Optimal TR-band weaning strategy while minimizing vascular access site complications

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ABSTRACT

Introduction: The purpose of the study is to develop an optimal TR-Band weaning strategy while minimizing vascular access site complications of hematoma or radial artery occlusion (RAO).
Methods: The trial was a randomized, prospective, single center study of 129 patients who underwent cardiac catheterization via the radial artery. Group A was an accelerated protocol in which weaning was initiated 20 min after sheath removal. Group B was an adjusted protocol, in which weaning was dependent on the amount of anti-platelet or anti-coagulation used. All patients underwent radial artery ultrasound to demonstrate arterial patency.
Results: Baseline characteristics were similar in both groups, and PCI was performed in 36.7% of patients in Group A and 37.7% of patients in Group B. RAO occurred in 7.7% of patients overall, with no statistical difference between groups (Group A 5% versus Group B 10.1%, p-value = 0.337). Hematoma formation >5 cm in diameter occurred in 4.6% of patients in the overall cohort, without statistical difference between groups (Group A 5% versus Group B 4.3%, p-value = 1). The TR-Band duration was significantly shorter in Group A compared to Group B (112.9 ± 50.7 versus 130.7 ± 51.1 in minutes, respectively, p-value = 0.013).
Conclusion: We have demonstrated an accelerated weaning protocol is simple to utilize for nursing staff without increased vascular site complications of RAO or hematoma formation.

1. Introduction

Transradial (TR) cardiac catheterization was first described in 1989 by Campeau, but has not yet gained widespread acceptance in the United States. Approximately 16% of percutaneous interventions in the U.S. are performed utilizing the radial artery [1]. The TR approach is associated with less bleeding complications, earlier ambulation, and increased patient satisfaction [2]. In a comprehensive meta-analysis comparing the radial versus femoral approach for primary angioplasty in STEMI's, TR access has consistently shown reductions in mortality and major bleeding [3].

The primary advantage of radial artery access, compared to a femoral artery approach, is lower rates of access site complications. The radial artery is easily compressible due to the flat surface of the radius bone without major nerves or structures in the vicinity [4]. The most common radial artery access site complications include hematoma, ecchymosis and radial artery occlusion (RAO), and these complications are thought to be related to intimal trauma from instrumentation. The number of attempts, or single-wall versus double-wall puncture techniques, are believed to have little impact on bleeding or RAO [5]. Although RAO is generally benign and clinically asymptomatic, it is the most common reason to discourage repeat catheterization from the radial artery should it be needed again.

A compression device is most commonly used to achieve hemostasis following sheath removal. Premature weaning of the compression device may increase the risk of hematoma, and paradoxically increase time to device removal. Conversely, prolonged placement of the compression device may increase the risk of RAO [6]. The purpose of this study was to develop an optimal TR-Band weaning strategy to minimize the risk of hematoma, RAO and potentially eliminate any unnecessary delays in the weaning process. All patients underwent radial artery ultrasound after removal of the TR-Band to assess for RAO.

2. Methods

After approval of the methodology by IRB we conducted a randomized, prospective, single center study of 131 patients who underwent cardiac

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catheterization via the radial artery. Patients were enrolled between February and August 2016 based on the availability of research investigators to randomize patients and perform radial ultrasound. Patients were excluded if the operator decided not to enroll due to their opinion of high-risk for complications. Two patients were excluded by the operator after randomization due to severe thrombocytopenia (platelet count <50). Patients undergoing PCI were included regardless of use of intravenous anti-coagulation or anti-platelet medications such as Heparin, Bivalirudin, or GPIIB/IIIA inhibitors. Patients were assigned to either group A or group B based upon a standard randomization process using predesignated sealed envelopes (Table 1).

All patients underwent cardiac catheterization via radial artery access and received conscious sedation with 1–2 mg IV midazolam and 25-50 mg IV fentanyl, dosage at the discretion of the operator. After infiltrating the radial artery area with 1% lidocaine, the radial artery was cannulated using either an anterior puncture (modified Seldinger technique) or double wall puncture (Seldinger technique) with advancement of a 6Fr slender, 10 cm length, hydrophilic-coated introducer sheath. A vasodilator cocktail was administered consisting of 200 micrograms nitroglycerin and 100–200 micrograms nicardipine. All patients were given 5000 units of intra-arterial heparin. If patients presented to the laboratory on a heparin drip, then the initial dose was 3000 units. PCI was performed using 6Fr guiding catheters and additional IV heparin was given to maintain ACT values between 250 and 300. Following the procedure, a TR-Band was placed with the initial air content 3 mL above when oozing occurred and with a palpable radial artery distally to demonstrate patent hemostasis.

Group A underwent an accelerated protocol regardless of anti-platelet or anti-coagulation use during the procedure. All group A patients had a TR-Band placed in the lab along with a wrist immobilizer. The first wean of air occurred at 20 min with 2 mL removed. Subsequently, 2–3 mL of air were removed every 15 min until the compression bladder was empty. The wrist immobilizer was maintained for 2 h following TR-Band removal. If bleeding occurred, the TR-Band was immediately re-inflated with 2-3 mL of air and the weaning protocol was restarted 15 min later.

Group B underwent an adjusted protocol with modifications of the weaning process made according to procedure performed. Patients undergoing diagnostic procedures had weaning initiated at 30 min. Those who received PCI with Heparin or Bivalirudin had weaning started at 60 min, while patients who received PCI with GPIIB/IIIA in addition to Heparin or Bivalirudin had weaning started at 120 min. No wrist

immobilizers were placed and patients were permitted to use their wrist for light activity such as writing, eating, or using a TV remote control. The first wean of air occurred with 3 mL of air, then subsequently 3 mL of air removed every 15 min until the compression bladder was empty. If bleeding occurred, the TR-Band was immediately re-inflated with 2-3 mL of air and weaning protocol restarted in 30 min. In both groups, once the TR-Band was removed, a Tegaderm with a rolled 2 × 2 gauze was placed tightly over the arteriotomy site. In addition, early ambulation was encouraged in both groups. All patients underwent radial artery ultrasound within 12 h after removal of the TR-Band to assess for RAO. Microsoft Excel 2010 (Microsoft, Redmond, WA) and SAS 9.2 (SAS Institute, Cary, NC) were used for all data acquisition and analysis.

3. Results

Group characteristics are shown in Table 2. Comorbidities between both groups were similar including hypertension, diabetes, chronic kidney disease, and peripheral arterial disease. PCI was performed in 36.7% in Group A and 37.7% in Group B, with no statistical difference in anticoagulant or anti-platelet strategies. In addition, pre-procedure INR and platelet counts were similar between both groups. The right radial artery was the preferred access site and there was no significant difference in utility of the single-wall versus double-wall puncture techniques. The 6Fr slender-sheath was upgraded to a larger sheath in a total of ten patients between both groups, without a statistically significant difference between groups and without impact on radial artery occlusion or hematoma formation.

We set out to compare rates of radial artery occlusion and hematoma formation between two weaning strategies. RAO occurred in 7.7% overall, with no statistical difference between groups (Group A 5% versus Group B 10.1%, p-value = 0.337). In addition, there was no statistically significant predictor for the development of RAO. Technique

Table 1
Description of weaning protocols.

Group A – Accelerated protocol	Group B – Adjusted protocol
1. All patients regardless of anti-platelet or anti-coagulation received start wean at 20 min	1. Diagnostic procedure: start wean at 30 min 2. PCI with Heparin or Bivalirudin: start wean at 60 min 3. PCI with GPIIB/IIIa use or INR > 2 – start wean at 120 min
TR Band with wrist immobilizer placed in lab	No wrist immobilizer for any patient. Okay to use wrist for light activity, i.e. writing, eating, using TV remote control
Start wean at 20 min and remove 2 mL of air	Start wean depending on above protocol. Initial air content is 3 mL
Then every 15 min, remove 2–3 mL of air until compression bladder empty	Then every 15 min, remove 3 mL's of air until compression bladder empty
Maintain wrist immobilizer for 2 h after TR band removed	No use of wrist immobilizer
If bleeding/oozing – re-inflate 2–3 mL and wait 15 min before resuming deflation protocol	If bleeding/oozing – re-inflate 2-3 mL and wait 30 min before resuming deflation protocol
Once TR band is removed, use a Tegaderm tightly placed over a rolled 2 × 2 gauze as a "pressure dressing". Early ambulation encouraged	Once TR band is removed, use a Tegaderm tightly placed over a rolled 2 × 2 gauze as a "pressure dressing". Early ambulation encouraged

Table 2
Baseline characteristics.

	Group A ($N = 60$)	Group B ($N = 69$)	p-Value
Right radial artery	56 (93.3%)	64 (92.8%)	1
Modified Seldinger technique	20 (33.3%)	35 (50.7%)	0.46
Seldinger technique	40 (66.7%)	34 (49.3%)	0.46
Upgraded sheath (>6 Fr)	3 (5%)	7 (10.1%)	0.337
Age	62.9 ± 12.1	64.6 ± 11.4	0.395
Male	37 (61.7%)	39 (56.5%)	0.554
BMI	31.6 ± 6.4	29 ± 8.9	0.004
Caucasian	34 (56.7%)	37 (53.6%)	0.729
African American	21 (35%)	22 (31.9%)	0.550
Prior CABG	3 (5%)	3 (4.3%)	1
CKD	10 (16.7%)	19 (27.5%)	0.140
ESRD	3 (5%)	4 (5.8%)	1
Prior CVA	2 (3.3%)	6 (8.7%)	0.283
PAD	3 (5%)	9 (13%)	0.117
DM	25 (41.7%)	27 (39.1%)	0.770
HTN	53 (88.3%)	56 (81.2%)	0.261
Dyslipidemia	37 (61.7%)	45 (65.2%)	0.676
Prior MI	12 (20%)	12 (17.4%)	0.704
Prior heart failure	17 (28.3%)	19 (27.5%)	0.920
Prior PCI	17 (28.3%)	19 (27.5%)	0.920
Platelet count	229.6 ± 63.2	229.4 ± 67.5	0.992
INR	1.10 ± 0.20	1.09 ± 0.17	0.876
PCI performed	22 (36.7%)	26 (37.7%)	0.905
Unfractionated heparin	59 (98.3%)	67 (97.1%)	1
Coumadin	3 (5%)	1 (1.4%)	0.337
Aspirin	60 (100%)	68 (98.6%)	1
Bivalirudin use	1 (1.7%)	0 (0%)	0.465
GP IIB/IIIA use	8 (13.3%)	6 (8.7%)	0.398
Clopidogrel	24 (40%)	23 (33.3%)	0.433
Ticagrelor	2 (3.3%)	7 (10.1%)	0.174
Prasugrel	0 (0%)	2 (2.9%)	0.499

Categorical data is given as frequency (percent of group). Numeric data is given as mean ± standard deviation. Statistically significant if p-value < 0.05.

for obtaining radial access, number of times the needle enters the radial artery to successfully obtain access, sheath diameter, and duration of access prior to sheath removal did not predict the development of RAO (Table 3). Although recompression is associated with higher rates of RAO, in our study a total of thirteen patients had re-bleeding and recompression without any resulting in RAO.

Hematoma formation >5 cm in diameter occurred in 4.6% of the overall cohort, with no statistical difference between groups (Group A 5% versus Group B 4.3%, p-value = 1). Hematoma formation occurred at similar frequencies regardless of the anti-coagulant or anti-platelet strategy (Table 4). Pre-procedural platelet counts and INR values were similar between patients who developed hematomas and those who did not.

The TR-Band duration was significantly shorter in Group A compared to Group B (112.9 ± 50.7 versus 130.7 ± 51.1 in minutes, respectively, p-value = 0.013) (Fig. 1). Delays in weaning the TR-Band due to re-bleeding and re-compression of the bladder were similar between both groups (Group A 15% versus Group B 20.3%, p-value = 0.083). Weaning protocols were followed by nursing staff and delays in weaning the TR-band due to clinical responsibilities were similar between both groups (Group A 15% versus Group B 20.3%, p-value = 0.434).

4. Discussion

Transradial cardiac catheterization is increasing in the United States due to the advantages of less access site complications and patient preferences. The optimal weaning strategy to expedite TR-Band removal while minimizing access site complications has yet to be defined.

In our study, we have compared two different TR-Band weaning strategies following transradial cardiac catheterization. The first strategy is an accelerated protocol to start weaning the TR-Band 20 min from the time of sheath removal. The second strategy is an adjusted protocol to wean the TR-Band in accordance with the amount of anti-platelet or anti-coagulation used during the procedure. The purpose of our study was to create a safe and effective protocol for TR-Band weaning, while minimizing access site complications including hematoma formation and RAO.

Prior studies have investigated strategies to minimize the development of RAO and access site complications. Pancholy et al. evaluated the effect of duration of hemostatic compression on the incidence of RAO [6]. In this study, a shorter duration of hemostatic compression (2 h) was associated with a lower incidence of early and chronic RAO without increasing bleeding complications. Carrington et al. demonstrated an accelerated weaning protocol starting at 1 h from sheath removal was shown to be safe and without a higher incidence of hematoma formation [7]. More recently Shroeder et al. demonstrated that short (1.5 h) and soft (10 cm^3 of air) compression with the TR-Band resulted in low rates of RAO and has been the largest study to date [8].

Another mechanism for the development of RAO appears to be related to the use of heparin. The effect of heparin in reducing the incidence

Table 3
Radial artery occlusion (RAO).

		No RAO by ultrasound ($N = 119$)	RAO by ultrasound ($N = 10$)	p-Value
Group A		57 (44%)	3 (30%)	0.337
Group B		62 (48%)	7 (70%)	
Seldinger technique		50 (42%)	5 (50%)	0.743
Modified Seldinger technique		69 (58%)	5 (50%)	
Number of attempts in radial artery	1	104 (87.4%)	6 (60%)	0.060
	2	14 (11.8%)	4 (40%)	
	3	1 (0.8%)	0 (0%)	
Radial access duration in minutes		57.1 ± 39.7	73.5 ± 76.3	0.728
Rebleeding with recompression		13 (10.9%)	0 (0%)	0.597
Sheath upgraded to >6 Fr		9 (7.3%)	1 (10%)	0.567

Categorical data is given as frequency (percent of group). Numeric data is given as mean ± standard deviation. Statistically significant if p-value <0.05.

Table 4
Hematoma formation >5 cm.

	Hematoma >5 cm ($N = 6$)	No significant hematoma ($N = 123$)	p-Value
Group A	3 (50%)	57 (46.3%)	1
Group B	3 (50%)	66 (53.7%)	
Unfractionated heparin use	6 (100%)	120 (97.6%)	1
Coumadin use	1 (16.7%)	3 (2.4%)	0.175
PCI performed	3 (50%)	45 (36.6%)	0.670
Bivalirudin	0 (0%)	1 (0.8%)	1
GP IIB/IIIA	0 (0%)	14 (11.4%)	1
Platelet count	207.3 ± 106.8	230.6 ± 63.1	0.619
INR	1.31 ± 0.45	1.08 ± 0.15	0.082

Categorical data is given as frequency (percent of group). Numeric data is given as mean ± standard deviation. Statistically significant if p-value <0.05.
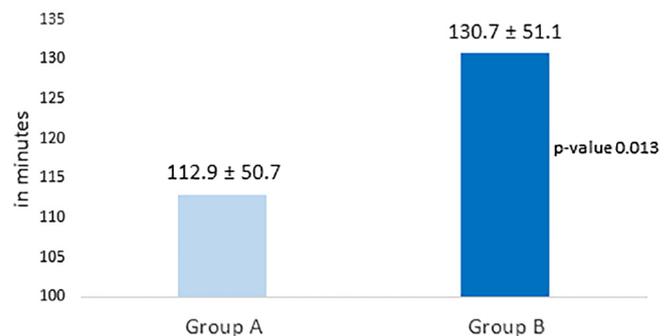
of RAO appears to be dose dependent, with significant reductions of RAO appreciated by an increased dose of heparin from 2000 to 3000 units to 5000 units [9]. In addition, the administration of heparin can be given either intra-arterially or intravenously with similar rates of preventing RAO [10]. The most common strategies to prevent RAO include the use of heparin, minimizing the "sheath to artery ratio," shorter duration of hemostatic compression, and utilizing patent hemostasis [4].

Our study was unique by having all patients obtain a radial artery ultrasound within 12 h of removal of the TR-Band to confirm radial artery patency. The incidence of RAO was relatively high at 7.7% overall. All patients who demonstrated RAO by ultrasound also had an abnormal reverse Barbeau's test. This finding suggests all patients should have an evaluation for radial artery patency once the TR-Band is removed, either by radial artery ultrasound or by performance of a reverse Barbeau's test. In addition, half the patients with RAO recanalized their radial artery within 48 h utilizing a technique to augment radial artery flow by temporarily compressing the ulnar artery. The TR-Band was reversed on the patient's wrist and compression bladder applied to the ulnar artery with maximal pressure allowing a palpable distal pulse. The ulnar artery was compressed for 1 h and the TR-Band subsequently removed. The effect of recanalizing acutely occluded radial arteries after TR access has been promising [11]. While an accelerated protocol for weaning has previously been shown to reduce the incidence of RAO, there has been concern for increased risk of hematoma formation. In our study, the incidence of significant hematoma formation was similar between both weaning protocols.

The main limitation of our study is the small sample size of our population and single center experience. In our institution, the operators and nursing staff are experienced with TR access and managing post-procedure TR-Band weaning. Despite our proficiency in TR access, we had high rates of RAO 7.7% and hematoma formation 4.6%.

We did not measure time to discharge as this may be affected by external variables including patient recovery from sedation and pick-up by a family member. While it can be inferred that shorter duration of TR-Band placement will reduce hospital stay, we did not specifically evaluate this variable.

Fig. 1. Duration of TR Band.

5. Conclusion

An accelerated weaning protocol is safe and effective at achieving hemostasis without increasing vascular site complications of RAO or hematoma formation. In addition, radial artery ultrasound or performance of a reverse Barbeau's test is an adequate method to evaluate for RAO upon removal of the TR-Band.

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