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Comparison of Access Site Complications After Early or Late Sheath Removal in Patients with PCI, Regardless of ACT Levels

ORIGINAL INVESTIGATION

ABSTRACT

Background: Despite the lack of supporting data, many clinics perform sheath removal 4-6 hours after femoral percutaneous coronary intervention to reduce the risk of possible access site complications. This study aims to examine the effects of sheath removal immediately after the procedure on access site complications and patient comfort.

Methods: This prospective study included 349 patients who underwent percutaneous coronary intervention via the femoral site and 6 French guiding catheters. The sheath in the early group was removed immediately after the procedure without checking the activated clotting time levels but after 4 hours in the late group. Access site complications were recorded and patient comfort was evaluated using the Visual Analog Scale.

Results: Patients were divided into 2 groups: patients in the early removal group (n = 171) and in the late removal group (n = 178). There was no statistically significant difference between the 2 groups in terms of access site complications. Three patients in the early removal group and 4 patients in the late removal group developed a hematoma. Six patients in the early removal group and 10 patients in the late removal group showed ecchymosis. The Visual Analog Scale score was statistically significantly lower in the early removal group compared with that in the late removal group [2 (1-3) vs. 3 (2-4), $P < .001$].

Conclusion: This study shows that immediate sheath removal is safe and more comfortable for patients with percutaneous coronary intervention who received weight-adjusted dose of heparin, regardless of the percutaneous coronary intervention levels after the procedure.

Keywords: Access site complications, percutaneous coronary intervention, Visual Analog Scale

INTRODUCTION

According to current data from the World Health Organization, cardiovascular causes are still the leading cause of death. Among them, the most common cause is ischemic heart disease (IHD). This shows us that the number of people suffering from IHD is very high and so are the related costs. Although the guidelines recommend a radial access site as a priority to reduce the risk of complications in percutaneous coronary interventions (PCI) used in the treatment of IHD, the femoral access site is still used extensively due to experience, operator preference, and complex interventions.[1,2]

No increase was observed in access site complications after coronary angiography and interventional procedures performed without an interruption of drug treatment in patients using oral anticoagulants.[3] In addition, in practice, many clinics perform sheath removal 4 hours (2-6 hours) after heparin administration on average after femoral interventions. Afterward, bed rest is ordered for approximately 6 hours by applying weight on the access area or without moving and without applying pressure. Because of this prolonged process, patients experience back and waist pain and extended hospitalization, which, in return, increases the treatment costs.

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Studies have been performed on early post-procedure sheath removal with limited and special patient groups, and they have shown no increase in complications.[4] The current study aims to, contrary to previous studies, compare access site complications and waist-back discomfort in patients from whom sheath was removed immediately without considering the activated clotting time (ACT) before the post-procedure sheath removal and those in patients from whom sheath was removed after 4 hours (as routine), among all the patients with PCI who received weight-adjusted heparin.

METHODS

This prospective study is a clinical trial that included patients who underwent PCI with femoral access. Before the procedure, the patients were divided into 2 groups in terms of age, gender, and antiaggregant used. A total of 349 patients who underwent PCI using 6 French (Fr) guiding catheters were included in the study.

Inclusion criteria were patients at least 18 years of age, who have stabil angina and/or chronic coronary syndrome, receiving acetylsalicylic acid (ASA), receiving clopidogrel or not, receiving ticagrelor or not, and having a body mass index (BMI) of <40 kg/m^2. Exclusion criteria were having thrombolytic therapy, having glycoprotein IIb/IIIa inhibitor, receiving warfarin and new-generation oral anticoagulant therapy, having a BMI of ≥40 kg/m^2, having undergone an intervention in the same area and subsequently developed a hematoma or arteriovenous (AV) fistula, a history of hemorrhagic diathesis, use of sheaths larger or smaller than 6F, having end-stage renal disease, having uncontrolled hypertension (systolic blood pressure above 200 mm Hg), having post-procedure hemodynamic instability, having coronary thrombolysis in myocardial infarction (TIMI) flow <3, and/or having an unsatisfactory image (as early re-intervention may be required). The Ethics Committee of the institution approved the study (Celal Bayar University, Faculty of Medicine, Clinical Research Ethics Committee. Date: March 15, 2021, No: E-85252386-050.04.04-49149) and all the patients signed an informed consent form.

Endpoints of the study were determined as a hematoma of >5 cm, retroperitoneal hematoma, access site bleeding, pseudoaneurysm, AV fistula, distal limb ischemia, access site infection, and back pain. Hematoma was defined as bleeding under the skin in the access area and a hard mass larger than 5 cm in diameter. After the access site was closed with pressure dressing after stabilization of bleeding, bleeding that caused a decrease in the hemoglobin level of more than 3 g/dL and required compression was defined as bleeding requiring transfusion and bleeding less than 3 g/dL was defined as bleeding not requiring transfusion. Computed tomography for retroperitoneal hematoma investigation was applied in patients with hemodynamic instability and progressive decrease in hemoglobin level in the follow-up but without bleeding and hematoma at the access site, and detection of hematoma in the retroperitoneal area was defined as retroperitoneal hematoma. Ultrasonography evaluation was carried out for pseudoaneurysm and AV fistula. Ecchymosis was defined as a subcutaneous discoloration greater than 4 cm in diameter that did not cause hardness due to blood leakage. Pain in the back and the lumbar region was scored by showing and explaining the visual analog scale (VAS) to the patient and was defined as back pain.

All patients received 100 mg ASA. Patients using clopidogrel used a dose of 75 mg/day, while those using ticagrelor used a dose of 180 mg/day (bid). During the procedure, 100 IU/kg intravenous heparin adjusted for body weight was administered to the patients. An additional dose of heparin was added, if necessary, by checking the ACT for the patients in whom the procedure was prolonged.

After the procedure, the patients in the early sheath removal group were taken to the sheath removal department and their sheaths were removed immediately without ACT measurement. Bleeding stabilization was achieved with manual compression. After that, the area was bandaged in the shape of an 8 and pressure was applied with a weight made from a sandbag. The patients in the control group were taken to their beds after the procedure and their sheaths were removed 4 hours later without ACT measurement, and the same procedures were applied. After this stage, all patients were checked for hematoma, bleeding, and extremity ischemia after 15 and 30 minutes and after 1, 2, 4, 6, 8, and 12 hours. All patients were mobilized 6 hours after sheath removal. Patients were informed about the complications that may occur after discharge. They were advised to return to the hospital in case of abnormal situations and the access area was re-evaluated 3 weeks later in outpatient clinics.

The severity of back pain due to immobilization was evaluated by VAS scoring. According to the cognitive/intellectual levels of the patients, a scale with numbers from 1 to 10 from left to right and emojis were shown. According to this scale, the patients were told to score 1 point for the absence of pain and 10 points for the highest level of pain to be predicted.

HIGHLIGHTS

- Although the radial site preference has increased in patients undergoing percutaneous coronary intervention (PCI), the femoral site is still widely used due to experience, operator preference, and complex interventions.
- In patients undergoing PCI from the femoral site (despite no strong data available), the sheath is usually removed 3-4 hours after the procedure in daily practice, considering that the complications of the intervention site may increase.
- The results of this study showed that intervention site complications did not increase in patients who had sheath removed immediately after PCI, regardless of the activated clotting time level. In addition, patient comfort has been shown to increase due to the shortening of the immobilization time.

When we started working, we made a power analysis with the G*Power program.[5] All statistical analyses were performed with Statistical Package for the Social Sciences software version 26.0 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). The demographic data and outcome measures were presented as proportions and summarized by descriptive statistics. Continuous variables are presented as median (interquartile ranges) and categorical variables as numbers (percentage). Associations between categorical variables were analyzed using the Chi-square or Fisher's exact test as appropriate. The Kolmogorov–Smirnov test was used to check whether the continuous variables were distributed normally. Non-normally distributed continuous variables were compared with the Mann–Whitney *U* test and Wilcoxon matched-pairs signed-rank test. A *P*-value < .05 was deemed statistically significant.

RESULTS

A total of 349 consecutive patients were included in the evaluation during the study period. Of these patients, 171 underwent early sheath removal (early removal group) and 178 underwent the traditional protocol (late removal group). The baseline characteristics were similar between the 2 groups except that hypertension and diabetes mellitus were statistically significantly higher in the early removal group (Table 1). While the hemoglobin level was 14 g/dL in the early removal group before sheath removal, it was 13.5 g/dL in the late removal group. The hemoglobin levels after sheath removal were found to have significantly decreased in the late removal group compared to that in the early removal group (12.7 g/dL vs. 13.5 g/dL, $P < .001$). Delta hemoglobin levels were 0.45 ± 0.68 g/dL in early removal group and 0.75 ± 0.58 g/dL in late removal group. The comparison of delta hemoglobin between groups was significant ($P < .001$) (Figure 1).

When we evaluated the groups in terms of access site complications, 3 patients in the early removal group and 4 patients in the late removal group developed a hematoma. There was no significant difference between the 2 groups in terms of hematoma incidence ($P = .743$). Ecchymosis was observed in 6 patients in the early removal group and 10 patients in the late removal group. There was no significant difference between the 2 groups in terms of ecchymosis ($P = .445$). Complications such as retroperitoneal hematoma, active bleeding, pseudoaneurysm, AV fistulae, peripheral ischemia, and site infection were not encountered. There was no statistically significant difference between the 2 groups in terms of access site complications (Table 2).

While no hematoma was observed in any of the patients using ASA alone, 2 patients using ASA + clopidogrel and 5 patients

Table 1. Baseline Characteristics of the Study Population

		Total (n = 349)	Early (n = 171)	Late (n = 178)	*P*
Age, year		65 (57-71)	64 (56-72)	65 (57-71)	.782
Gender (male), n (%)		260 (74.4%)	131 (76.6%)	129 (72.4%)	.375
Body mass index, kg/m^2		27.5 (25.3-29.9)	27.6 (24.7-30.8)	27.3 (25.7-29.3)	.721
Comorbidities, n (%)					
	Diabetes mellitus	111 (31.8%)	63 (36.8%)	48 (29.9%)	.048
	Hypertension	192 (55.0%)	80 (46.7 %)	112 (62.9)	<.005
	Coronary artery disease	175 (50.1%)	82 (47.9%)	93 (52.2%)	.423
	Peripheral vascular disease	20 (5.7%)	13 (7.6%)	7 (3.9%)	.140
	Hyperlipidemia	102 (29.2%)	48 (28.0%)	54 (30.3%)	.642
	Smoking	160 (45.8%)	77 (45.0)	83 (46.6)	.830
Antiaggregant medications					
	ASA	117 (33.5%)	50 (29.2%)	67 (37.6%)	.116
	ASA + clopidogrel	179 (51.3%)	92 (53.8%)	87 (48.8%)	.709
	ASA + ticagrelor	53 (15.2%)	29 (16.9%)	24 (13.4%)	.492
Laboratory data					
	Creatinine, mg/dL	0.75 (0.62-0.87)	0.73 (0.62-0.84)	0.77 (0.62-0.88)	.127
	Potassium, mEq/L	4.11 (3.92-4.40)	4.12 (3.95-4.40)	4.10 (3.90-4.40)	.489
	AST, U/L	26 (21-35)	26 (21-35)	26 (22-36)	.489
	ALT, U/L	26 (18-38)	28 (19-40)	25 (17-36)	.207
	WBC, 10^3/μL	6.52 (4.81-8.58)	6.44 (5.15-8.51)	6.64 (4.74-8.57)	.958
Hemoglobin, g/dL					
	Before sheath removal	13.8 (12.5-14.7)	14.0 (12.7-15.0)	13.5 (12.2-14.6)	.022
	After sheath removal	13.2 (11.8-14.2)	13.5 (12.3-14.5)	12.7 (11.4-13.9)	<.001

Data are presented as median (IQR) and number (%) of patients.
ALT, alanine aminotransferase; ASA, acetylsalicylic acid; AST, aspartate transaminase; WBC, white blood cell count.

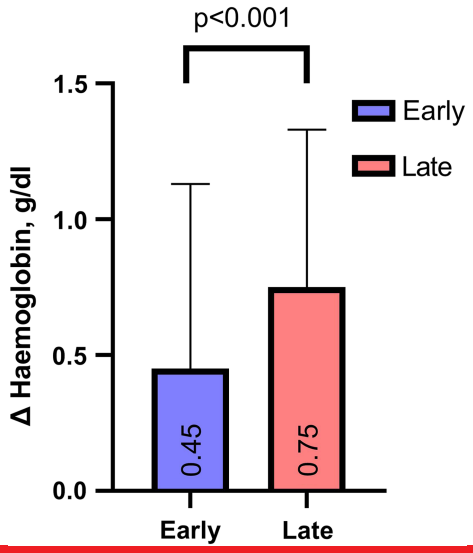

Figure 1. Comparison of delta hemoglobin levels between groups.

Table 2. Comparison of Access Site Complications in the Sheath Removal Groups

	Early (n = 171)	Late (n = 178)	*P*
Hematoma	3 (1.75%)	4 (2.24%)	.743
Retroperitoneal hematoma	0	0	NS
Active bleeding	0	0	NS
Pseudoaneurysm	0	0	NS
AV fistulae	0	0	NS
Ecchymosis	6 (3.50%)	10 (5.61%)	.455
Peripheral ischemia	0	0	NS
Site infection	0	0	NS

Data are presented as the number (%) of patients.
NS, nonsignificant.

using ASA + ticagrelor developed hematoma. While there was no significant difference between the ASA alone vs. ASA + clopidogrel ($P = .251$) groups in terms of hematoma development, a statistically significant difference was found between ASA vs. ASA + ticagrelor ($P < .001$) and ASA + clopidogrel vs. ASA + ticagrelor ($P = .002$) groups (Table 3). While ecchymosis was seen in 3 patients each in the ASA alone and ASA + clopidogrel groups, it was observed in 10 patients in the ASA + ticagrelor group. There was no statistically significant difference between the ASA vs. ASA + clopidogrel groups ($P = .596$), but there was a statistically significant difference between the ASA vs. ASA + ticagrelor ($P < .001$) and the ASA + clopidogrel vs. ASA + ticagrelor groups ($P < .001$) in terms of ecchymosis.

Compression time applied to the femoral intervention area after sheath removal is another point of interest in the current study. The compression time was 9 (8-10) minutes in the early removal group and 8 (7-9) minutes in the late removal group ($P = .005$) (Table 4).

On the other hand, when we compared the compression time in the early removal group according to the use of antiaggregant, we observed no significant difference between those using ASA alone or ASA + clopidogrel ($P = .320$); however, the compression duration was significantly longer in those using ASA + ticagrelor than in those using ASA alone ($P < .001$) or ASA + clopidogrel ($P < .001$). Similarly, in the late removal group, the compression time was significantly longer in those using ASA + ticagrelor compared to those using ASA alone ($P < .001$) or ASA + clopidogrel ($P < .001$) (Table 5).

The inactivity of the patients for a certain period of time after the procedure causes some physical symptoms. One of them is back pain. We used the VAS score to evaluate the complaints of the patients in this direction. The VAS score was statistically significantly lower in the early removal group compared to that in the late removal group [2 (1-3) vs. 3 (2-4), $P < .001$] (Figure 2). On the other hand, if we evaluate the scale visually, 15.2% of the patients in the early removal

Table 4. Comparison of Compression Time (in Minute) in the Sheath Removal Groups

	Early (n = 171)	Late (n = 178)	*P*
All	9 (8-10)	8 (7-9)	.005
ASA	8 (8-9)	8 (7-9)	.087
ASA + clopidogrel	8.75 (7-10)	8 (7-9)	.058
ASA + ticagrelor	11 (10-13)	11 (10-11.25)	.141

Data are presented as median (IQR).
ASA, acetylsalicylic acid.

Table 3. Comparison of Access Site Complications in Antiaggregant Treatment Regimes

	ASA (n = 117)	ASA + clopidogrel (n = 179)	ASA + ticagrelor (n = 53)	*P*
Hematoma, n (%)	0 (0%)	2 (1.11%)	5 (9.43%)	<.001
ASA vs. ASA + clopidogrel				.251
ASA vs. ASA + ticagrelor				<.001
ASA + clopidogrel vs. ASA + ticagrelor				.002
Ecchymosis, n (%)	3 (2.56%)	3 (1.67%)	10 (18.86%)	<.001
ASA vs. ASA + clopidogrel				.596
ASA vs. ASA + ticagrelor				<.001
ASA + clopidogrel vs. ASA + ticagrelor				<.001

Data are presented as the number (%) of patients
ASA, acetylsalicylic acid.

Table 5. Comparison of Compression Time (in Minute) in the Antiaggregant Treatment Regimes by the Sheath Removal Period

	ASA (n = 117)	ASA + clopidogrel (n = 179)	ASA + ticagrelor (n = 53)	*P*
Early	8 (8-9)	8.75 (7-10)	11 (10-13)	<.001
ASA vs. ASA + clopidogrel				.320
ASA vs. ASA + ticagrelor				<.001
ASA + clopidogrel vs. ASA + ticagrelor				<.001
Late	8 (7-9)	8 (7-9)	11 (10-11.25)	<.001
ASA vs. ASA + clopidogrel				.204
ASA vs. ASA + ticagrelor				<.001
ASA + clopidogrel vs. ASA + ticagrelor				<.001

Data are presented as median (IQR).
ASA, acetylsalicylic acid.

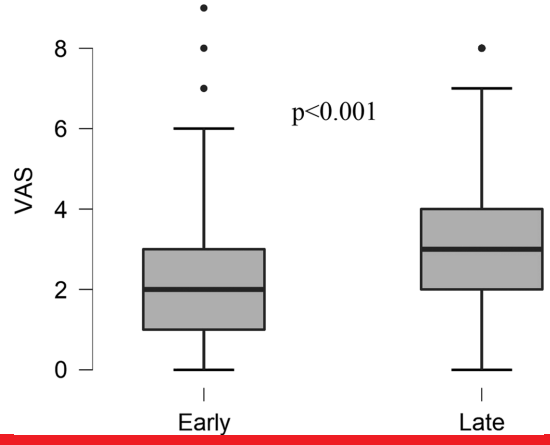

Figure 2. Comparison of VAS score between sheath remove groups. VAS, visual analog scale.

group stated that they did not feel any pain, while this rate was only 1.1% in the late removal group (Figure 3). Also, there was a statistically significant difference between the sheath removal groups when we divided the patients into 2 groups as no pain and mild and the other group as moderate to worst. ($P < .001$) (Table 6).

DISCUSSION

Although there is neither a guideline recommendation nor clear data on the waiting time for sheath removal after PCI, many clinics wait approximately 2-6 hours due to the increased risk of access site complications. This study aimed to investigate whether a difference existed between early sheath removal and late sheath removal in terms of access site complication rates and patient comfort. In contrast to similar previous studies, this study included patients who received weight-adjusted heparin. Regardless of the ACT level before sheath removal and without excluding patients who received antiaggregant such as ASA and thienopyridine, we made the study more adaptable to patients in daily practice. Hematoma was detected in 3 patients in the early sheath removal group and 4 in the late sheath removal group. Complication rates were significantly higher in patients using ticagrelor. In addition, no bleeding requiring transfusion was detected in either group. Although not statistically significant, the complication rates were found to be lower in the early sheath removal group. However, the compression time was moderately longer in the same group. Although there was a significant difference between the pre- and post-procedure hemoglobin values in both groups, we thought that the small clinically insignificant decrease in hemoglobin value may be due to both dilution due to fluid intake and some bleeding during the procedure.

Although a wide variation exists according to inclusion and exclusion criteria and definition findings of the study, the information according to the general literature states that complications of the access site after PCI vary between 1.5% and 9%.[6,7] In both groups of the current study, the complication rates of the access site were lower than those in the general literature.[8] Similar studies explained the low complication rate by excluding patients with high bleeding risk.[9] We believe that the low complication rate in the current study was because all sheaths were removed by a single technician with extensive experience and a tight 8-shaped compression band after hemostasis.

In routine practice, sheaths are usually removed late not to increase the complications of the access site. In a manual compression group of 102 patients in a study with vascular closure devices, the sheaths were removed after an average of 3.5 hours, and hematoma developed in 24 patients. However, ironically, 18 of these patients developed hematoma before the sheath removal.[10] In another study, sheath extraction was performed immediately after PCI using the mechanical compression method (FemoSCop, RADI Medical Systems, Uppsala, Sweden). Although control manual compression groups were not included in the study, the complication rate at the access site was equal or even lower than that in the literature data.[11] Considering that the risk of access site complications increases due to the effect of heparin after the procedure in patients undergoing PCI, the sheath is removed after a few hours, with or without checking the ACT level. In addition, the data obtained both in the current study and in the aforementioned studies indicate that prolonging the time during which patients wait with the sheath may increase complication rates.[2] This may be due to the following 2 reasons. First, although the access area is regularly checked by a nurse while waiting with a sheath, the immobilization compliance of patients may be low due to age and sociocultural reasons. Thus, a complication may

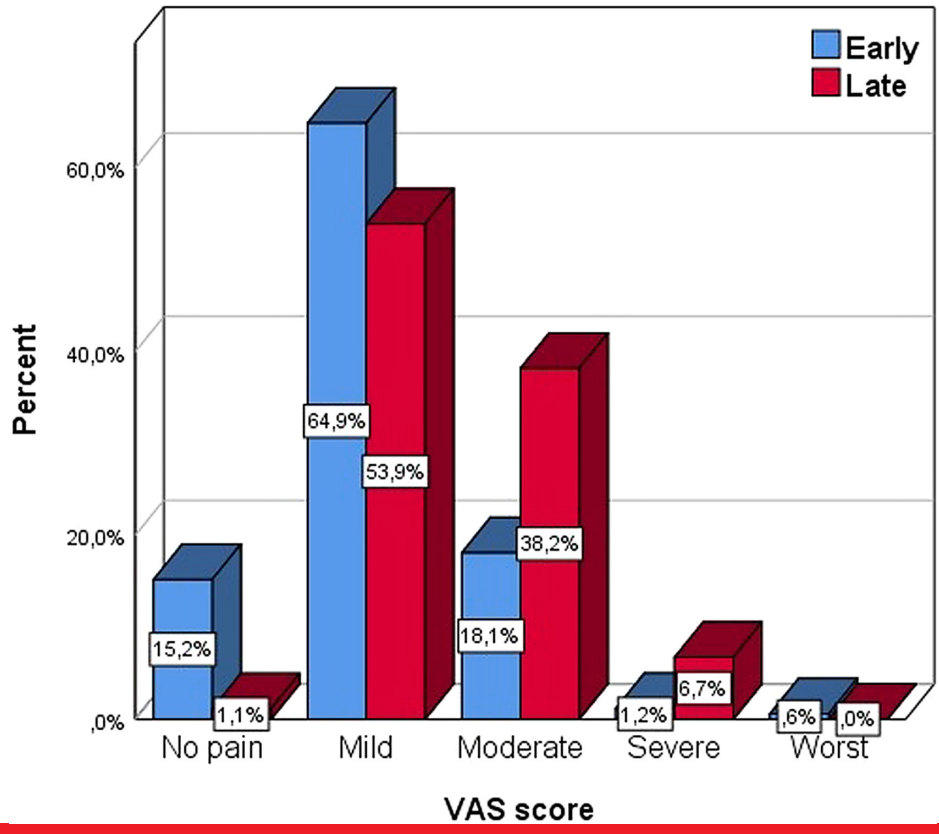

Figure 3. Visual evaluation of VAS score. VAS, visual analog scale.

Table 6. Comparison of Visual Evaluation of VAS Score Between Groups

	Early (n = 171)	Late (n = 178)	*P*
No pain or mild	137 (80.1%)	98 (55.1%)	<.001
Moderate to worst	34 (19.9%)	80 (44.9%)	

Data are presented as number (%) of patients
VAS, visual analog scale.

have started even if it was not recognized clinically.[12] Second, a tunnel-like formation can be seen under the skin when the dialysis catheter or venous catheters are removed because they stay there for a longer time. Although the arterial wall is more elastic than the skin and subcutaneous tissue, the same mechanism may be involved here, and therefore, the risk of complications may increase. However, this hypothesis needs experimental evidence.

In a study with an early sheath removal, 6F sheaths were used and patients with low-dose heparin were included. No increase was reported in the complication rate compared with the literature data.[13] Another similar study used 7F sheaths, applied low-dose heparin, and performed early sheath removal and showed no increase in complication rates compared with the literature data.[4] Studies on femoral access site complications showed a wide range of complication rates. Not including a control group in these studies may be an important limiting factor, which is why we created a control group with late sheath removal. In addition, by applying weight-adjusted heparin, we made the study more compatible with routine patients. Augustin et al[9] compared complications after early and late sheath removal and found a nonsignificant increase in the early removal group. In addition, in the early sheath removal group, the sheath was immediately removed if the ACT level was <350 s, but it was removed 90 minutes later if the ACT level was >350 s. In the current study, the sheaths of the early sheath removal group were removed immediately after the procedure and regardless of the ACT level, and the complication rate was lower although not statistically significant.[9]

The study of Höglund et al[14], which was performed with patients who underwent coronary angiography, showed that vascular complications did not increase in patients using ASA and clopidogrel. In the current study, while no significant difference was observed in the complications rates and compression time in patients using ASA and ASA + clopidogrel, both a significant increase in complication rate and a significant prolongation in compression time were found in the ASA + ticagrelor group. In a study of patients with acute coronary syndrome, it was found that ASA and clopidogrel did not cause an increase in in-hospital major bleeding but ticagrelor was an independent risk factor for major in-hospital bleeding.[15] Another study conducted with approximately 38 000 patients who underwent PCI found that ticagrelor was an independent risk factor for bleeding.[16]

As heparin inhibits thrombin through antithrombin, it is called an indirect thrombin inhibitor. The findings of this study and those of some of the aforementioned studies support the safety and comfort of sheath removal under the effect of heparin after PCI. Some published studies also showed that sheath removal after PCI with an oral anticoagulant vitamin K antagonist is safe. No significant difference was found in terms of access site complications between patients with an international normalized ratio between 2.0 and 3.0 who used warfarin and did not stop using it before the procedure among patients who underwent PCI and a control group, and the procedure was reported to be safe.[17,18]

The VAS score used to evaluate back pain that developed due to prolonged lying/immobilization was significantly lower in the early sheath removal group. In the study of Augustin et al[9], low back pain was evaluated in the comparison of early sheath extraction and mobilization with late sheath extraction and mobilization. As we found in our study, significantly lesser low back pain was observed in patients who were mobilized early. In another study, in which early mobilization was attempted with the closure device and reversal of heparin effect, significantly lesser back pain was observed in the early mobilized group.[19]

Study Limitations

This study has several limitations. How many attempts performed to puncture artery were not recorded. Also, PCI procedure time and type were not recorded.

CONCLUSION

The results of the current study, which was performed with patients who underwent PCI, showed that early sheath removal is safe in terms of access site complications, regardless of the ACT value after the procedure. In addition, back, waist, and leg pains were reduced due to the shortening of the immobilization time. Thus, early sheath removal can be considered a safe and comfort-enhancing approach that reduces costs because it simultaneously shortens hospitalization duration. More studies involving larger numbers of patients are needed to support these results.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Celal Bayar University (approval no: 150 Date: March 15, 2021, No: E-852 52386-050. 04.04-4914 9).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

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