Innovative Approach to Reduce the Complications of Transradial Percutaneous Coronary Interection Using a 260-cm Amplatz Super Stiff™ Guidewire

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Abstract

Objective: To investigate the safety and feasibility of the 260-cm Amplatz Super Stiff™ Guidewire for reducing the rate of complications associated with transradial percutaneous coronary intervention (TR-PCI).

Methods: Five hundred patients with positive Allen’s test results were divided into three groups according to the angiography guidewire type: Group A, 150-cm EMERALD Guidewire Standard J-Tip (n=156); Group B, 150-cm RADIOFOCUS Guidewire M (n=173); and Group C, exchangeable 260-cm Amplatz Super Stiff™ Guidewire after placement of a 150-cm RADIOFOCUS Guidewire M (n=171).

Results: Significant intergroup differences were observed in the passing rates of transradial approach anatomic variations and success rates of TR-PCI (P<0.001). Group C had the highest success rate, as well as the lowest incidence of operative complications, including radial artery spasm and hematoma (P<0.01 and P<0.05, respectively). Additionally, the groups differed significantly in terms of the fluoroscopy time and catheter-in-place time (P<0.05 and P<0.01, respectively); Group C had the shortest times.

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

Keywords: Radial artery; Transradial percutaneous coronary intervention (TR-PCI); 260-cm Amplatz Super Stiff™ Guidewire; Exchangeable guidewire

Background

Transradial angiography was first reported in 1989. Since then, this approach and related interventions have been widely accepted as a safe and cost-effective alternative to the traditional transfemoral approach [1-4]. Compared to femoral artery, the anatomic structure of the radial artery (RA) plays a key role in the occurrence of complications and failure of the procedure [5]. First, the RA contains more smooth muscle than other vessels, and its vascular wall expresses primarily α1 adrenergic receptors with fewer β2 adrenergic receptors; accordingly, the RA is extremely sensitive to catecholamines and prone to spasms if directly or repeatedly stimulated by the guidewire [5]. Second, transradial anatomic variations (TRAV; e.g., tortuosity of radial, brachial, and subclavian arteries, and loops and variations of the brachiocephalic trunk/ascending aorta) (Figures 1A and 2A) and branches must be carefully noticed to avoid injury during TR-PCI [6,7]. So, the failure of transradial percutaneous intervention (TR-PCI) consequent to guidewire-related complications remains challenging [8-10]. However, 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 (general guidewire) and the 150-cm RADIOFOCUS Guidewire M (super-slide guidewire), which easily induce radial artery spasm (RAS) (Figure 1B) and injury to the transradial vasculature [6-11], respectively, especially in repeated catheter exchange. The 260-cm Amplatz Super Stiff™ Guidewire, which may have certain advantages for catheter advancement and exchange, is an appropriate method.
Figure 1: 150-cm EMERALD Guidewire Standard J-Tip (general guidewire) in Group A cannot pass radial artery tortuous (A) and is liable to cause RAS (B) 150-cm RADIOFOCUS Guidewire M (super-slide guidewire) in Group B can easily slide into small vascular branches and result in stimulation and injury to the upper limb vasculature leading to hematoma.

Figure 2: Subclavian artery tortuous reduce catheter supporting force (A) 260-cm Amplatz Super Stiff™ Guidewire (exchangeable guidewire) in Group C can straighten toutuous artery and connecting segment between soft J Tip and stiff pussing rod can fix on the root of the ascending aorta without damaging the vascular wall (B) RAS: radial artery spasm.
In the current study, we hypothesized that the use of the 260-cm Amplatz Super Stiff™ Guidewire could reduce RA complications, decrease fluoroscopy times, and increase the TR-PCI success rate. To verify our hypothesis, we conducted a two-center prospective study of TR-PCI success rates and vascular access complications when using 260-cm Amplatz Super Stiff™ Guidewire (as an exchangeable guidewire) in comparison to the 150-cm EMERALD Guidewire Standard J-Tip and 150-cm RADIFOCUS Guidewire M.

Materials and Methods

Study population

From August 2016 to April 2017, 500 patients with positive Allen’s test results who underwent TR-PCI were enrolled. The exclusion criteria included a contraindication of percutaneous coronary intervention, absence of a radial pulse, and abnormal Allen’s test result. 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.

Grouping and TR-PCI Strategy

All patients received aspirin 300 mg and clopidogrel 300–600 mg orally before the procedure, and a daily minimum of aspirin 100 mg and clopidogrel 75 mg thereafter. During TR-PCI, all patients received heparin via an adjunctive intravenous bolus infusion of 100–150 IU/kg, followed by a continuous intravenous infusion at 15 IU/kg/hour 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 (156 cases), Group B (173 cases), and Group C (171 cases), which corresponded to the use of a 150-cm EMERALD Guidewire Standard J-Tip (general guidewire), 150-cm RADIFOCUS Guidewire M (super-slide guidewire), and 260-cm Amplatz Super Stiff™ Guidewire (exchangeable guidewire), respectively, for catheter placement and exchange during coronary angiography and TR-PCI.

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 the 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 5F or 6F RA sheath was inserted via a 21–22G puncture needle at 30–45°, and 3000 IU heparin were injected after successful puncture.

Under fluoroscopy, the respective guidewires for catheter placement were inserted into the RA lumen of patients in Groups A and B. In Group C, the advancement of a 260-cm Amplatz Super Stiff™ Guidewire into the aortic root was completed via the catheter in-advanced placement, using a 150-cm RADIFOCUS Guidewire M (super-slide guidewire) advanced into the aortic root. Subsequently, the 260-cm Amplatz Super Stiff™ Guidewire was left in the aortic root to serve as an exchangeable guidewire for catheter exchange (Figure 2B). Selective angiography of the radial, brachial, or subclavian artery was performed when difficulty was encountered while advancing the guidewire or catheter. 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 2–3 h while monitoring for access site bleeding or hematoma, and finally removed after satisfactory access site hemostasis was achieved.

Definitions and study outcomes

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

Related definitions: Procedural success was defined as the completion of TR-PCI with <10% residual stenosis and a Thrombolysis in Myocardial Infarction flow grade 3 in the intervened artery. TR-PCI failure was defined as a failure to complete a percutaneous coronary intervention procedure via the transradial approach or failure to meet the coronary artery blood flow improvement criteria as described above. Severe RAS was defined as an intense contraction of the intervened artery resulting in failure to insert the arterial sheath, guidewire, or catheter in a smooth and pain-free manner and thus severely impeding the operation process. Hematoma was defined as clinically overt bleeding in the transradial approach vessels, resulting in the presence of a hematoma ≥5 cm, carpal tunnel syndrome, or a requirement for blood transfusion or vascular repair. MACE was defined as in-hospital death, recurrent myocardial infarction, the need for urgent repeat revascularization, or stroke during hospital stay.

Statistical analysis

Continuous and categorical variables are presented as means ± standard deviations and absolute numbers (percentages), respectively. Differences in the means or percentages among the three groups were assessed using a one-way analysis of variance (ANOVA) or the chi-square test. SPSS 19.0 software (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. Two-sided P values of <0.05 were considered statistically significant.

Results

Patients’ baseline and procedural characteristics

A total of 500 patients who underwent TR-PCI were randomly divided into group A (150-cm EMERALD Guidewire Standard J-Tip, general guidewire, 156 cases), group B (150-cm RADIFOCUS Guidewire M, super-slide guidewire, 173 cases), and group C (260-cm Amplatz Super Stiff™ Guidewire, exchangeable guidewire, 171 cases). There were no significant differences in patient demographics and risk factors in terms of mean age, sex, body mass index, cardiovascular risk factors (smoking, hypertension, diabetes, dyslipidemia, family history of CAD) (Table 1). Among total 500 patients, 475 patients (95%) had completed TR-PCI via the transradial approach, and the rest 25 patients (5%) switched to transfemoral percutaneous coronary intervention. There was significant statistic difference in TR-PCI success rate (129 of 156, 82.7%, Groups A; 164 of 173, 94.8%, Groups B; 168 of 171, 98.2%, Groups C; P<0.001). TR-PCI could not be completed as planned in 14 patients from Group A owing to TRAV, who subsequently underwent treatment according to the protocol for Group C. 13, 9, and 3 patients in Groups A, B, and C switched to the transfemoral approach, respectively, these procedural failures included RA puncture failure (1 patient in Groups A; 2 patient in Groups B; 1
patient in Groups C), severe TRAV (6 patients in Groups A; 2 patients in Groups B; 1 patient in Groups C), severe RAS (4 patients in Groups A; 1 patients in Groups B; 0 patient in Groups C), complex coronary artery lesions and catheter inner diameter (2 patients in Groups A; 3 patients in Groups B; 1 patient in Groups C).

In a comparison of TR-PCI procedure-related data, significant inter-group differences were observed in the fluoroscope time and catheter-in-place time (P <0.05 and P <0.001, respectively, Table 2), with Group C having the shortest durations. Additionally, the TRAV passing rate and TR-PCI success rate differed significantly among the groups, with the highest rates observed in Group C (both P<0.001, Table 2), suggest that the 260-cm Amplatz Super Stiff™ Guidewire markedly facilitated the performance of TR-PCI, especially in cases with RA variant tortuosity (Figure 2B). There were no statistically significant differences of TRAV in three groups (P>0.05, Table 1). There were no statistically significant differences in procedural duration and contrast volume among the groups (both P>0.05, Table 2).

### Table 1: Baseline characteristics of patients who underwent TR-PCI.

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=156)</th>
<th>Group B (n=173)</th>
<th>Group C (n=171)</th>
<th>Statistics (Chi-square or one-way ANOVA)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (n, male/ female)</td>
<td>100/56</td>
<td>106/67</td>
<td>107/64</td>
<td>χ²=0.281</td>
<td>0.869</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.4 ± 9.3</td>
<td>61.4 ± 10.5</td>
<td>60.8 ± 10.0</td>
<td>F=1.130</td>
<td>0.324</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>22.8 ± 3.3</td>
<td>23.4 ± 3.6</td>
<td>23.1 ± 3.8</td>
<td>χ²=1.091</td>
<td>0.337</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>67 (42.9%)</td>
<td>74 (42.8%)</td>
<td>69 (40.4%)</td>
<td>χ²=0.291</td>
<td>0.865</td>
</tr>
<tr>
<td>Hypertension</td>
<td>66 (42.3%)</td>
<td>71 (36.4%)</td>
<td>62 (32.7%)</td>
<td>χ²=3.237</td>
<td>0.198</td>
</tr>
<tr>
<td>Smoker</td>
<td>73 (46.8%)</td>
<td>79 (45.7%)</td>
<td>82 (48.0%)</td>
<td>χ²=2.024</td>
<td>0.364</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>87 (55.8%)</td>
<td>86 (49.7%)</td>
<td>79 (46.2%)</td>
<td>χ²=3.659</td>
<td>0.161</td>
</tr>
<tr>
<td>Stroke</td>
<td>21 (13.5%)</td>
<td>35 (20.2%)</td>
<td>31 (18.1%)</td>
<td>χ²=2.720</td>
<td>0.258</td>
</tr>
<tr>
<td>Family history of CHD</td>
<td>44 (28.2%)</td>
<td>45 (26.0%)</td>
<td>43 (25.1%)</td>
<td>χ²=0.413</td>
<td>0.813</td>
</tr>
<tr>
<td>CHD Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable angina</td>
<td>37 (23.7%)</td>
<td>48 (27.7%)</td>
<td>40 (23.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>80 (51.3%)</td>
<td>89 (51.4%)</td>
<td>95 (55.6%)</td>
<td>χ²=2.933</td>
<td>0.817</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>25 (16.0%)</td>
<td>20 (11.6%)</td>
<td>23 (13.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>14 (9.0%)</td>
<td>17 (9.8%)</td>
<td>13 (7.6%)</td>
<td>χ²=0.880</td>
<td>0.664</td>
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<tr>
<td>TRAV</td>
<td>24 (15.4%)</td>
<td>31 (17.9%)</td>
<td>33 (19.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LMWH</td>
<td>119 (76.3%)</td>
<td>136 (78.6%)</td>
<td>126 (73.7%)</td>
<td>χ²=1.153</td>
<td>0.562</td>
</tr>
<tr>
<td>GPIIb/IIa inhibitor</td>
<td>58 (37.2%)</td>
<td>51 (29.5%)</td>
<td>47 (27.5%)</td>
<td>χ²=3.936</td>
<td>0.14</td>
</tr>
</tbody>
</table>

### Table 2: Comparison of procedure-related parameters.

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=156)</th>
<th>Group B (n=173)</th>
<th>Group C (n=171)</th>
<th>Statistics (Chi-square or one-way ANOVA)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy time (min)</td>
<td>16.7 ± 6.1</td>
<td>15.8 ± 6.2</td>
<td>14.9 ± 5.8</td>
<td>F = 3.443</td>
<td>0.03  3</td>
</tr>
<tr>
<td>Procedure duration (min)</td>
<td>61.1 ± 18.2</td>
<td>60.9 ± 24.1</td>
<td>59.1 ± 20.8</td>
<td>F = 0.436</td>
<td>0.64  7</td>
</tr>
<tr>
<td>Catheter-in-place time (s)</td>
<td>39.9 ± 22.9</td>
<td>26.1 ± 14.3</td>
<td>28.0 ± 12.9</td>
<td>F = 21.20</td>
<td>0</td>
</tr>
<tr>
<td>Contrast volume (ml)</td>
<td>215.7 ± 73.4</td>
<td>214.4 ± 66.0</td>
<td>208.3 ± 69.2</td>
<td>F = 0.540</td>
<td>0.58  3</td>
</tr>
<tr>
<td>Passing rate TRAV (%)</td>
<td>3/24 (12.5%)</td>
<td>24/31 (77.4%)</td>
<td>32/33 (96.7%)</td>
<td>χ²=0</td>
<td>0</td>
</tr>
<tr>
<td>Success rate (%)</td>
<td>129 (82.7%)</td>
<td>164 (94.8%)</td>
<td>168 (98.2%)</td>
<td>χ²=0</td>
<td>0</td>
</tr>
</tbody>
</table>

The abbreviations are:
- BMI: body mass index
- CHD: coronary heart disease
- NSTEMI: non-ST-segment elevation myocardial infarction
- STEMI: ST-segment elevation myocardial infarction
- LMWH: Low molecular weight heparin
- GPIIb/IIIa: glycoprotein IIb/IIIa

Abbreviations: TRAV, transradial approach anatomic variations.
Table 3: Comparison of TR-PCI complications

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Statistics (Chi-square-test)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAS (%)</td>
<td>15 (9.6%)</td>
<td>8 (4.6%)</td>
<td>3 (1.8%)</td>
<td>χ²=10.404</td>
<td>0.006</td>
</tr>
<tr>
<td>Hematoma (%)</td>
<td>3 (1.9%)</td>
<td>8 (4.6%)</td>
<td>1 (0.6%)</td>
<td>χ²=6.211</td>
<td>0.045</td>
</tr>
</tbody>
</table>

Abbreviations: RAS, radial artery spasm

Discussion

In this study, we proposed the 260-cm Amplatz Super Stiff™ Guidewire as a novel method for exchanging the catheter in TR-PCI. The results of our prospective study demonstrated that when compared with two commonly used guidewires, the 260-cm Amplatz Super Stiff™ Guidewire greatly facilitated catheter exchange, decreased the incidence of vascular complications, reduced the patients’ exposure to radiation, and increased the TR-PCI success rate [12]. In brief, our findings suggest that this exchangeable guidewire facilitates a safe, effective and convenient method of TR-PCI.

Compared to transfemoral percutaneous coronary intervention, TR-PCI is associated with a lower risk of access site bleeding and hematoma, early patient ambulation, a shorter hospital stay [2], and lower hospital costs [4], but the RA approach involves more variations, such as multiple blood vessel bifurcations and abnormalities (e.g., vascular tortuosity and arterial loops) [6] and lesions (e.g., severe atherosclerosis) [13], which increase the likelihood of a difficult guidewire insertion or inadequate catheter back-up support, a significantly prolonged fluoroscopy time [11,14], an increased contrast volume and, therefore, TR-PCI failure [15,16]. These conditions are even more common in elderly patients, who comprise an increasing segment of the patient population undergoing TR-PCI and face a higher risk of peri-procedural complications relative to their younger counterparts. Compared with the 150-cm EMERALD Guidewire Standard J-Tip (Figure 3A) and 150-cm RADIOFOCUS Guidewire M (Figure 3B), the 260-cm Amplatz Super Stiff™ Guidewire (Figure 3C) possesses a stiff larger inner core (0.035-inch) to provide a strong supporting force, and a stiff pushing rod to provide additional strength and facilitate and stabilize catheter advancement during placement or exchange. Furthermore, the soft J-Tip and the hydrophilic membrane of the exchangeable catheter reduce the risk of damage to the vascular intima. In our experience, these structural characteristics improve the ability of the exchangeable guidewire to ease the passage of the catheter beyond TRAV (Figure 2B) (Figure 3C), thus significantly decreasing the discomfort experienced by the patient and the risk of arterial injury. An exchangeable guidewire also contributes to a reduction in the emergency percutaneous coronary intervention door-to-balloon time, thus improving the opportunity for rescue. The 260-cm Amplatz Super Stiff™ guidewire is superior for TRAV passage and is therefore the good option for TR-PCI.

Hematoma are the most common adverse events associated with TR-PCI procedures and are significant predictors of 1-year mortality [17]. The 150-cm RADIOFOCUS Guidewire M easily slides into the peripheral branches, including the mediastinal vessels; however, forcible insertion of the guidewire can perforate the vessel (Figure 1C). In addition, repeated guidewire insertion for catheter exchange is likely to cause hematoma, including mediastinal hematoma. Interestingly, only one case of RA hematoma was observed in Group C; however, this injury resulted from the advancement of the 150-cm RADIOFOCUS Guidewire M for in-advance catheter placement, rather than from the 260-cm Amplatz Super Stiff™ Guidewire itself. One patient each in Group B and B developed a mediastinal hematoma and thoracic wall hematoma; the former was transferred to a surgical operation for dyspnea resulting from a hematoma-compressed airway.

RA, 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 a switch to the transfemoral approach [15]. Morphine, diazepam, calcium antagonists, nitrate esters can relieve RA to some extent. However, severe RAS is one of the most important causes of a failure to complete TR-PCI [15]. Our study revealed that the 150-cm EMERALD Guidewire Standard J-Tip was most likely to cause RA (Figure 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 RADIOFOCUS Guidewire M, the 260-cm Amplatz Super Stiff™ Guidewire has the advantage of markedly decreasing the incidence of RAS. First, this latter guidewire serves as a bridge to ease the subsequent catheter switch by minimally stimulating the RA. Second, this guidewire remains in the transradial approach throughout the TR-PCI and is used as an exchangeable guidewire, thus avoiding the repeated insertion of guidewires for catheter exchange...
every time X-ray radiation is required (e.g., Groups A and B). Therefore, the exchangeable guidewire greatly facilitates catheter exchange and increases the safety of TR-PCI. Additionally, 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 StiffTM Guidewire provides excellent advantages, although we suggest that structural and performance improvements could allow its independent advancement to the aortic root (i.e., without requiring the 150-cm RADIOFOCUS Guidewire M). This would further reduce the incidence of TR-PCI complications resulting from the super-slide 150-cm RADIOFOCUS Guidewire M. Additionally, we note that the generalizability of the findings from this pilot study is limited by the small sample size. Future studies with larger sample sizes are required to validate our results.

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

Supporting Information
S Table. Raw data used in the study analyses.

References