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Original research

EFFICACY AND SAFETY OF EARLY RELEASE RADIAL COMPRESSION TIME IN PATIENT WITH RADIAL AIR-INFLATED PRESSURE DEVICE IN HA NOI MEDICAL UNIVERSITY HOSPITAL

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ABSTRACT

Objectives: *The study aims to evaluate the safety of early - release radial compression time in patients with radial air-inflated pressure devices and to compare the efficacy of early - release radial compression time in patients with radial air - inflated pressure devices with standard methods. Short-time hemostasis is one of the strategies to prevent complications related to the radial artery compression band. Long - time hemostasis in standard protocol may not be necessary.*

Methods: *141 patients having radial air-inflated devices were observed. Group 1 contains patients with the early releasing method in which medical staff releases 10 percent of air volume in the compression device every hour. Group 2 contains patients with the standard method of medical staff releasing 10 percent of air volume in compression devices every two hours. The bleeding rate, pain score, and discomfort level were compared between the two groups.*

Results: *There was no statistical difference in the distribution of baseline characteristics. 2.8% of the group 1 developed swollen in the radial area, which had a diameter of less than 5 cm and needed to re - inflate again. There was no statistical difference between the two groups in bleeding percentages, with a p - value of 0,496 ($p > 0.05$). There is an obvious statistical difference in pain score and discomfort level between group 1 and group 2. The patients in Group 1 had less pain and lower discomfort level than Group 2.*

Conclusions: *Release the proper pressure in the compression device from the first hour to every continuous hour is safe and benefits the patient by reducing pain, and uncomfortable level.*

Keywords: *Radial artery compression, hemostasis, early - releasing, bleeding*

I. BACKGROUND

Transradial access is the most common approach to performing angiography and cardiac intervention [1, 2]. After the procedure, the cath lab medical staff removes the sheath, and radial hemostasis is typically achieved by using a radial compressed device and an air-inflated device is the most common choice [3]. The directly applied pressure on the wrist regularly causes pain and discomfort for the patient [4, 5]. Otherwise, continuous long-time pressure can cause radial artery occlusion [4-9]. Multiple research conducted in numerous cardiovascular centers point out the importance of effectively reducing radial compression time to prevent complications [3-9]. Research by Adel Aminian and colleagues showed the mean hemostasis time was 6 hours which was completely safe in 98% of patients with no bleeding event observed [6]. In the CRASOC I study, 4 hours of continuous compression time was the maximum duration for radial patency with the rate of re-bleeding/compression being 0.9% [5]. In Vietnam, cardiology has more than 25 years of cardiovascular intervention history but there is still little information about compression procedures. There is no officially consistent protocol in radial hemostasis among cardiovascular centers in Viet Nam. Indeed, there is a gap in investigating and researching the safety and satisfaction of patients

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with radial compression devices. In Hanoi Medical University Hospital, the hemostasis duration lasts at least 8-12 hours and is released every two hours which is longer than other cardiovascular centers in the world [4-6]. The patient under the procedure often notifies the pain, numbness, and unpleasant feeling. After considering other research about the safety of air compression devices and discussing co-operate with interventional doctors, a new method that releases the pressure every 1 hour, which shortens half time than the standard method, is recommended to reliably apply for the patient. We conduct this research to evaluate the safety and efficacy of early-release radial compression time in patients with radial air-inflated pressure devices in Ha Noi Medical University Hospital.

II. MATERIALS AND METHODS

After being catheterized through the radial artery, all patients were observed. We divided the patients into two groups to compare. The first group contains patients with the early releasing method in which medical staff releases 10 percent of air volume in the compression device every hour. The second group contains patients using the standard method , in which medical staff releases 10 percent of air volume in compression devices every two hours. The comparison will be determined in some aspects: the safety which focuses on the percentage of bleeding cases and hematoma in both groups, the pain score, and the uncomfort level. We assessed the features at every point at which we released the pressure in an air-inflated device. To observe the bleeding events, we inspected the gauze to see whether it would have blood or any swollen signs around the compression device. The observed bleeding events were going to prove the hypothesis of whether the early releasing method was safe. The pain score was assessed by VAS score and a questionnaire-based Likert scale was used to evaluate the discomfort level. These two indexes in VAS score and uncomfort level were compared between two groups, the early releasing group, and the standard group.

III. RESULTS

From July to October 2023, 141 patients with radial air-inflated devices were observed in the research efficacy and safety of early release radial compression time in patients with radial air-inflated pressure devices in Ha Noi Medical University Hospital. Table 1 shows there was no statistical difference in the distribution of baseline characteristics. Of 141 patients, there were 71 patients in the group early releasing time procedure, and the remaining 70 patients were in the standard procedure group. In the bleeding event observation, there was no patient seen with red compression gauze; there were 2 patients who accounted for 2.8% of the group early releasing technique developed swollen in the radial area, which had a diameter of less than 5 cm and needed to re-inflate again. There was no statistical difference between the two groups in bleeding percentages, with a p-value of 0,496 ($p > 0.05$). The result is demonstrated in Figure 1. From the first time received from the cath lab, the group early releasing time procedure had a mean VAS score of 3,41 ± 1,591; the standard group had a mean VAS score of 3.43 ± 2,137. There was no statistical difference in the pain score between the two groups, with a p-value of 0.949 and Levene's test of 0.004. In the second time point observing the patient, the early releasing time procedure group had a mean VAS score of 1.73 ± 1,095; the standard group had a mean VAS score of 3.33 ± 2,178. There was a statistical difference in the pain score between the two groups, with a p-value of 0 and Levene's test of 0. In the sixth time point, the group early releasing time procedure had a mean VAS score of 1.11 ± 0.433; the standard group had a mean VAS score of 2.67 ± 2,097. The result is shown in Figure 2. There was a statistical difference in the pain score between the two groups, with the p-value being 0 and Levene's test being 0. The uncomfort level was also compared between the two groups; in the first time point, there were 66 people in both groups expressed uncomfortable feelings, which took nearly 93% of the whole sample; there was no statistical difference between the two groups in the uncomfort level with the p-value was 1. The distinction was initiated in the second time point and was clear in the last time point because there were statistical differences between the two groups in uncomfort level with the p-value sequentially at 0.013 in the second time point and 0 in the sixth time point. The result is demonstrated in Figure 3

Table 1: Baseline characteristics

Characteristics / GROUP	Age	Gender	BMI	Sheath size	Air inflated amount	Intervention types	Heparin dose	Radial puncture history
Early releasing time procedure	67.37±11.87	Male: 69%	22.69±3.30	5F: 12.7%	19.85±0.71	Coronary stent: 54.9%	None heparin: 1.4%	The 1st time: 77.5%
				6F: 85.9%			500 IU/kg: 43.7%	The 2nd time: 21.1%
		Female: 31%		7F: 1.4%		Angiography: 45.1%	1000IU/ kg:54.9%	The 3rd time: 1.4%
Standard procedure	63.47±10.28	Male: 61.4%	22.85±2.85	4F: 1.4%	20.26±1.51	Coronary stent: 42.9%	None heparin: 2.9%	The 1st time: 84.3%
				6F: 97.1%			500IU/kg: 54.3%	The 2nd time: 12.9%
		Female: 38.6%		7F: 1.4%		Angiography: 57.1%	1000IU/ kg:42.9%	The 3rd time: 2.9%
p-value	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05

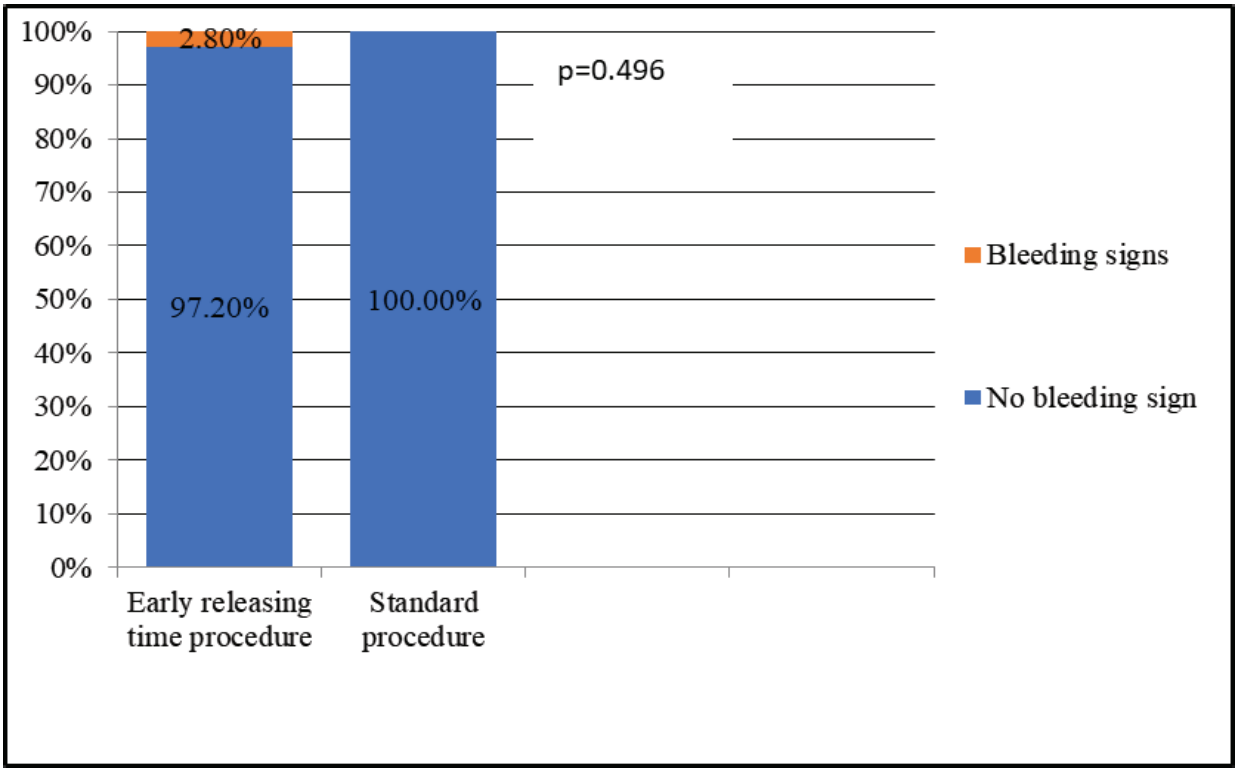

Figure 1: Bleeding event observation

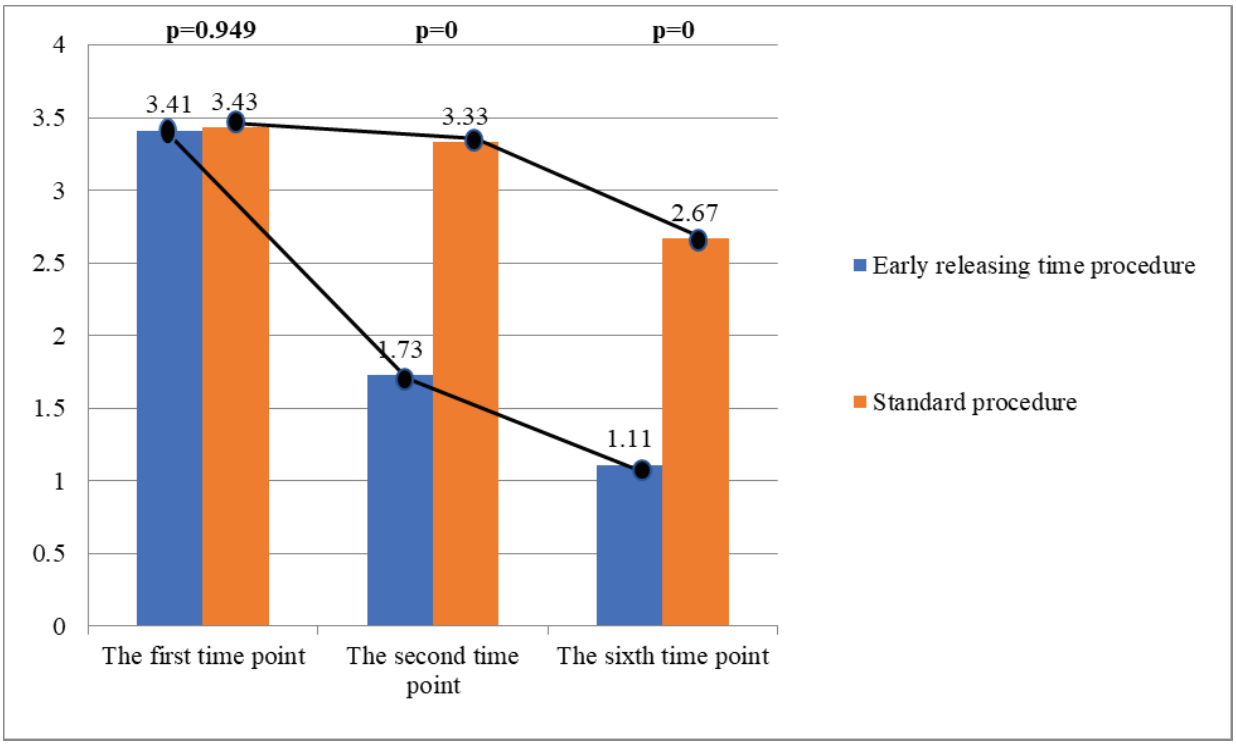

Figure 2: Pain level by mean vas score through time points

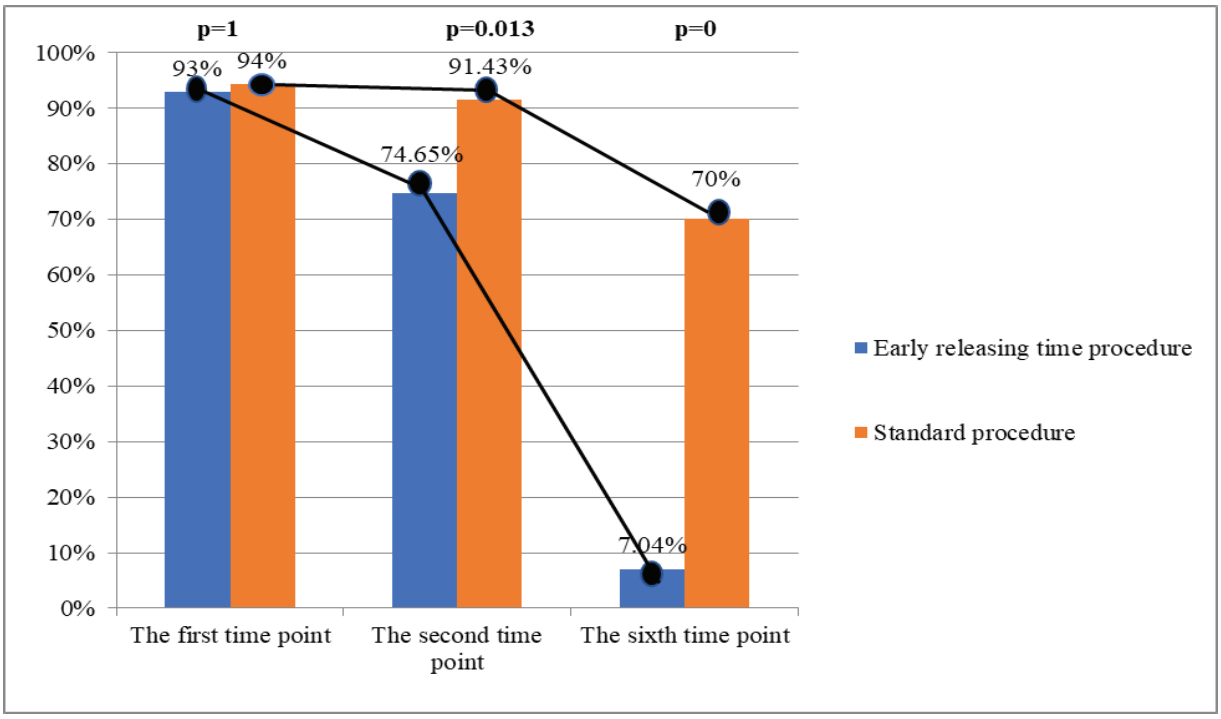

Figure 3: Discomfort level through time points

III. DISCUSSION

The early - release radial compression procedure takes only half the time to compare with the standard method to achieve effective radial hemostasis. The total hemostasis time of the early releasing radial compression is similar to research conducted in Japan-an Asia country which Aminian et al put the hemostasis device last at least 6 hours [6]. However, the early releasing radial compression procedure was safer than Aminian's research when comparing the bleeding percentage [6]. Our bleeding event observation percentage was 2.8%, and Aminian et al. research was 20.7%. We did not know exactly the hemostasis device in Aminian research , but the difference in the hemostasis device may be the reason which led to the higher bleeding percentage in Aminian's research. The early releasing radial compression procedure has longer time hemostasis than other research in Europe and America [4, 5, 8, 9]. Samir Pancholy et al show that decreasing the whole compression time to 2 hours with maximum releasing pressure after 15 minutes did not lead to an increase in bleeding complications [8]. CRASOC I study demonstrates that hemostasis time was 4 hours with 10cc of air-inflated, and has only 0.9% of re-bleeding [5]The initial air pressure in our study was much higher than that of other studies mentioned because the standard protocol at Ha Noi Medical University has 15 - 20ml of the injected air amount in the hemostasis device. The higher air amount and longer hemostasis time make the early releasing procedure as reliable and safe as other protocols in other studies.

The new procedure, in a shorter time, improves impressively the patient's pain and discomfort level in total duration when patients have compression devices in their wrists. The first time, even though the level of pain in both groups was mild pain (3.41 vs 3.43), the early releasing time procedure had a remarkable decrease in the level of pain compared with the standard protocol immediately after the first assessed time point (1.73 vs 3.33), the p-value was 0. The pain level observed in both groups was mild, which has little effect on patients. The reason may come from the cath lab nurse always covering the contact area between the hemostasis band and the patient skin with a gauze layer, which helps reduce the pain level. In CRASOC I, II, III, the

local pain was mentioned as local pain which only showed under percentage but not in the pain level scale to compare [5]. The discomfort level has the same progression as the pain level. In the first handover patient from the cath lab, there was no difference in the discomfort level in either group (66 patients in the two groups, equal to 93% of the whole sample, clarified they were uncomfortable). However, when assessing the patient in the second time point, the uncomfort level reduced dramatically in the early releasing time procedure (74.65%); on the other hand, the standard group still had an uncomfort level of 91.43%, p-value was 0.013. In the last deflating time, the number of patients has uncomfortable feelings was 7.04% in the early releasing time group , and the standard group had 70%. The discomfort level mostly comes from the numbness and tired feeling in the arm. Early releasing time procedure reduces the direct pressure in the radial artery, leading to a decrease ahead of time in the uncomfort level compared with the standard procedure.

V. CONCLUSION

Release the proper pressure in the compression device from the first hour to every continuous hour is safe and benefits the patient by reducing pain, and uncomfortable level

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