

Efficacy and safety of a 260-cm Amplatz Super Stiff guidewire during transradial percutaneous coronary intervention

Xuguang Feng, MD^{a,b}, Xiaoyun Zhang, MD^b, Jun Dai, MD, PhD^{c,*}, Jianping Bin, MD, PhD^{a,*}

Abstract

Background Although transradial percutaneous coronary intervention (TR-PCI) is widely used in clinical practice, guidewire-related complications are an important cause of transradial approach failure. We investigated the prognostic value of the 260-cm Amplatz Super Stiff guidewire for reducing the complication rate during TR-PCI.

Methods Five hundred patients with positive Allen's test results were divided into 3 groups according to the type of angiography guidewire: group A, 150-cm Emerald guidewire standard J-tip (n=160); group B, 150-cm Radifocus guidewire M (n=176); and group C, exchangeable 260-cm Amplatz Super Stiff guidewire after placement of a 150-cm Radifocus guidewire M (n=164).

Results Group C had the highest success rate ($P=.008$) and the lowest incidence of operative complications such as radial artery spasms and hematomas ($P=.030$ and $P=.036$, respectively). In addition, the groups differed significantly in terms of fluoroscopy and catheter placement times ($P=.02$ and $P<.001$, respectively); group C had the shortest times for these occurrences.

Conclusions The exchangeable 260-cm Amplatz Super Stiff guidewire markedly decreased the incidence of guidewire-related complications, reduced fluoroscopy times, and increased the procedural success rate. Therefore, this tool can be considered a safe, effective, and feasible exchangeable guidewire for TR-PCI.

Abbreviations: ANOVA = analysis of variance, PCI = percutaneous coronary intervention, RA = radial artery, RAS = radial artery spasm, TRAV = transradial anatomic variations, TR-PCI = transradial percutaneous coronary intervention.

Keywords: exchangeable guidewire, radial artery, transradial percutaneous coronary intervention

1. Introduction

Transradial angiography was first reported in 1989.^[1] Since then, this approach and other related interventions have been widely accepted as safe and cost-effective alternatives to the traditional transfemoral approach.^[2–4] Compared with the femoral artery, the anatomic structure of the radial artery (RA) plays a key role in the occurrence of complications and failure of transradial percutaneous coronary intervention (TR-PCI).^[5] The RA contains more smooth muscles than other vessels, and its vascular wall expresses primarily α_1 adrenergic receptors with fewer β_2 adrenergic receptors; accordingly, the RA is extremely sensitive to catecholamines and is prone to spasms if directly or repeatedly stimulated by a guidewire.^[5] Transradial anatomic variations (TRAVs), such as variations of radial, brachial, and subclavian

arteries, and the brachiocephalic trunk/ascending aorta and branches (Figs. 1A and 2A), must be carefully observed to avoid injury during TR-PCI.^[6,7] Therefore, the failure of TR-PCI due to guidewire-related complications remains challenging.^[8–10]

The guidewires currently used in clinical practice are not sufficiently safe or easily manipulated. Two guidewires are commonly used in current practice: the 150-cm Emerald guidewire standard J-tip (Cordis Corporation, Milpitas, CA) (general guidewire) and the 150-cm Radifocus guidewire M (Terumo Medical Corporation, Tokyo, Japan) (super-slide guidewire). These guidewires easily induce radial artery spasms (RAS) (Fig. 1B) and transradial vasculature injury (Fig. 1C),^[6,7,11] especially during repeated catheter exchanges. In contrast, the 260-cm Amplatz Super Stiff guidewire (Boston Scientific Corporation, Boston, MA) (exchangeable guidewire) features certain advantages intended to avoid repeated guidewire entry for catheter advancement and exchange; therefore, it may be an appropriate alternative option.

In the present study, we hypothesized that the use of the 260-cm Amplatz Super Stiff guidewire could reduce RA complications and increase the TR-PCI success rate. To verify our hypothesis, we conducted a 2-center prospective study of TR-PCI success rates and vascular access complications when using the 260-cm Amplatz Super Stiff guidewire (as an exchangeable guidewire) compared with the 150-cm Emerald guidewire standard J-tip and 150-cm Radifocus guidewire M.

2. Methods

2.1. Study population

Five hundred patients with positive Allen's test results who underwent TR-PCI from August 2016 to April 2017 were enrolled in this study. The exclusion criteria included a

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^a Department of Cardiology, State Key Laboratory of Organ Failure Research, Nanfang Hospital, Southern Medical University, Guangzhou, Guangdong,

^b Affiliated Hospital of Inner Mongolia Medical University, Huhhot, ^c Fuwai Hospital, Chinese Academy of Medical Sciences, Beijing, China.

* Correspondence: Jianping Bin, 1838 North Guangzhou Avenue, Guangzhou, Guangdong 510515, China (e-mail: jianpingbin@126.com); Jun Dai, 167 North Lishi Road, XiCheng District, Beijing 100037, China (e-mail: jundaimd@126.com).

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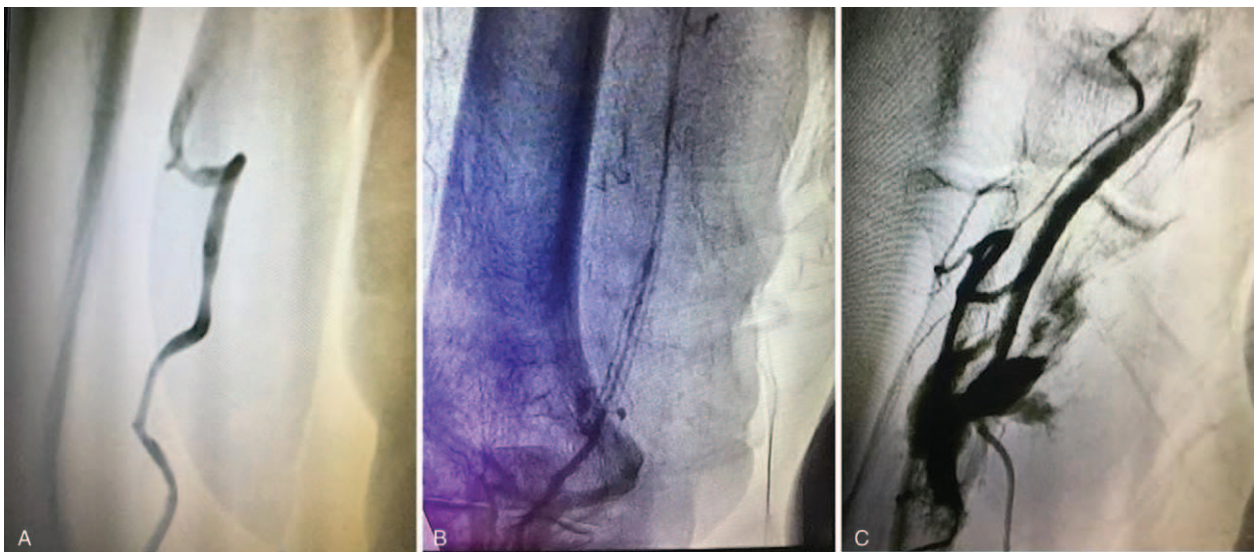


Figure 1. The 150-cm Emerald guidewire standard J-tip (general guidewire) used in group A cannot pass the radial artery tortuosity (A) and is likely to cause RAS (B). The 150-cm Radifocus guidewire M (super-slide guidewire) in group B can easily slide into small vascular branches and cause stimulation and injury to the upper limb vasculature, thus leading to hematoma (C). RAS = radial artery spasm.

contraindication for percutaneous coronary intervention (PCI), absence of a radial pulse, and abnormal Allen's test results. The study was approved by the ethics committees of Fuwai Hospital and Inner Mongolia Medical University, and written informed consent was obtained from all patients.

2.2. Grouping and TR-PCI strategy

All patients received aspirin 300 mg and clopidogrel 300 to 600 mg orally before the procedure; thereafter, they received daily minimum doses of aspirin 100 mg and clopidogrel 75 mg. During TR-PCI, all patients received heparin via an adjunctive intravenous bolus infusion of 100 to 150 IU/kg, followed by a continuous intravenous infusion at 15 IU/kg/h until the end of the procedure. The activated clotting time was monitored (therapeutic range, 250–350 seconds). All patients were randomly divided into group A (160 cases), who were subjected to the 150-cm Emerald guidewire standard J-tip (general guidewire), group B (176 cases), who were subjected to the 150-cm Radifocus guidewire M (super-slide guidewire), and group C (164 cases), who were subjected to the 260-cm Amplatz Super Stiff guidewire (exchangeable guidewire) for catheter placement and exchange during coronary angiography and TR-PCI.

During the procedure, the patient was placed in the supine position with the right arm abducted to 70°, and the wrist was hyperextended. Next, routine aseptic sterilization was performed, and the arm was placed on a sterile towel. The point where the RA pulse was most obvious was selected as the point of puncture (1–2 cm above the styloid process of the radius). A subcutaneous injection of 0.5 mL 1% lidocaine was administered for local anesthesia. Next, a 5-F or 6-F RA sheath was inserted via a 21-G to 22-G puncture needle at 30° to 45°, and an injection of 3000 IU of heparin was administered after successful puncture.

Using fluoroscopy, the respective guidewires for catheter placement were inserted in the RA lumen of each patient in groups A and B. In group C, the advancement of a 260-cm Amplatz Super Stiff guidewire in the aortic root was completed via a catheter placed in advance using a 150-cm Radifocus

guidewire M (super-slide guidewire) that had been advanced in the aortic root. Selective angiography of the radial, brachial, or subclavian artery was performed when difficulty was encountered while advancing the guidewire or catheter. Subsequently, the 260-cm Amplatz Super Stiff guidewire was left in the aortic root to serve as an exchangeable guidewire for catheter exchange (Fig. 2B). The RA sheath was removed immediately after completing TR-PCI, and hemostasis was achieved by applying an adjustable plastic clamp to the RA. The clamp was gradually released over the course of 2 to 3 hours while monitoring for access site bleeding or hematoma. It was finally removed after satisfactory access site hemostasis was achieved.

2.3. Definitions of study outcomes

The primary outcome measures were the TR-PCI success rate and related procedure data, including fluoroscopy time, procedure duration, catheter placement time (time required for the catheter to reach the coronary artery ostium), contrast volume, catheter TRAV passing rate, and the incidence of vascular complications, including RAS and hematoma.

2.4. Related definitions

Procedural success was defined as the completion of TR-PCI with <10% residual stenosis and a Thrombolysis in Myocardial Infarction flow grade of 3 in the intervened artery. TR-PCI failure was defined as the failure to complete the PCI procedure via the transradial approach or failure to meet the coronary artery blood flow improvement criteria as described. Severe RAS was defined as an intense contraction of the intervened artery, resulting in the failure to insert the arterial sheath, guidewire, or catheter in a smooth and pain-free manner, thus severely impeding the surgical process. Hematoma was defined as clinically overt bleeding in the transradial approach vessels due to the advancement or exchange of a guidewire or catheter, resulting in the presence of a hematoma or carpal tunnel syndrome or the requirement for blood transfusion or vascular repair.

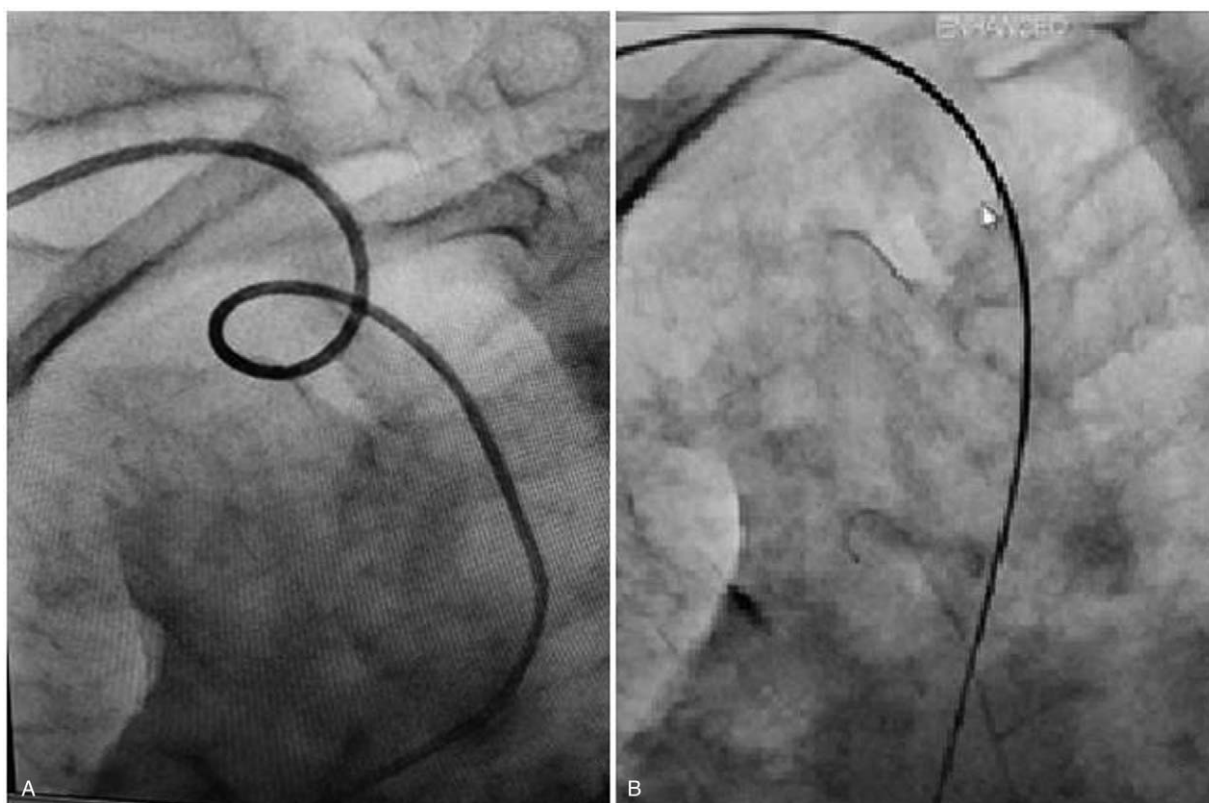


Figure 2. Subclavian artery tortuosity reduces catheter support (A). The 260-cm Amplatz Super Stiff guidewire (exchangeable guidewire) used in group C can straighten tortuous arteries, and the connecting segment between the soft J-tip and stiff pushing rod can be affixed to the root of the ascending aorta without damaging the vascular wall (B).

2.5. Statistical analysis

Continuous and categorical variables are presented as means \pm SD and absolute numbers (percentages), respectively. Differences in the means or percentages among the 3 groups were assessed using a one-way analysis of variance (ANOVA) or the χ^2 test. SPSS 19.0 software (SPSS Inc., Chicago, IL) was used for statistical analysis. Two-sided $P < .05$ was considered statistically significant.

3. Results

3.1. Baseline characteristics

A total of 500 patients who underwent TR-PCI were randomly divided into groups A, B, and C, as described. The groups did not differ significantly in terms of patient demographics (mean age, sex, body mass index), cardiovascular risk factors (smoking, hypertension, diabetes, dyslipidemia, family history of coronary artery disease), or TRAV (Table 1).

3.2. Comparison among groups and intragroup

Among the 500 total patients, 477 (95.4%) underwent TR-PCI via the transradial approach; the remaining 23 patients (4.6%) switched to transfemoral PCI. The groups differed significantly in terms of the TR-PCI success rate (group A: 145 of 160, 90.6%; group B: 168 of 176, 95.5%; group C: 161 of 164, 98.2%; $P = .008$). TR-PCI could not be completed as planned for 9 patients in group A because of TRAV; these patients subsequently underwent treatment according to the protocol for group C.

Twelve, 8, and 3 patients in groups A, B, and C, respectively, switched to the transfemoral approach; these procedural failures included RA puncture failure (0, 2, and 1 patients in groups A, B, and C, respectively), severe TRAV (6, 2, and 1 patients in groups A, B, and C, respectively), severe RAS (4, 1, and 0 patients in groups A, B, and C, respectively), and complex coronary artery lesions and catheter inner diameter (2, 3, and 1 patients in groups A, B, and C, respectively).

A comparison of the TR-PCI procedure-related data indicated significant intergroup differences in the fluoroscopy times and catheter placement times ($P = .02$ and $P < .001$, respectively) (Table 2), with group C having the shortest durations. These results suggested that the 260-cm Amplatz Super Stiff guidewire markedly facilitated the performance of TR-PCI, especially in cases of RA variant tortuosity (Fig. 2B). There were no statistically significant differences in procedural duration and contrast volume among the groups ($P = .554$ and $P = .451$, respectively) (Table 2).

3.3. Procedure-related complications

No severe catheter-related complications such as coronary artery dissection or aortic dissection were observed among the 477 patients who successfully underwent TR-PCI with right radial artery access. A comparison of TR-PCI complications indicated significant differences among the groups in terms of RAS and hematoma ($P = .030$ and $P = .036$, respectively) (Table 3), with the lowest incidence in group C. This suggested that the 260-cm Amplatz Super Stiff guidewire markedly decreased the incidence of severe TR-PCI complications. No other severe postprocedural

Table 1**Baseline characteristics of patients who underwent transradial percutaneous coronary intervention.**

	Group A (n=160)	Group B (n=176)	Group C (n=164)	Statistics (χ^2 test or one-way ANOVA)	P
Sex (n, male/female)	104/56	109/67	99/65	$\chi^2=0.767$.682
Age, y	62.3±9.5	62.0±10.2	60.5±9.9	F=1.560	.211
BMI, kg/m ²	26.4±3.4	26.1±3.7	26.7±3.8	F=1.072	.343
Diabetes mellitus	69 (43.1%)	79 (44.9%)	87 (53.0%)	$\chi^2=3.689$.158
Hypertension	70 (43.8%)	73 (41.5%)	63 (38.4%)	$\chi^2=0.960$.619
Smoker	85 (53.1%)	85 (48.3%)	76 (46.3%)	$\chi^2=1.580$.454
Dyslipidemia	79 (49.3%)	86 (48.9%)	66 (40.2%)	$\chi^2=3.492$.174
Stroke	27 (16.9%)	33 (18.8%)	28 (17.1%)	$\chi^2=2.462$.292
Family history of CHD	34 (21.3%)	45 (25.6%)	40 (24.4%)	$\chi^2=0.909$.635
CHD type					
Chronic stable angina	39 (23.8%)	48 (27.3%)	38 (23.2%)		.786
				$\chi^2=1.728$.842
				$\chi^2=2.730$	
Unstable angina	81 (50.0%)	91 (51.7%)	91 (55.5%)		
Acute/recent MI	40 (25%)	37 (21.0%)	35 (21.3%)		
TRAV	26 (15.6%)	25 (14.8%)	28 (17.1%)		
Radial variation	5 (3.1%)	4 (2.3%)	3 (1.8%)		
Brachial variation	0 (0%)	1 (0.6%)	1 (0.6%)		
Subclavian tortuosity	18 (11.3%)	19 (10.8%)	21 (12.8%)		
Brachiocephalic trunk/ascending aorta tortuosity	3 (1.9%)	1 (0.6%)	3 (1.8%)		
LMWH	122 (76.3%)	138 (78.4%)	121 (73.8%)	$\chi^2=1.003$.606
GPIIb/IIIa inhibitor	61 (38.1%)	52 (29.5%)	46 (28.0%)	$\chi^2=4.428$.109

ANOVA=analysis of variance, BMI=body mass index, CHD=coronary heart disease, GPIIb/IIIa=glycoprotein IIb/IIIa, LMWH=low-molecular-weight heparin, MI=myocardial infarction, TRAV=transradial approach anatomic variations or tortuosity.

Table 2**Comparison of procedure-related parameters.**

	Group A (n=160)	Group B (n=176)	Group C (n=164)	Statistics (χ^2 test or one-way ANOVA)	P
Fluoroscopy time, min	17.0±7.6	15.7±7.3	14.6±8.5	F=3.810	.023
Procedure duration, min	60.5±17.8	60.2±23.9	58.3±18.0	F=0.590	.554
Catheter placement time, s	44.8±32.0	36.6±14.4	28.8±15.2	F=22.175	.000
Contrast volume, mL	216.4±68.8	212.7±66.2	206.8±71.4	F=0.798	.451
Catheter passing rate TRAV, %	11/26 (42.3%)	23/25 (92.0%)	27/28 (96.4%)	$\chi^2=26.989$.000
Success rate, %	145 (90.6%)	168 (95.5%)	161 (98.2%)	$\chi^2=9.590$.008

ANOVA=analysis of variance, TRAV=transradial approach anatomic variations.

complications, including bleeding, false aneurysms, arteriovenous fistulas, or osteofacial compartment syndromes, were observed. One case of mediastinal hematoma and one case of thoracic wall hematoma were observed only in group B.

4. Discussion

In this study, we proposed that the 260-cm Amplatz Super Stiff guidewire is an effective and safe tool for catheter exchange during TR-PCI. The results of our prospective study demonstrated that, when compared with the 2 commonly used guidewires,

the 260-cm Amplatz Super Stiff guidewire greatly facilitated catheter exchange, decreased the incidence of vascular complications, decreased the patients' exposure to radiation, and increased the TR-PCI success rate. Our findings suggested that this exchangeable guidewire is safe, effective, and convenient for catheter exchange during TR-PCI.

Compared with transfemoral PCI, TR-PCI is associated with a lower risk of access site bleeding and hematoma, earlier patient ambulation, shorter hospital stays,^[2] and lower hospital costs.^[4] However, the risk factors and clinical impact of failure of TR-PCI^[12] involve more variations specific to the RA approach, such

Table 3**Comparison of transradial percutaneous coronary intervention complications.**

	Group A (n=160)	Group B (n=176)	Group C (n=164)	Statistics (χ^2 test)	P
RAS (%)	13 (7.5%)	8 (4.5%)	3 (1.8%)	$\chi^2=6.983$.030
Hematoma (%)	3 (1.9%)	7 (4.0%)	0 (0.0%)	$\chi^2=6.870$.036

RAS=radial artery spasm.

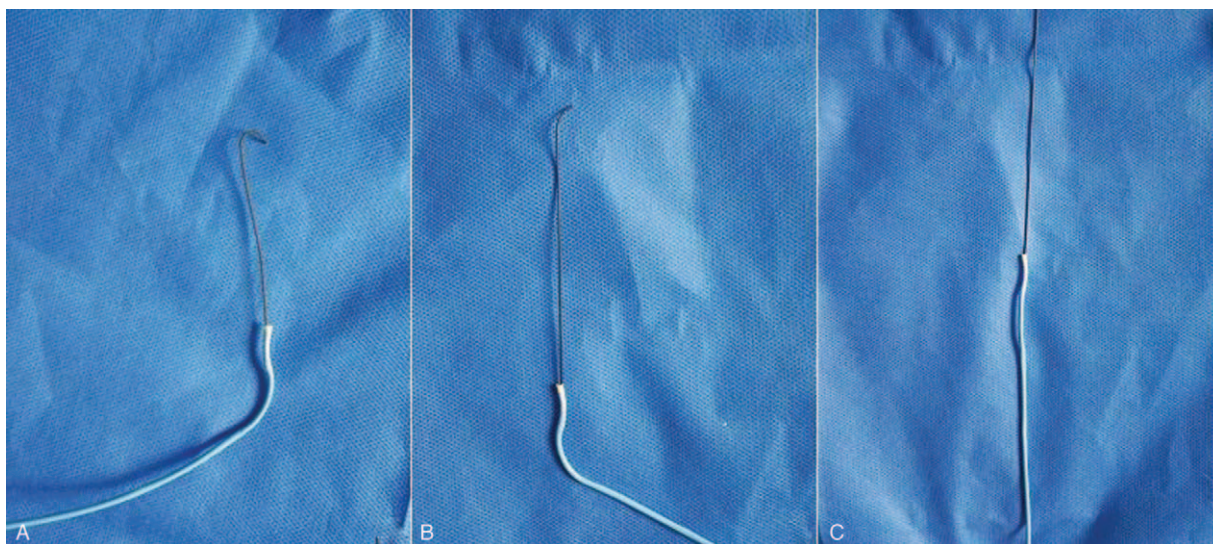


Figure 3. The 150-cm Emerald guidewire standard J-tip (general guidewire) used in group A cannot easily damage blood vessels, but it exhibits poor advancement ability and can cause pain and discomfort to patients if inserted forcibly. In addition, the guidewire or catheter can cause blood vessel rupture, hematoma, and surgical failure (A). The 150-cm Radifocus guidewire M (super-slide guidewire) can advance the catheter past the TRAV; however, the soft pushing rod cannot easily straighten the guiding head, thus requiring forced pushing of the catheter and potential RAS, rupture and dissection, pain and discomfort of the patients, and even hematoma or surgical failure (B). The stiff pushing rod of the 260-cm Amplatz Super Stiff guidewire (exchangeable guidewire) used in group C allows straightening of the catheter tip, decreases friction with the vessel wall during catheter advancement and exchange, decreases the incidence of RAS, increases patient comfort, and improves the TR-PCI success rate (C). RAS = radial artery spasm, TR-PCI = transradial percutaneous coronary intervention.

as multiple blood vessel bifurcations, abnormalities (e.g., vascular tortuosity and arterial loops), and lesions (e.g., severe atherosclerosis)^[6,13,14]; these factors increase the difficulty of guidewire and catheter advancement, thus leading to TR-PCI failure.^[15,16,17] Notably, these conditions are relatively more common among elderly patients,^[18] who comprise an increasing segment of the patient population undergoing TR-PCI and are at higher risk for periprocedural complications relative to their younger counterparts.

These challenges demonstrate the need for a method that mitigates the deficiencies of the transradial approach. Compared with the 150-cm Emerald guidewire standard J-tip (Fig. 3A) and 150-cm Radifocus guidewire M (Fig. 3B), the 260-cm Amplatz Super Stiff guidewire (Fig. 3C) possesses a larger stiff inner core (0.035-inch) that provides a strong supporting force and a stiff pushing rod that provides additional strength while facilitating and stabilizing catheter advancement during placement or exchange. Furthermore, the soft J-tip and hydrophilic membrane of the exchangeable catheter reduces the risk of damage to the vascular intima. In our experience, these structural characteristics improve the ability of the exchangeable guidewire to facilitate catheter passage of the TRAV (Figs. 2B and 3C). The 260-cm Amplatz Super Stiff guidewire is superior for catheter passage of the TRAV; therefore, it is a good option for TR-PCI.

RAS, which is a common complication of TR-PCI, is characterized by severe RA narrowing and intolerable discomfort, which severely impedes the progress of TR-PCI and necessitates switching to the transfemoral approach.^[17] Severe RAS is among the most important causes of failure to complete TR-PCI.^[17] Anatomical variations have been identified as a distinct predictor of RAS,^[19] but some reports have suggested that diazepam, calcium antagonists, and nitrate esters can relieve RAS to some extent.^[2-5] Our study found that the 150-cm Emerald guidewire standard J-tip was most likely to cause RAS (Fig. 1B) because it produces strong friction with the vessel wall

and does not advance smoothly enough through the vessel. Compared with the 150-cm Emerald guidewire standard J-tip and 150-cm Radifocus guidewire M, the 260-cm Amplatz Super Stiff guidewire was associated with a markedly decreased incidence of RAS. Therefore, the Amplatz Super Stiff guidewire serves as a bridge that can ease the subsequent catheter switch with minimal RA stimulation.

Hematoma is the most common adverse event associated with TR-PCI procedures and is a significant predictor of 1-year mortality.^[20] Although the 150-cm Radifocus guidewire M easily slides into peripheral branches, including the mediastinal vessels, forcible insertion of the guidewire can perforate the vessel (Fig. 1C). In addition, repeated guidewire insertion for catheter exchange is likely to cause hematoma, including mediastinal hematoma. In group B, one patient developed a mediastinal hematoma and one patient developed a thoracic wall hematoma; the former was transferred to surgery for dyspnea resulting from a hematoma-compressed airway. Interestingly, only one case of RA hematoma was observed in group C; however, this injury resulted from the advancement of the 150-cm Radifocus guidewire M for catheters placed in advance, rather than from the 260-cm Amplatz Super Stiff guidewire itself. However, the soft J-tip and the hydrophilic membrane of the exchangeable catheter reduced the risk of damage to the vascular intima, thus significantly decreasing the discomfort experienced by the patient and the risk of arterial injury.

Some trials^[21,22] and previous studies^[23,24] have reported prolonged fluoroscopy and procedure times associated with the transradial approach compared with the transfemoral approach. Therefore, we used the 260-cm Amplatz Super Stiff guidewire to try to overcome the defect of the transradial approach. Interestingly, our outcome demonstrated that the exchangeable guidewire not only reduced transradial approach complications but also reduced fluoroscopy times. This latter outcome may be attributable to the fact that the 260-cm Amplatz Super Stiff

guidewire remained in the artery undergoing the transradial approach and was used as an exchangeable guidewire throughout TR-PCI, thus avoiding the repeated insertion of guidewires for catheter exchange under X-ray radiation (e.g., groups A and B). In other words, the exchangeable guidewire greatly facilitated catheter exchange and increased the safety of TR-PCI. An exchangeable guidewire also helps to reduce the emergency PCI door-to-balloon time, thus improving the opportunity for rescue. In addition, the operative technique is easier to master, which increases the confidence of the operator.

When used as an exchangeable guide, the 260-cm Amplatz Super Stiff guidewire provides excellent advantages. Some operators have suggested that structural and performance improvements might allow the independent advancement of this guidewire to the aortic root (i.e., without requiring the 150-cm Radifocus guidewire M). This improvement would further reduce the incidence of TR-PCI complications resulting from the super-slide 150-cm Radifocus guidewire M. However, we noted that the generalizability of the findings from our pilot study is limited by the small sample size. Future studies with larger sample sizes are required to validate our results.

In conclusion, this 2-center prospective study revealed a correlation between the incidence of TR-PCI complications and the type of guidewire used. The use of the 260-cm Amplatz Super Stiff guidewire as an exchangeable guidewire can markedly facilitate catheter exchange, decrease fluoroscopy time, decrease the risk of surgical vascular complications, and increase the success rate.

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Author contributions

Conceptualization: Xuguang Feng.

Data curation: Xiaoyun Zhang.

Formal analysis: Xuguang Feng, Jun Dai.

Funding acquisition: Xiaoyun Zhang.

Investigation: Xuguang Feng, Xiaoyun Zhang, Jun Dai.

Methodology: Xuguang Feng.

Project administration: Xuguang Feng, Jianping Bin.

Resources: Xiaoyun Zhang.

Software: Xuguang Feng, Jianping Bin.

Supervision: Xuguang Feng, Jun Dai, Jianping Bin.

Writing – original draft: Xuguang Feng, Jun Dai.

Writing – review and editing: Xuguang Feng, Jun Dai, Jianping Bin.

Xuguang Feng orcid: 0000-0001-7124-9565.

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