

Randomized Trial of Compression Duration After Transradial Cardiac Catheterization and Intervention

Shahar Lavi, MD; Asim Cheema, MBBS; Andrew Yadegari, MD; Zeev Israeli, MD; Yaniv Levi, MD; Sabrina Wall, BSc; Mistre Alemayehu, MSc; Yasir Parviz, MBBS; Bogdan-Dorian Murariu, MSc; Terry McPherson, MD; Jaffer Syed, MD; Rodrigo Bagur, MD, PhD, FAHA

Background—Radial artery occlusion is a known complication following transradial cardiac catheterization. A shorter duration of postprocedural radial clamp time may reduce radial artery occlusion (RAO) but might be associated with incomplete hemostasis.

Methods and Results—In total, 568 patients undergoing transradial diagnostic cardiac catheterization were randomly assigned to either 20 minutes (ultrashort) or 60 minutes (short) hemostatic compression time using patent hemostasis. Subsequently, clamp pressure was reduced gradually over 20 minutes. Access site hemostasis and RAO were assessed after clamp removal. Repeated assessment of RAO was determined at 1 week in 210 (37%) patients. Mean age was 64 ± 11 years, and 30% were female. Percutaneous coronary intervention was performed in 161 patients. RAO immediately after clamp removal was documented in 14 (4.9%) and 8 (2.8%) patients in the 20- and 60-minute clamp application groups, respectively ($P=0.19$). The incidence of grade 1 hematoma was higher in the 20-minute group (6.7% versus 2.5%, $P=0.015$). RAO at 1 week after the procedure was 2.9% and 0.9% in the 20- and 60-minute groups, respectively ($P=0.36$). Requirement for clamp retightening (36% versus 16%, $P=0.01$) was higher among patients who had RAO. Need for clamp retightening was the only independent predictor of RAO ($P=0.04$).

Conclusions—Ultrashort radial clamp application of 20 minutes is not preferable to a short duration of 60 minutes. The 60-minute clamp duration is safe and provides good access site hemostasis with low RAO rates.

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Key Words: angiography • cardiac catheterization • percutaneous coronary intervention • vascular complications

The transradial approach (TRA) for diagnostic coronary angiography and percutaneous coronary intervention (PCI) is associated with a lower risk of vascular complications^{1,2} and allows earlier ambulation, shorter hospital stays,¹ improved patient satisfaction, and decreased cost compared with a femoral approach.^{3,4}

Radial artery occlusion (RAO), however, is an important complication seen in up to 8% of patients undergoing transradial procedures, limiting subsequent use of the radial artery for access or as a conduit for surgical revascularization.^{5–8}

RAO is caused by arterial thrombosis and is associated with use of a large-size catheter, lack of procedural anticoagulation, and prolonged duration of radial compression after sheath removal.

Among the various strategies used to prevent RAO, patent hemostasis and reduction of radial artery compression time have shown the most promise. Recent data suggest that shorter clamp time in conjunction with the patent hemostasis technique significantly reduced the incidence of RAO.^{2,8–10} It is unclear, however, if ultrashort duration of clamp application will reduce RAO further without compromising the hemostasis achieved.¹¹

The purpose of the present randomized trial was to investigate the safety and efficacy of ultrashort duration of clamp application after transradial procedures. Our standard clamp duration was 60 minutes, but occasionally we used shorter durations, between 20 and 40 minutes; therefore, we chose to compare 20 and 60 minutes.

From the London Health Sciences Centre, London, Ontario, Canada (S.L., A.Y., Z.I., Y.L., S.W., M.A., Y.P., B.-D.M., T.M., J.S., R.B.); Western University, London, Ontario, Canada (S.L., A.Y., Z.I., Y.L., Y.P., T.M., J.S., R.B.); St. Michael's Hospital, Toronto, Ontario, Canada (A.C.); University of Toronto, Ontario, Canada (A.C.).

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Correspondence to: Shahar Lavi, MD, Division of Cardiology, Western University, 339 Windermere Road PO Box 5339, London, Ontario, Canada N6A 5A5. E-mail: shahar.lavi@lhsc.on.ca

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Methods

The Postcath Radial Arterial Clamp Time In the CAth Lab (PRACTICAL) trial was a randomized controlled trial performed at 2 institutions (London Health Sciences Centre, London, and St. Michaels Hospital, Toronto, both in Ontario, Canada) that examined the safety and efficacy of ultrashort radial clamp application after transradial cardiac procedures. The research ethics boards of both sites approved the study. All patients provided written informed consent prior to enrollment.

Study Population

Patients undergoing cardiac catheterization (diagnostic or intervention) via the TRA with evidence of ulnopalmar circulation patency (type A, B, or C), as described by Barbeau et al,¹² were eligible to participate.

Patients with D pattern (ie, no plethysmography waveform or oximetry reading after 2 minutes of radial artery occlusion) were excluded. Patients who had prior radial artery thrombosis or prior surgery close to the access site or who were undergoing emergent cardiac catheterization were also excluded.

Protocol

Diagnostic cardiac catheterization and PCI (if applicable) were performed using standard techniques and equipment at the discretion of the operators. This included the modified Seldinger (anterior wall puncture only) or through-and-through (posterior wall puncture) techniques for radial access, ultrasound-guided if required,¹³ and use of a 5- or 6-French introducer sheath. Local anesthesia was given using 2% lidocaine.

The recommended intra-arterial vasodilator cocktail included nitroglycerin 200 µg and verapamil 2.5 mg. Patients undergoing diagnostic cardiac catheterization received 50 U/kg of unfractionated heparin administered intravenously.^{8,14} When ad hoc PCI was performed, additional unfractionated heparin was administered to achieve a therapeutic level of activated clotting time. Patients who were scheduled for PCI received 70 U/kg of unfractionated heparin that was further adjusted according to activated clotting time. Glycoprotein IIb/IIIa inhibitors were not recommended but could be given at the operator's discretion. All patients undergoing PCI received dual antiplatelet agents. All procedure-related decisions, including the choice of sheath size and antiplatelet and anticoagulant therapy, were made at each operator's discretion prior to randomization.

Immediately at the end of the procedure, the radial sheath was removed and the RadAR (Advanced Vascular Dynamics) compression hemostatic device was placed. The device

includes a clear movable compression pad, a strap, and an adjustment knob. Immediately following placement of the device, release of the knob was performed with a goal of achieving patent hemostasis.¹⁵ Patent hemostasis was assessed using plethysmography and pulse oximetry while compressing the ipsilateral ulnar artery. If bleeding was seen under the clear compression pad while releasing the knob, the knob was turned in the opposite direction to retighten the device until bleeding stopped.

Randomization and Hemostatic Device Release

Opaque randomization envelopes containing the study groups (20 or 60 minutes) were prepared by study coordinators following a computer-generated randomization sequence. The randomization sequence was 1:1 and set in random blocks of 6, 8, and 10. Randomization was stratified by site.

Randomization envelopes were opened once the procedure was completed and the radial clamp was placed. The patients, cardiac catheterization nurses, and operators were not blinded to randomization allocation; however, the procedure and all related therapeutic decisions were already made prior to randomization.

At the end of the randomly allocated clamp time (20 or 60 minutes), both groups of patients underwent a gradual 20-minute clamp release, which consisted of a quarter turn of the clamp knob every 5 minutes, followed by clamp removal.

Access site bleeding or hematoma during clamp loosening and removal was recorded and treated with retightening for an additional 10 minutes, followed by loosening the clamp according to the protocol. All time intervals were measured using preset timers.

End Points

The primary end point was the proportion of patients with RAO shortly after clamp removal. Patency or occlusion of the radial artery was assessed using a pulse oximeter and a reverse Barbeau test.¹⁵

Hemostasis was assessed according to the presence of hematoma or bleeding. The Early Discharge After Transradial Stenting of Coronary Arteries (EASY) scale was used for the grading of hematomas.¹⁶ Any other bleeding was recorded. A Likert scale was used to assess patients' comfort during and after the procedure. Patients living within a reasonable driving distance (up to a 1-hour drive) were requested to return after 1 week for reassessment of radial artery patency. The rest of the patients were not requested to come for follow-up.

Assessment of study outcomes, radial artery patency, and bleeding was performed in a blinded manner. A research coordinator collected the data in a blinded fashion.

The study was investigator initiated. The manufacturer and distributor of the clamp device had no role in this study and did not provide funding or support for the study.

Sample Size

Based on prior studies, we estimated that the risk of RAO would be 5% in the control (60-minute) group. To reduce this risk to 1% with a power of 80% and a type 1 error of 0.05, we required 282 patients in each group.

Statistical Analysis

Baseline variables were summarized by mean and standard deviation (continuous variables) and by counts and percentages (categorical variables). Comparisons between continuous variables were performed using the *t* test. Categorical variables were compared with the Pearson χ^2 or Fisher exact test, as appropriate. For the primary analysis, a modified intention-to-treat analysis was performed, including patients according to randomization and excluding patients for whom data were not collected. Logistic regression analysis including

variables with $P < 0.10$ in the bivariate analysis were used to identify the independent predictors of RAO immediately after clamp removal. Odds ratio estimates were adjusted for confounders, such as the allocation to the 20-minute group in the logistic regression model. Outcomes were also assessed following stratification according to sheath size. *P* values are 2-tailed, and statistical significance was defined as $P < 0.05$ for all statistical comparisons. Data analyses were performed using SPSS version 20.0 (IBM Corp).

Results

Patients and Procedures

A total of 283 patients receiving ultrashort clamp time of 20 minutes and 285 patients receiving short (standard) clamp time of 60 minutes were enrolled. The enrollment period was between September 2014 and February 2016. The flow diagram of the study is shown in Figure. Baseline characteristics were comparable, with 11.4% having undergone a prior procedure via the TRA and 89% exhibiting good ulnopalmar arterial circulation (Table 1). Procedural characteristics are

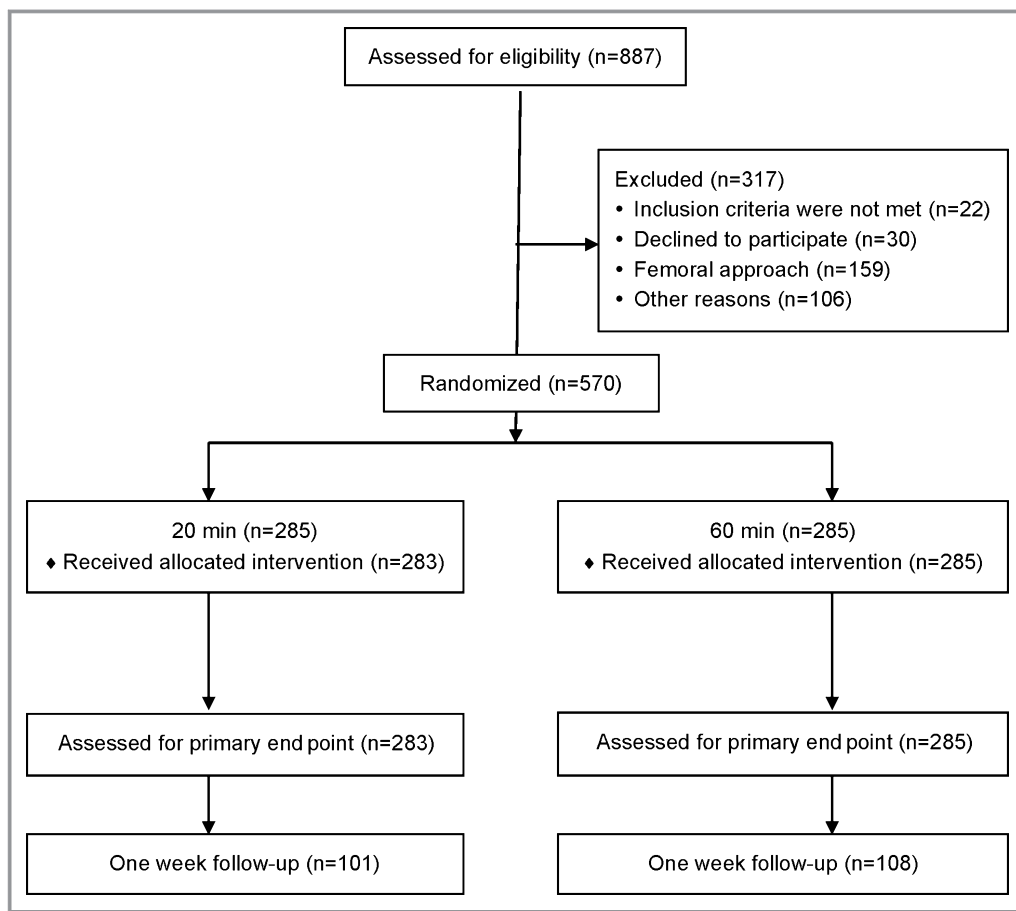


Figure. PRACTICAL study flow diagram.

Table 1. Baseline Clinical Characteristics

	20 Minutes (n=283)	60 Minutes (n=285)	P Value
Female	81 (28.6%)	88 (30.9%)	0.56
Age, y	64.7±12.0	63.8±10.1	0.33
Weight, kg	89.9±20.2	87.6±20.6	0.18
BMI, kg/m ²	32.2±18.2	30.4±8.96	0.13
Hypertension	208 (73.5%)	208 (73.0%)	0.89
Dyslipidemia	202 (71.4%)	204 (71.6%)	0.96
Diabetes mellitus	83 (29.3%)	77 (27.0%)	0.54
Current smoker	44 (15.5%)	42 (14.7%)	0.77
Creatinine, μmol/L	84.5±32.8	87.2±43.2	0.43
Prior radial approach	26 (9.2%)	39 (13.7%)	0.09
Prior CVA	9 (3.2%)	12 (4.2%)	0.52
Prior myocardial infarction	36 (12.7%)	55 (19.3%)	0.04
Prior PCI	46 (16.3%)	54 (18.9%)	0.40
Prior CABG	5 (1.8%)	8 (2.8%)	0.41
CCS grade			
0	71 (25.1%)	85 (29.8%)	0.21
1	63 (22.3%)	67 (23.5%)	0.40
2	92 (32.5%)	86 (30.2%)	0.94
3	30 (10.6%)	26 (9.1%)	0.74
4	23 (8.1%)	17 (6.0%)	0.42
NYHA class			
I	178 (62.9%)	187 (65.6%)	0.49
II	78 (27.6%)	67 (23.5%)	0.26
III	19 (6.7%)	21 (7.4%)	0.76
IV	0	2 (0.7%)	
Barbeau's type			
A/B	248 (87.6%)	260 (91.2%)	0.17
C	10 (3.5%)	5 (1.8%)	0.20

BMI indicates body mass index; CABG, coronary artery bypass grafting; CCS, Canadian Cardiovascular Society; CVA, cerebrovascular accident; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.

shown in Table 2. Radial sheath size used was either 5 or 6 French. Unfractionated heparin was the standard anticoagulant, with 4.4% also receiving glycoprotein IIb/IIIa inhibitors. Aspirin was given to 91%, whereas 51% of patients were on dual antiplatelet agents.

Outcomes

The primary outcome, RAO immediately following clamp removal, occurred in 4.9% of patients in the 20-minute group and in 2.8% of the 60-minute group ($P=0.19$).

Table 2. Procedure Characteristics

	20 Minutes (n=283)	60 Minutes (n=285)	P Value
Sheath size (French)			
5	92 (32.5%)	99 (34.7%)	0.60
6	191 (67.5%)	186 (65.3%)	0.57
Left ventricle ejection fraction			
≤40%	38 (13.4%)	43 (15.1%)	0.56
41–50%	35 (12.4%)	42 (14.7%)	0.40
≥51%	181 (64.0%)	174 (61.1%)	0.51
PCI performed	78 (27.6%)	77 (27.0%)	0.90
Artery intervened			
LAD/diagonal	32 (11.3%)	32 (11.2%)	0.98
Cx/OM/intermediate	18 (6.4%)	22 (7.7%)	0.53
RCA	33 (11.7%)	24 (8.4%)	0.20
Other (LM/graft)	1 (0.4%)	4 (1.4%)	0.18
Anticoagulants			
Heparin	282 (99.6%)	284 (99.6%)	1
GP IIb/IIIa bolus	14 (4.9%)	11 (3.9%)	0.53
GP IIb/IIIa infusion	9 (3.2%)	11 (3.9%)	0.66
Antiplatelets			
Clopidogrel	117 (41.3%)	123 (43.2%)	0.66
Ticagrelor/prasugrel	25 (8.8%)	25 (8.8%)	0.98
Aspirin	261 (92.2%)	256 (89.8%)	0.32

Cx indicates circumflex; GP, glycoprotein; LAD, left anterior descending; LM, left main; OM, obtuse marginal; PCI, percutaneous coronary intervention; RCA, right coronary artery.

The incidence of bleeding or hematoma is described in Table 3. There was no significant difference in bleeding or hematomas while the clamp was still at full pressure, although, numerically, the values were higher in the 60-minute group. There were significantly more grade 1 hematomas after clamp release in the 20-minute group. Only a few patients had grade 2 hematoma, with no difference between groups. None of the patients experienced a hematoma larger than grade 2. In the 20-minute group, there was a more frequent need for clamp retightening (20.5% versus 12.3%, $P<0.01$). There was no difference in the degree of comfort or satisfaction between groups during or following the procedure (Table 4). In the subgroup of patients completing 1-week follow-up, patency of the radial artery was documented in 101 of 104 (97.1%) patients in the ultrashort 20-minute group and in 108 of 109 (99.1%) in the short 60-minute group ($P=0.36$). None of the patients died during the week following the procedure.

Following stratification according to the use of 5- or 6-French sheaths, the need for retightening of the clamp was higher in the 20-minute group with both sheaths sizes

Table 3. Study Outcomes

	20 Minutes (n=283)	60 Minutes (n=285)	P Value
RAO (primary end point)	14 (4.9%)	8 (2.8%)	0.19
Hemostasis during full pressure			
Hematoma <5 cm	4 (1.4%)	7 (2.5%)	0.37
Hematoma >5 cm	1 (0.4%)	4 (1.4%)	0.37
Any bleeding or hematoma*	10 (3.5%)	19 (6.7%)	0.09
Hemostasis after release			
Hematoma <5 cm	19 (6.7%)	7 (2.5%)	0.015
Hematoma >5 cm	5 (1.8%)	4 (1.4%)	0.75
Any bleeding or hematoma*	53 (18.7%)	40 (14.0%)	0.13
Retightening required (at any time)	58 (20.5%)	35 (12.3%)	<0.01

RAO indicates radial artery occlusion.

*Number of participants who have at least 1: ooze, hematoma, and/or bleeding.

(Table 5). These differences were significant only in the 6-French sheath cohort, which was larger. RAO was numerically higher in the 20-minute group with both 5- and 6-French sheaths.

Those who had RAO underwent more PCI compared with those who did not (50% versus 26%, $P=0.02$) and required significantly more clamp retightening (36% versus 16%, $P=0.01$) (Table 6). Bivariate logistic regression analysis identified the need for clamp retightening as the independent predictor of RAO (odds ratio 2.76, 95% CI 1.10–6.90, $P=0.03$). Notably, after including adjustment for 20-minute hemostasis time in the model, the need for clamp retightening remained the only independent predictor of RAO (odds ratio 2.61, 95% CI 1.04–6.56, $P=0.042$).

Discussion

This study demonstrates that ultrashort clamp release 20 minutes after cardiac catheterization via the TRA is not associated with reduction in the incidence of RAO compared

Table 4. Patient Satisfaction

Patient Satisfaction*	20 Minutes (n=177)	60 Minutes (n=175)	P Value
During procedure			
Access site comfort	4.44±0.87	4.42±1.04	0.82
Overall satisfaction	4.67±0.67	4.64±0.79	0.73
Following procedure			
Access site comfort	4.42±0.92	4.33±1.09	0.42
Overall satisfaction	4.46 (±0.62)	4.69±0.63	0.82

*Scores on each item range from 1 (unsatisfied) to 5 (satisfied).

with a short clamp release after 60 minutes. Rapid release required more frequent retightening of the clamp and was associated with higher incidence of hematomas. Moreover, retightening was an independent predictor of RAO and potentially was the cause of higher incidence of RAO in the ultrashort group.

Previous studies demonstrated that the incidence of RAO, when there is intention to use patent hemostasis, is reduced from 12% with 6 hours of compression to 5.5% with 2 hours of compression.⁹ More recently, Edris et al¹⁰ showed that a partial deflation of the TR Band (Terumo Medical) balloon after 15 minutes to allow patent hemostasis was associated with a reduction in the incidence of RAO from 14.9% to 2%. It should be highlighted, however, that among patients who had a standard deflation protocol, patent hemostasis was not assessed and the TR Band was maintained for 2 hours until removal.¹⁰ In this regard, Dharma and colleagues¹⁷ showed that the duration of hemostasis was found to be a strong predictor of RAO, increasing the risk by 3-fold.

Our study extends the results of previous observations by being larger and randomized and by using more rapid clamp release in both groups. Clamp release after either 20 or 60 minutes was associated with good outcome and low incidence of RAO, and both strategies used in our study involved relatively rapid clamp release compared with usual care at many centers.⁹ Such rapid clamp release translates to early mobilization and may lead to early patient discharge. Indeed, our patients were discharged home 1 hour following clamp removal. RAO is an important complication of TRA, and efforts are made to avoid it. It was previously shown that smaller sheath size, patent hemostasis, shorter duration of clamp compression time, use of heparin, and administration of vasodilators reduce the incidence of RAO.^{8,10,18}

In our study, we used all of those methods in both groups, and even in our control group, the clamp duration was relatively short. Consequently, the incidence of RAO was low in both groups, although further shortening of clamp duration was not associated with further reduction in the incidence of RAO. There was a numerically higher incidence of RAO in the 20- versus 60-minute group. Although this difference was not statistically significant, to better explore this finding, we performed a logistic regression analysis and found that bleeding and retightening of the clamp were independent predictors of RAO. Retightening was associated with a 2.5-fold increase in RAO, and this may explain the higher incidence of RAO in the 20-minute group.

It seems that the incidence of RAO is decreasing with better management of patients undergoing TRA and improvement of techniques and equipment; however, instrumentation of an artery is routinely associated with vascular injury,¹⁹ and we likely cannot reduce the incidence of RAO much further. It was recently shown in the Prevention of Radial Artery

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Table 5. Study Outcomes According to Sheath Size

	5 French (n=191)			6 French (n=377)		
	20 Minutes (n=92)	60 Minutes (n=99)	P Value	20 Minutes (n=191)	60 Minutes (n=186)	P Value
RAO (primary end point)	3 (3.3%)	1 (1%)	0.35	11 (5.7%)	7 (3.8%)	0.36
Hemostasis during full pressure						
Hematoma <5 cm	0	4 (4%)	0.12	4 (2.1%)	3 (1.6%)	1.00
Hematoma >5 cm	1 (1%)	0	0.48	0	4 (2.1%)	0.058
Any bleeding or hematoma*	3 (3.2%)	8 (8.1%)	0.15	7 (3.7%)	11 (5.9%)	0.34
Hemostasis after release						
Hematoma <5 cm	6 (6.5%)	4 (4%)	0.53	13 (6.8%)	3 (1.6%)	0.01
Hematoma >5 cm	3 (3.2%)	2 (2%)	0.67	2 (1%)	2 (1%)	1.00
Any bleeding or hematoma*	17 (18.5%)	12 (12.1%)	0.23	36 (18.9%)	28 (15%)	0.33
Retightening required (at any time)	15 (16.3%)	10 (10%)	0.20	43 (22.5%)	25 (13.4%)	0.02

RAO indicates radial artery occlusion.

*Number of participants who have at least 1: ooze, hematoma, and/or bleeding.

Occlusion: Prophylactic Hyperperfusion Evaluation Trial (PROPHET-II)²⁰ that prophylactic compression of the ulnar artery is associated with significant reduction in the incidence of RAO immediately following the procedure, from 13.9% to 1.5%. The PROPHET-II study included only patients that underwent diagnostic coronary angiography with a 5-French sheath. In our study, we included patients that received PCI, which was found to be a predictor of RAO. Furthermore, in two-thirds of our patients, a 6-French sheath was used and associated with increase in RAO, although this was not statistically significant. Despite the inclusion of patients who underwent PCI or in whom we used a larger sheath, the incidence of RAO was only 2.8% in our patients who received a clamp for 60 minutes, much lower compared with the control group in PROPHET-II but higher compared with the group that underwent ulnar artery compression. In addition, in our study, only 1% of patients in whom a 5-French sheath was used with 60-minute clamp duration had RAO. In PROPHET-II, gradual deflation was initiated following continuous pressure for 2 hours. Considering the results of these 2 studies, it seems that 1-hour compression time may be preferred. It is unknown what the effect of ulnar compression would be on the incidence of hematomas and bleeding with shorter compression duration. In PROPHET-II, the incidence of hematomas was similar with and without ulnar compression and was lower compared with our study. None of our patients had hematoma larger than grade 2, but we found that bleeding was a predictor of RAO. It would be interesting to test the combination of short (1-hour) clamp duration with ulnar compression. Nevertheless, with the low incidence of RAO with short clamp duration, it will be difficult to demonstrate further reduction in RAO.

The potential benefit of ultrashort clamp duration when there is no further reduction in RAO includes early mobilization and patient comfort, although we have not seen significant differences in patient satisfaction scores between groups. One can consider rapid clamp release, accepting the increased need to retighten in about 8% of patients; however, considering that the outcome with 20-minute clamp time was not better and was somewhat worse and that 60 minutes is already a relatively short duration, we recommend using 60 minutes of hemostasis time.

The best time point at which to assess RAO is unknown; however, previous studies demonstrated that the incidence of RAO is reduced over time compared with day 1, and if the artery was patent initially, it usually does not occlude later.^{8,15,21} There is variability in different studies in the time at which RAO was assessed. We chose to assess RAO on the day of the procedure because the majority of our patients were discharged the same day and resided at large distances from the hospital. At this time, the incidence of RAO is highest. Patients who resided closer were asked to come back for follow-up, and indeed, we found that the incidence of RAO was reduced after 1 week compared with the day of the procedure. These results suggest that there is no need to assess radial artery patency at a later stage if it is found to be patent on the day of the procedure.

We used the same compression hemostatic device (RadAR) in all patients to allow objective comparison between groups. It is possible that such rapid release of the clamp is not possible with all compression devices. Given the variety of compression devices available, the methods of compression-device removal are inconsistent. For the TR Band, one of the most common devices used,²² it is now recommended to

Table 6. Predictors of RAO

Variables	RAO (n=22)	No RAO (n=546)	P Value
Female	3 (13.6%)	166 (30.4%)	0.09
Age, y	63.7±11.0	64.3±11.1	0.70
Weight, kg	88.2±19.4	88.7±20.5	0.57
BMI, kg/m ²	31.0±6.2	31.4±14.6	0.73
Hypertension	15 (68.2%)	401 (73.4%)	0.59
Dyslipidemia	5 (22.7%)	157 (28.8%)	0.54
Diabetes mellitus	12 (57.1%)	394 (72.3%)	0.13
Current smoker	6 (27.3%)	80 (14.8%)	0.11
Creatinine, μmol/L	88.3±20.1	85.7±39.0	0.73
Prior radial approach	4 (18.2%)	61 (11.2%)	0.31
Prior CVA	0 (0%)	21 (3.8%)	0.35
Prior myocardial infarction	2 (9.1%)	89 (16.3%)	0.37
Prior PCI	5 (22.7%)	95 (17.4%)	0.52
Prior CABG	0 (0%)	13 (2.4%)	0.46
Sheath size (French)			
5	4 (18.2%)	187 (34.2%)	0.12
6	18 (81.8%)	359 (65.8%)	
PCI performed	11 (50.0%)	144 (26.4%)	0.02
Antithrombotic			
Heparin	22 (100%)	546 (100%)	—
GP IIb/IIIa inhibitors bolus	1 (4.5%)	24 (4.4%)	0.97
GP IIb/IIIa inhibitors infusion	0 (0%)	20 (3.7%)	0.36
Retightening required (at any time)	8 (36.4%)	85 (15.6%)	0.01

BMI indicates body mass index; CABG, coronary artery bypass grafting; CVA, cerebrovascular accident; GP, glycoprotein; PCI, percutaneous coronary intervention; RAO, radial artery occlusion.

keep the device at high pressure for 1 hour when using a low dose of heparin (up to 50 U/kg) and for 2 hours when a higher dose of heparin is used (eg, for PCI; data on file). Such instructions regarding duration are not available for all devices. Nevertheless, the concept of early release is likely applicable to all devices, and it seems that the compression clamp starts to be released only after 2 to 4 hours at most institutions.^{9,10,17,23}

Limitations

The patients and physicians were not blinded to randomization; however, randomization was performed after sheath removal and clamp placement; therefore, group assignment had no impact on treatment, including the use of

anticoagulants or antiplatelet agents. Furthermore, assessment of outcome was performed in a blinded fashion in accordance with the PROBE (prospective randomized open blinded end point) design.

In both groups, we utilized short clamp duration with no comparison to more prolonged clamp duration that may be utilized at other centers; however, our standard clamp duration was already 60 minutes prior to the study, and the incidence of hematomas according to the EASY scale in the 60-minute group was well within the accepted range.¹⁶

We used patent hemostasis and other techniques proven to reduce the incidence of RAO in both groups. The incidence of RAO in the 60-minute group was 2.8% and thus below the expected 5% in our sample size calculation and well below the incidence of RAO immediately after clamp removal in the recent large trial PROPHET-II.²⁰ Considering that RAO was also <5% in the 20-minute group but numerically higher compared with the 60-minute group, a larger sample size would likely not have demonstrated a benefit with ultrashort compression.

Although we used different methods shown to reduce the incidence of RAO, we did not perform any specific intervention once RAO was detected. Such an intervention would not affect the main results but might have affected the incidence of RAO 1 week later.

Conclusion

Ultrashort duration of 20 minutes is feasible but was not associated with further reduction in the incidence of RAO and was associated with an increased risk of bleeding. Short compression clamp release of 1 hour after transradial cardiac catheterization and intervention is safe and is associated with low incidence of RAO.

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Disclosures

None.

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