Distal versus conventional radial access for coronary angiography and intervention: Design and rationale of DISCO RADIAL study ☆

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Background Transradial access (TRA) has become the default access method for coronary diagnostic and interventional procedures. As compared to transfemoral access, TRA has been shown to be safer, cost-effective and more patient-friendly. Radial artery occlusion (RAO) represents the most frequent complication of TRA, and precludes future coronary procedures through the radial artery, the use of the radial artery as a conduit for coronary artery bypass grafting or as arteriovenous fistula for patients on hemodialysis. Recently, distal radial access (DRA) has emerged as a promising alternative to TRA, yielding potential for minimizing the risk of RAO. However, an international multicenter randomized comparison between DRA, and conventional TRA with respect to the rate of RAO is still lacking.

Trial Design DISCO RADIAL is a prospective, multicenter, open-label, randomized, controlled, superiority trial. A total of 1300 eligible patients will be randomly allocated to undergo coronary angiography and/or percutaneous coronary intervention (PCI) through DRA or TRA using the 6 Fr Glidesheath Slender sheath introducer. Extended experience with both TRA and DRA is required for operators' eligibility and optimal evidence-based best practice to reduce RAO systematically implemented by protocol. The primary endpoint is the incidence of forearm RAO assessed by vascular ultrasound at discharge. Several important secondary endpoints will also be assessed, including access-site cross-over, hemostasis time, and access-site related complications.

Summary The DISCO RADIAL trial will provide the first large-scale multicenter randomized evidence comparing DRA to TRA in patients scheduled for coronary angiography or PCI with respect to the incidence of RAO at discharge. (Am Heart J 2022;244:19–30.)

Keywords: Distal radial access; Radial artery occlusion; Transradial access ; Transradial approach

Transradial access (TRA) has become the standard vascular access for coronary angiography and percutaneous coronary intervention (PCI) and is currently endorsed with a class IA recommendation in the latest European

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Abbreviations: ACS, Acute coronary syndrome; DRA, Distal radial access; EACTS, European Association for Cardio-Thoracic Surgery; EAPCI, European Association of Percutaneous Cardiovascular Interventions; ESC, European Society of Cardiology; Fr, French; ITT, Intention-to-treat; PCI, Percutaneous coronary intervention; PP, Per protocol; RAO, Radial artery occlusion; TFA, Trans femoral access; TRA, Transradial access.

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Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) Guidelines on myocardial revascularization, irrespective of clinical presentation.[1-3] Similarly, a radial first strategy in patients with acute coronary syndromes (ACS) has been advocated in a Scientific Statement from the American Heart Association.[4]

Multiple studies and meta-analysis comparing TRA versus transfemoral access (TFA) have demonstrated compelling evidence for TRA to reduce the risk for access-site bleeding and vascular complications,[5-8] to be more cost-effective due to a shorter hospital stay,[9,10] to be more patient friendly[9] and to reduce all-cause mortality.[6,7,11] The latter is especially evident in high-risk patients such as those presenting with ACS.[5-7,11] Owing to such relevant advantages, TRA is also increasingly adopted in an expanding range of non–coronary procedures, including interventional oncology, neuroradiology, and peripheral arterial interventions.[12]

The clinical benefits of TRA however rely on the operator's experience and TRA may be limited by a smaller arterial diameter compared to TFA yielding a higher access failure rate, vascular spasm, and radial artery occlusion (RAO), a complex process involving several interplaying factors ultimately leading to thrombosis, with a reported incidence up to 33% of the cases.[13,14] Owing to the extensive network of forearm vascular anastomoses, RAO is mostly asymptomatic, from an ischemia standpoint, yet it precludes the use of the same radial artery for future percutaneous diagnostic, and interventional procedures.[15] Such a complication is expected to be of growing importance given the array of transradial procedures to which the same individual may be subjected during his lifetime. Moreover, an occluded radial artery is obviously not suitable as a conduit for coronary artery bypass grafting surgery or for an arteriovenous fistula in patients requiring hemodialysis.

Several clinical and procedural characteristics have been linked to the occurrence of RAO,[15] and best practices recommendations for the prevention of RAO include reduction of the sheath/catheter size, adequate procedural anticoagulation, non–occlusive hemostasis, and a minimal pressure strategy with short ($\leq$ 120 min) hemostasis time.[15-21] The use of the distal radial artery, with arterial access in the anatomical snuffbox or on the dorsum of the hand, has recently emerged as a promising alternative access route to further reduce the risk of RAO, and has been endorsed by a recent International Consensus Paper on the prevention of RAO.[15,22] However, the level of evidence in support of this recommendation is limited.

Rationale for distal radial access

Distally to the styloid process of the radius bone, the radial artery gives rise to the superficial palmar branch forming the superficial palmar arch and then crosses the anatomical snuffbox beneath the tendons of the abductor pollicis longus and the extensor pollicis brevis muscles, just above the scaphoid, and trapezium bones. The radial artery continues its course on the dorsum of the hand and finally swerves medially into the palm to form the deep palmar arch connecting with a branch of the ulnar artery.[22,23] The distal radial artery may be punctured proximally to the tendon of the extensor pollicis longus muscle in the anatomical snuffbox or distally to it in the dorsum of the hand *(Figure 1)*. These 2 alternative puncture points are distal to the carpal anastomotic networks and the superficial palmar arch and yield the same advantages as conventional TRA with an additional potential to maintain antegrade flow in the forearm radial artery during hemostatic compression of the distal radial artery, reducing thereby the risk of retrograde thrombus formation, and forearm RAO.[24]

The occurrence of thrombosis at the conventional radial cannulation site just proximally to the styloid process of the radius bone may extend back up to the origin of the radial artery that generally lacks important branching in the forearm. Contrariwise, if thrombosis complicates a vascular access in the anatomical snuffbox or the dorsum of the hand, flow in the forearm radial artery will be maintained owing to the wrist and hand anastomoses, thus preventing blood stasis during hemostasis and proximal thrombus growth.[25] This description is supported by the Distal Radial Access Doppler Study that demonstrated virtually unchanged flow in the forearm artery during simulated RAO at the anatomical snuffbox level in contrast to the severe reduction of flow observed during simulated RAO at wrist.[26]

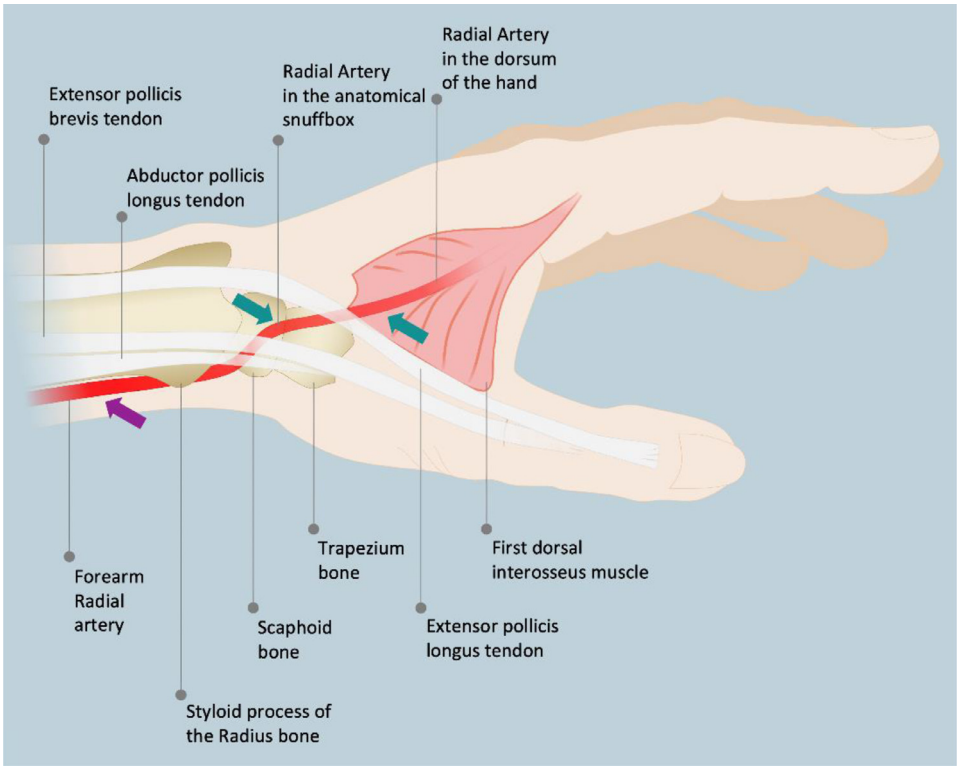
Moreover, the distal radial artery lies in the subcutaneous space superficial to the fascial compartments of the hand, thus favoring a faster, and safer hemostasis as compared to conventional TRA. When performed in the left upper limb, another potential advantage of DRA is an ergonomically improved position for both the operator and the patient, granting an excellent compromise to save the right arm from immobilization.[27]

Those relevant advantages are contrasted by a slightly smaller size of the distal radial artery potentially impacting on device selection and procedural planning and by its less predictable course, due to the pronounced tortuosity and angulation of the vessel, leading to an overall higher number of puncture attempts, a longer time to achieve arterial access and a higher rate of access failure.[24]

Critical appraisal of the evidence

The feasibility of DRA has been evaluated in a number of observational clinical registries showing some variability owing to the inclusion in certain studies of the very first DRA procedures performed by the operators.[27-44] Yet, the overall success rate was high, and no major

Figure 1



Anatomical landmark of distal radial access. Violet arrow points to conventional transradial access puncture site at wrist level; turquoise arrows point to the distal radial access punctures sites in the anatomical snuffbox and in the dorsum of the hand.

safety signals have been reported despite the lack of specific attention paid to an optimal hemostasis. Especially, the rate of RAO was extremely low in these early series.

Moreover, a few trials have been performed with the aim to compare DRA with conventional TRA (*Table I*). A 1:1 randomized study from Greece included 200 patients undergoing percutaneous coronary angiography through conventional TRA or DRA.[45] A low dose of heparin was administered in all patients and hemostasis was performed by manual compression. Access-related complications including ultrasound-assessed RAO which was quite high (5% in DRA group and 9% in conventional TRA group) but did not differ between the 2 groups.

The Dorsal Radial Artery Access Versus Classical Radial Artery Access for Percutaneous Coronary Angiography (DORA) trial randomized 970 patients undergoing coronary angiography at 3 Indian centers.[46] The rate of forearm RAO at 12 h was 2% in the DRA group and 13% in the conventional TRA ($P < .0001$). The incidence of radial artery spasm was significantly lower in the DRA group, whereas the rate of hematoma did not differ between the 2 groups. Notably, in this study hemostasis was achieved with an elastic hemostatic bandage in the DRA group, and an air-filled compression device in the conventional TRA group.

In a small study from China, 80 patients undergoing coronary angiography were assigned to DRA or TRA.[47] Hemostasis was achieved in all patients with an elastic hemostatic bandage and RAO was reported in only 1 patient in the conventional TRA group (2.5% vs 0% in DRA group, $P = .31$).

In a single-center randomized trial from China, 620 patient undergoing PCI were divided in 2 group according to access site: 312 underwent conventional TRA and 308 underwent DRA.[48] The rate of RAO prior to discharge assessed by vascular ultrasound occurred in 6 (1.9%) patients in the DRA group and in 16 (5.2%) in the conventional TRA group ($P = .031$). No differences were observed in the rate of other access-related complications. Similarly, hemostasis was achieved with an elastic hemostatic bandage in the DRA group, and an air-filled compression device in the conventional TRA group.

Table I. Published randomized studies comparing distal radial access with conventional transradial access

Study	Y	Sites	Country	Patients (n)	Primary outcome	Hemostasis	RAO assessment	RAO inDRA group	RAO in TRA group	*P*-value
Koutouzis et al.[45]	2019	1	Greece	200	Access switch	Manual compression	Vascular ultrasound	5%	9%	.407
Sharma et al.[46] (DORA)	2020	3	India	970	Multiple endpoints	Air-filled Compression device after TRA, elastic hemostatic bandage after DRA	Pulse Palpation	2%	13%	<.0001
Lu et al.[47]	2020	1	China	80	Undetailed	Elastic hemostatic bandage	Vascular ultrasound	0%	2.5%	.31
Wang et al.[48]	2020	1	China	620	Multiple endpoints	Air-filled compression device after TRA, elastic hemostatic bandage after DRA	Vascular ultrasound	1.9%	5.2%	.031
Lin et al.[49]	2020	1	China	900	Access success	Dedicated hemostatic device after TRA, elastic hemostatic bandage after DRA	Vascular ultrasound	1.56%	3.78%	.035
Eid-Lidt et al. [50] (DAPRAO)	2021	1	Mexico	282	RAO at 24 h	Air-filled Compression device	Vascular Ultrasound	0.7%	8.4%	.002

In another single-center randomized trial from China, 900 patients undergoing a percutaneous coronary procedure were randomized to conventional TRA or DRA.[49] The rate of RAO prior to discharge assessed by vascular ultrasound occurred in 7 (1.6%) patients in the DRA group and in 17 (3.8%) in the conventional TRA group ($P = .033$). The rate of hematoma did not significantly differ between the 2 groups while the incidence of access site bleeding was significantly lower in the DRA group. Hemostasis was achieved with an elastic hemostatic bandage in the DRA group and a dedicated hemostatic device in the conventional TRA group.

The recently published Distal Radial Approach to Prevent Radial Artery Occlusion (DAPRAO) was a prospective, randomized, single-center Mexican study, in which patients undergoing a percutaneous coronary procedure were randomly assigned (1:1) to conventional TRA or DRA.[50] The primary outcome of forearm RAO assessed by vascular ultrasound at 24 h occurred in 1 (0.7%) of 140 patients in the DRA group compared to 12 (8.4%) of 142 patients in the conventional TRA group (odds ratio 12.8, $P = .002$) in the per protocol analysis. The 24 h forearm RAO rate in the intention-to-treat analysis, and the forearm RAO rates at 30 days for both the per protocol, and intention-to-treat analyses showed similar improved outcomes with DRA. Importantly, the crossover rate from DRA to TRA was high (13.3%), while the crossover rate from TRA to DRA was only 0.7% ($P < .001$). No significant differences were found between the 2 groups in the incidence of forearm and hand hematoma and radial artery spasm.

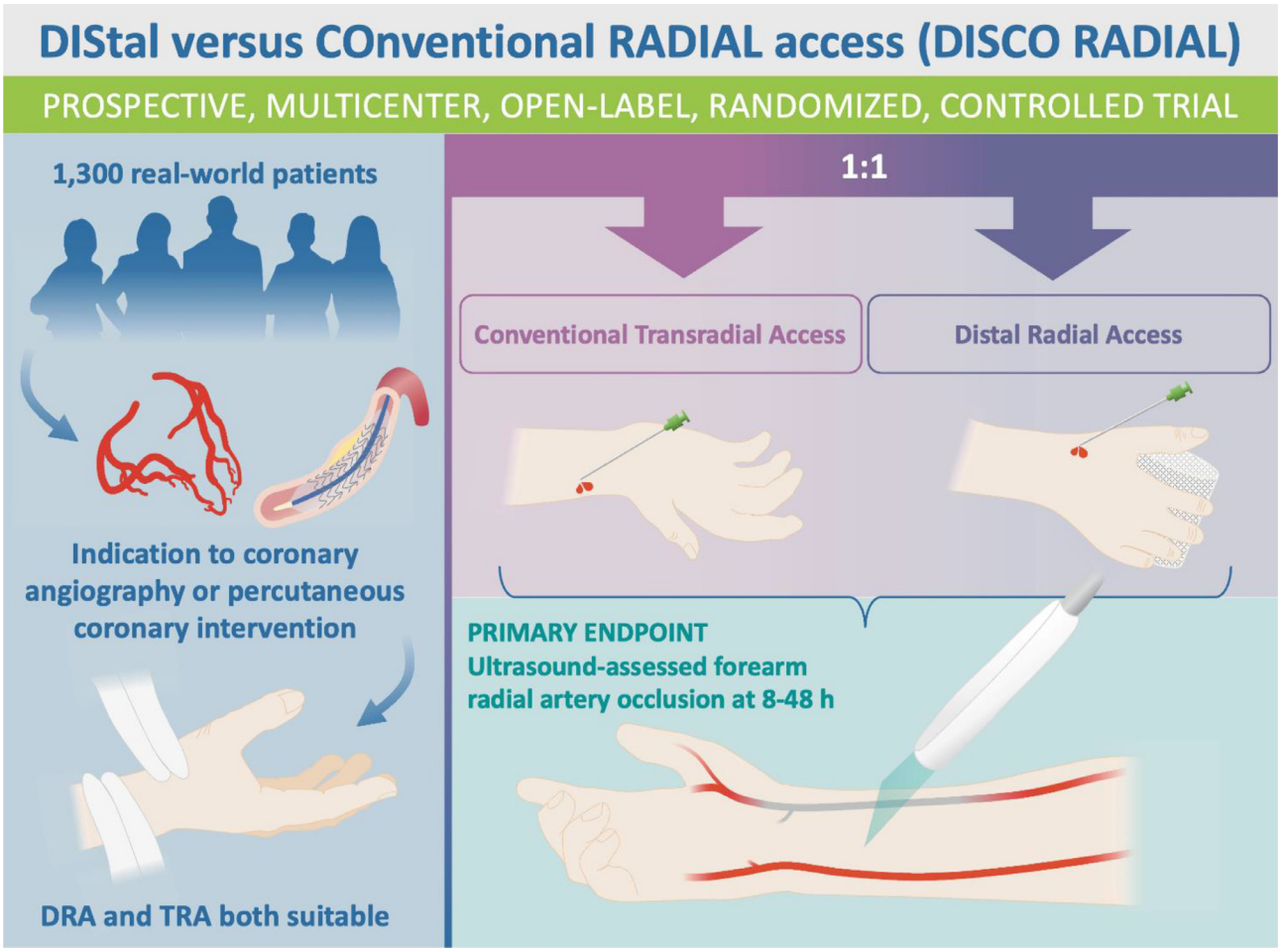
Overall results of comparative assessments of DRA and TRA are far from being conclusive. Relevant shortcomings affecting these studies include a single-center design in all but one of them; an heterogenous hemostasis technique (even within the same trial) that is not oriented to RAO prevention; an essentially high rate of RAO and its inconsistent definition across the studies. The DAPRAO trial is the only randomized study of DRA versus conventional TRA including forearm RAO as the primary endpoint. Yet, it is similarly limited by its single-center design and by a high rate of forearm RAO in the conventional TRA group despite the use of patent hemostasis and slender sheaths, which is in contrast with recent trials using best prevention methods showing lower RAO rates, hence questioning the external validity of its findings in a more contemporary interventional practice.[51,52]

Study methods

Study objective and design

The DIStal vs COnventional RADIAL access (DISCO RADIAL) trial is a prospective, multicenter, open label, randomized, controlled study designed to demonstrate the superiority of DRA compared to conventional TRA with respect to the incidence of forearm RAO at discharge. Up to 1300 eligible patients who will undergo a diagnostic coronary angiography and/or a PCI using a 6 Fr GlideSheath Slender (Terumo Europe, Leuven, Belgium) as the standard access sheath will be randomly allocated in a 1:1 ratio to DRA versus TRA. Centers from Europe and Japan will participate only if proficient with DRA. The study outline is shown in *Figure 2*. Follow-up is set until discharge. The study will be conducted according to the Declaration of Helsinki and approval from each center's ethical committee will have to be obtained

Figure 2



Outline of the DISCO RADIAL trial. Real-world patients (n = 1300) will be enrolled following compliance to limited selection criteria (see Table II), indication to coronary angiography or percutaneous coronary intervention and suitability to both distal radial access (DRA) and conventional transradial access (TRA). Afterwards, patients will be randomized 1:1 to one or another access, and will be followed-up until hospital discharge. Ultrasound-assessed radial artery occlusion at 8 to 48 h is the primary endpoint of the study.

before starting patient enrolment. The ClinicalTrials.gov identifier is NCT04171570.

Study population and follow-up

Inclusion and exclusion criteria have been restricted *(Table II)* to enroll a broad patient population with an indication for coronary angiography and/or a PCI representative of routine clinical practice. Patients aged 18 years or older, who have provided written informed consent and who are suitable for both DRA and TRA with the 6 Fr GlideSheath Slender are eligible for enrolment. Exclusion criteria are medical conditions that may cause non–compliance with the study protocol and/or may confound the data interpretation, patients on chronic hemodialysis, presenting with ST-elevated myocardial infarction or undergoing PCI for chronic total occlusion. Patients will be followed-up for the prespecified endpoints until hospital discharge, and there are no scheduled follow-up contacts after hospital discharge.

Radial sheath

The 6 Fr GlideSheath Slender is a 6 Fr-compatible radial sheath with a hydrophilic coating and has especially been designed to provide access to smaller arteries. The outer diameter has been reduced from 2.63 mm to 2.46 mm through a reduction in wall thickness from 0.20 mm to 0.12 mm.[53] This wall thickness is thinner than current non–Slender 6 Fr sheaths. The inner diameter has been

Table II. DISCO RADIAL inclusion and exclusion criteria

Inclusion criteria
Aged ≥18 y
Signed informed consent form
Indication to diagnostic coronary angiography or PCI
Patient's willingness to comply with all protocol-required evaluations during the hospitalization
Patient's suitability for both DRA and conventional TRA using 6 Fr Glide Sheath Slender
Exclusion criteria
Medical condition that may cause non–compliance with the protocol and/or confound the data interpretation
Chronic hemodialysis
ST-elevated myocardial infarction (STEMI)
Treatment of a coronary chronic total occlusion (CTO) lesion

maintained at 2.22 mm to allow compatibility with all 6 Fr devices.

Randomization and arterial access procedure

Concealed allocation of study treatment is to be performed via a Web-based interactive randomization system available at https://secure.eclinicalos.com. Randomization is achieved with computer-generated random sequence with a random block size stratified at site level.

For both patients randomized to DRA or TRA, intravenous access, preferably in the contralateral arm for the administration of medications is recommended for the administration of medications. The choice of right or left radial artery is left to the discretion of the operator, as well as the use of ultrasound to guide the access procedure. After local anesthesia, either the Seldinger or the modified-Seldinger technique is used to obtain arterial access. After placement of the GlideSheath Slender, a cocktail of 5 mg verapamil, and 100 or 200 mg nitroglycerine is administered to prevent arterial spasm. Administration and dosage of heparin and other anti–thrombotic agents is per hospital routine. If the initial attempt to obtain vascular access at the randomized access site (DRA or TRA) fails, all further attempts will be considered as cross-over, and include the use of the contralateral arm or other arteries (femoral or ulnar artery) or cross-over to the other group. For TRA, the patient's hand is positioned in an extended position with the palm positioned supinated. It is advised to puncture the radial artery 2 cm proximal to the styloid process of the radial bone with a 30 to 45° entry angle to the skin. For DRA, the patient's hand is positioned with the anatomic snuffbox upward. After confirming by manual palpation, the presence of a well-developed distal radial artery in the anatomical snuffbox or the dorsum of the hand, the artery is punctured with 30 to 45° entry angle to the skin in the direction of the strongest pulse. The anterior wall puncture technique is preferred, but the through-and-through puncture can also be used.[24] In both cases, careful manipulation of the needle is advised to avoid touching the periosteum of the scaphoid or trapezium bones, as this can be painful. After successful arterial puncture, the rest of the access procedure is similar as for TRA.

Hemostasis protocol

For patients in whom arterial access is obtained through the conventional TRA method, hemostasis with a closure device is recommended with patent hemostasis implemented according to the PROPHET study protocol.[18] Briefly, after placement of the hemostatic compression device and removal of the sheath, hemostatic pressure is set to a level just enough to maintain hemostasis without compromising radial artery patency as assessed by the reverse Barbeau test. This is performed by observation of the pulsatile waveforms from a plethysmographic sensor placed on the index finger after compression of the ulnar artery. Absence of a plethysmographic waveform indicates occlusive compression of the radial artery and the pressure in the hemostatic device should gradually be reduced until return of the waveform. For patients who received DRA, access site closure, and hemostasis are per hospital practice. Details regarding hemostasis techniques and protocols will be collected for every patient.

Operator criteria for eligibility

Conventional TRA and DRA require both specific skills and dedicated training. The present study is not aimed at investigating the learning curve of DRA, rather assessing the comparative efficacy, and safety of DRA versus TRA by fully trained interventional cardiologists with effective operating experience with both accesses. Hence, single operators qualify for the study providing: (1) they are experienced operators regularly performing transradial PCI in the whole spectrum of coronary artery disease, including ACS, (2) they are fully independent with DRA, (3) they have performed a minimum of 100 procedures by DRA.

Study endpoints

The primary endpoint of the DISCO RADIAL trial is the incidence of forearm RAO at hospitalization discharge as-

Table III. DISCO RADIAL Endpoints

Primary endpoint
Forearm radial artery occlusion at hospital discharge
Secondary endpoints
Successful sheath insertion
Access site cross-over
Total procedure time
Sheath insertion time
Puncture site bleeding according to EASY criteria[54]
Overall bleeding according to BARC criteria[55]
Vascular access-site complication
Radial artery spasm
Distal radial artery occlusion
Patent hemostasis (conventional transradial access group)
Hemostasis time
Pain associated with the procedure

BARC, Bleeding Academic Research Consortium; EASY, Early Discharge after Transradial Stenting of Coronary Arteries Study

sessed by an independent investigator, who was not involved in the procedure. The presence or absence of a duplex ultrasound anterograde flow signal distal to the radial artery access site is checked according to hospital routine, ideally between 8 to 48 hours post-procedure. The artery is considered occluded if no flow signal can be detected. For patients assigned to DRA, both the forearm and the distal artery are assessed. The secondary endpoints are listed in Table III. Endpoint's definitions are fully detailed in Appendix.

Statistical methods

The primary hypothesis of the study is that DRA is superior to conventional TRA with respect to the incidence of forearm RAO at discharge. For the TRA group, the assumption is that 3.5% of the patients will experience a RAO based upon data of the Glidesheath Slender 6 Fr subgroup from the RAP and BEAT study.[20] For the DRA group, an incidence of forearm RAO of 1.0% is assumed, based on numerous previous studies. For a statistical power of 80% and a 2-sided alpha error of 0.05, assuming a cross-over rate of 10% and a drop-out rate of 5%, 648 patients per group are needed. The total sample size was therefore set to 1300 patients. The primary endpoint analysis will be performed on the intention-to-treat (ITT) population, ie, based upon randomization assignment to either the TRA or the DRA group. A tipping point analysis will be performed should the number of missing data exceed 15% to 20%, although not expected because of the short observation period. For the secondary endpoint analyses, the safety analyses will be performed on the as-treated population only, while the efficacy analyses will be performed on the ITT, and the per-protocol (PP) populations. The PP population will exclude patients who crossed over or had major violations to the study protocol. Normality of data will be assessed with the Shapiro-Wilk test and continuous variables will be reported as mean and standard deviation or as median (interquartile range) if skewed. Comparison of continuous variables will be performed with the Student *t* test or Mann-Whitney test, as appropriate. Categorial variables will be reported as count (percentages) and comparative testing will be performed with the χ^2 tests or Fisher exact test, as appropriate. As sensitivity analyses, logistic regression will be carried out to estimate odd ratios, and 95% confidence interval comparing the tested treatment options. To evaluate for consistency of results among subgroups of interest, exploratory subgroup analyses are pre-specified (Online Appendix).

Study timelines, data monitoring and funding source

The first patient was randomized at the coordinating center in December 2019, and the study was projected to be completed within 1 year. Because of the negative impact of COVID-19 pandemics on catheterization laboratories activity and the overall reassignment of healthcare workers, study enrolment was significantly slowed with a corrected estimate of ending enrollment at the end of the Summer of 2021.

The DISCO RADIAL trial is sponsored by Terumo Europe which is responsible for the study management, risk-based data monitoring, and statistical analysis. The supportive company has no role in design of the study and publication of the paper reporting the final study findings.

Discussion

The annual median of over 5,000 diagnostic coronary angiographies and over 2,400 PCIs both per million people reported for sixteen ESC member countries participating in the European Association of Percutaneous Cardiovascular Interventions (EAPCI) Atlas survey of 2016 indicate the large scale on which these procedures are performed annually and reinforce the importance of achieving safe arterial access to the coronary artery system.[56] In that perspective, great progress has been made over the last 3 decades with the development of TRA which has become the default access method for coronary procedures, unless there are overriding procedural considerations.[1-4] With the advent of TRA, dedicated equipment has been developed to further improve the access success rate, hemostasis and procedural safety, including guide catheters, hemostasis devices and vascular sheaths with a smaller outer diameter to accommodate the smaller diameter of the radial artery.[20,53] All in all, these devices have promoted a progressive reduction in RAO that however still remains the major limitation of TRA.[15]

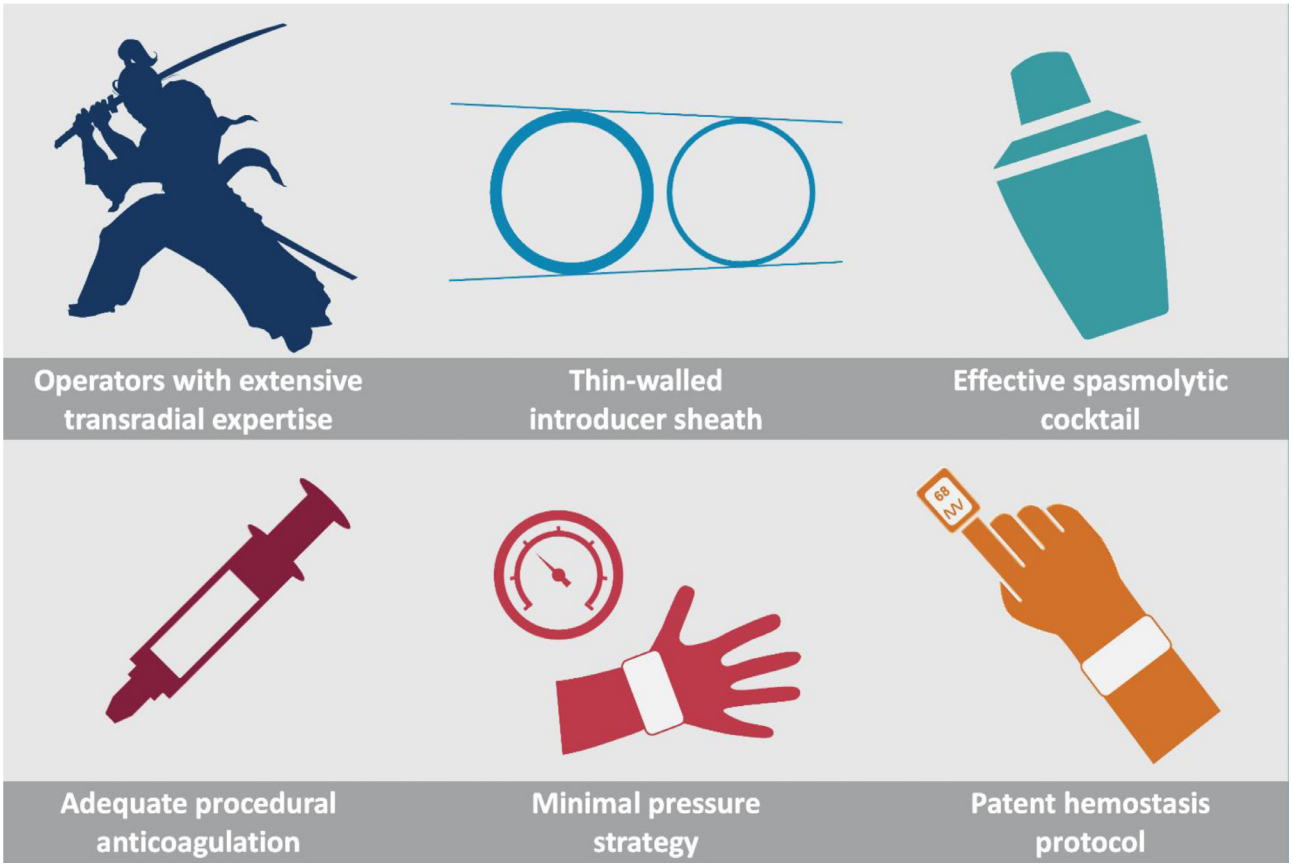
Against this background, DRA has enthusiastically emerged as an alternative access pledging to virtually cancel RAO.[22,24] The feasibility and safety of DRA has been demonstrated in observational registries[27-44] and

Table IV. Overview of registered randomized trial comparing conventional transradial access versus distal radial access

ClinicalTrial.gov identifier	Study title	Number of patients	Indication	Primary endpoint	Time of primary endpoint assessment	Status
NCT03986151	Anatomical sNuffbox for Coronary anGiography and IntervEntions (ANGIE)	1,042	CAG/PCI	Right radial artery occlusion	≥30 d	Completed
NCT04125992	Distal vs Forearm Radial Artery Access (DRAvsFRA)	212	CAG	Radial artery occlusion by doppler ultrasonography	<24 h	Completed
NCT04171570	DIStal Versus COnventional RADIAL Access for Coronary Angiography and Intervention (DISCO RADIAL)	1,300	CAG/PCI	Forearm radial artery occlusion by doppler ultrasonography	Before discharge	Recruiting
NCT03611725	Comparison of Success Rate Between Distal Radial Approach and Radial Approach in STEMI (DRAMI)	352	ST-segment elevation myocardial infarction undergoing PCI	Puncture success rate (procedure complications)	6 h	Recruiting
NCT04194606	CORonaRy Angiography and intErventions Via Distal vs Proximal aCcess (CORRECT Radial)	500	CAG/PCI	Radial artery occlusion by doppler ultrasonography	30 d	Recruiting
NCT04318990	DIstal vs Proximal Radial Artery Access for Cath (DIPRA)	300	CAG	Hand function questionnaire; hand function; hand grip test	1 mo	Recruiting
NCT04211584	Randomized Controlled Trial Comparison Between Traditional ENtry Point and Distal puncturE of RAdial Artery (TENDERA)	1,500	CAG/PCI	Radial artery occlusion by doppler ultrasonography	1 y	Recruiting
NCT04023838	Randomized Comparison of Radiation Exposure in Coronary Angiography Between Right Conventional and Left Distal Radial Artery Approach (DOSE)	100	CAG	Radiation dose of the operator (μSv)	6 h	Not yet recruiting
NCT04232488	Distal vs Proximal Radial Approach for Coronary Interventions	750	CAG/PCI	Radial artery occlusion by doppler ultrasonography	3 mo	Not yet recruiting
NCT04784078	Randomized Comparison of Distal Radial Versus Conventional Radial Access for Coronary Angiography and Intervention	938	CAG/PCI	Radial artery occlusion by doppler ultrasonography	<24 h	Not yet recruiting
NCT04801901	A PRospEctive Randomized Clinical Study Comparing Radial ArtERy Intimal Hyperplasia Following Distal Vs ForEarm TransRadial Arterial Access for Percutaneous Coronary Intervention (PRESERVE Radial)	62	PCI	Radial artery intimal medial thickness	90 d	Not yet recruiting

CAG, coronary angiography; PCI, percutaneous coronary intervention

Figure 3



Radial artery occlusion preventive measures in the DISCO RADIAL trial.

a decent number of randomized studies[45-49] comparing DRA versus TRA are either ongoing or have been published to indicate the scientific interest to investigate this emerging arterial access modality. An overview of the ongoing randomized trial comparing TRA versus DRA registered on ClinicalTrial.gov is provided in Table IV. The primary endpoint of the majority of these studies is RAO assessed by duplex ultrasound. The time point of assessment varies from <24 hours to 1-year post-procedure and the sample sizes vary between 212 and 1,500 patients.

DISCO RADIAL emerges as the first large-scale international randomized controlled trial designed to investigate the benefits of DRA over conventional TRA, appearing unique in several respects. First, the participating centers are highly proficient with transradial practice and all qualifying operators have to provide extended experience with both conventional TRA and DRA. Moreover, since the radial artery becomes the access site of choice for an increasing number of indications and the need for RAO prevention is bound to grow in the near future, the study protocol mandates the rigorous implementation in the catheterization laboratory of best practice to reduce RAO as summarized in *Figure 3*. Notably, the use of the thin-walled 6 Fr GlideSheath Slender, that is especially valued in the slightly smaller distal radial artery, has been set as the default sheath for both TRA, and DRA in order to excludes the variation in access devices as confounding factor. Indeed, to fully unravel the role of DRA, DISCO RADIAL has been designed to compare this newer access with TRA implementing optimal, up to date, evidence-based care to preserve radial artery patency. Hence, the RAO rate in the conventional group has been estimated in terms of 3.5%, a figure that is substantially lower than the goal suggested by the recent International Consensus Statement on the prevention of RAO for internal quality control of every transradial programs.[15] Yet, the definition of RAO is very conservative, requiring systematic vascular ultrasound assessment in all patients within 48 hours. The sample size is sufficiently large to yield an adequately powered multicenter trial comparing DRA with conventional TRA according to a randomized design results in a real-world setting.

Finally, multiple, rigorously detailed, relevant secondary endpoints will also be assessed, including access-site cross over, hemostasis time and access-site related complications, and will reflect the current DRA practice and outcome in a real-world setting of experienced centers and operators using both radial access techniques.

Conclusion

DISCO RADIAL is a prospective, multicenter, open-label, randomized, controlled superiority trial designed to compare DRA versus TRA with respect to the incidence of RAO at discharge. The study aims at generating reliable clinical evidence on the potential benefits of this novel approach over the conventional TRA, and to support the use of DRA as an alternative to the conventional TRA. The principal results are expected in Fall 2021.

Authors' contribution

Adel Aminian: Conceptualization, Methodology, Investigation, Writing – original draft; Gregory A. Sgueglia: Conceptualization, Methodology, Investigation, Writing – original draft; Marcus Wiemer: Investigation, Writing – review & editing; Gabriele Luigi Gasparini: Investigation, Writing – review & editing; Joelle Kefer: Investigation, Writing – review & editing; Zoltan Ruzsa: Investigation, Writing – review & editing; Maarten A.H. van Leeuwen: Investigation, Writing – review & editing; Bert Vandeloo: Investigation, Writing – review & editing, Claudiu Ungureanu: Investigation, Writing – review & editing; Sasko Kedev: Investigation, Writing – review & editing, Juan F Iglesias: Investigation, Writing – review & editing; Gregor Leibundgut: Investigation, Writing – review & editing; Karim Ratib: Investigation, Writing – review & editing; Ivo Bernat: Investigation, Writing – review & editing; Irene Barriocanal: Conceptualization, Methodology, Investigation, Writing – review & editing; Vladimir Borovicanin: Conceptualization, Methodology, Investigation, Writing – review & editing; Shigeru Saito: Conceptualization, Methodology, Investigation, Writing – review & editing.

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Conflict of interest

IB and VB are full-time employees of Terumo Europe N.V. The other authors report no conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ahj.2021.10.180.

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