provided supervision, methodological guidance, and resources.

All authors reviewed and approved the final manuscript.

Conflict of Interest

There is no conflict of interest between the authors.

Financial Disclosure

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Peer-review

Externally peer-reviewed.

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