Performance Analysis of a Novel Hydrophilic-Coated Transradial Guiding Catheter

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Abstract

Aim: The transradial approach (TRA) has taken an upswing, however access-site complications still exist. The choice of potentially less traumatic materials may minimize these complications. This article describes the use of a hydrophilic-coated 6F guiding catheter for diagnostic and interventional procedures and upper extremity dysfunction following these procedures.

Materials and Methods: This prospective observational study enrolled 217 patients who underwent elective transradial percutaneous coronary intervention (TR-PCI) for stable and unstable angina, or acute coronary syndrome between May 2014 and November 2016. All patients were treated using a 6F hydrophilic-coated guiding catheter (PRIMUM, PendraCare, Wellinq, the Netherlands). Catheter performance was assessed on a five-point scale ranging from very bad to very good. Procedure safety was assessed using the Major cardiac and cerebrovascular events (MACCE) criteria.

Results: The average number of guiding catheters used was 1.2 per patient. Overall performance of the catheters was rated Average/Good. Procedural success, defined as TIMI grade 3 flow and successful stent deployment, with a residual diameter stenosis of <25%, was 97.7%. MACCE occurred in 1.5% during the 6-months of follow-up.

Conclusion: These data indicate that the use of a hydrophilic-coated guiding catheter to perform percutaneous coronary interventions is safe and effective, with high procedural success and low complication rates. In addition, the short and long-term MACCE outcomes of the PCI were favorable.

Key words: catheterization; complication; coronary disease; hydrophilic-coated guiding catheter; TR-PCI

Running title: Guiding Catheter Performance

Abbreviations:

| Abbreviation | Description |
|--------------|-------------|
| ACC/AHA      | American College of Cardiology/American Heart Association classification |
| CAG          | Coronary artery angiography |
| MACCE        | Major adverse cardiac and cerebrovascular events |
| NRS         | Numeric Rating Scale for Pain |
| NSTEMI       | Non ST-elevation myocardial infarction |
| PCI          | Percutaneous coronary intervention |
| RAO          | Radial artery occlusion |
| RAS          | Radial artery stenosis |
| STEMI        | ST-elevation myocardial infarction |
| TIMI         | Thrombolysis in myocardial infarction |
| TRA          | Transradial approach |
| TR-PCI       | Transradial percutaneous coronary intervention |
| 6F           | 6 French |

Introduction

Throughout the years, transradial approach (TRA) has become the standard access site during coronary interventions. The major factors...
contributing to this are the occurrence of less vascular site complications, cross target lesions and contrast was injected manually in all cases. Non-patent hemostasis of the radial artery was achieved by using a compression device (Terumo Medical Corporation, Tokyo, Japan).

Procedural endpoints

The primary endpoint of this registry was procedural success, defined as thrombolysis in myocardial infarction (TIMI) coronary flow grade 3, and successful stent deployment, with an angiographic visual estimated final residual diameter stenosis of <25%. [11] Secondary endpoints were guiding catheter safety (rate of catheter-related complications).

Guiding catheter performance characteristics

Guiding catheter insertion, torque control, opacification of the vessel, tip and catheter radiopacity, back-up support, and persistent catheter stiffness was rated by experienced operators on a five-point scale (1: Very Bad; 2: Bad; 3: Average; 4: Good; 5: Very Good). Furthermore, friction in and outside the sheath, the occurrence of kinking, the need for a guide liner or for deep intubation, vessel damage, guiding cannulation failure, and defective catheter were recorded. Back-up support was defined as the ability to advance a guiding catheter in coronary vessels conveniently, represented by the efficacy of transfer or the proximally applied push force to the catheter tip.

Torqueability was defined as the capacity of a guiding catheter to tolerate torque between the proximal hub and the tip without kinking or other irreversible damage to the system. Friction was defined as a contact force accumulated when two surfaces (i.e. sheath vs. guiding catheter or guiding catheter vs. vessel wall) interact and which can affect advancement/movement of the catheter tip (e.g. resistance).

Kinking of the catheter was defined as a visually observed in vivo indentation of one side of the catheter wall touching the opposite side of the catheter wall with a sharp curvature. Catheter stiffness was defined as the force needed to bend the wire. Overall guiding catheter performance was scored on a five-point scale by the operators.

Catheter induced pain and spasm

Procedural pain was assessed using the validated Numeric Rating Scale for Pain (NPRS). [12] Procedural radial artery spasm was also evaluated. Moderate spasm was defined as some resistance perceived by the operator, while the catheter still is effectively maneuverable, and distinct painful perception for the patient. Severe spasm was defined as catheter not steerable or retractable, with severe pain for the patient when the catheter was being manipulated.

Access-site complications

Access-site complications were noted during the procedure and clinical outpatient visits (after two weeks, one month and six months of follow-up) and when necessary patients were referred to a hand specialist. [3] Swelling, access-site bleeding, hematomas and their proportions were assessed. Furthermore, upper extremity function as a composite endpoint consisting of (isometric) strength, sensibility of all digits, and circumference measurements was also assessed.

Measures of long-term clinical outcome

All patients were interviewed personally and examined at their outpatient clinical visit up to approximately six months after their catheterization, to assess the long-term TR-PCI treatment outcomes and also specifically the complications involving the hand intervention. Long-clinical outcomes were measured in terms of Major adverse cardiac and cerebrovascular events (MACCE) defined as myocardial infarction, according to the Third Universal definition of Myocardial Infarction, target vessel...
revascularization, either by percutaneous coronary intervention (PCI) or coronary artery bypass grafting, death from any cause or a cerebrovascular accident. [13]

**Statistical analysis**

Descriptive statistics were provided for all variables considered in the analysis. For categorical variables, the data was presented as percentages. Continuous variables with normal distribution were presented using means and standard deviation (SD), non-normally distributed variables were presented using median and interquartile (IQR)-range. Between-group differences of dichotomous/ordinal variables were analyzed using Chi-square test with Yates continuity correction or for trend, respectively. Comparisons of continuous variables for more than two groups were analyzed using the Kruskal Wallis test. Statistical tests were carried out two-tailed at the 5% level of significance. Statistical analyses were performed with SPSS for Mac version 26.

**Results**

A total of 234 patients treated with TR-PCI were included in the ARCUS study between May 2014 and November 2016. Seventeen (7.2%) patients were excluded from this registry because of crossover to the femoral or contralateral radial artery. In all these patients access to the radial artery was unsuccessful and crossover was not related to the performance of the guiding catheter.

The demographic and baseline characteristics of the total patient population (N =217) in this registry are presented in Table 1.

The mean age was 64.9 ± 11 years and 176 patients (81.1%) were male. Procedural characteristics and PCI complexity are summarized in Table 2.

**Table 1: Demographic and baseline characteristics**

| Patient Characteristics | Study patients |
|-------------------------|----------------|
| Men                     | 176 (81.1)     |
| Age, y                  | 64.9 ± 11.0    |
| Body Mass Index         | 27.6 ± 4.1     |
| Height, cm              | 176.2 ± 9.1    |
| Smoking                 |                |
| Active Smoker           | 39 (18.0)      |
| Previous                | 110 (50.7)     |
| No                      | 65 (30.0)      |
| Hypertension            | 113 (52.1)     |
| Dyslipidemia            | 78 (35.9)      |
| Diabetes Mellitus       | 41 (18.9)      |
| Family History of Heart disease | 98 (45.2) |
| Previous TR-PCI         | 107 (49.3)     |
| Previous TR-procedures (CAG+PCI) | 167 (77.0) |
| Previous Hand Disease Intervention Arm | 95 (43.8) |
| Indications for coronary intervention | 151 (69.6) |
| Stable angina           | 14 (6.5)       |
| Unstable angina         | 50 (23.0)      |
| NSTEMI                  | 2 (0.9)        |
| STEMI                   |                |

| Values are mean ± SD, median ± IQR or n (%). Abbreviations: CAG: Coronary artery angiography; NSTEMI: Non ST-elevation myocardial infarction; PCI: Percutaneous coronary intervention; STEMI: ST-elevation myocardial infarction; TR-PCI: transradial percutaneous coronary intervention. |

**Table 2: Angiographic findings and characteristics of 347 coronary artery lesions**

Among the 217 included patients, 116 patients underwent treatment of a single lesion, 76 patients had two lesions, 22 patients had three lesions, two patients had four lesions, and one patient had five lesions treated. The procedural characteristics and outcomes are listed in Table 3.

| Mean number of items per patient | Study patients |
|----------------------------------|----------------|
| Stents                           | 1.4 ± 1.2      |
| Balloons                         | 1.8 ± 1.4      |
| Guiding catheters                | 1.5 ± 0.8      |
| Guidewires                       | 2.3 ± 1.3      |

| Stent length, mm                 |                |
|----------------------------------|----------------|
| >22                              | 40.8%          |
| 18 - 22                          | 6.1%           |
| 14 - 18                          | 34.5%          |
| 10 - 14                          | 15.2%          |
| <10                              | 3.4%           |

| Stent diameter, mm               |                |
|----------------------------------|----------------|
| 2.0 - 2.5                        | 30.7%          |
| 2.5 - 3.0                        | 37.9%          |
| 3.0 - 3.5                        | 25.2%          |
| 3.5 - 4.0                        | 5.8%           |
| >4.0                             | 0.4%           |

| Reference vessel diameter, mm    | 2.98 ± 0.5     |
| Largest balloon diameter, mm     | 2.98 ± 0.7     |
| Maximal pressure, atm             | 16 ± 3.5       |

Data presented are mean value ± SD or n (%).

**Table 3: Procedural results**
The average number of guiding catheters was 1.2 per patient. During 176 procedures, one type of guiding catheter shape was used. In respectively 35, five and one procedure there were two, three or four different catheter shapes used. Procedure success rate was 97.7%. Guiding cannulation failure resulted in procedural failure in five (2.3%) patients, in which nine guiding catheters in total were used. The reasons of guiding cannulation failure were wrong sizing (N=1) and severe calcifications, such as chronic total occlusions, whereupon the guiding catheter could not be advanced (N=4).

**Operator survey**

The guiding catheter performance as was reported by an opinion survey among the operators is listed in Table 4. The handling of the PRIMUM guiding catheter was rated Good-Average as it enhances good insertion control, exhibits good torque response, and effective back-up support, enabling adequate wiring, minimal guiding switches and sufficient equipment delivery. Operators considered the vessel visualization good, however, the visualization of the catheter tip was rated Bad-Average, although manageable by using a gentle puff of contrast, without affecting the procedure or its outcome.

The lowest scores were Average for the performance of the Judkins Left and Tiger (TIG) guiding catheter (Table 4). Friction during passage of the stent through the guiding catheter was reported in 4.9%, while friction outside the sheath was reported in 6.1% (Table 4).

![Table 4: Operators experience on Catheter Performance](image)

**Procedural complications**

Dissection occurred in two patients during balloon dilatation. Both were adequately treated with stents (Table 4). Radial artery spasm was reported in 23 patients (10.6%), ranging from moderate spasm (N=19, 8.8%) to severe spasm (N=4, 1.9%). All spasms were alleviated during the procedure and there was no patient injury reported (Table 5).

Chi-square test for trend indicated there was only a significant difference in spasms between gender groups, in favor of male patients, \( \chi^2(2) = 7.54, p=0.023 \). A Kruskal-Wallis Test revealed no statistically difference in body mass index across the three spasm severities (no spasm, N=192, moderate spasm, N=19, severe spasm, N=4), \( \chi^2(2, N=215) = 2.85, p=0.240 \).

**MACCE during follow-up**

Major events during follow-up were scarce, with a mean follow-up period of 182 ±36 days. At two weeks after the procedure one patient, who presented with progressive angina, had a revascularization by means of PCI.

Furthermore, one patient had a successful resuscitation after a STElevation myocardial infarction (STEMI) followed by a coronary angiography, but there were no signs of stent thrombosis or significant coronary stenosis. One month after the procedure one patient underwent a PCI due to stent thrombosis. One patient required a semi-urgent coronary artery bypass grafting at six months due to stent thrombosis. No cerebral complications occurred during the study.

**Post-procedural Access-site complications**

The access-site complications and hand dysfunction are presented in Table 5. Noteworthy are the radial artery occlusions, which recanalized in 50%. Of this cohort 22 patients were referred to a hand rehabilitation specialist during the 6-month follow-up period.
Upper extremity dysfunction following TR-PCI has never been examined, as thoroughly as in our study, therefore we cannot compare our outcomes with the existing literature. Although we did not compare the hydrophilic-coated catheter to an uncoated catheter, hydrophilic coating might limit upper extremity dysfunction following TR-PCI. Future research is needed and should focus on comparing hydrophilic vs. uncoated catheters in relation to upper extremity function in order to optimize TR-PCI and minimize access-site related complications. We believe that the current report can be used as a tool for comparison with other novel guiding catheters (e.g. Railway Cordis Sheathless).

Procedural complications and long-term clinical outcomes were similar to previous studies. [19] Overall, the patient characteristics of our cohort, with amongst others 73% B/C lesions, were comparable to the general population. These results may therefore also be applicable to a general patient population undergoing TR-PCI.

**Limitations**

This registry was a prospective multicenter non-randomized registry. Patients were selected from the ARCUS trial when operators had completely filled out the catheter performance survey and procedural data was complete, which might cause selection bias, as this was not randomly achieved. Nevertheless, the data on upper extremity dysfunction represent objective measurements and reflect a higher level of evidence. The main limitation of this study is that there was no comparison with other, uncoated 6F guiding catheters or with sheathless interventions. A conclusion on the effect of hydrophilic coatings on upper extremity function could therefore not be drawn and should be a focus point for future research. Randomized studies are warranted.
Conclusion

In conclusion, this registry indicates the 6F PRIMUM guiding catheter to show high eligibility for use in TR-PCI. Use of the hydrophilic-coated PRIMUM catheter as a default system in routine TR-PCI was both feasible and safe, associated with high procedural success and a low complication rate. In addition, it showed favorable short and long-term MACCE outcomes. This report could serve as a tool for comparing the performance of different (novel) guiding catheters in the future.

Conflict of Interest:

The authors have no financial relationships or conflicts of interest to disclose regarding the contents of this article.

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