Comparison of The Effectiveness of Different Prototypes of Wrist Support in Prevention of Radial Hematoma and Bleeding After Transradial Coronary Angiography among Patients Undergoing Percutaneous Coronary Interventions: A Retrospective Study

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Abstract

OBJECTIVES: To compare the proportion of hematoma and bleeding occurrences between P1, P2, and P3 holding wrist supports as well as to evaluate the user satisfaction of P3 wearers among patients who underwent transradial access site procedures.

MATERIALS AND METHODS: This study is retrospective drawing on analytical data from Bangkok Hospital Chiang Mai medical records whose patients underwent percutaneous coronary interventions (PCI); 136 cases were gathered between June 1, 2019 – December 31, 2021. The division of the samples into three groups was based on the duration of use for each device namely prototypes as follows: Wrist Supported Prototype 1 (P1) group, Wrist Supported Prototype 2 (P2) group, and Wrist Supported Prototype 3 (P3) group. The baseline characteristics were presented as frequency (%) and Chi-square test or Fisher's exact test was used to evaluate the difference in variables between the 3 groups. Chi-square test was used to compare the proportion of hematoma and bleeding. A $p < 0.05$ was considered statistically significant.

RESULTS: Patients undergoing PCI, 133 cases, who satisfied the criteria for eligibility were divided into 3 groups; 8 cases in P1 group, 80 cases in P2 group and 45 cases in P3 group. The findings on hematoma revealed 1 case (1.3%) among the P2 group and no hematoma among the P1 and P3 groups, respectively, 6 hours after the sheath was taken off. The number of cases of bleeding were discovered as follows: 2 cases (25.0%), 33 cases (41.2%) and 13 cases (28.9%) among P1, P2 and P3 groups, respectively, 6 hours after sheath was taken off. There were no significant differences on the proportion of bleeding among three groups ($p = 0.307$). The demographic data differences between the three groups were not statistically significant, except for dyslipidemia which was significantly different ($p = 0.023$). In this study, wrist support Prototype 3 users was 45 cases, and the overall patient satisfaction average score was 4.96 ± 0.23. The wrist support Prototype 3's ease of use and patient satisfaction average scores were 5.00 at the highest possible level.

CONCLUSION: Wrist support is used for support and limited moving of the wrist after a patient has undergone PCI. P3 group had the highest satisfaction rating for wrist support among users. This study revealed that the differences in bleeding post-PCI between P1, P2 and P3 groups were not statistically significant ($p = 0.307$). The hematoma results were not deemed sufficient for statistical analysis.

Keywords: Coronary angiography, transradial access, Bleeding, Hematoma, wrist support

The transradial coronary angiography is favored more than transfemoral access because of its safety, comfort, and economical aspects as a procedure, as shown in the study by Garg et al.[1] Additionally, recent studies found that transradial access reduced bleeding, vascular complications, and major adverse access events.[2-3] The literature review of Nakarin et al.,[4] Thai PCI registry, found that transradial access site elected in 10,385 cases (44.96%) due to its safety then began to promote an upward trend.

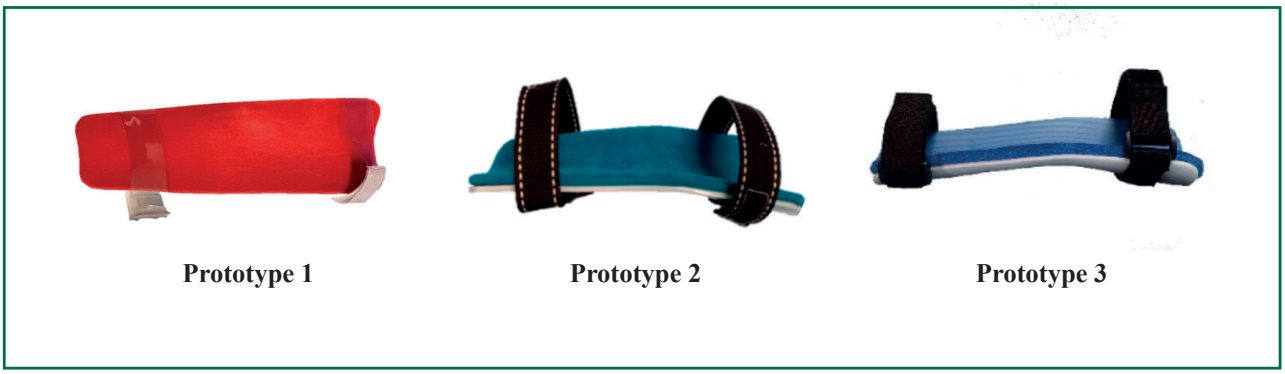
Though transradial access is safe as mentioned above, the recently published study by Aunsinee et al.[3] reported that hematoma was 1.6% prior to off-sheath, and after off-sheath ecchymosis was found at 1.6% and bleeding at 1.6%. Riangwiwut T,[5] studied the vascular complications of transradial access for cardiac catheterization, and found that radial artery spasm was 4.6 (16%), radial artery occlusion was 3.9 (8.1%) and hematoma was 1.2 (2.6%) respectively. Data corresponding to a 3.98% hematoma rate after transradial access at Bangkok Hospital Chiang Mai from January 2017 to May 2019 prompted investigators to look at factors associated with vascular complications in these patients including; patient characteristics (aging, female, body surface area less than 1.6 m^2, body mass index of more than 28 or less than 18.5 kg/m^2, renal insufficiency, peripheral vascular disease, and history of PCI)[1,4-7], procedural variables (place of catheter, sheath size, type and duration of operation, equipment to stop bleeding, prolonged compression to stop bleeding, intravenous closure devices, anticoagulants, and antiplatelet agents)[1,6,8], and nursing practices (insufficient knowledge and skill in distal compression bandage and misplacement and decreased vascular complication risk).[9]

Factors related to vascular complications, as mentioned above, were reviewed by researchers in the standard of nursing practice prior to and after the procedure. When the PCI was finished, the sheath was removed, and the TR band® was placed and compressed on the bleeding site for 4 hours. Patients were then required to limit moving their wrists for bleeding prevention. It took from twenty to sixty minutes to complete the coagulation system. Patients' wrists will bleed and develop a hematoma if they move them.[10]

Corrugated papers were covered in non-woven paper, and a conform bandage was clouted around the wrists to support the wrist and limit wrist movement. The disadvantages of using corrugated papers included: bending easily, difficult abnormal assessment at the puncture site, difficult to use steps that are complicated, and being unkind to nursing care.

In 2019, the researchers created wrist support Prototype 1 (P1) despite the fact that commercial wrist supports are too costly and not widely available. Their characteristics were sturdy, user-friendly, practical, and supportive of the wrist during compression balloon placement (TR band® radial compression device) on the access site until the end of the air titration process.

Furthermore, data was gathered on how simple, convenient, and completely satisfied P1 users were. The next wrist support prototypes, P2 and P3, were developed using all of the patient feedback and results. A continuous quality improvement project called "Save Life, Zero Hematoma in PCI Patients" was also started (as seen in Figure 1).



Prototype 1 **Prototype 2** **Prototype 3**

This study aims to compare the proportion of hematoma and bleeding occurrences between P1, P2, and P3 holding wrist supports as well as to evaluate the user satisfaction of P3 wearers among patients who underwent transradial access site procedures.

Materials and Methods

This study was a comparative retrospective data review to compare the proportion of hematomas and bleeding as well as the factors that influenced the patients who underwent transradial access site procedures.

Sample

The sample size for a Chi-square analysis was estimated in this study using G*Power version 3.1.9.7. In three groups, we established the power $(1-\beta) = 0.80$ and $\alpha = 0.05$ to compare the proportion of hematoma and bleeding incidents in holding wrist support users between P1, P2, and P3 group. This indicated a minimum sample size of 51 samples per group. Finally, 136 medical records were enrolled in this study and the research data was completed.

This data was gathered from Bangkok Hospital Chiang Mai medical records, with 136 cases of patients undergoing PCI between June 1, 2019 and December 31, 2021. The inclusion criteria are as follows:

1. Be older than twenty years old.
2. Patients undergoing transradial access site procedures.
3. Able to read and write Thai or English.
4. Use the TR band® radial compression device with wrist support Prototypes 1, 2, or 3 for at least four hours.

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Patients with hematomas between transradial access sites were excluded in the study. Organizing study participants into groups, the researcher separated the sample into three groups based on the duration of using each device, as shown below.

- **P1 Group:** patients who applied wrist supported Prototype 1 between June 1 and 30, 2019.
- **P2 Group:** patients who applied wrist supported Prototype 2 between July 1, 2019 and December 31, 2020.
- **P3 Group:** patients who applied wrist supported Prototype 3 between January 1 and December 31, 2021.

Wrist support prototypes

The three wrist support Prototypes, P1, P2, and P3, were made several times. P1 was designed and invented between April 1 and May 30, 2019, and was later applied to patients. Then the next prototype (P2) was invented after the research team got patients' feedback data after using P1 from patients, and the inventive final prototype (P3) was tested the next time, in the same was as P2. P1, P2, and P3 were constructed from solid acrylic pads. The three prototypes' various materials were straps and materials that were laid on an acrylic pad. The plastic wrist straps of P1 irritated users' skin. Then the next prototype (P2) changed the plastic wrist straps to an elastic band for a gentle touch. But the feedback was found to be too close-fitting. After that, the inventor adapted Velcro so it could adjust properly in Prototype 3. The arm support forms were developed from velvet, sponge with velvet, and a conform pad in P1, P2, and P3, respectively, for the purpose of decreasing arm pressure (as seen in Figure 1).

Tool

The Case Record Form (CRF) was used to gather and record the data from medical records. Demographic (age, gender, and education) and clinical (underlying disease, prior percutaneous coronary intervention, body mass index, and body surface area) information as well as procedural (procedure type, Glycoprotien IIb/IIIa inhibitor therapy, non-clopidogrel agent use for dual antiplatelet therapy during treatment, air-inflated volume in TR band®, duration during TR band® compression, duration during TR band® deflation, and usable satisfaction of P3) information comprised the subject of CRF. The de-identified and reviewed data were performed.

Data collection process

The Institution Review Board (IRB) of Bangkok Hospital Chiang Mai (BCM-IRB-2022-07-01) conducted the research ethical review for this study. The data was collected from Trakcare®2021 at Bangkok Hospital Chiang Mai between June 1, 2019 and December 31, 2022. The research assistant collected data, which were then confirmed by the principal investigator.

Data Analysis

The study was conducted using STATA version 15 with Chi-square test to compare the proportion of hematoma and bleeding between the P1, P2, and P3 groups. The baseline characteristics were presented as frequency (%). The difference in variables between the 3 groups were compared using the Chi-square test or Fisher's exact test. A p-value of less than 0.05 ($p < 0.05$) was considered statistically significant, along with a 95% confidence interval (95% CI). The user satisfaction of P3 was reported as frequency (%) and means with standard variations.

Results

A total of 136 patients underwent PCI; two patients had hematomas during PCI, and one patient was excluded from the study because no medical record was available. 133 patients were eligible for the study and were divided into 3 groups based on the time of use of each device, as follows: 8 cases in the P1 group, 80 cases in the P2 group, and 45 cases in the P3 group. The results of patient demographic data were as follows: age, gender, education, underlying diseases, previous PCI, body mass index (kg/m^2), and body surface area (m^2) between the 3 groups were not significantly different, except for dyslipidemia, which was significantly different ($p = 0.023$), as shown in Table 1.

There were no significant differences on procedural characteristics in patients undergoing PCI between P1, P2, and P3 groups, which consisted of glycoprotien IIb/IIIa inhibitor therapy, non-clopidogrel agent for dual antiplatelet therapy, duration during TR band® compression, and duration during TR band® deflation. The procedure type and air-inflated volume in TR band® between the 3 groups showed significant differences, $p = 0.024$ and 0.015, respectively, as shown in Table 2.

This study found that 1 patient (1.2%) had a hematoma among patients undergoing PCI in P2 group. Most patients did not develop a hematoma. The incidence of bleeding during 6 hours after sheath removal was found to be 2 (25.0%), 33 (41.2%), and 13 (28.9%) in the P1, P2, and P3 groups, respectively. There were no significant differences between the three groups, as shown in Table 3.

In this study, wrist support Prototype 3 users were 45 cases, and the average overall patient satisfaction was 4.96 ± 0.23. These patients did not worry about their wrists becoming flexible during TR band® compression; instead, they scored clean, handy, had fixed wrist movement, and rested their arms (4.87 ± 0.34). The wrist support Prototype 3's ease of use and patient satisfaction average scores were 5.00 at the highest possible level. Furthermore, 44 patients, or 97.3%, rated the wrist support Prototype 3 as convenient and satisfying.

Table 1: Patient Demographic (n = 133)

Patient Demographic	P1 Group n (%)	P2 Group n (%)	P3 Group n (%)	p^1
Total	8 (100)	80 (100)	45 (100)	
Age (Years)				
25 - 40	0 (0.0)	4 (5.0)	4 (8.9)	0.201
41 - 59	1 (12.5)	34 (42.5)	12 (26.7)	
< 60	7 (87.5)	42 (52.5)	29 (64.4)	
Gender				
Male	5 (62.5)	70 (87.5)	39 (86.7)	0.190
Female	3 (37.5)	10 (12.5)	6 (13.3)	
Education				
Elementary	0 (0.0)	2 (2.5)	2 (4.5)	0.079
Secondary	2 (25.0)	10 (12.5)	0 (0.0)	
Associate Degree	0 (0.0)	0 (0.0)	0 (0.0)	
Bachelor Degree	6 (75.0)	63 (78.8)	42 (93.3)	
Above Bachelor Degree	0 (0.0)	2 (2.5)	1 (2.2)	
Unknown	0 (0.0)	3 (3.7)	0 (0.0)	
Underlying disease				
No	0 (0.0)	16 (20.0)	9 (20.0)	0.538
Yes	8 (100.0)	64 (80.0)	36 (80.0)	
yes (n = 108)				
Diabetes mellitus	4 (50.0)	16 (25.0)	11 (30.6)	0.328
Hypertension	7 (87.5)	41 (64.1)	21 (58.3)	0.340
Dyslipidemia	4 (50.0)	42 (66.0)	28 (44.0)	0.023*
Chronic Kidney disease	1 (12.5)	7 (11.0)	2 (5.6)	0.537
Other	0 (0.0)	11 (17.2)	2 (5.6)	0.157
Previous Percutaneous Coronary Intervention				
No	7 (87.5)	64 (80.0)	39 (86.7)	0.607
Yes	1 (12.5)	16 (20.0)	6 (13.3)	
Body mass index (Kg/m^2)				
< 18.5	0 (0.0)	5 (6.3)	0 (0.0)	0.881
18.5 - 28	4 (50.0)	47 (58.7)	28 (62.2)	
> 28	4 (50.0)	28 (35.0)	17 (37.8)	
Body surface area (m^2)				
< 1.6	3 (37.5)	11 (13.8)	4 (8.9)	0.120
≥ 1.6	5 (62.5)	69 (86.2)	40 (91.1)	

[1]Fisher's exact test, *statistically significant as $p < 0.05$.

Table 2: Procedural Characteristics (n= 133)

Procedural Characteristics	P1 Group n (%)	P2 Group n (%)	P3 Group n (%)	p^1
Total	8 (100)	80 (100)	45 (100)	
Procedure Type				
Coronary Angiogram (CAG)	3 (37.5)	51 (63.75)	18 (40)	0.024*
CAG and PCI	5 (62.5)	29 (36.3.5)	27 (60)	
Glycoprotien IIb/IIIa inhibitor therapy				
No	0 (0.0)	0 (0.0)	0 (0.0)	NA
Yes	8 (100.0)	80 (100.0)	45 (100.0)	
Non clopidogrel agent use for dual antiplatelet therapy				
No	0 (0.0)	8 (10.0)	3 (6.7)	0.875
Yes	8 (100.0)	72 (90.0)	42 (93.3)	
Air inflated volume in TR band® (ml)				
12 ml	2 (25.0)	21 (26.3)	6 (13.4)	0.015*
13 ml	0 (0.0)	1 (1.2)	1 (2.2)	
14 ml	2 (25.0)	41 (51.3)	28 (62.2)	
15 ml	1 (12.5)	0 (0.0)	0 (0.0)	
16 ml	2 (25.0)	15 (18.8)	9 (20.0)	
17 ml	0 (0.0)	1 (1.2)	0 (0.0)	
18 ml	1 (12.5)	1 (1.2)	1 (2.2)	
Duration during TR band® compression (hours)				
< 4.00	0 (0.0)	1 (1.2)	0 (0.0)	0.69
4.01 - 5.00	5 (62.5)	39 (48.8)	17 (37.8)	
5.01 - 6.00	3 (37.5)	20 (25.0)	15 (33.4)	
6.01 - 7.00	0 (0.0)	13 (16.3)	4 (8.9)	
7.01 - 8.00	0 (0.0)	4 (5.0)	6 (13.3)	
8.01 - 9.00	0 (0.0)	1 (1.2)	1 (2.2)	
9.01-10.00	0 (0.0)	0 (0.0)	1 (2.2)	
> 10.00	0 (0.0)	2 (2.5)	1 (2.2)	
Duration during TR band® deflation (hour)				
< 0.30	1 (12.5)	34 (42.5)	16 (35.5)	0.268
0.31 – 1.00	5 (62.5)	25 (31.3)	13 (28.9)	
> 1.00	2 (25.0)	21 (26.2)	16 (35.5)	

[1]Fisher's exact test, *statistically significant as $p < 0.05$

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Table 3: Complications

Incidence	P1 Group n (%)	P2 Group n (%)	P3 Group n (%)	p^1
Total	8 (100)	80 (100)	45 (100)	
Hematoma				
Yes	0 (0.0)	1 (1.2)	0 (0.0)	NA*
No	8 (100.0)	79 (98.8)	45 (100.0)	
Bleeding				
Yes	2 (25.0)	33 (41.2)	13 (28.9)	0.307[1]
No	6 (75.0)	47 (58.8)	32 (71.1)	

*Due to insufficient sample size, the significant differences were not analyzed.
[1]Pearson's Chi-square test

In this study, wrist support Prototype 3 users were 45 cases, and the average overall patient satisfaction was 4.96 ± 0.23. These patients did not worry about their wrists becoming flexible during TR band® compression; instead, they scored clean, handy, had fixed wrist movement, and rested their arms (4.87 ± 0.34). The wrist support Prototype 3's ease of use and patient satisfaction average scores were 5.00 at the highest possible level. Furthermore, 44 patients, or 97.3%, rated the wrist support Prototype 3 as convenient and satisfying.

Discussion

The three prototypes' various materials presented that preventing the hematoma incidence during 6 hours after sheath removal in this study was consistent with a previous study by Mookda et al.,[11] which showed a 2% incidence of hematoma or bleeding proportion among patients undergoing PCI and placing their arms on wrist support KhunprakongKhansabai. Air volume inflated in TR band® may cause bleeding incidents among patients undergoing PCI; the bleeding proportion result of this study was inconsistent with the findings of the earlier studies.[3,11]

The wrist support Prototype 3 was rated as the highest score in the convenient and satisfying rating; we found that, consistent with the current study, a recent study showed a mean patient satisfaction score of 4.17 after the use of the PCI Navee wrist support, in a nylon bandage, with the arm of the base made of acrylic fabric, and EVA foam for the top, with square-shaped controls.[12]

The population characteristics in this study are consistent with CAD patient data in Thailand among the epidemiology division, the Department of Disease Control, and the Ministry of Public Health. In 2018, it was found that the properties of CAD incidents between females and males were 1:1.3, fifty percent were over 70 years old, and 26% were 60–69 years old. Additionally, the risk factors associated with the present illness were hypertension (73.79%), diabetes mellitus (37.27%), and dyslipidemia (54.84%).[13] The factors were consistent with the study of Malik J et al.,[14] which found no statistical differences among baseline characteristics and coronary catheter procedures between two groups, including age, sex, comorbid conditions, antiplatelet therapy, coronary procedure, sheath size, activated clotting time, and hemostasis time.

The procedural characteristics in this study were defined as the air-inflated volume in TR band® being 12–18 ml, the duration during TR band® compression, and the duration during TR band® deflation. These factors were in accordance with the Riyami HA et al.[15] study, which found that the protocol for deflation of the TR band included 16 ml of air, the mean time of band removal was about 275 ± 30 minutes, and there was no significant delay with regard to the actual time of air removal versus the expected time of air removal for each group.

The prior study showed that periprocedural antithrombotic/fibrinolytic medicine (prolonged, excessive use), repeat procedures, bigger sheath size, and prolonged sheath length are general risk factors for vascular access problems.[16] The study's consistency was not reflected in the outcomes.

The air-inflated volume of TR band® and the procedure's complexity could both contribute to hematoma following transradial access, according to the hypothesis, which was confirmed by the study's statistically significant differences in the findings ($p = 0.015$ and 0.024, respectively). Consistent with the current analysis, the previous investigation found that the transradial coronary intervention complex was a significant predictor of hematomas (OR: 3.192; 95% CI: 2.092-4.869, $p < 0.001$).[6] The air-inflated TR band® with 18 ml was applied in the previous study.

It was noted that the risk assessment of the nursing process together with the prototype development process led to nursing innovation; wrist support for fixed wrist movement led to the zero hematoma incident.

In spite of the development of all wrist support prototypes, this study collected primarily retrospective data, which resulted in several limitations, such as incomplete data and a limited sample size that would result in an unreliable comparison. Future research should be able to test the efficacy of P3 in order to obtain more reliable results, and an increase in sample size is necessary. So additional data such as hematoma, bleeding, and pain score after P3 was applied is also needed to be collected on other risk factors.

We are supposed to apply P3 to patients' arms when they were getting arterial blood pressure monitoring or contrast media injections while the radiological diagnostic was being performed.

Conclusion

Wrist supports are used to support and restrict movement of the wrist after the patient undergoes PCI. P3 had the highest patient satisfaction with wrist support. The analysis showed that the difference in bleeding between P1, P2 and P3 groups was not statistically significant (p = 0.307). Hematoma data were insufficient for statistical analysis.

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