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Transradial percutaneous coronary intervention for left main bifurcation lesions using 7.5-Fr sheathless guide catheter

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Abstract

Recent studies have shown sheathless guide catheters (GCs) to be safe and effective during complex lesions such as bifurcations, chronic total occlusion (CTO), and/or calcified lesions. We investigated the feasibility and safety of using 7.5-Fr sheathless GC for transradial percutaneous coronary intervention (PCI) to treat left main bifurcation lesions.

A total of 82 patients were consecutively enrolled from March 2013 to February 2016. They underwent transradial PCI for left main bifurcation lesions using the 7.5-Fr sheathless GC.

The mean syntax score was 28.1 ± 6.1, and the majority (n = 55, 67.1%) was intermediate scores (23~32). The unprotected LM disease was present in 67 of 82 patients (81.7%), and true bifurcation (Medina 1, 1, 1) was present in 46 of 82 patients (56.1%). The 2-stent technique was used in 62 of 82 patients (75.6%). The 2-stent technique included 31 cases (37.8%) of "Crush," 18 cases (22.0%) of "Cullote," and 13 (15.8%) cases of "T stent and modified T stent" (T stent). Immediate angiographic success rate was 100% (82/82), and procedural success rate was 97.6% (80/82). The vascular complications occurred in 3 patients (3/82, 3.7%).

The use of 7.5-Fr sheathless GC is safe and allows PCI for complex bifurcation lesions located in the distal of left main to be performed transradially with a high success rate.

Abbreviations: CABG = coronary artery bypass grafting, CTO = chronic total occlusion, EF = ejection fraction, FFR = fractional flow reserve, GC = guide catheter, IABP = intra-aortic balloon pump, IVUS = intravascular ultrasound, LM = left main, MACE = major adverse cardiovascular events, NSTEACS = non-ST-elevation acute coronary syndromes, PCI = percutaneous coronary interventions, SB = side branch, TIMI = thrombolysis in myocardial infarction, TRA = transradial approach, TVR = target vessel revascularization.

Keywords: bifurcation lesions, left main lesions, percutaneous coronary intervention, radial artery, sheathless

1. Introduction

The transradial approach (TRA) is increasingly used worldwide for percutaneous coronary interventions (PCIs). Multiple observational and randomized trials performed to date have shown fewer access site complications compared with the transfemoral approach,[1–3] and the radial approach has already been endorsed by many guidelines.[4–6] However, the ability of the radial artery to accommodate large guiding catheters (GCs) is limited by its relatively small size diameter. This limitation may become an impediment to performing transradial complex coronary PCI, such as of the left main (LM) bifurcation. To overcome these limitations, a sheathless GC (Asahi Intecc, Aichi, Japan), which does not require an introducer sheath, has been developed with a larger inner diameter.[7] A 7.5-Fr sheathless GC has an outer diameter slightly smaller than a 6-Fr introducer sheath, and the 6.5-Fr sheathless GC has an outer diameter is slightly smaller than a 5-Fr introducer sheath. Furthermore, the hydrophilic coating, which covers the whole length of the sheathless GC, reduces friction, discomfort, and pain-induced by radial artery spasm.[8] Some series have shown this GC to be safe and effective during complex lesions such as bifurcations, chronic total occlusion (CTO), and/or calcified lesions.[7,9–11] The objective of this study is to assess the feasibility and safety of using the 7.5-Fr sheathless GC for transradial coronary revascularization of LM bifurcation lesions.

2. Methods

2.1. Study population

This retrospective, descriptive study was conducted between March 2013 and February 2016 in patients admitted to Beijing Friendship Hospital with symptomatic coronary heart disease. The ethics committee of Beijing Friendship Hospital approved the study. The patients were considered eligible for inclusion in this study if they had LM bifurcation lesions. LM bifurcation lesions were defined as a stenosis with a diameter of >50% involving the distal LM with or without involvement of the side branch (SB) ostium (SB diameter >2.25 mm by visual estimation). Bifurcation lesions were classified according to the Medina classification.[12] There were no exclusion criteria. The decision to perform PCI

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was made by a heart team comprising of interventional cardiologists and cardiac surgeons. The decision to use 7.5-Fr sheathless GC was at the discretion of the interventional cardiologist.

2.2. Equipment

A 7.5-Fr sheathless GC was used for PCI in all the patients of this study. As the sheathless GC requires no introducer sheath, the catheters outer diameters (2.49 mm) are slightly smaller than 6.0-Fr introducer sheaths (2.62 mm), whereas the inner diameter (2.06 mm) is equivalent to conventional 7-Fr GC (2.06 mm). The sheathless GC has a hydrophilic outer coating and a tapered central dilator to enhance trackability and reduce vascular spasm and flat wire braiding to maximize the inner lumen and provide support.

2.3. Procedure

Access was via either the right or left radial artery in all patients. Local anesthetic (1% lidocaine, 1–2 mL) was injected subcutaneously with a 5-gauge needle, followed by puncture of the radial artery with a short beveled 20-gauge needle. A soft 0.025-inch straight guidewire was advanced through the needle, and 5-Fr sheath (Terumo, Japan) was initially placed. Vasodilators, nitroglycerin 200 μg was given intra-arterially following sheath insertion. Heparin was administered intravenously to achieve a target activated clotting time of whole blood (ACT) of 300 s except in cases where a glycoprotein IIb/IIIa receptor antagonist was used when the target ACT was 250 s. All patients were pretreated with aspirin and clopidogrel (or ticagrelor). After completion of diagnostic angiography, an exchange length 0.035-inch wire was inserted. The 5F radial sheath was removed and the sheathless GC and central dilator were then pushed into the ascending aorta. The central dilator was then removed and the GC engaged into the coronary artery in the routine manner. Stents were sized to a ratio of 1.1:1.0. Post-PCI, the sheathless GC was removed immediately by reintroducing the central dilator over a 0.035-inch wire.

2.4. Data collection and definitions

Patient demographics, procedural variables, and in-hospital outcomes were obtained from review of the cardiac catheterization laboratory database and medical records. The primary efficacy end point corresponding to the technical feasibility was the procedural success, which was defined as angiographic success without major adverse cardiovascular events [MACE, cardiac death, myocardial infarction, and target vessel revascularization (TVR)] before discharge. Angiographic success was defined as a composite of the following: residual diameter stenosis $< 30\%$ of the main vessel, thrombolysis in myocardial infarction (TIMI) flow grade 3 in all branches. Myocardial infarction was defined as a CK-MB $> 5 \times$ the upper limit of normal. TVR was defined as the requirement for either emergency coronary artery bypass grafting (CABG) or urgent PCI of the index artery. The primary safety end point included coronary complications, access site hematoma > 5 cm in its greatest diameter, radial artery occlusion, radial artery pseudoaneurysm, or perforation. Coronary complications included wire perforation and coronary dissection. The procedural time, amount of contrast media, crossover to transfemoral approach, the need for additional techniques, and technique of bifurcation PCI were also recorded.

Table 1

Clinical features.

Clinical features	N = 82
Age, y	66.4 ± 8.9
Male (%)	63 (76.8%)
Diabetes (%)	38 (46.3%)
Hypertension (%)	52 (63.4%)
Current smoking (%)	31 (37.8%)
Hyperlipidemia (%)	37 (45.1%)
Previous MI (%)	20 (24.4%)
Previous PCI (%)	17 (20.7%)
Clinical characteristics	
SA (%)	7 (8.5%)
UA (%)	54 (65.9%)
NSTEMI (%)	21 (25.6)
EF (%)	58.7 ± 5.1

EF = ejection fraction, MI = myocardial infarction, NSTEMI = non-ST-elevation myocardial infarction, PCI = percutaneous cardiac intervention, SA = stable angina pectoris, UA = unstable angina pectoris.

2.5. Statistical analysis

The statistical analysis was performed with SPSS version 20-software (SPSS Inc, Chicago, IL). Continuous variables were expressed as mean ± 1 standard deviation (SD). Discrete variables were summarized as percentages.

3. Results

3.1. Study population

Between March 2013 and February 2016, a total of 82 consecutive patients with LM bifurcation lesion were treated using the 7.5Fr sheathless GC via a TRA. Demographic data and clinical characteristics for all 82 patients are summarized in Table 1. Mean patient age was 66.4 ± 8.9 years (range 46–87), and 63 patients (76.8%) were male. Twenty (24.4%) patients had previous history of myocardial infarction, and 75 (91.5%) had an index episode of non-ST elevation acute coronary syndromes (NSTEACS). The mean value of left ventricular ejection fraction (EF) was 58.7 ± 5.1%.

3.2. Lesions characteristics

The angiographic characteristics of the coronary lesions are summarized in Table 2. Fifty-eight of 82 patients (70.7%) had a right dominant system, while left dominant and codominant systems were seen in 10 patients (12.2%) and in 14 patients (17.1%), respectively. Syntax score was 28.1 ± 6.1, and the majority (n = 55, 67.1%) was intermediate scores (23~32). The unprotected LM disease was present in 67 patients (81.7%), and true bifurcation (Medina 1, 1, 1) was present in 46 patients (56.1%). The patients with LM bifurcation and 3-vessel disease were 65 of 82 patients (79.3%).

3.3. Procedural characteristics

The procedural characteristics are summarized in Table 3. We treated 231 target lesions, including 216 de novo lesions (93.5%) and 15 in-stent restenosis (6.5%), in 82 patients. One hundred ninety-six stents were implanted in 82 patients (2.4 stents per patient). A total of 75 patients (91.5%) were treated via the right radial route and 7 patients (8.5%) via the left radial. Selection of the route was at the operator's discretion. Before insertion of the

Table 2

Lesions characteristics.

Lesions characteristics	N = 82 (%)
Coronary artery anatomy	
Right dominant system	58 (70.7%)
Left dominant system	10 (12.2%)
Codominant system	14 (17.1%)
Syntax score	28.1 ± 6.1
Low (0~22)	10 (12.2%)
Intermediate (23~32)	55 (67.1%)
High (≥33)	17 (20.7%)
LM bifurcation disease	
True bifurcation (1:1:1)	46 (56.1%)
LM + LAD ostium (1:1:0)	21 (25.6%)
LM + LCX ostium (1:0:1)	12 (14.6%)
Isolated distal LM disease (1:0:0)	3 (3.7%)
Protected LM	15 (18.3%)
Unprotected LM	67 (81.7%)
Disease extent	
2-vessel disease	17 (20.7%)
3-vessel disease	65 (79.3%)

LAD = left anterior descending coronary artery, LCX = left circumflex coronary artery, LM = left main coronary artery.

sheathless GC, a 5-Fr introducer sheath was successfully used in all the patients (100%) patients. The original 7.5-Fr sheathless GC selected was used to complete the PCI in 78 (98.3%) of the cases. In 4 cases, a different shaped 7.5-Fr sheathless GC was required to complete the case. In all the LM bifurcated lesions, the 2-stent technique was the most frequently used strategy (62 patients, 75.6%). The 2-stent techniques included 31 (37.8%) "Crush," 18 (22.0%) "Cullote," and 13 (15.8%) "T stent and modified T stent" (T stent). Final kissing balloon was performed successfully in 74 cases (90.2%), including all the 62 patients with 2-stent techniques and 12 patients with provisional stenting technique. Fractional flow reserve (FFR) was measured in 10 patients in order to assess branch vessel ostium lesions before pre-dilation or after stent implanted in main vessel. A FFR ≤0.80 value was the threshold for performing PCI. Intravascular ultrasound (IVUS) was used in 32 cases. Rotablator atherectomy was implemented in 3 patients. Intra-aortic balloon pump (IABP) was used in 13 patients with unprotected LM lesions and reduced EF (≤40%) during procedure.

Table 3

Procedural characteristics.

Procedural characteristics	Results
Transradial route	
Right radial artery	75 (91.5%)
Left radial artery	7 (8.5%)
Types of 7.5-Fr catheters used	
PB (3.5/4.0) (%)	38 (46.3%)
SPB (3.5/4.0) (%)	23 (28.1%)
JL (JL3.5/4.0) (%)	17 (20.7%)
AL (1.0/2.0) (%)	4 (4.9%)
Total target lesions	231
De novo lesions	216 (93.5%)
In-stent restenosis	15 (6.5%)
Bifurcation technique	
Provisional stent	20 (24.4%)
Crush	31 (37.8%)
Culotte	18 (22.0%)
T stent	13 (15.8%)
Final kissing balloon	74 (90.2%)
FFR	10 (12.2%)
IVUS	32 (39.0%)
Rotablation	3 (3.7%)
IABP	13 (15.9%)
Mean contrast volume, mL	170.8 ± 35.7
Fluoroscopy time, min	23.1 ± 6.3
Total number of stents implanted	196
Number of stents implanted/patient	2.4 ± 0.8
Mean stent diameter, mm	3.3 ± 0.4

AL = amplatzer left, FFR = fractional flow reserve, IABP = intra-aortic balloon pump, IVUS = intravascular ultrasound, JL = judkin left, PB = power back-up, SBP = super power back-up.

3.4. Procedural outcome

Immediate angiographic success rate was 100% in all patients, with no crossover to femoral approach. Peri-procedural non-ST-elevation myocardial infarctions occurred in 1 patient (1.2%), which was considered as PCI-related myocardial infarction because of a diagonal branch occluded during the procedure. One patient died of ventricular fibrillation due to subacute stent thrombosis (1.2%). There was no in-hospital TVR. MACE in all patients is 2.4% during hospitalization. Overall procedural success was achieved in 97.6%.

The end point of procedural safety without coronary and vascular complications was achieved in 96.3%. There was no coronary complication induced by the GC or wire. Radial occlusion was found in 2 patients before discharge and radial hematoma >5 cm occurred in only 1 patient after the procedure. The sheathless catheters reached the right spot of target coronary arteries via radial arteries successfully in all 82 patients. In 1 case, a different shaped sheathless catheter (power back-up [PB] 4.0) was required to change the initial catheter (amplatzer left [AL] 1.0) because of the poor backup (100%).

4. Discussion

The TRA has been increasingly used, especially in China where it has accounted for more than 80% of PCI since 2012, reached 90% in 2015. Radial access has a great deal of advantages, including reduced bleeding and vascular complications as well as greater patient comfort.[1–3,13–15] However, the small diameter of the radial artery is associated with anatomical limitation. Yan et al[16] reported that the diameter of right radial artery is (2.47 ± 0.57) mm in adult males and (2.17 ± 0.48) mm in adult females, and the diameter of left radial artery is (2.44 ± 0.48) and (2.07 ± 0.41) mm, respectively, in China. Saito et al [17] found that only 72.6% of female and 85.7% of male Asian patients could physically accept the 6-Fr sheath into the radial artery, and the frequency of the ratio of radial inner diameter/sheath outer diameter (> or =1.0) for 7 and 8-Fr sheaths was 71.5% and 44.9% in male patients and 40.3 and 24.0% in female patients, respectively. The limitation becomes more remarkable when complex lesions, such as LM, bifurcation lesions, need to be treated, requiring large-bore GC. Traditionally, a crossover approach through a femoral artery access site has been required, which adds to patient discomfort and extends the recovery time.

The recently developed sheathless GC (Asahi Intecc, Aichi, Japan) allows performance of transradial PCI without an introducer sheath, thus reducing the size of equipment within the radial artery. The 6.5-Fr sheathless outer diameter is slightly smaller than a 5-Fr introducer sheath, which was often used in conventional PCI in patients with small radial arteries or with noncomplex coronary lesions.[9–11] The 7.5-Fr sheathless GC was

more used in PCI for complex lesions (bifurcation, CTO, etc) and specific techniques or adjunctive devices, including 2-stent techniques, rotablation, IVUS, distal protection systems, thrombectomy device.[8,10,18–21] The outer diameter (2.49 mm) of 7.5-Fr sheathless GC is smaller than 6.0-Fr introducer sheaths (2.62 mm), and the inner diameter (2.06 mm) is equivalent to conventional 7-Fr GC (2.06 mm). So, the 7.5-Fr GC maybe is more suitable for PCI for LM bifurcation lesions. To date, there have been limited reports on PCI for LM bifurcation lesions using sheathless catheters.

Li et al [22] reported a series of 43 cases with bifurcation (33 with LM bifurcation lesion) treated with sheathless techniques (but not Sheathless Eaucath GC); the procedural efficacy was 100%. The author described the techniques that a 7-Fr standard GC with an inner 5-Fr multifunctional catheter was advanced over the wire as a single assembly to the ascending aorta. The inner 5-Fr multifunctional catheter is similar to the central dilator of sheathless GC. García-Blas et al [23] observed that LM lesions were treated by PCI using a sheathless GC in 109 consecutive patients. In all cases, true bifurcation lesion (1:1:1) was found in 38 of 109 (34.9%) patients. In bifurcated lesions, provisional stenting was the most frequently used strategy (72 patients, 66.1%). Two-stent techniques were used in only 26 (23.9%) patients. Immediate angiographic success was achieved in 104 (95.5%) patients. There were no vascular complications attributable to the sheathless catheter.

In the present study, the results showed that the use of the sheathless GC was safe and effective for transradial PCI in patients with LM bifurcation lesions. We have a high rate of procedural success (97.6%) with few complications despite the complex nature of the interventions being undertaken. MACE in all patients with LM bifurcation lesions was 2.4% during hospital stay. No conversion to a conventional GC was required, and neither did the crossover through a femoral artery access site. In all cases, 7.5-Fr sheathless GC passed through the radial arteries smoothly and no spasm occurred. The second sheathless GCs were used only in 4 patients because of inappropriate size or shape of the first sheathless GC.

In our study, a higher rate of true bifurcation lesions (46 patients, 56.1%) was treated by PCI. The sheathless GC allowed use of a wide range of bifurcation techniques and adjunctive devices. Two-stent technique was the most frequently used strategy (62 patients, 75.6%) in all the patients. Complex techniques included 31 (37.8%) "Crush," 18 (22.0%) "Cullote," and 13 (15.8%) "T stent." In cases treated by Crush technique, classic Crush was most frequently used than step crush, because 2 stents can be allowed to enter the big hole of 7.5-Fr sheathless GC.

The type of 7.5-Fr sheathless GC with strong support, including PB, super power back-up, and AL, was used in 61 of 82 patients (74.4%), and the type of judkin left was also used in 17 patients (20.7%). Even without an introducer sheath, 7.5-Fr sheathless GC has a powerful backup for PCI because of thicker catheter wall than 7-Fr conventional GC.

The safety of 7.5-Fr sheathless GC was also strongly concerned. There was no coronary complication induced by the GC or wire. The incidence of vascular complications was also very low in all patients. Hematoma greater than 5 cm developed only in 1 patient after procedure because of puncture with difficulty and recovered before discharge. Radial occlusion occurred in 2 (2.4%) patients, similar to the previous report.[21]

Although CABG has been considered the "gold standard" for unprotected LM disease revascularization, more recently, PCI has emerged as a possible alternative strategy of revascularization in patients with low and intermediate syntax scores,[24,25] and is becoming a more attractive choice of therapy over CABG.[26,27] In our study, there was a favorable outcome of PCI for LM bifurcation lesions during hospitalization despite of high syntax scores (average score of 28.1). But long-term follow-up is needed.

5. Conclusion

This report shows that PCI for LM bifurcation disease by TRA using a 7.5-Fr sheathless GC not only is feasible but also provides high efficacy with acceptable safety. Our study still has a number of limitations. First, this is a nonrandomized, observational study, the results of which may have been affected by a selection bias. Other limitations of the study are related to the single-center experience design and the limited sample size.

Author contributions

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