Complex percutaneous coronary interventions by transradial approach using sheathless guiding catheters

Stephane Noble, Robert Francis Bonvini, Caroline Frangos, Pierre-Frédéric Keller, Marco Roffi

Division of Cardiology, Department of Medicine, University Hospital of Geneva, Switzerland

Summary

Objective: To analyse our single centre experience with sheathless guiding catheters (GC) for complex percutaneous coronary interventions (PCI).

Background: Failure of performing transradial approach (TRA) increases with the sheath size used, especially in cases of small and tortuous radial arteries. The use of recently developed sheathless GC may facilitate performance of TRA for complex PCI requiring large-lumen GC.

Methods and results: We retrospectively analysed 20 consecutive patients who underwent complex PCI performed by TRA with a Sheathless Eaucath® GC (Asahi Intecc, Japan). The patients mean age was 68.9 ± 11.3 years. Indications for PCI were ST elevated myocardial infarction in 2 patients (10%), acute coronary syndrome in 4 (20%), and chronic stable angina in 14 (70%). Right TRA was used in all but one case. The 7.5-French (F) sheathless GC was used in all the procedures. Radial and brachial arteries crossing was possible in all cases with no associated procedural or GC-related complications. The number of vessels treated per patient was 1.30 ± 0.47 with 1.70 ± 0.92 stents implanted per vessel. The left main stem was the treated lesion in 9 patients (45%), 5 patients (25%) had complex bifurcation lesions and one (5%) had chronic total occlusion. The remaining 5 patients (25%) had severely tortuous and/or calcified coronary lesions. Rotablation was required in 2 procedures. Mean fluoroscopic time was 20.3 ± 7.5 min and mean volume of contrast media was 254 ± 83 ml.

Conclusion: This preliminary experience in complex PCI, suggests that TRA using 7.5-F sheathless GC might be an attractive alternative to transfemoral access using 7-F conventional.

Key words: transradial approach; sheathless guiding catheters; percutaneous coronary intervention

Funding / potential competing interests: No financial support and no other potential conflict of interest relevant to this article were reported.

Introduction

Vascular complications and the need for transfusion have been implicated in an increased mortality rate after percutaneous coronary interventions (PCI) [1], whereas the transradial approach (TRA) for coronary interventions has been shown to be associated with less vascular and bleeding complications than the transfemoral approach (TFA) [2, 3].

In the Mortal study which examined the association between access site, transfusion and outcomes in more than 32 000 consecutive patients undergoing PCI, TRA resulted in a relative reduction in 30-day and 1-year mortality of 29 and 17%, respectively (p <0.001) [4]. Furthermore the subgroup analysis of the recent RIVAL trial, with their inherent limitations, showed a reduction in mortality for STEMI patients treated by TRA compared to TFA. Despite these proven benefits, the potential difficulty of using large guiding catheters (i.e., >6-French [F]) by the TRA, often dissuades the operator from using this approach for complex coronary procedures. Nowadays, 7F guiding catheters (GC) are still required in complex PCI involving rotablation (burr >1.75 mm), chronic total occlusions or true bifurcation lesion treatment using a simultaneous double-stenting technique.

The recently developed Sheathless Eaucath® GC (Asahi Intecc, Japan) may theoretically be of great help to overcome these difficulties. These GC do not require any introducer sheath, thus reducing the equipment size within the radial artery lumen by approximately 2-F sizes. The aim of this report was to describe our early experience with the 7.5-F sheathless GC in complex PCI.

Correspondence:
Stephane Noble, MD
Interventional Cardiology Unit
Division of Cardiology
University Hospital, Geneva
CH-1211 Genève 14
Switzerland
stephane.noble[at]hcuge.ch

Methods and materials

From our computerised catheterisation laboratory database, we identified and retrospectively analysed 20 consecutive patients who underwent PCI performed by TRA with a 7.5-F Sheathless Eaucath GC. All the procedures involved complex lesions for which the operators considered to be safer to use a 7-F GC. These procedures were performed in a tertiary cardiac catheterisation laboratory between October 2009 and 2010 by four different interventional cardiologists, all experienced in TRA and all using the TRA as the default approach since January 2009. The objective of the study was to assess the feasibility of complex PCI by TRA using 7.5-F Sheathless Eaucath® GC.

Prerequisites for TRA were a palpable radial artery and a patent palmar arch based on a plethysmography test. Plethysmography type A, B and C were considered adequate for TRA whereas plethysmography type D (loss of pulse tracing without recovery within 2 minutes of radial artery compression) was not [5]. Coronary angiography was performed through a 5-F or 6-F Terumo introducer (Terumo, Tokyo, Japan) using classical 5-F diagnostic catheters as per routine practice in our centre.

The sheathless 7.5-F GC (fig. 1) has an inner diameter equivalent to a 7-F conventional GC and an outer diameter (2.49 mm) slightly inferior to that of a 6-F conventional introducer sheath (2.62 mm). Furthermore, the sheathless GC has a hydrophilic coating which facilitates crossing radial or brachial tortuosity as well as catheterising small calibre radial arteries (e.g., <2.5 mm). The sheathless GC is supplied with its own removable central dilator that extends beyond the distal tip in a tapered fashion allowing a very smooth GC-0.035' wire transition.

Technique of insertion

The 5- or the 6-F introducer sheath was exchanged over a standard 175 cm J-tipped 0.035" wire for a 7.5-F sheathless GC of the most adapted shape for the scheduled PCI. The sheathless GC insertion was performed using wet gauze in the left hand to lubricate the hydrophilic coating of the GC (fig. 2). Once the sheathless GC had reached the proximal ascending aorta, the central dilator and the 0.035" wire were removed. Finally coronary intubation was performed in the usual way. In the case of unadapted GC shape for the procedure, the exchange for a different guiding catheter was performed over the regular 175 J-tipped cm 0.035" wire while performing manual compression at the puncture site during the exchange manoeuvre.

Sheath removal and haemostasis

Immediately at the end of the procedure the sheathless GC was removed over a standard 175 cm J-tipped

Figure 1
7.5-F sheathless characteristics (modified from Frangos C, Noble S. How to transform you into a radialist: tips and tricks. Cardiovascular Medicine. 2011;14(10):315–24 [11]. Reprinted with permission).

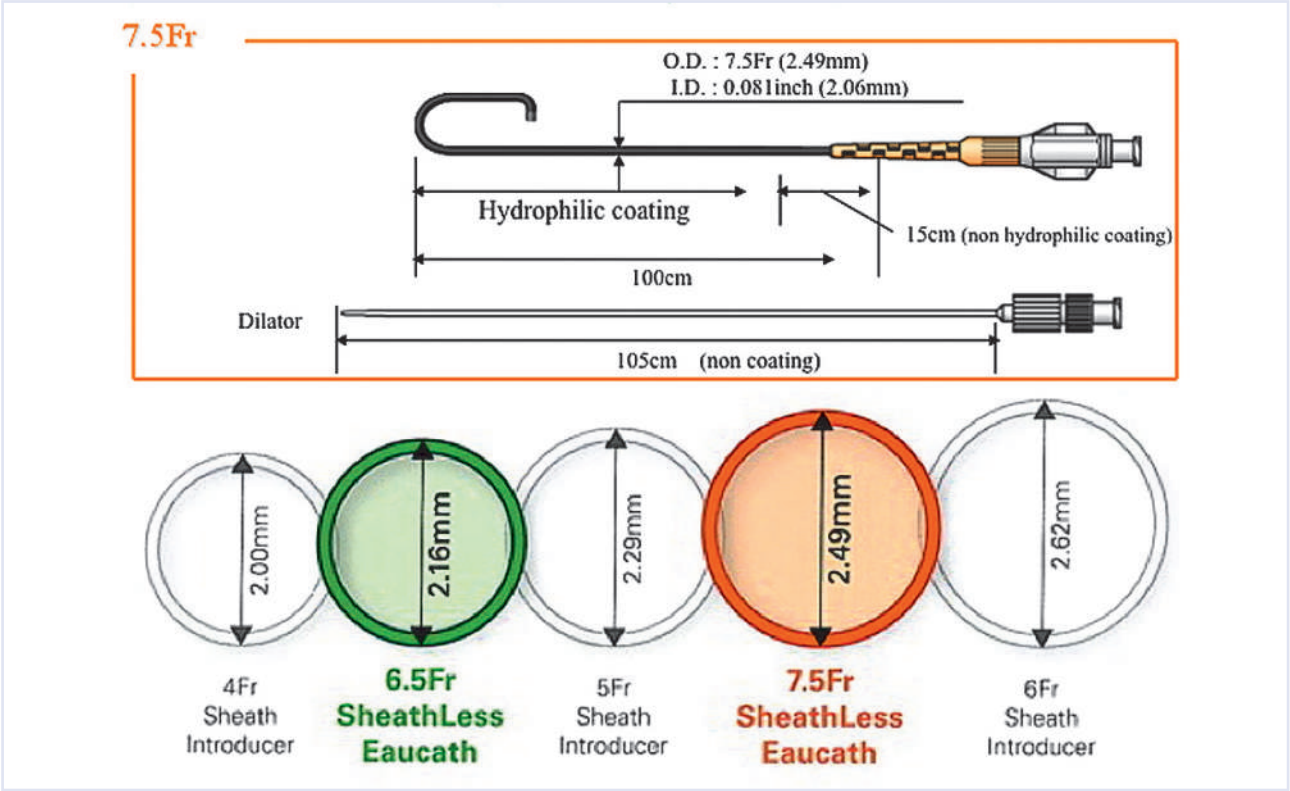
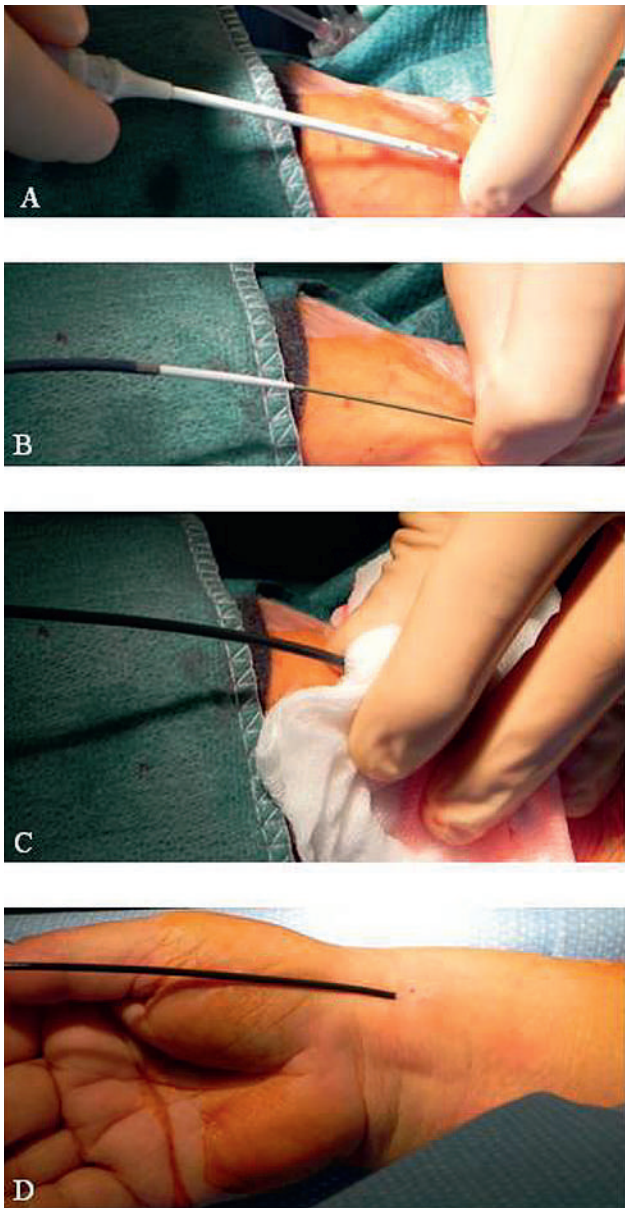


Figure 2
A 5-F sheath is removed.
B The Sheathless Eaucath® catheter is advanced over a 0.035" wire. The tapered tip is shown.
C Insertion of the sheathless GC through the skin to the artery using wet gauze to lubricate the hydrophilic coating.
D At the end of the procedure, before TR band use, sheathless GC goes into the radial artery. The catheter will be removed over a 0.035" wire.



0.035" wire with a radial TR Band (Terumo) ready to be applied at the puncture site in order to obtain immediate haemostasis. The TR band was maintained for 3 hours with an initial inflation between 13 and 15 ml of air, subsequently decreased every 30 minutes by 2 ml of air.

Definition

The number of diseased coronary arteries was defined by the number of major arteries with at least 70% stenosis by visual assessment. Stenosis ≥50% in the left main were considered as a two-vessel disease when the right coronary artery was dominant or codominant and as a three-vessel disease when the right coronary artery was rudimentary. Chronic total occlusion (CTO) was defined as an occlusion of more than 3 months duration [6].

Complex PCI were defined as treatment of lesions involving the left main stem, bifurcation lesion involving at least two major branches (i.e., >2.0 mm vessel diameter), chronic total occlusion, tortuous and/or severely calcified coronary segments.

Data analysis and statistical methods

Baseline characteristics were analysed for all patients. Continuous variables were expressed as means ± standard deviation or medians (interquartile range) and categorical variables as frequencies (%).

Results

In the 12-month period of this retrospective analysis, we included all 20 consecutive patients who underwent TRA complex PCI performed with a 7.5-F Sheathless Eaucath® GC. A total of 26 coronary lesions were treated. Baseline characteristic data and main procedural characteristics are provided in table 1 and 2, respectively. Radial puncture was performed on the right in all (95%) but one patient in whom the left radial artery was used because of a type D right radial artery plethysmography test. In all cases radial and brachial arteries crossing was without significant complication or technical difficulty.

Indications for PCI were chronic angina in 14 (70%), acute coronary syndrome in four (20%) and ST elevation myocardial infarction (STEMI) in two pa-

Table 1
Baseline characteristics (n = 20).

Baseline characteristics	Number of patients (%)
Mean age ± SD (years)	68.9 ± 11.3 (range 44–88)
Men	17 (85)
Diabetes	8 (40)
Hypertension	13 (65)
Hyperlipidaemia	12 (60)
Smoking history	9 (45)
Previous	6 (30)
Current	3 (15)
BMI ≥30 kg/m^2	6 (30)
Mean number of diseased CA ± SD	2 ± 0.84
1 VD	7 (35)
2 VD	6 (30)
3 VD	7 (35)

SD = standard deviation; BMI = Body Mass Index; CA = coronary artery; VD = vessel disease.

tients (10%). In 14 cases (70%) one vessel was treated and in the remaining 30% (six cases) two vessels were treated during the same procedure. The shapes of the GC used were mainly PB 3.5 (power back-up GC) for the left system and exclusively JR 4 (judkins right) for the right coronary artery ostium cannulation.

The number of vessels treated per patient was 1.30 ± 0.47 with 1.70 ± 0.92 stents implanted per vessel. Drug-eluting stents were used in 16 patients (80%). The left main stem was the culprit lesion in nine patients (45%), five patients (25%) had complex bifurcation lesions treated and one (5%) chronic total occlusion was successfully recanalised. The remaining five patients (25%) had tortuous and/or severely calcified coronary lesions. Rotablation was required in two procedures (fig. 3). The two patients with STEMI presentation had a large RCA bifurcation lesion and an ostial LAD lesion in the presence of trifurcation anatomy (i.e., LAD-LCX, intermediate branch), respectively. The NSTEMI patients had culprit lesions involving the left main (n = 2), an LAD-diagonal bifurcation (n = 1) and a circumflex-marginal bifurcation. Finally, kissing balloon inflation was used in all but one bifurcation lesion not involving the left main (80%), and in five out of nine left main lesions (56%). The reasons not to perform a final kissing balloon inflation in the left main stem were lesions involving the ostial portion (1), the mid shaft (1), the use of a V-stenting technique (1), and a trifurcation lesion with a good result after stent implantation.

Table 2
Procedural characteristics (n = 20).

Procedural characteristics	Number of patients (%)
PCI indication	
STEMI/Primary PCI	2 (10)
NSTEMI/UA	4 (20)
Stable angina/elective	14 (70)
Target vessel	
LAD	11
LCX	6
RCA	4
LM	4
Catheter used for the procedure	
PB 4.0	1 (5)
PB 3.5	9 (45)
SPB 3.5	4 (20)
SPB 4.0	1 (5)
SC 3.5	1 (5)
JR 4.0	4 (20)
Stent use	
DES	16 (80)
BMS	4 (20)
Mean number of vessels treated ± SD	1.3 ± 0.47
Mean number of stents used ± SD	1.7 ± 0.92
Mean fluroscopic time (min) ± SD	20.3 ± 7.5
Mean contrast volume (ml) ± SD	254 ± 83

BMS = bare metal stent; CTO = chronic total occlusion; DES = drug eluting stent; LM = left main; NSTEMI = non ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; UA = unstable angina; PB = power back; SPB = super power back; SC = special curve; JR = Judkins right; SD = standard deviation.

Discussion

With this series of 20 consecutive cases, we report our early experience with the 7.5-F sheathless GC used for complex PCI in both elective and emergency settings. Our experience confirms the previous results reported in other single-centre studies [7, 8]. We could perform the scheduled procedure without the need to exchange to conventional GC similarly to the recently reported largest series with 213 consecutive interventions using the 6.5 and 7.5-F Sheathless Eaucath® GC system [9].

In our study, for the RCA interventions the JR4 was the only catheter used. An Amplatzer® left 1–2 shape could have been an alternative in the case of insufficient back-up support or challenging RCA ostia take-off. For the left system the PB GC, with a shape similar to the Voda Left® Curve (Boston Scientific, MA, USA), was the most commonly used catheter and allowed successful procedure in all the attempted cases. Alternatively, the SPB (Super Power Back-up) or the SC (Special Curve) curves might also be used, however, these special shapes are slightly more challenging to manipulate especially for inexperienced radialists (fig. 4).

The potential advantage of the sheathless GC is to reduce the calibre of the vascular puncture since no sheath introducers are required, and therefore does not force the operator to use smaller GC which are associated with less effective back-up support. Indeed, sheathless GC are approximately 2-F sizes smaller than the corresponding introducer sheath and thus they are likely to significantly reduce radial artery injuries, especially in patients presenting with smaller radial artery size. Despite these theoretical advantages, our retrospective series cannot confirm a lower radial artery complication rate, since we did not routinely perform a Doppler examination of the radial puncture site after the procedure.

Moreover, procedures involving rotational atherectomy or left main stenting are commonly performed with a 7-F GC which is often difficult to insert by TRA, especially in the elderly, in women or in patients with low body mass index (BMI <18).The possibility of using large GC is particularly important in the elderly population, who often develop calcified coronary lesions requiring important back-up support in order to safely perform these complex PCI.

For routine PCI in patients with small radial artery (e.g., women), the 6.5-F sheathless GC is availa-

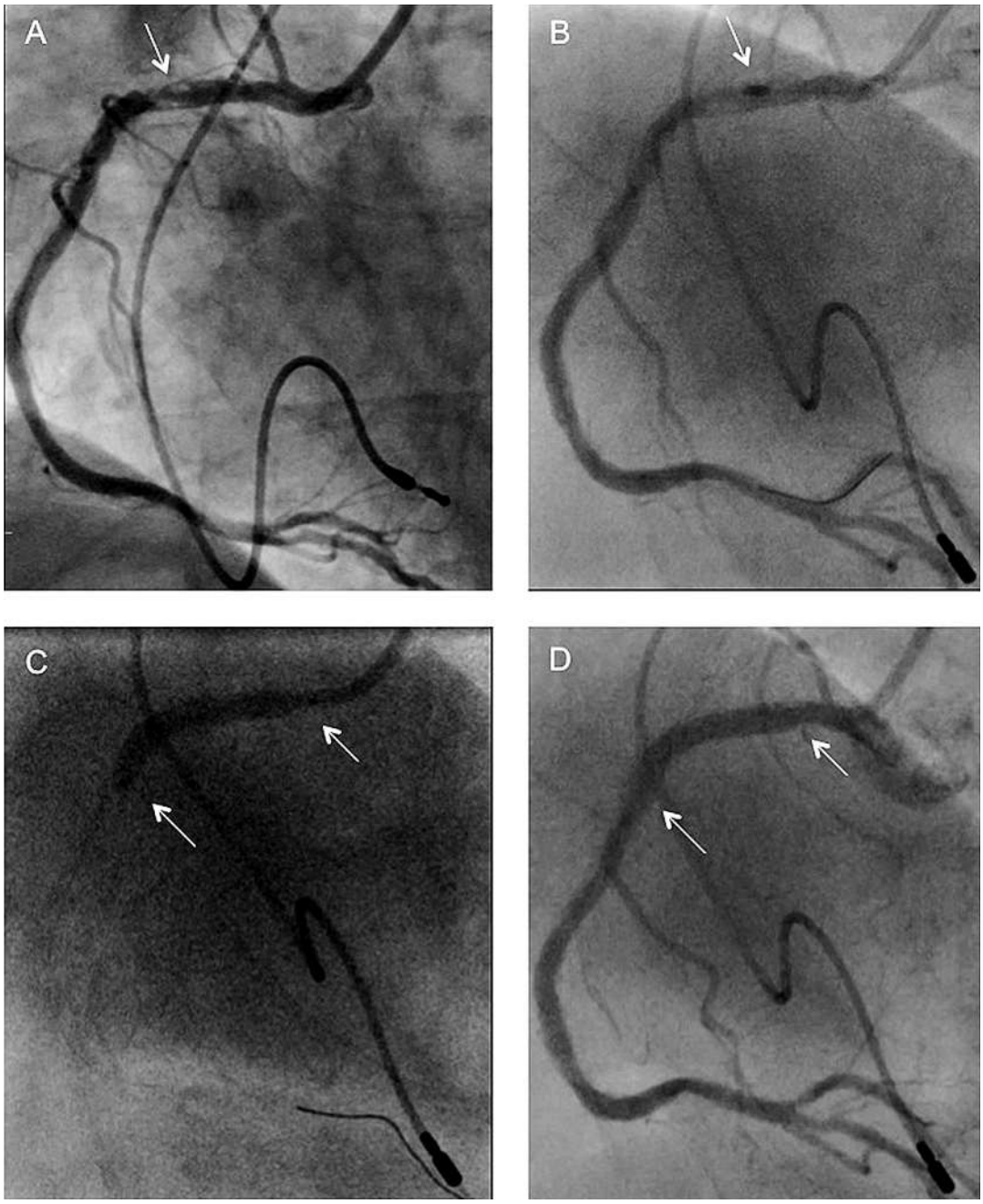


Figure 3
Right coronary artery rotablation. A 75-year-old man with severe symptomatic infero-apical ischaemia caused by a calcified right coronary artery severe lesion (arrow) (**A**) was treated by left TRA (right radial artery plethysmography type D) using a 7.5-F JR4 sheathless GC. Once the floppy rotawire (Boston Scientific) was positioned distally in the posterior descending artery, a 1.75 mm burr (arrow) was used for high-speed rotational atherectomy (**B**). Subsequently, a universal body middleweight wire and an Extrasport wire (buddywire) were positioned distally to the lesion. Predilatation was followed by the implantation of a 3.5 × 30 mm bare metal stent (arrows on panel **C** and **D**) at 18 atmospheres (**C**) with an excellent final angiographic result (**D**).

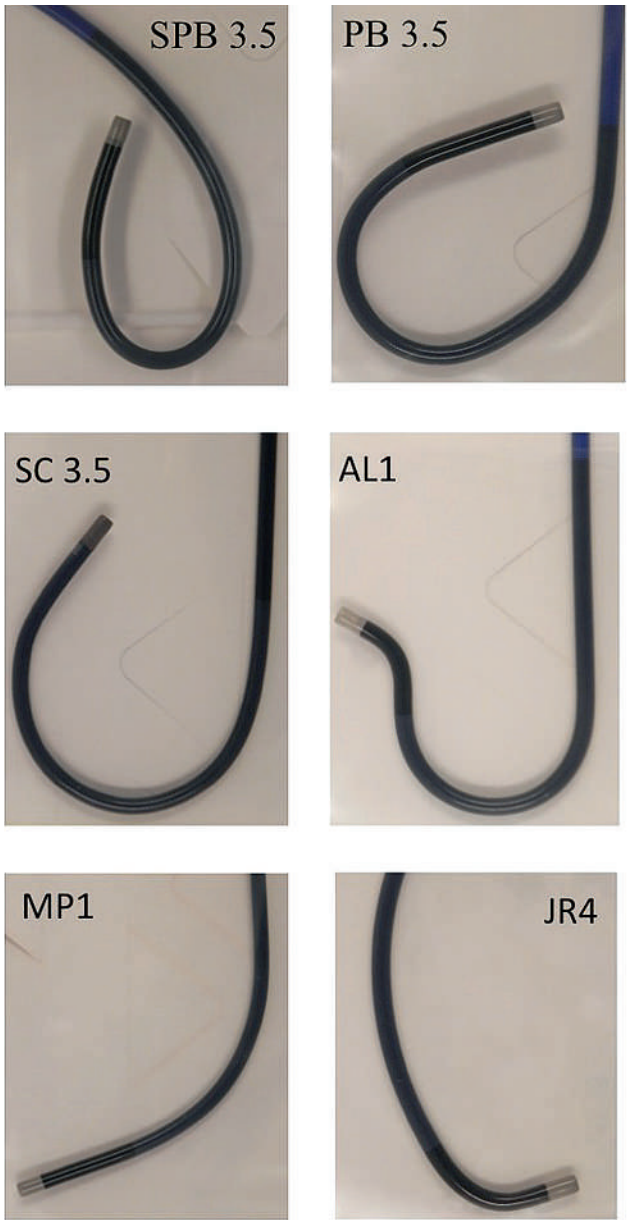


Figure 4
Different shapes of the Eaucath Sheathless® guiding catheter.

ble. This latter GC is an interesting alternative to a conventional 5-F GC, because it has an inner diameter equivalent to a 6-F conventional GC with an outer diameter (2.16 mm) inferior to that of a 5-F conventional sheath (2.29 mm). Medikit in Japan produces another sheathless guiding catheter called Virtual 3-F (10), but up to now it has only been available in a 5-F GC, comparable in size with a 3-F sheath.

Other advantages of these sheathless GC are the hydrophilic coating and the tapered profile which facilitate radial and brachial arteries crossing. In the case of tortuous or small radial and brachial arteries, the "telescoping technique" or the "mother and child technique" (using a long 125 cm 5-F JR diagnostic catheter inserted into a 100 cm 6- or 7-F GC) is a possible alternative to simulate the tapered profile of the sheathless GC [11]. However this technique uses material that is not covered with a hydrophilic coating and the tapered profile is suboptimal especially when using a 7-F GC.

Different reports [7, 9] have mentioned the use of a transparent adhesive film at the radial entry to avoid GC slippage during the procedure. In our series we did not use such a technique and did not experience GC slippage. Indeed, when the hydrophilic coating of the sheathless GC is not wet (i.e., few minutes after the insertion), it remains as stable as a sheath at the radial entry since it is gripped by the skin.

When using this innovative device, the operators should know that the dilator is not radio-opaque and particular attention should be paid to not push the dilator too deep into the ascending aorta in order to avoid aortic cusp perforation. Furthermore, as the catheter has a hydrophilic coating, using wet gauze positioned at the skin incision will lubricate the catheter and facilitate the insertion.

Conclusions

This preliminary experience in complex PCI suggests that TRA using 7.5-F sheathless GC might be an attractive alternative to transfemoral access using a 7-F conventional guide catheter. This innovative device might increase the spectrum of patients treated by the transradial approach. Further investigations are required to define the exact role of these catheters in daily practice and their impact on the rate of radial occlusion.

References

1 Doyle BJ, Rihal CS, Gastineau DA, Holmes DR Jr. Bleeding, blood transfusion, and increased mortality after percutaneous coronary intervention: implications for contemporary practice. J Am Coll Cardiol. 2009; 53:2019–27.
2 Agostoni P, Biondi-Zoccai GGL, De Benedictis ML, Rigattieri S, Turri M, Anselmi M, et al. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures. J Am Coll Cardiol. 2004;44:349–56.
3 Jolly SS, Amlani S, Hamon M, Yusuf S, Mehta SR. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: A systematic review and meta-analysis of randomized trials. Am Heart J. 2009;157:132–40.
4 Chase AJ, Fretz EB, Warburton WP, Klinke WP, Carere RG, Pi D, Berry B, Hilton JD. Association of the arterial access site at angioplasty with transfusion and mortality: the MORTAL study (Mortality benefit Of Reduced Transfusion after percutaneous coronary intervention via the Arm or Leg). Heart. 2008;94:1019–25.
5 Barbeau GR, Arsenault F, Dugas L, Simard S, Larivière MM. Evaluation of the ulnopalmar arterial arches with pulse oxymetry and plethysmography: Comparison with the Allen's test in 1010 patients. Am Heart J. 2004;147:489–93.
6 Stone GW, Kandzari DE, Mehran R, Colombo A, Schwartz RS, Bailey S, et al. Percutaneous recanalization of chronically occluded coronary arteries: a consensus document: Part I. Circulation. 2005;112:2364–72.
7 Mamas M, D'Souza S, Hendry C, Ali R, Iles-Smith H, Palmer K, et al. Use of the sheathless guide catheter during routine transradial percutaneous coronary intervention: a feasibility study. Catheter Cardiovasc Interv. 2010;75:596–602.
8 Mamas MA, Fath-Ordoubadi F, Fraser DG. Atraumatic complex transradial intervention using large bore sheathless guide catheter. Catheter Cardiovasc Interv. 2008;72:357–64.
9 Sciahbasi A, Mancone M, Cortese B, Pendenza G, Romagnoli E, Fischetti D, et al. Transradial percutaneous coronary interventions using sheathless guiding catheters: a multicentre registry. J Interv Cardiol. 2011;24:407–12.
10 Mizuno S, Takeshita S, Taketani Y, Saito S. Percutaneous coronary intervention using a virtual 3-Fr guiding catheter. Catheter Cardiovasc Interv. 2010;75(7):983–8.
11 Frangos C, Noble S. How to transform you into a radialist: tips and tricks. Cardiovascular Medicine. 2011;14(10):315–24.