Advantages of a workbench reshaped AR1 mod catheter for right coronary angiography by right radial approach

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Abstract: Transradial approach in cardiac catheterization is increasing. In daily practice, coronary angiography via radial artery is usually performed by using catheters designed for femoral approach. The aim of this study was to evaluate advantages in the use of a workbench reshaped AR1 mod catheter, in terms of procedural duration time, number of catheters per procedure, fluoroscopy time, contrast agent administered volume, images quality and costs. Two hundred patients, submitted to coronary angiography via right radial artery in our institution, have been retrospectively reviewed. Patients have been divided in two groups, depending on whether a workbench reshaped Cordis Amplatz AR1 mod catheter (rAR1 mod), or catheters in their original shape (OC) have been employed. In the rAR1 mod group (100 patients) a lower number of catheters per procedure (1.07 ± 0.25 vs. 1.47 ± 1.65; \( p < 0.001 \)), a more frequent right coronary selective engagement (76.76% vs. 53.12%; \( p < 0.001 \)), a smaller amount of contrast agent (63.02 ± 27.77 vs. 80.85 ± 29.22 ml, \( p < 0.001 \)), a reduced fluoroscopy and global procedural time (4.19 ± 2.91 vs. 5.69 ± 3.85 min, \( p = 0.004 \); and 34.58 ± 17.05 vs. 42.58 ± 17.26 min, \( p = 0.001 \), respectively) were observed. According to our experience, when right coronary angiography via right radial approach is performed, the utilization of rAR1 mod catheter correlates with multiple advantages in terms of procedural parameters.

Keywords: coronary angiography, right coronary artery, right radial artery approach, suggestions for radial approach beginners, coronary catheter

Introduction

The radial approach is rapidly earning consensus among interventional cardiologists to perform selective coronary angiography, since it shows lower incidence of major vascular bleedings and associated mortality [1–4]. Moreover, it could rely on a higher patient compliance, because of a shorter hospitalization and the possibility to walk earlier after the intervention [5]. The right radial route is the preferred approach compared to the left one, since the left radial artery is a potential surgical conduit; meanwhile, it has been reported to be feasible and effective as much as the left radial approach but it is associated with a longer procedure and a higher radiologic exposure [6]. Despite the increasing diffusion, only few manufacturers have produced catheters specifically designed for trans-radial cardiac catheterization and catheters conventionally designed for femoral approach are commonly used [6]. Among these, the Cordis Amplatz AR1 mod 5F (Cordis Corporation, Miami Lakes, FL, USA) has been routinely used in our cathlab. Recently we have started to use a workbench reshaping of the Cordis Amplatz AR1 mod 5F (rAR1 mod), in order to obtain a more selective cannulation of the right coronary artery. To test its usefulness we have compared the performance of rAR1 mod vs. Cordis Amplatz AR1 mod 5F or other wild catheters, in terms of procedure duration, number of catheters per procedure, fluoroscopy time, total amount of administered contrast agent, selective efficacy in right coronary cannulation and costs.
Methods

Study population

Having accomplished a learning curve (at least 200 procedures for each of four operators, according to the suggested ESC recommendations [7]), 200 patients undergoing coronary angiography with a right radial approach in our Institution have been retrospectively reviewed. Patients were divided in two groups: the former consisted of the 100 consecutive patients, studied between May and August 2012, in whom right coronary angiography was performed by using a workbench reshaped AR1 mod (rAR1 mod group) and the latter consisted of the 100 consecutive patients, evaluated between January and March 2012, in whom right coronary angiography was carried out with the original Cordis Amplatz AR1 mod 5F or other 5F right catheters (OC group). After some positive attempts with the rAR1 mod all the operators decided to move to using the workbench reshaped catheter on a regular basis. Our retrospective analysis was restricted only to the findings of diagnostic native coronary artery angiography, regardless surgical conduit evaluation or percutaneous coronary intervention (PCI) treatment; patients who underwent IVUS or FFR have also been excluded.

Procedural time was calculated as the interval between the registration of the patient and the end of the procedure. Fluoroscopy time was automatically measured by our catheterization laboratory control system (SAMPTE, Philips, Koninklijke Philips Electronics N.V.). Selective engagement was visually evaluated by two expert operators (CB and MM) in relation to the proper seating of the catheter tip beyond the right coronary ostium. Costs analysis was comprehensive of procedural standard kit, vascular wires, catheters and contrast agent, as automatically generated by our data-base system (CardioPlanet, V.4.1, ESAOTE S.p.A.).

Amplatz AR1 mod reshaping

Amplatz AR1 mod workbench reshaping is performed in two steps, first by neutralizing the secondary curve and reversing it in an opposite way to achieve a convex shape (Fig. 1A), then stretching the primary curve in order to elongate it by increasing its bending radius (Fig. 1B). A comparison between original catheter (upper) and workbench reshaped Cordis Amplatz AR1 mod (lower) (Fig. 1C).
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to increase its bending radius (Fig. 1B): in our observation these combined maneuvers allow the catheter, coming from the right subclavian artery, to easily engage the right coronary ostium. The final Amplatz AR1 mod reshaping, compared to the original Amplatz AR1 mod, is shown in Fig. 1C.

Statistical analysis

Continuous variables have been expressed as the mean ± standard deviation and categorical variables as percentage. The analysis of differences between the two groups has been performed by Student’s unpaired t-test for continuous variables and χ² test for categorical variables. All values have been analyzed bilaterally and p values < 0.05 have been considered significant. All statistical analyses have been performed using SPSS for Windows, version 19.0 (SPSS Inc., Chicago, IL, USA).

Results

No significant differences were observed in demographic and clinical findings between the two study groups (Table I). Technical and procedural aspects are listed in Table II.

In the OC group the AR1 mod catheter was the most frequently used, while AR1 and JR 4 catheters were used at a lesser extent.

In rAR1 mod group a reduced number of right catheters (1.07 ± 0.25 vs. 1.47 ± 1.65; p < 0.001) has been used. The selective engagement of right coronary ostium was more frequently achieved in rAR1 mod population (76.76% vs. 53.12%; p < 0.001). Fluoroscopy time and global procedural time were reduced in rAR1 mod (4.19 ± 2.91 min vs. 5.69 ± 3.85 min, p = 0.004; and 34.58 ± 17.05 min vs. 42.58 ± 17.26 min, p = 0.001, respectively). Finally, in rAR1 mod group a significantly smaller volume of administered contrast agent and lower costs have been observed (63.02 ± 27.77 ml vs. 80.85 ± 29.22 ml, p < 0.001;
Fig. 2. The histogram graph shows the reduction of catheter numbers, fluoroscopy time, total contrast volume, whole procedural time and cost, with a higher rate of selective engagement obtained by the use of rAR1 mod catheter. Error bars represent one standard deviation.

| Number of catheters | Fluoroscopy time (mean ± SD) | Procedural time (mean ± SD) | Contract volume (ml; mean ± SD) | Selective engagement (%) | Costs (euros; mean ± SD) |
|---------------------|------------------------------|-----------------------------|---------------------------------|--------------------------|--------------------------|
| rAR1 mod | 7.5 ± 2.0 | 15 ± 3.0 | 1.2 ± 0.3 | 80 ± 10 | 200 ± 50 |
| OC | 10 ± 4.0 | 20 ± 5.0 | 1.5 ± 0.5 | 60 ± 15 | 250 ± 70 |

Fig. 3. Right coronary artery cannulation, by using original and reshaped AR1 mod catheters. In the left side, panels A (upper) and B (lower) show left radial and femoral approaches, respectively. In the right side, panel C (upper) shows the pathway of the original catheter in subclavian-innominate-aorta axis, leading to an unselective engagement of right coronary ostium; panel D (lower) shows the reshaped Cordis Amplatz AR1 mod that, by inverting secondary curve in a convex shape (see arrow), provides a selective engagement of right coronary ostium.
and 142.96 ± 27.32 vs. 167.82 ± 50.69 euros, p < 0.001; respectively). Figure 2 shows the global benefit obtained by using the rAR1 mod for the right radial approach in right coronary artery cannulation. No peri- or post-procedural complications occurred in both groups.

Discussion

Our retrospective study demonstrates that a workbench reshaping of an Amplatz AR1 mod catheter results in a faster and easier performance of right coronary artery angiography via right radial approach, with a significant reduction of contrast use, X-rays exposure, catheters number and procedural costs, with an increased percentage of right coronary selective cannulation.

The increase in radial approach for cardiac catheterization is associated with a reduction in bleeding complications with a lower mortality [2, 8–13]. However, in a recent randomized trial radial and femoral approaches showed comparable efficacy in terms of procedural success, despite the reported more prolonged fluoroscopy time in patients managed by the radial route [14]. According to the indications of a consensus document edited by European Society of Cardiology, radial approach should be preferred, in patients with high bleeding risk, such as elderly and patients treated by triple antiplatelet therapy [7, 15, 16]. A recent meta-analysis demonstrated a lack of advantage, in terms of death rate, for radial approach even though two different randomized studies reported a lower mortality in STEMI patients [17–19].

In the left radial approach (Fig. 3A) the catheter proceeds along the aortic arch, in the same way as in the femoral approach (Fig. 3B), whereas in the right radial approach (Fig. 3C) the catheter is twisted in an S shape along the subclavian-innominate-aorta axis, which translates in a more difficult engagement of the coronary ostia, especially in elderly patients [20]. Consequently both an increased fluoroscopy time and a higher contrast agent administration frequently occur. Compared to other types of right coronary catheters, in rAR1 mod we carry out an inversion of its secondary curve, that allows the catheter to lean against the posterior side of ascending aorta, thus favoring the selective engagement of the right coronary ostium (Fig. 3D). Accordingly, the statistically significant reduction of the number of catheters used and the significant reduction of global procedural and fluoroscopy times, with a consequent shorter chest irradiation, due to a faster procedure are derived from the use of the rAR1 mod catheter. Furthermore, rAR1 mod provides a more frequent selective engagement of right coronary ostium, with better quality images (Fig. 3). In this way the potential weak point of the radial approach compared to the femoral one, in terms of more prolonged procedural time, should be neutralized by a workbench maneuver able to reduce total radiation exposure. Moreover, the significant smaller volume of contrast agent, due to a better and faster right coronary engagement, is obviously useful in decreasing potential contrast induced nephropathy [21]. A systematic use of rAR1 mod leads to a mean sparing of 25 euros for each diagnostic procedure.

Furthermore, the reduction of catheters number to be used possibly results in a reduction of radial artery manipulations and traumatism, thus reducing the rate of local spasm and improving the patient’s compliance to the procedure. Finally, the global benefit observed by using the rAR1 mod could make easier and faster the learning curve of the beginners in the phase of transition from femoral to right radial approach; this transition has been revealed particularly demanding, since Sciahsbasi et al. have shown that a learning curve associated with a right radial approach is longer than the left radial one [22].

Study Limitations

The main limitation of our study is the retrospective design: we are aware of the potential confounders within a comparative analysis, even though the significant advantages in terms of easier and faster selective engagement of RCA show a global better performance of the rAR1 mod catheter in our study. Another important limitation is the fact that we were unable to compare the customized rAR1 mod catheter to the specifically designed for radial approach TIG catheter which is not commercially available in our region. The length of the procedure was done by a comparison with a control group in a non-randomized manner; therefore, possible bias associated with this type of analysis cannot be ruled out. Furthermore, all our data have been evaluated in a comparative manner. In our retrospective study we did not perform a more specific sub-analysis to the coronary ostium engagement with rAR1 mod catheter in unfavorable anatomical settings, such as shepherd’s crook or posterior takeoffs; probably it should be of a great interest to address systematically the performance of rAR1 mod catheter in challenging approaches of the right coronary artery. Individual manual skills of the operators might have influenced the procedural outcomes, but all of them had a similar experience in radial approach and moved at the same time to the use of the customized catheter. Finally, our findings have been validated only in the diagnostic setting of coronary angiography.

Conclusions

In the present study the utilization of a workbench reshaped AR1 mod catheter showed an advantage in terms of catheters number, procedural time, radiation expo-
sure, contrast medium total volume, selective engagement and costs. This proposed reshaping of a commercially available catheter may represent a useful suggestion for the beginners involved in the right radial approach learning curve. Furthermore it could potentially open new opportunities in the design of catheters for right radial approach. Further randomized studies are needed to extend the value of our findings in procedural settings such as, preliminary non-angiographic evaluation (IVUS or FFR), elective PCI or acute coronary syndromes percutaneous treatment.

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Authors’ contribution: CB designed the study, wrote the manuscript and made revisions; MM assisted the study design, wrote the manuscript and performed the statistical analysis; MDM contributed to take the data; TA, MRDM, FV, RF performed coronary angiographies, MVP contributed to take the data; PG revised the manuscript; FP improved the quality of the manuscript in the subsequent revisions.

Conflict of interest: We have no conflict of interest to declare.

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