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# Sheathless radial approach in contemporary coronary rotational atherectomy: data from two high-volume centers

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## Abstract

**Aim:** To analyze the feasibility and procedural outcome of percutaneous coronary intervention (PCI) using rotational atherectomy (RA), performed via transradial sheathless guiding catheter, as compared to a standard radial and femoral vascular approach.

**Methods:** All consecutive patients undergoing RA at two high-volume PCI centers from May 2011 to May 2023 were included. Comparisons were made between the two transradial approaches and between the three types of vascular access.

**Results:** Two hundred twenty-three patients were enrolled. Baseline characteristics were similar, with the exception of gender. We observed, in percentages, fewer cases of failure for sheathless than standard transradial attempts (7.5% *vs.* 11.5%, respectively), whereas all trans-femoral attempts were successful. Transfemoral procedures were longer and more frequently performed under mechanical circulatory support. There was no difference in procedural success between the three vascular approaches. A trend towards a higher rate of vascular and bleeding complications was found in the femoral group.

**Conclusion:** Sheathless transradial vascular access is a viable option when performing RA during complex PCI procedures, tending to result in fewer failures than the standard transradial approach and reduced bleeding and vascular complications compared to the femoral method.

**Keywords:** Rotational atherectomy, coronary calcium, percutaneous coronary intervention, vascular access, sheathless guiding catheter

## INTRODUCTION

There is compelling evidence of reduced overall mortality, major adverse cardiovascular events, and vascular complications with the use of radial rather than femoral access for percutaneous coronary interventions (PCIs)[1]. Although the femoral artery has traditionally been chosen to perform coronary rotational atherectomy (RA), the contemporary approach is based on mindfully selecting the vascular access according to the required burr size and operator experience[2]. Data from the British Cardiovascular Intervention Society registry show the feasibility of RA through the radial artery, and a reduction in major bleeding and vascular complications compared with femoral access in a large cohort[3]. Indeed, a standard radial approach has relatively few limitations, such as cases of radial artery occlusion, calcific narrowing, tortuosity of the supra-aortic vessels, and the need for a large bore catheter or increased backup.

Key elements in choosing the guiding catheter for RA are aorto-ostial disease, backup and burr size requirement, and vascular access status[2]. Of note, a thin-walled hydrophilic sheath or a sheathless guiding catheter (SGC) are alternative options to the standard radial approach in complex procedures, allowing the previously listed limitations to be overcome[4]. Few reports describe cases of RA through an SGC[5]. One single-center analysis of 135 patients undergoing RA reported similar outcomes between procedures performed via standard femoral and radial access using an SGC[6]. In addition to maintaining the advantages of a transradial approach over the femoral one, the use of an SGC could conceivably increase procedural feasibility compared to the standard radial approach, thanks to its ability to navigate unfavorable vascular anatomies. Considering the paucity of data, we analyzed RA outcomes according to vascular access route and use of an SGC.

## METHODS

This is a retrospective longitudinal analysis including two high-volume Italian PCI centers: the Cardiology Unit of the "Morgagni-Pierantoni" Hospital in Forlì, and the Cardiology Unit of the "Gaetano Martino" University Hospital in Messina.

### Patient selection

All consecutive patients who underwent coronary revascularization with the use of RA between May 2011 and May 2023 were included, irrespective of clinical presentation.

### Data collection

The study was approved by the local ethics committee (CE-ROM) and submitted to the regional web-based platform on health research in Emilia-Romagna (SIRER). Clinical, imaging, and follow-up data were obtained from hospital and outpatient clinical records. Data were processed anonymously in accordance with local privacy procedures. This study was conducted in line with the declaration of Helsinki and the national principles regarding clinical trials.

### Procedural characteristics and definitions

All procedures were performed by trained interventional cardiologists, consistent with international recommendations[2]. Vascular access choice, use of intravascular imaging, stenting strategy, and antithrombotic therapy were at the operator's discretion. The target activated clotting time value was between 250 and 300 s. In the standard radial or femoral approach, a 6 to 8 Fr vascular sheath was placed to accommodate the equivalent guiding catheter. Alternatively, a 7.5 Fr SGC Eaucath™ (ASAHI Eaucath SGC; Vascular Perspectives Ltd., Manchester, UK) was used for radial procedures.

RA was performed using the Rotablator™ or, in the last three years, the Rotapro™ Rotational Atherectomy System (Boston Scientific, Natick, MA, USA), with a default targeted 0.5-0.6 burr-to-artery ratio, speed between 140,000 and 170,000 rotations per minute, continuous lavage with heparinized saline, and a pecking motion of the burr in series lasting about 10 s. A temporary pacemaker lead was placed only in the event of a new onset of a persistent rhythm disorder [Figure 1].

Access-related feasibility was evaluated by analyzing the initial approach and technique in relation to the subsequent need for a change in vascular access (radial *vs.* femoral) or device (standard *vs.* sheathless) in order to engage the coronary ostium and initiate revascularization. Procedural success was defined as coronary stenosis < 20% of the lumen diameter after successful delivery and withdrawal of the employed devices[7]. Bleedings were classified according to the Bleeding Academic Research Consortium (BARC)[8].

### Study objective

The purpose of our study was to analyze procedural feasibility, final success, and complication rate, comparing the use of a transradial sheathless catheter to the standard radial and femoral vascular approach. Long-term survival was a secondary outcome measure.

### Statistics

The population was divided according to the vascular approach in the femoral group, the standard radial group (in both, the guiding catheter was inserted through a sheath), and the sheathless radial group. Categorical variables were stated as numbers and percentages, continuous variables as mean and standard deviation or median and interquartile range. Analysis was performed comparing the three groups of patients, and the two transradial groups. The chi$^2$ test and Fisher's exact test were used to compare categorical data. The T Student or Mann-Whitney rank-sum test was used for continuous variables in two groups and analysis of variance in the case of multiple groups. Long-term survival was shown via Kaplan-Meier curves, with differences evaluated by the log-rank test. A $P$ value of < 0.05 was considered statistically significant. Analyses were performed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA).

## RESULTS

Two hundred twenty-three patients underwent RA PCI at the participating centers. Table 1 shows the baseline characteristics of our cohort. Male gender was the only characteristic that was unevenly distributed between the groups. The radial approach was preferred in the majority of cases (67.7%). Of note, 44.4% of our patients underwent *ad hoc* PCI with RA when the indication was an acute coronary syndrome. Only one-third of the whole population received double antiplatelet therapy pretreatment.

### Procedural data and outcome

The feasibility analysis, based on vascular access and technique, showed a failure rate of 7.5% (3 out of 40 attempts) in the transradial sheathless cohort, 11.7% (15/128) in the standard radial, and 0.0% (0/55) in the femoral [Figure 2]. The reason for seven of the 18 failed radial attempts was unfavorable peripheral anatomy (e.g., faint pulse, occluded artery, remnant artery, tortuosity), while the remaining 11 cases were due to poor backup, which also included tortuosity of the supra-aortic vessels [Figure 3].

**Table 1. Baseline characteristics**

| Variable | Overall *n* = 223 | Fem 72 (32.2) | Rad_Stand 114 (51.1) | Rad_SGC 37 (16.6) | *P*[1] | *P*[2] |
|---|---|---|---|---|---|---|
| Age, years | 74.8 ± 9.1 | 74.8 ± 9.1 | 74.0 ± 9.2 | 74.7 ± 8.4 | 0.259 | 0.700 |
| Male gender | 162 (72.6) | 47 (65.3) | 92 (80.7) | 23 (62.2) | 0.021 | 0.021 |
| Hypertension | 193 (86.5) | 62 (86.1) | 99 (86.8) | 32 (86.5) | 0.990 | 1.000 |
| Hypercholesterolemia | 166 (74.4) | 52 (72.2) | 88 (77.8) | 26 (70.3) | 0.613 | 0.395 |
| Current smoker | 80 (35.9) | 28 (38.9) | 37 (32.5) | 15 (40.5) | 0.545 | 0.369 |
| BMI > 30 Kg/$m^2$ | 51 (22.9) | 17 (23.6) | 29 (25.4) | 5 (13.5) | 0.319 | 0.131 |
| Diabetes mellitus | 97 (43.5) | 32 (44.4) | 52 (45.6) | 13 (35.1) | 0.525 | 0.263 |
| Dialyses | 13 (5.8) | 7 (9.7) | 6 (5.3) | 0 (0.0) | 0.114 | 0.337 |
| PAD | 78 (35.0) | 30 (41.7) | 35 (30.7) | 13 (35.1) | 0.311 | 0.615 |
| Ejection fraction, % | 50 (40-55) | 50 (42-55) | 50 (45-55) | 50 (40-60) | 0.416 | 0.503 |
| Ejection fraction < 30% | 14 (6.4) | 8 (11.3) | 3 (2.7) | 3 (8.3) | 0.060 | 0.155 |
| Clinical presentation: | | | | | 0.101 | 0.051 |
| - ACS | 99 (44.4) | 29 (40.3) | 58 (50.9) | 12 (32.4) | | |
| - Stable/staged | 124 (55.6) | 43 (59.7) | 56 (49.1) | 25 (67.6) | | |
| Antithrombotic therapy: | | | | | | |
| - Vit.K ant./DOAC | 25 (11.2) | 12 (16.7) | 9 (7.9) | 4 (10.8) | 0.181 | 0.522 |
| - DAPT pretreatment | 68 (30.5) | 22 (30.6) | 32 (28.1) | 14 (37.8) | 0.533 | 0.262 |

Categorical variables are shown as number (percentage); continuous variables as median (interquartile range) or mean value (±standard deviation). ACS: Acute coronary syndrome; BMI: body mass index; DAPT: double antiplatelet therapy; DOAC: direct oral anticoagulant; Fem: femoral access; PAD: peripheral artery disease; Rad_SGC: radial sheathless guiding catheter access; Rad_Stand: radial standard access; Vit.K ant: vitamin K antagonist; *P*[1]: comparison between the three groups; *P*[2]: comparison between the two radial groups.

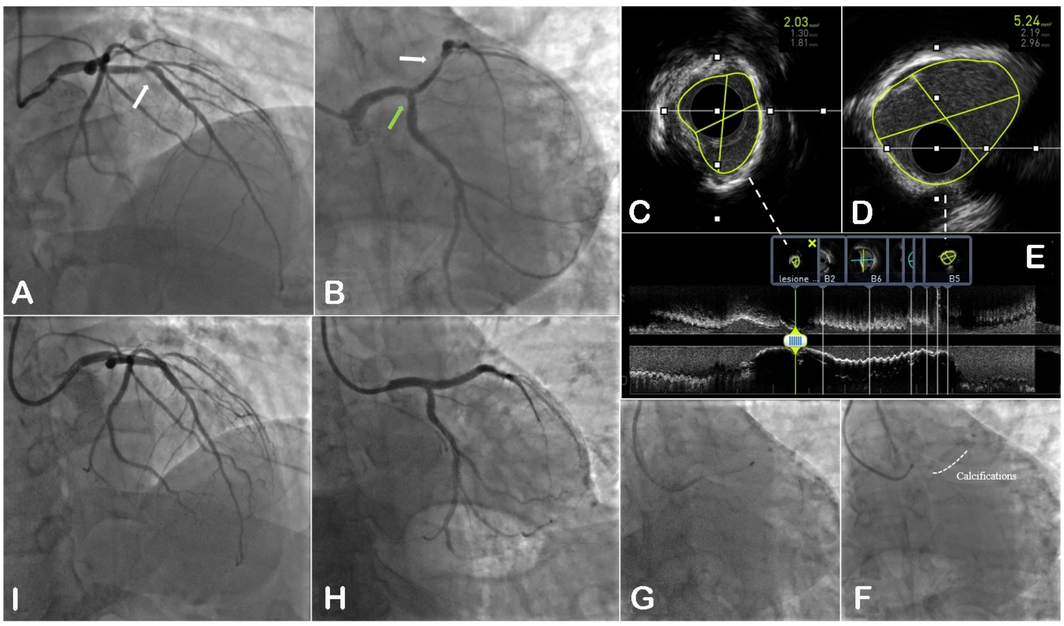



**Figure 1.** A case of RA PCI using an SGC. Panels (A and B) show diagnostic angiography in cranial and caudal view, respectively; (C) IVUS evaluation of the minimal lumen area of the calcific lesion; (D) left anterior descending artery ostial calcific lesion; (E) longitudinal IVUS view; (F) radio-opacities on both side of the lumen on still cardiac fluoroscopy images; (G) ongoing rotational atherectomy; (H) and (I) final angiography.

Procedural time was longer in the case of femoral access [Table 2]. Only 27.4% of the procedures were performed with a 6 Fr guiding catheter. We did not perceive any differences between groups in terms of

**Table 2. Procedural data**

| Variable | Overall n = 223 | Fem 72 (32.3) | Rad_Stand 114 (51.1) | Rad_SGC 37 (16.6) | $P^1$ | $P^2$ |
|---|---|---|---|---|---|---|
| Procedural time, min | 100 (80-126) | 110 (90-141) | 98 (75-120) | 100 (88-117) | 0.004 | 0.641 |
| Fluoroscopy time | 26 (20-33) | 26 (19-33) | 26 (20-35) | 25 (19-30) | 0.289 | 0.206 |
| Contrast dye, ml | 165 (130-202) | 160 (129-226) | 162 (130-210) | 167 (127-190) | 0.451 | 0.459 |
| Catheter size, Fr | | | | | 0.000 | 0.000 |
| - 6.0 | 61 (27.4) | 17 (23.6) | 44 (38.6) | 0 (0.0) | | |
| - 7.0 | 123 (55.2) | 53 (73.6) | 70 (61.4) | 0 (0.0) | | |
| - 7.5 | 37 (16.6) | 0 (0.0) | 0 (0.0) | 37 (100.0) | | |
| - 8.0 | 2 (0.9) | 2 (2.8) | 0 (0.0) | 0 (0.0) | | |
| Vessel | | | | | 0.011 | 0.056 |
| - LAD | 134 (60.1) | 33 (45.8) | 74 (64.9) | 27 (73.0) | | |
| - RCA | 44 (19.7) | 21 (29.2) | 21 (18.4) | 2 (5.4) | | |
| - LCX | 16 (7.2) | 6 (8.3) | 9 (7.9) | 1 (2.7) | | |
| - LM | 19 (8.5) | 10 (13.9) | 4 (3.5) | 5 (13.5) | | |
| - Protected-LM | 10 (4.5) | 2 (2.8) | 6 (5.3) | 2 (5.4) | | |
| Vessel diameter, mm | 3.5 ± 0.6 | 3.6 ± 0.6 | 3.3 ± 0.5 | 3.3 ± 0.5 | 0.421 | 0.589 |
| Special lesion | | | | | | |
| - intrastent | 6 (2.7) | 4 (5.6) | 2 (1.8) | 0 (0.0) | 0.160 | 0.569 |
| - aorto-ostial | 24 (10.8) | 8 (11.1) | 10 (8.8) | 6 (16.2) | 0.444 | 0.165 |
| - CTO | 1 (0.4) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0.619 | 0.755 |
| Rota wire | | | | | 0.058 | 0.348 |
| - floppy | 191 (85.7) | 56 (77.8) | 103 (90.4) | 32 (86.5) | | |
| - stiff | 32 (14.3) | 16 (22.2) | 11 (9.6) | 5 (13.5) | | |
| Burr size | | | | | 0.512 | 0.200 |
| - 1.25 mm | 91 (40.8) | 29 (40.3) | 45 (39.5) | 17 (45.9) | | |
| - 1.5 mm | 118 (52.9) | 38 (52.8) | 60 (52.6) | 20 (54.1) | | |
| - 1.75 mm | 13 (5.8) | 4 (5.6) | 9 (7.9) | 0 (0.0) | | |
| Burr/artery ratio | 0.43 ± 0.06 | 0.43 ± 0.06 | 0.31 ± 023 | 0.42 ± 0.06 | 0.182 | 0.103 |
| Stent type | | | | | | |
| - DES | 194 (87.0) | 57 (79.2) | 104 (91.2) | 33 (89.2) | 0.05 | 0.463 |
| - BMS | 3 (1.3) | 1 (1.4) | 1 (0.9) | 1 (2.7) | 3 .711 | 0.436 |
| Total stent length, mm | 38 (24-54) | 31 (18-49) | 48 (30-58) | 31 (18-43) | 0.000 | 0.002 |
| Additional device | | | | | | |
| - modifying Balloon | 8 (3.6) | 3 (4.2) | 3 (2.6) | 2 (5.4) | 0.696 | 0.357 |
| - IVL | 15 (6.7) | 2 (2.8) | 12 (10.5) | 1 (2.7) | 0.068 | 0.124 |
| - SHP balloon | 2 (0.9) | 0 (0.0) | 2 (1.8) | 0 (0.0) | 0.381 | 0.569 |
| Intracoronary imaging | 53 (23.8) | 11 (15.3) | 33 (28.9) | 9 (24.3) | 0.102 | 0.375 |
| Temporary pacemaker | 2 (0.9) | 1 (1.4) | 1 (0.9) | 0 (0.0) | 0.767 | 0.755 |
| MCS | 13 (5.8) | 10 (13.9) | 3 (2.6) | 0 (0.0) | 0.002 | 0.428 |

Categorical variables are shown as number (percentage); continuous variables as median (interquartile range) or mean value (±standard deviation). BMS: Bare metal stent; CTO: chronic total occlusion; DES: drug-eluting stent; Fem: femoral access; IVL: intra-vascular lithotripsy: LAD: left anterior descending artery; LCX: left circumflex artery; LM: left main stem; MCS: mechanical circulatory support; Rad_SGC: radial sheathless guiding catheter access; Rad_Stand: radial standard access; RCA: right coronary artery; SHP: super high pressure; $P^1$: comparison between the three groups; $P^2$: comparison between the two radial groups.

burr size or burr-to-artery ratio. Conversely, as expected, significant differences were found in evaluating the treated vessel, the catheter size, and the total stent length. Thirteen patients underwent PCI assisted by percutaneous micro axial flow pump ($n$ = 8), or intra-aortic balloon pump (IABP) ($n$ = 5). Mechanical circulatory support (MCS) was required more frequently in the transfemoral cohort, but indications did not differ between groups ("protected PCI" in 11/13 cases, bailout IABP insertion due to unstable hemodynamics).

Procedural success was similar between groups, as reported in Table 3. We observed a trend towards a higher rate of clinically relevant bleedings (BARC > 2) and overall vascular injury in the femoral population [Figure 2]. Other procedural complications were rare and did not differ between groups.

**Table 3. Procedural and long-term outcome**

| Variable | Overall *n* = 223 | Fem 72 (32.3) | Rad_Stand 114 (51.1) | Rad_SGC 37 (16.6) | $P^1$ | $P^2$ |
|---|---|---|---|---|---|---|
| Procedural success | 199 (89.2) | 60 (83.3) | 105 (92.1) | 34 (91.9) | 0.145 | 0.601 |
| Procedural complication | | | | | | |
| - MI | 7 (3.1) | 3 (4.2) | 3 (2.6) | 1 (2.7) | 0.831 | 1.000 |
| - stroke | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | n.a. | n.a. |
| - no-reflow | 3 (1.3) | 2 (2.8) | 1 (0.9) | 0 (0.0) | 0.405 | 1.000 |
| - coronary perforation | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | n.a. | n.a. |
| - burr entrapment | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | n.a. | n.a. |
| - unsealed dissection | 4 (1.8) | 2 (2.8) | 2 (1.8) | 0 (0.0) | 0.585 | 1.000 |
| Bleeding ARC > 2 | 5 (2.2) | 4 (5.6) | 1 (0.9) | 0 (0.0) | 0.066 | 1.000 |
| Any vascular complication | 9 (4.0) | 6 (8.3) | 3 (2.6) | 0 (0.0) | 0.062 | 1.000 |
| Procedural death | 2 (0.9) | 1 (1.4) | 0 (0.0) | 1 (2.7) | 0.275 | 0.245 |
| TLR at follow-up | 8 (3.6) | 5 (6.9) | 3 (2.7) | 0 (0.0) | 0.136 | 1.000 |

Categorical variables are shown as number (percentage); continuous variables as median (interquartile range) or mean value (±standard deviation). Fem: Femoral access; MI: myocardial infarction; n.a.: not applicable; Rad_SGC: radial sheathless guiding catheter access; Rad_Stand: radial standard access; TLR: target lesion revascularization; $P^1$: comparison between the three groups; $P^2$: comparison between the two radial groups.

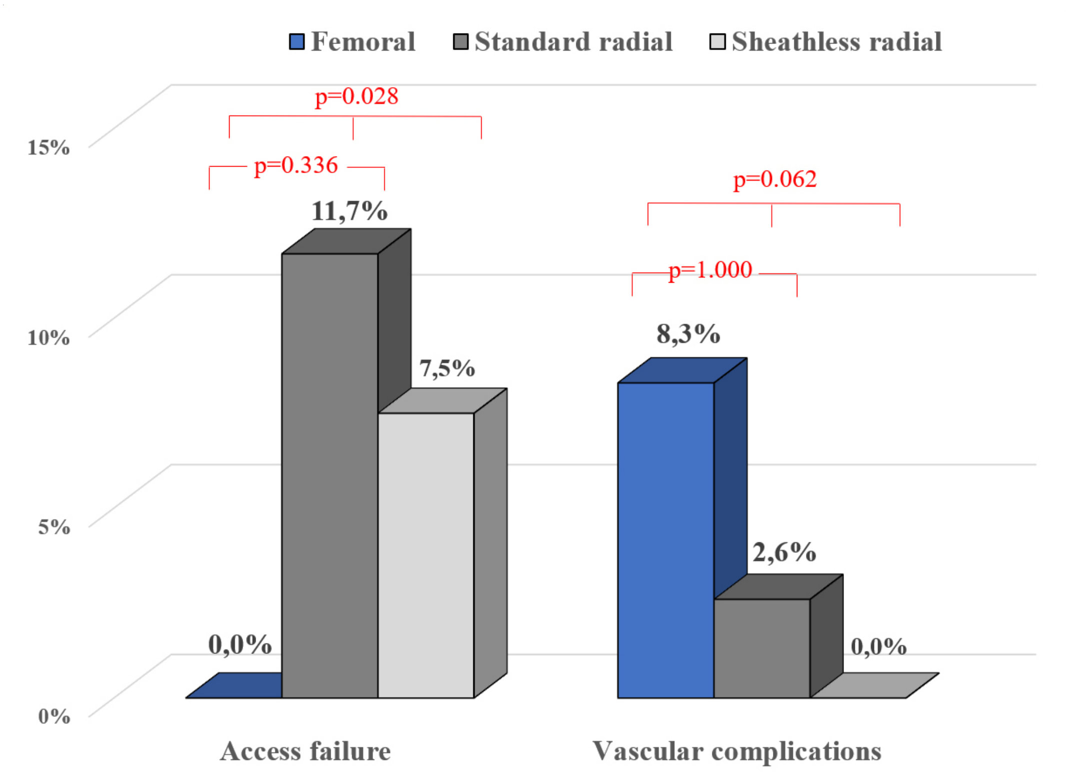



**Figure 2.** Comparison of access failures and vascular complications between groups.

## Long-term outcome

Twenty-two patients (9.9%) were lost during the long-term follow-up, and the median follow-up duration was 612 (156-1,301) days. We had 8/221 (3.6%) cases of target lesion revascularization, evenly distributed between the two groups [Table 3]. In Figure 4, Kaplan-Meier curves illustrate 3-year overall survival, showing no differences between the three groups (log-rank: $P$ = 0.757) or the two radial ones (log-rank: $P$ = 0.503).

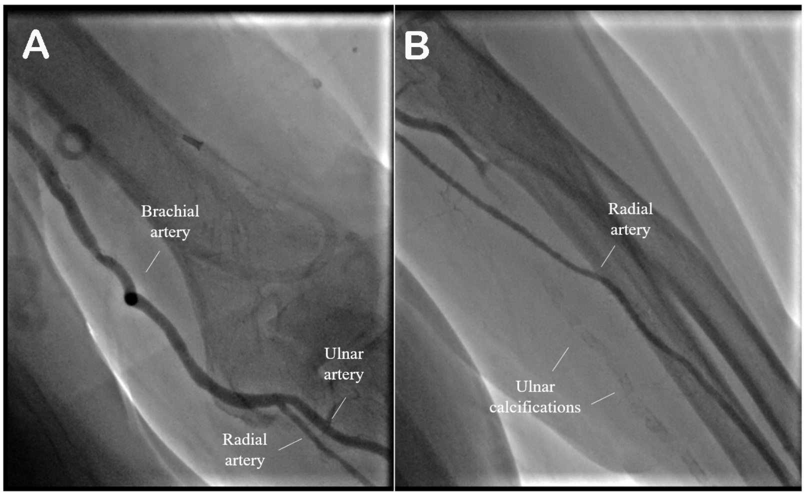
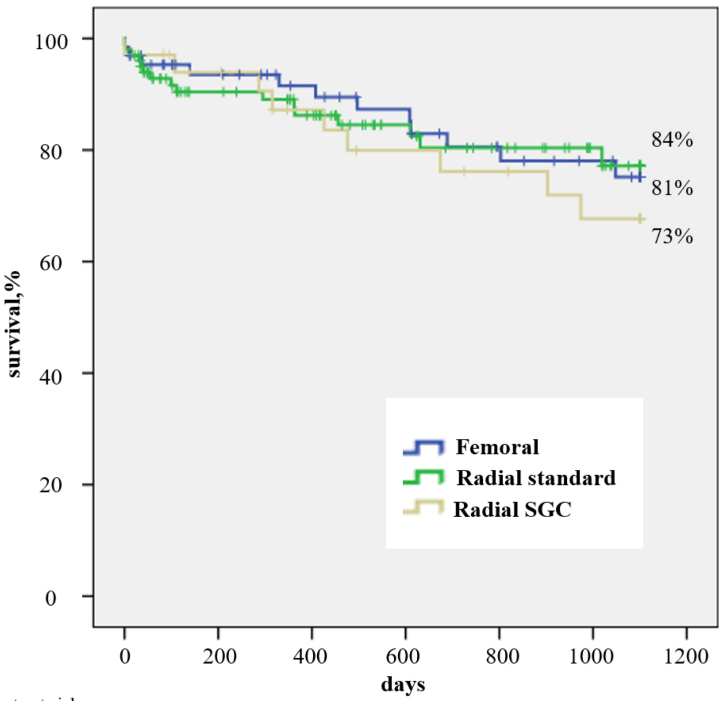



**Figure 3.** Left arm (A) and forearm (B) angiography. A case of standard radial approach failure due to calcific artery narrowing, which was overcome using an SGC.




| Patients at risk | | | |
|---|---|---|---|
| Overall | 201 | 175 | 164 |
| Femoral | 65 | 58 | 53 |
| Radial standard | 102 | 89 | 86 |
| Radial SGC | 34 | 28 | 25 |

**Figure 4.** Long-term survival analysis according to the vascular approach. SGC: sheathless guiding catheter.

## DISCUSSION

In terms of coronary revascularization via RA, this is the first comparison between the sheathless and the standard transradial approaches, as well as the largest series published thus far on RA plaque modification performed using a sheathless guiding catheter. The femoral access cohort, representing the traditional technical method in such complex procedures, is an additional point of comparison.

Of note, despite not reaching statistical significance, our analysis found a lower failure rate with the use of an SGC than the standard transradial technique, which consists of using a guiding catheter placed through a vascular sheath. Conversely, in this real-world setting of complex patients, the femoral approach allowed coronary RA to be performed in all the attempted cases. The average rate of radial access failure (10.7%) requiring vascular crossover was slightly higher than in a large randomized trial, likely due to different baseline characteristics in patients, our population being older, with a higher prevalence of peripheral vascular disease, and selected because of extensive coronary calcifications[9]. Transradial failure was mainly due to faint radial pulse, radial artery occlusion or narrowing, or tortuous anatomy of the subclavian artery. We must highlight that operators often prefer to perform complex procedures using a size ≥ 7 French catheter, with possible limitations deriving from the bulky size and stiffness of the device. Indeed, a smooth, iodophilic, and less bulky SGC may overcome several trackability issues and, at the same time, ensure sufficient backup during the procedure. This may explain the slight advantage observed in our analysis of using an SGC. On the other hand, there was only one case of crossover from SGC to the standard radial approach in order to improve catheter support during PCI.

When the transradial approach was feasible, this study confirmed that RA procedures via an SGC are as effective and safe as those performed through standard femoral and radial access. Finally, we confirmed the tendency towards reduced bleeding in the transradial approach compared to the transfemoral, with clear clinical implications[1].

Of note, the referral of patients with extensive coronary calcifications for revascularization has increased over time due to the aging of the population, as well as the high prevalence of chronic renal failure and diabetes mellitus[10]. The SGC represents a viable option to handle complex coronary anatomies, allowing RA to be performed with sufficient backup, accommodating multiple devices, and reducing forearm and proximal vasculature stress.

### Study limitations

The study is not devoid of potential bias, given its observational nature. Some differences in the baseline characteristics of the population are typical of a retrospective study, and we cannot estimate how much they influenced the choice of vascular access, the technique applied, and the procedural outcome. Longer procedural time in the transfemoral group may be due to the need for an echo-guided puncture or to time-consuming hemostasis. While more frequent use of MCS may have played a role in the 10-minute difference in median duration, the same cannot be said for varying complexity in the coronary anatomy [Table 2]. The main indication for MCS use was to perform a "protected PCI" in case of a combination of left main stem involvement, low ejection fraction, last remaining vessel, and multivessel disease.

Moreover, due to the limited population size, rare events may be underrepresented and the potential advantage of one approach over the others may not emerge significantly. Given the lack of statistical significance in the numerical advantage we observed in PCI feasibility using an SGC, larger studies are required to confirm the hypothesis of a possible benefit of SGC use over the standard radial approach.

We acknowledge that long-term follow-up was not available in 9.9% of patients. On the one hand, this is in line with many observational studies, and on the other hand, long-term survival was a secondary outcome.

In the last five years, echo-guided femoral artery puncture has increasingly replaced the traditional puncture with fluoroscopy guidance. This may have positively influenced outcomes in the femoral group, thus increasing the success rate and reducing vascular complications, but this effect was not measurable in the study[11].

In conclusion, transradial vascular access with an SGC is a viable option when performing RA during complex PCIs. In this two-center experience, we demonstrated a trend towards a lower failure rate in SGC procedures than the standard radial approach, and fewer bleeding and vascular complications than the transfemoral method.

## DECLARATIONS

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### Authors' contributions
Conception of the manuscript: Dall'Ara G, Tarantino F, Galvani M, Andò G
Data extraction: Dall'Ara G, Alagna G, Spartà D, Compagnone M, Grotti S, Guerrieri G, Campanella F, Taverna G
Writing the first draft of the manuscript: Dall'Ara G, Alagna G, Spartà D
Statistical analysis: Dall'Ara G
Writing and revision of the main manuscript: all authors

### Availability of data and materials
Anonymized data will be made available by the corresponding author upon reasonable request after publication.

### Financial support and sponsorship
None.

### Conflicts of interest
All authors declare that there are no conflicts of interest.

### Ethical approval and consent to participate
The study was approved by the ethics committee of the local health agency of Romagna (CE-ROM) and submitted to the regional web-based platform on health research in Emilia-Romagna (SIRER). Informed consent was acquired according to the indications of the ethics committee. No personal identifying information for any patient is provided in this manuscript.

### Consent for publication
Informed consent was acquired as per the instructions of the local ethics committee.



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