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Comparison of Radifocus versus Silverway Guidewires for Percutaneous Radial Angiography Following Failed Use of a J-Tip Guidewire

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: During transradial coronary angiography, when conventional J-tip wires fail to deliver catheters to the aortic root due to anatomical obstacles, additional hydrophilic wires, such as Radifocus (Terumo) or Silverway (Asahi), are used. We recently showed that the Silverway guidewire was effective at delivering the catheter to the aortic root. In this study, we aimed to compare the efficacy and safety of Radifocus and Silverway guidewires in 100 patients after failed use of the J-tip guidewire.

Material/Methods: After patients had a failure of a conventional J-tip wire to reach the aortic root, 100 patients were 1:1 randomized to either the Silverway or Radifocus wire. All patients with failure of the J-tip wire were eligible. The primary endpoint was the time between wire entry in the catheter and successful delivery of the catheter to the aortic root. Secondary endpoints included change of access site, number of complications, and questionnaires on subjective wire assessments by the performing interventional cardiologist.

Results: The primary endpoint was significantly shorter in patients randomized to the Silverway arm (median 30 s [21-39] vs 48 s [36-66]; *P*<0.001)). The percentage of patients with change of access site was not different between the groups (2 vs 2, not significant). Only 1 minor complication (2%) occurred, in the Radifocus group. Questionnaires revealed that torque control, crossing, and support were all significantly better with the Silverway wire (*P*<0.001).

Conclusions: Silverway showed superior torque control, resulting in faster catheter delivery to the aortic root when compared with the Radifocus guidewire.

Keywords: Cardiac Catheterization • Cardiac Catheters • Coronary Angiography • Radial Artery

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Background

Radial access is the preferred approach for coronary angiography, unless there are overriding procedural considerations [1-4]. During transradial coronary angiography, it is not always feasible to deliver catheters to the aortic root with the support a conventional J-tip wire, owing to spasm, tortuosity, or loopings at the level of the brachial or subclavian artery or brachiocephalic trunk [5,6]. These anomalies are prone to bleeding and vascular complications and increased procedure time [7,8]. Other hydrophilic wires, such as Radifocus (Terumo, Tokyo, Japan) and Silverway (Asahi Intecc Co., Tokyo, Japan), are used to overcome these anatomical challenges [9,10].

The Radifocus guidewire is a polymer-coated wire for more lubricity and has a nitinol core structure for better torque transmission than a conventional J-tip; however, it is less supportive and can easily enter side branches due to the high lubricity and therefore might cause dissections of perforations [7].

The Silverway guidewire has a hybrid coating, Asahi Cable Tube ONE (ACT ONE) technology on the proximal shaft and double coil structure at the tip that connects the core and coil to ensure one-to-one torque transmission. The combination of these technologies incorporates good deliverability, torque transmission, and safety [5]. We recently showed that the Silverway guidewire is successful at delivering the guidewire to the aortic valve when the J-tip guidewire fails due to anatomical obstacles [9].

To date, there are no data comparing the 2 wires. In this RADifocus VErsus Silverway (RADVES) study, we aimed to compare the efficacy and safety of both the Radifocus and Silverway guidewires for percutaneous transradial coronary angiography in 100 patients following the failed use of a J-tip guidewire.

Material and Methods

RADVES was a single-center, investigator-initiated, open-label randomized controlled pilot trial.

Ethics Statement

The trial was approved by the Institutional Review Board at Ziekenhuis Oost-Limburg Genk (Z-2021119) and registered at clinicaltrials.gov (NCT05231889). The principles of the Helsinki Declaration were followed in the execution of this investigation. Oral informed consent was given by each patient during the procedure. Written informed consent was obtained after the procedure.

Participants

Patients were eligible if the conventional J-tip wire failed to reach to aortic root during an elective non-emergent coronary procedure. ST-elevation myocardial infarction, non-ST elevation myocardial infarction, and hemodynamic instability were exclusion criteria.

After angiographic rule out of first-pass complications by the J-tip wire occurred and informed consent was given, patients were 1:1 randomized by an online module using permuted blocks to either the Silverway or Radifocus guidewire, stratified by whether the J-tip wire failed proximal or distal to the subclavian artery.

Materials

A 6 French radial sheath was used for radial access in all patients (Radifocus Introducer II Transradial Kit, Terumo). All patients received upfront transradial spasmolytic agents containing 1 mg of nitroglycerin, 1 mg of verapamil, and 5000 units of heparin. Subsequently, a 5 French or 6 French diagnostic catheter was used (Cordis); the choice of catheter was at the operators' discretion.

The Silverway guidewire was compared with the Radifocus guidewire. No additional spasmolytic agents were administered after the initial dose. Final hemostasis was achieved using a transradial band (Terumo). Timing of entry of the guidewire into the catheter to reaching the aortic root was performed by a timer that was built in to our system (Philips).

Data Collection

Baseline, procedural, and clinical outcome data were prospectively collected using Castor EDC software. The primary endpoint was the time between wire entry in the catheter and successful delivery of the catheter to the aortic root within a predefined time limit of 300 seconds. In case the assigned study wire failed to pass, cross-over to the other study wire was mandatory. Secondary endpoints included change of access site to the contralateral radial or femoral arteries and the number of complications (dissection, perforation, or hematoma), as assessed by post-procedural angiography and questionnaires on subjective wire assessments (1, not satisfactory, to 3, satisfactory) by the performing interventional cardiologist.

Statistical Analysis

All continuous data are reported as mean±standard deviation if normally distributed or median [interquartile range] if not normally distributed. Continuous endpoints were compared with a *t* test if normally distributed or with a Mann-Whitney *U* test

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Table 1. Patient numbers, baseline characteristics, and anatomical challenge.

	Silverway	Radifocus
Numbers		
# Randomized	49	51
# Cross-over*	2	4
# Excluded**	2	2
# Final analysis	47	49
Baseline characteristics		
Age	73±11	73±10
Male	14 (29%)	22 (43%)
Diabetes	7 (14%)	10 (20%)
Hypertension	40 (82%)	37 (73%)
Anatomical challenge		
Tortuosity	25 (53%)	28 (57%)
Spasm	12 (26%)	14 (29%)
Looping	2 (4%)	4 (8%)
Stenosis	4 (9%)	1 (2%)
Spasm and tortuosity	4 (9%)	2 (4%)

* Mandatory cross-over to other study wire after failure of assigned study wire; ** patients were excluded from final study analysis if both study wires failed to pass the anatomical obstacle within the pre-defined time limit.

if not normally distributed. Categorical variables are reported as observed frequencies and percentages. The data were analyzed using SPSS 13.0. A *P* value <0.05 was considered statistically significant.

Results

A total of 1408 transradial cardiac catheterizations were performed between February 2022 and July 2022 by 7 experienced interventional cardiologists. During this period, 100 consecutive patients, in whom the standard J-tip wire failed to deliver the catheter to the aortic valve, were 1:1 randomized between Radifocus (n=51) and Silverway (n=49) wires, stratified by whether the conventional J-tip wire crossing failed proximal (n=90) or distal (n=10) to the subclavian artery. Failure of the standard J-tip wire to deliver the catheter to the aortic root occurred in 7.1% of the procedures (100/1408).

Baseline Characteristics

Baseline pre-randomization characteristics were well balanced between the 2 groups (**Table 1**). Patients had a mean age of 73±11 years, the mean body mass index was 27±4.6 kg/m^2, most patients were female (64%), and most had a medical history of hypertension (87%).

The indication for the cardiac catheterization was stable angina in 56% of cases, heart failure in 12% of cases, a pre-operative indication in 3%, unstable angina in 9%, and other indications, such as rhythm disorders or silent ischemia, in 20% (**Table 1**).

Procedural Characteristics

The reasons for the failure of the initial J-tip wire to cross were tortuosity (n=53), spasm (n=26), loopings (n=10), stenosis (n=5), and a combination of spasm and tortuosity in the remaining 6 patients.

In 6% of the patients, the guidewire was combined with a 4 French catheter to reach the aortic valve, in 24% of patients the guidewire was combined with a 5 French catheter, and in 70% of patients the guidewire was combined with a 6 French catheter.

A total of 4 patients (2 patients randomized to Radifocus and 2 randomized to Silverway), all of whom had an arterial looping, were excluded from the final endpoint analysis because both study wires failed to pass within the pre-defined time limit of 300 s. In 2 additional patients, after initial failure of the assigned Radifocus wire, cross-over to Silverway was successful after 19 and 38 seconds (**Figure 1**). For these patients, the primary endpoint for the study wire was imputed according to the worst-case scenario (300 s).

Cross-over to a different access site was similar for the Silverway and Radifocus wires (**Table 2**).

Primary and Secondary Endpoints

The primary endpoint was significantly shorter in patients randomized to the Silverway arm (median 30 s [21-39] vs 48 s [36-66]; *P*<0.001; **Figure 2**). The percentage of patients with a change of access site did not differ between the 2 groups (2 vs 2, not significant).

The only complication was a small dissection without clinical implication in a single patient randomized to the Radifocus group (**Table 2**). Questionnaires revealed that torque control, crossing, and support were all significantly better with the Silverway wire (**Table 2**). Retrospective analysis showed no radial artery complications (eg, thrombosis) in our patient population.

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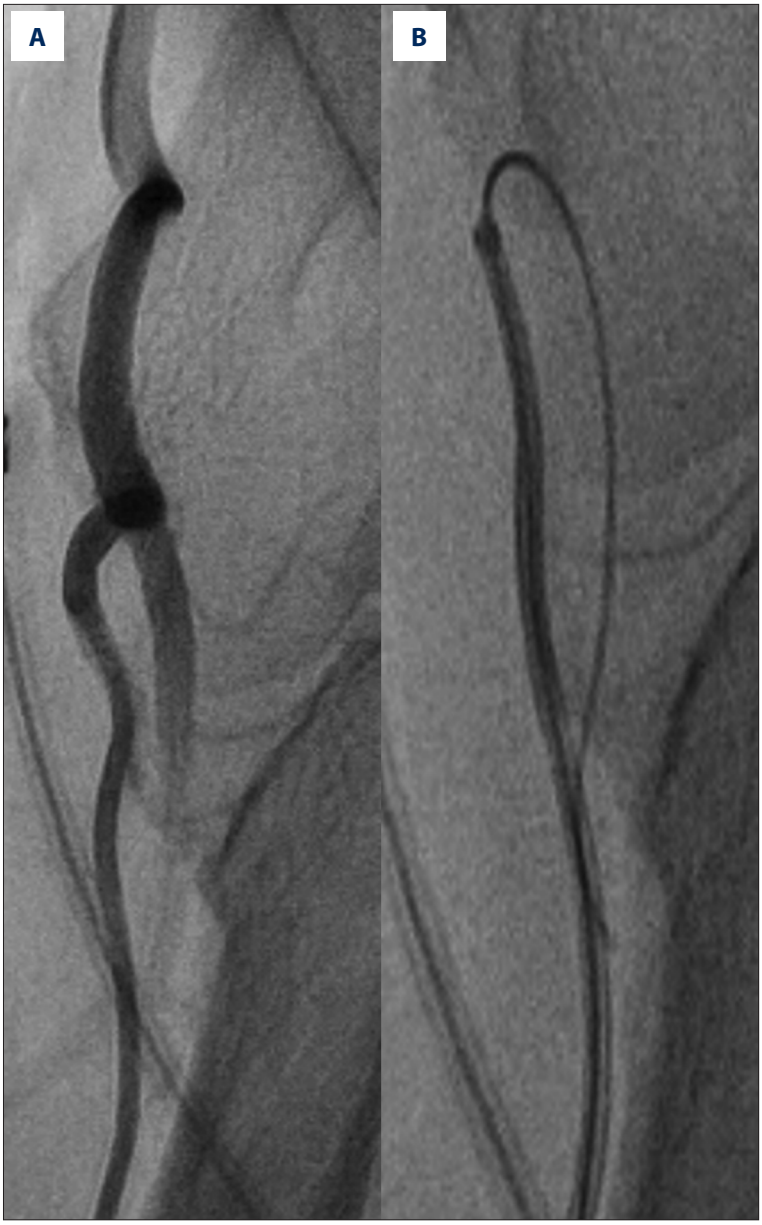

Figure 1. A case of tortuosity in the radial artery which could not be passed with the standard J-tip guidewire (**A**). The Radifocus wire had low steerability and torque transmission; therefore, it always chose the distal path (**B**). The Silverway wire was able to cross the tortuosity and reached the aortic valve in 19 seconds (no image available).

Discussion

Considering that this trial was conducted in a challenging anatomical environment in which a conventional J-tip wire had already failed to cross, we showed that both Radifocus and Silverway wires were highly efficient and safe, with a need to change access site in only 4% of patients and a complication occurring in only 1 patient (2%). However, the Silverway wire clearly outperformed the Radifocus wire by being 18 seconds faster and providing better crossing and torque control.

Our results are in line with a previous observational study showing that the Silverway wire could cross the lesion in 98% of patients and deliver catheters to the aortic root in 92% of patients after initial failure of the conventional J-tip wire, thus being highly efficient [5]. While the Radifocus wire has a nitinol core structure with moderate torque transmission, the Silverway wire has an ingenious hybrid shaft design derived from Asahi's percutaneous coronary intervention wires [10]. These features may provide better one-to-one torque control, support, and tactile feedback in comparison with the Radifocus wire. This hypothesis is supported by the questionnaires that showed torque control was significantly better with the use of the Silverway guidewire (**Figure 3**).

Radial artery occlusion has been described in 1% to 10% of patients after transradial coronary angiogram [11,12]. Although retrospectively no radial artery occlusion was reported in our

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Table 2. Primary and secondary endpoints.

	Silverway	Radifocus	
Primary endpoint			
Time in seconds	30 (IQR 21-39)	48 (IQR 36-66)	p<0.001
Secondary endpoints			
Change of access site	2 (4%)	2 (4%)	NS
Complication	0 (0%)	1 (2%)	NS
Torque control	3±0	2.09±0.67	p<0.001
Crossing	2.92±0.28	2.45±0.70	p<0.001
Support	2.96±0.20	2.33±0.68	p<0.001

IQR – interquartile range; NS – not significant.

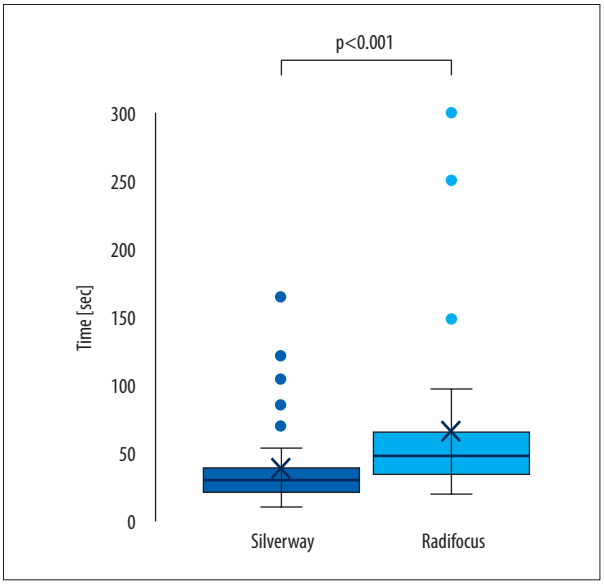

Figure 2. Boxplot chart showing the primary endpoint (time in seconds).

patient population, this does not exclude "silent occlusion", as routine radial ultrasound was not performed after the coronary angiogram. Even though spasm is a common cause for failure of the initial J-tip wire to cross (32% in our population), there is no clear relation in the literature between the occurrence of radial artery spasm and radial artery occlusion [13,14]. The percentage of patients with radial spasm in our study population was slightly higher than that described in other study populations [13,15]. This can be explained by selection bias, as patients were only included in our study when the conventional J-tip wire failed to cross. Most studies describing radial spasm include a total population undergoing coronary angiogram [13,15]. In addition, thus far, no association has been shown between procedure time and radial artery occlusion [16].

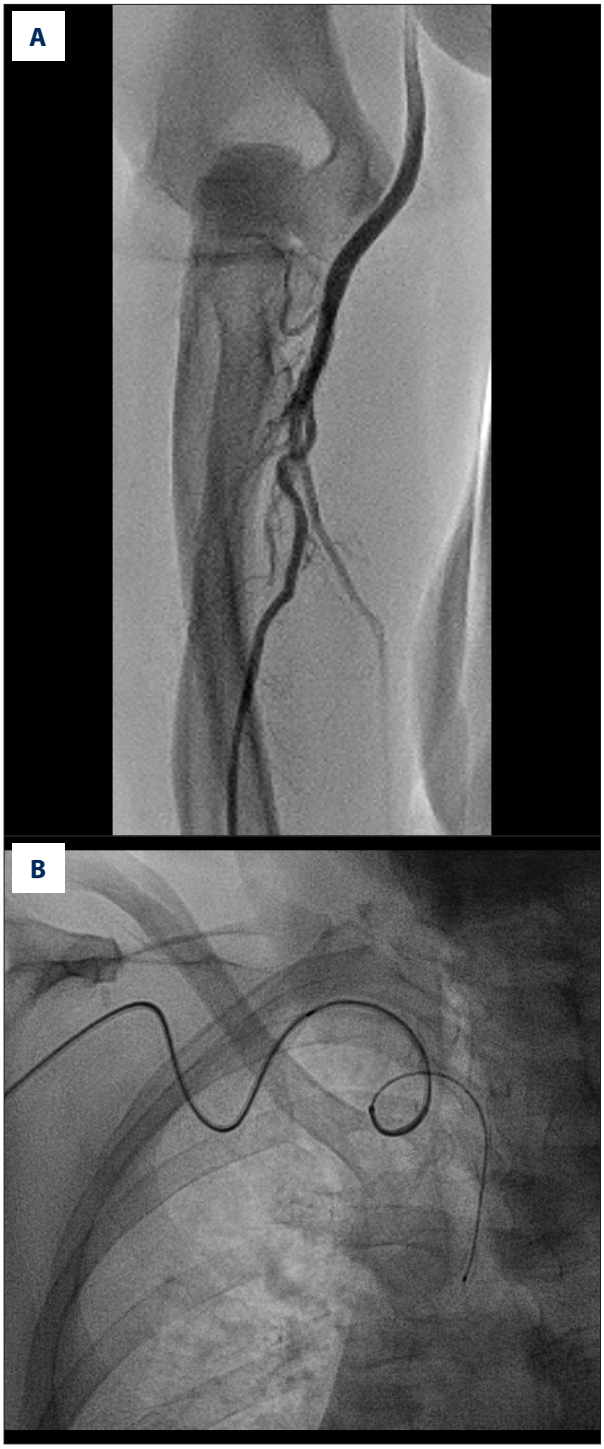

Figure 3. Tortuosity at radial artery level (**A**) and subclavian/brachiocephalic level (**B**) in 1 patient. The Silverway wire was able to cross both anomalies and deliver the catheter to the aortic valve in 127 seconds.

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It remains to be studied if faster delivery of the catheter to the aortic root by using a hydrophilic guidewire, and therefore a shorter procedure time, decreases the risk of radial artery occlusion.

Limitations

The major limitation of this study is the single-center open-label trial design. In addition, we limited our study to 2 different hydrophilic guidewires that are currently on the market (Silverway and Radifocus). The market, however, is not limited to these 2 hydrophilic wires, and other available hydrophilic wires might have similar results. A future trial comparing Silverway and a conventional J-tip as a workhorse wire would be of interest.

Conclusions

This study showed that when compared with the Radifocus guidewire, the Silverway guidewire had significantly better torque control, resulting in more rapid catheter delivery to the aortic root.

Declaration of Figures' Authenticity

All Figures submitted have been created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or part.

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