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Usefulness of sheathless guide catheter for the percutaneous coronary intervention of left main disease by radial approach



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Over the last decade the use of the radial approach for percutaneous coronary intervention (PCI) has increased [1]. This strategy offers several advantages over femoral access such as lower risk of related-vascular complications [2] and fewer major cardiovascular events in acute coronary syndromes (ACS) [3]. However, the small radial diameter and lower catheter-support are limitations for complex PCI, such as left main (LM) disease PCI.

Sheathless Eaucath® (ASAHI Intecc) catheter is designed to provide greater luminal diameter with smaller outer diameter in transradial PCI [4]. For this reason, it can potentially improve the results of PCI of LM through radial approach. Our study aims to assess the feasibility of radial approach and sheathless guide for PCI of the LM disease.

We conducted a prospective study of all consecutive patients in whom PCI was performed on LM by radial approach using this type of catheter between December 2009 and July 2015. Data was collected from two centers with more than 10 years of experience in transradial PCIs in Spain (more than 90% of the procedures in both cases). Indication for catheterization, revascularization and periprocedural treatment were in accordance with clinical guidelines and usual practice [5]. In stable clinical situations, decision of PCI was made according with local cardiology team. In unstable situations emergent PCI was performed. All technical aspects were left at the discretion of the operator. No formal exclusion criteria were applied once patients were selected for PCI.

Clinical, angiographic and procedural data were recorded. Efficacy of the procedure was defined as the achievement of optimal angiographic

result and TIMI 3 flow grade. Periprocedural complications and major clinical events (death, myocardial infarction or repeated revascularization) during the follow-up were ascertained.

Sheathless Eaucath guide catheter has a design that avoids the need of sheath use. Fig. 1A shows the inner and outer diameter of 6.5F and 7.5F sheathless. Different curve shapes are available. For its use, first a radial sheath is placed, and then, it is exchanged by the sheathless catheter using a 260 cm guidewire (Fig. 1B). The use of medications did not differ from the standard PCI. Anti-spasm medications were only administered before the exchange between the initial sheath and the sheathless catheter.

Continuous variables were expressed as mean \pm 1 standard deviation (SD) or median [interquartile range (IQR)] when appropriate. Discrete variables were summarized as percentages. Rates of major clinical events rates were depicted with Kaplan–Meier method. All analyses were performed using STATA 13.1 (StataCorp. 2013. Stata Statistical Software: Release 13.1. College Station, TX: StataCorp LP).

109 consecutive patients were included. Once sheathless catheter was initially selected as a guide catheter for PCI, no crossover to standard catheters were registered. Baseline characteristics are summarized in Table 1. Briefly, mean age was 73.6 (\pm 10.6) years, 89 (81.7%) were male, 55 (50.5%) patients had previous history of coronary artery disease, and 88 (80.7%) had an index episode of ACS. Regarding coronary anatomy, distal disease was present in 93 patients (85.3%), severe calcification was present in 68 patients (62.4%), and the mean \pm SD Syntax score was 32.4 \pm 15.8. Mean Euroscore was 9.05 \pm 8.5. In 14 (12.8%) cases intra-aortic balloon counterpulsation pump was required, either because of hemodynamic instability or high risk. Killip class at admission was 3 or 4 in 19 patients (17.2%).

In 94 cases (95.4%) procedure was performed by left radial approach. Guide catheter used was sheathless Eaucath (Ashahi®) in all cases, 7.5F wide in 86 (78.9%). In bifurcated lesions, provisional stenting was the most frequently used strategy (72 patients, 66.1%). Complex techniques included 23 (21.1%) “Crush”, 2 (1.8%) “T stent and minimal protrusion” (TAP), and 1 (0.9%) “Cullote”, using final kissing balloon in 37 cases (33.9%). Rotational atherectomy was required in 25 patients (22.9%). Intracoronary imaging was used in 54 (49.5%) patients.

Immediate angiographic success was achieved in 104 (95.5%) patients, with no crossover to femoral approach. 152 stents were implanted in 102 patients (1.49 stents per patient); in 2 cases paclitaxel eluting balloon were used.

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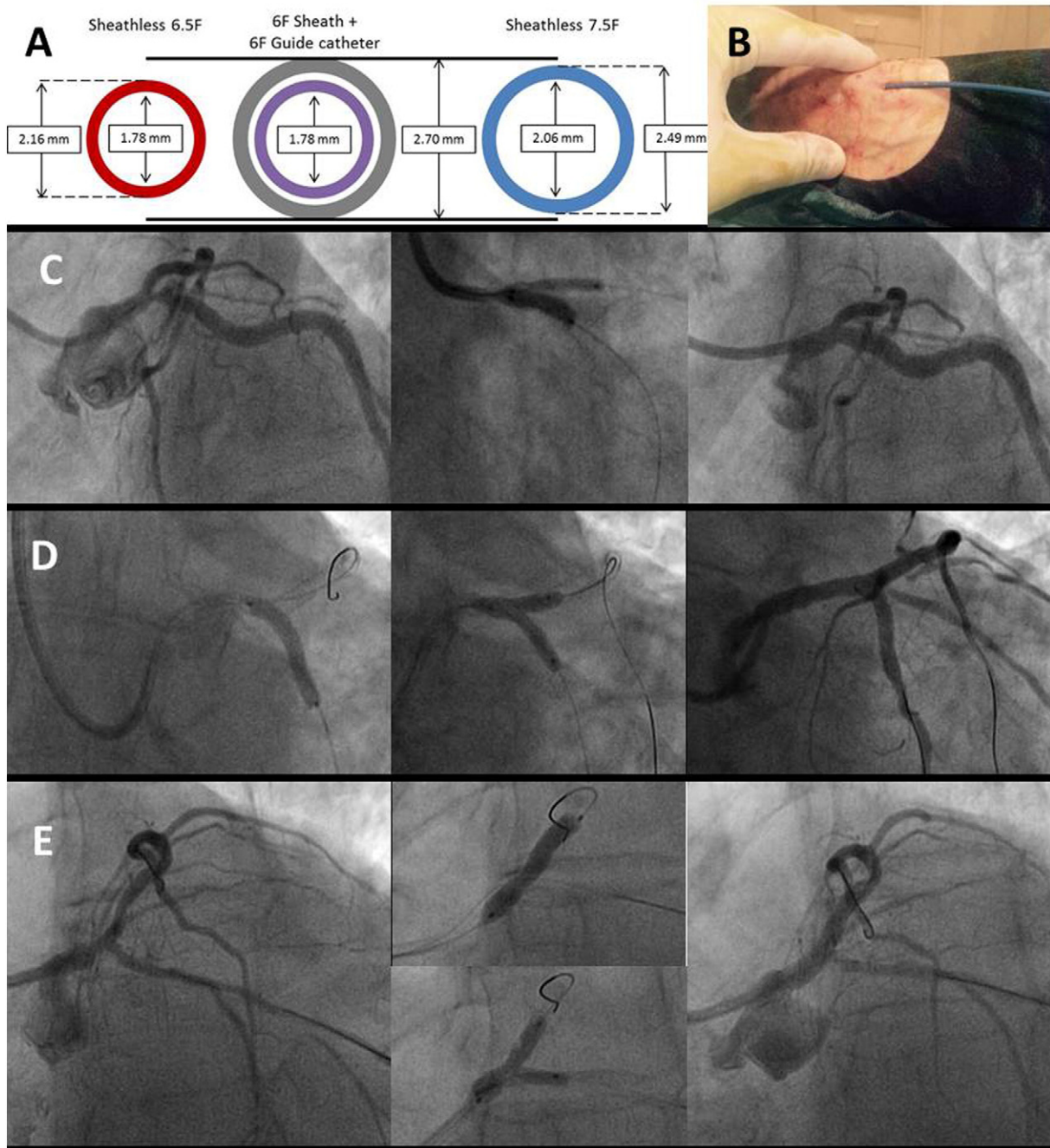


Fig. 1. (A) Comparison of inner and outer diameters of 6.5 and 7.5 sheathless catheters and 6F guide catheter with sheath. (B) Example of inserted sheathless catheter. (C–E) 3 examples of LM PCI with sheathless catheter. (C) Provisional stent from LM to Cx and kissing balloon. (D). 2-Stent Culotte technique. (E). Provisional stent LM to LAD.

Fig. 2 shows the Kaplan–Meier curve. At 30-day follow-up, there were 15 (13.8%) MACE, 13 deaths and 2 NSTEMI. During the extended follow-up [median of 292 days (interquartile range 115–472)], 30 major cardiovascular events were registered (27.4%), 25 (23%) of them were deaths for any cause (70% cardiovascular deaths). Six periprocedural complications were registered: 4 deaths, 1 cardiogenic shock, and 1 dissection of the distal edge of the implanted stent (Table 2). It is noteworthy that all periprocedural complications occurred in patients with ACS, and they were no related to Sheathless use. No vascular complications or major bleeding were observed during index hospitalization.

This report shows that PCI of LM disease by transradial approach using a sheathless guiding catheter not only is feasible but provides high efficacy with acceptable safety margin.

Currently, the role and importance of radial approach is increasing. It is a feasible route with high performance and lower risk of bleedings and vascular complications, particularly in patients with ACS [1–3]. However, the smaller arterial size (and risk of radial spasm) limit the guide diameter and thus, impose lower strength support for PCI. These challenges limit the use of this route for complex PCI.

Percutaneous treatment of LM disease is a feasible and safe alternative to CABG surgery, with comparable results in subgroups of low and intermediate anatomical complexity [5,6]. LM PCI is frequently challenging, especially if the distal segment is involved, requiring larger diameter guide and increased support. Sheathless guide catheter provides a wider lumen with smaller outer diameter. In all cases in our series it was possible to exchange and manipulate it properly for engaging selectively the LM ostium. These features provide a solution to the main limitation of

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