Minimalistic Approaches for Vascular Access in Minimally Invasive Transcatheter Interventions

Thesis Booklet

Alexandru Achim, MD

Supervisor: Zoltan Ruzsa, MD, PhD

Division of Invasive Cardiology,
Second Department of Internal Medicine and Cardiology Center,
University of Szeged
Doctoral School of Clinical Medicine,
University of Szeged

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INTRODUCTION

Until recently, in cardiovascular interventions there was only one transradial access and when speaking about the technique, the term “radial puncture” was unanimously used without the need to expand further details about its location at the forearm. Terms such as “proximal radial access” or “distal radial access” appeared only later, when it was proven that the radial artery can be punctured even more distally, at the anatomical snuffbox area, on the dorsal face of the hand. The initial one is now defined as the conventional or proximal transradial technique (PRA). This is quite established in everyday practice and in the following introductory chapters we will discuss details about the advent of other newer distal radial access, how it appeared, what advantages and disadvantages it brings and why it is considered more minimalist than its predecessor.

The distal radial access (DRA) is a novel access which consists of puncturing and accessing the distal segment of the radial artery which is situated superficially on the dorsal side of the hand, at two levels: the anatomical snuffbox and distal of the extensor pollicis longus tendon. These 2 alternative puncture points are distal to the carpal anastomotic networks and the superficial palmar arch and yield the same advantages as conventional PRA with an additional potential to maintain antegrade flow in the forearm radial artery

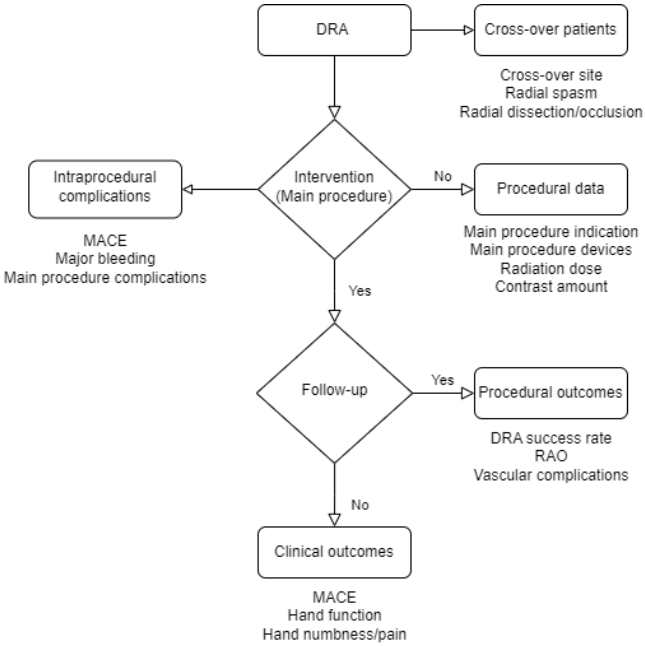
during hemostatic compression of the distal radial artery, reducing thereby the risk of retrograde thrombus formation, and forearm radial artery occlusion (RAO). Other significant advantages are faster hemostasis and much better patient and operator ergonomics, especially when performing left DRA. Those significant advantages are contrasted by a slightly smaller diameter of the distal radial artery, a less predictable angulated course and a different puncture curve, potentially impacting on device selection and procedural planning. Its place in cardiovascular interventions remains to be analyzed independently, to establish in an arbitrary way if DRA represents an evolution of PRA and not just a sophisticated alternative.

The aims of this doctoral thesis are as follows: (1) to explore the safety and feasibility of DRA in different clinical scenarios: acute coronary syndrome, chronic coronary syndromes (elective cases), dual radial access for chronic total occlusion interventions, radial access for structural interventions, and radial access for peripheral interventions; (2) to define the role of ultrasound in performing DRA; (3) to discuss procedural insights and technical aspects of DRA from the perspective of the enrolled cohorts; (4) to find new roles of DRA: from the correlation of radial artery calcification with other cardiovascular factors to new opportunities to recanalize RAO.

METHODS

Between 2019 and 2022, a total of 1450 patients were recruited prospectively in a large, multileveled database. This registry generated 5 major studies: (1) DRA in coronary and peripheral procedures (2) DRA vs PRA for CTO PCI procedures (3) distal radial balloon aortic valvuloplasty: the DR-BAV pilot study (4) transcatether aortic valve implantation: DRA as secondary access (5) DRA for chronic radial artery occlusion (RAO) recanalization: a pilot study. This thesis presents the findings of these five studies.

The flowchart of the enrollment is presented in Figure 1:



Because our study was a vascular access-related study, focused on the safety, feasibility and performance of DRA in various transcatheter interventions, 2 types of endpoints were defined. The primary outcomes of the study were the success (procedural plus clinical) and access site complications (severe arterial spasm, forearm hematoma, radial artery occlusion, bleeding, pseudoaneurysms and fistulae). Procedural success was defined as successful main procedure outcome via DRA.

The secondary endpoints included were major adverse cardiac and cerebrovascular events (MACCE) and procedural performance characteristics (volume of contrast, fluoroscopy time, radiation dose, procedure time, hospitalization time).

RESULTS

Overall, in all 5 studies there was a high rate of procedural success (>90%) and no significant rates of vascular complications. All main transcatheter interventions could be performed via DRA, with a loss cross-over rate (<5%). For coronary procedures, access was obtained within 1.26 ± 1.1 min. The overall technical success rate, which was described as a successful DRA sheath insertion, was achieved in 1208 (97.4%) patients. RAO was observed in five

patients (only 0.4% of the entire study population). No major complications occurred.

In the CTO cohort, we found that procedural and clinical success rates were comparable through DRA vs. PRA ($p = 0.6$), moreover, the 12-months rate of MACCE was similar across the 2 groups (9.09% vs. 18.2%, $p = 0.35$). Despite longer procedure times for DRA (median 70.0 min vs. 37.5 min, $p < 0.001$), it associated with lower radiation doses (median 1,000 mGy × cm2 vs. 1,515 mGy × cm2, $p = 0.018$). These findings suggest that DRA may be an attractive and ergonomic alternative to PRA that is as safe and effective for CTO procedures. Moreover, although not statistically significant, the RAO rate seems to be lower with DRA, which is of clinical importance because, for many patients, this is not their last intervention in the catheterization room.

For the aortic valvuloplasty cohort, we included 32 high-risk patients with severe symptomatic aortic stenosis in the study with a mean age of 80±8 years. Four main indications for BAV were included: 50% stratification (meaning BAV as emergency, with no prior Heart-Team decision for further TAVR/surgical aortic valve replacement), 31% bridge-to-TAVR, 6% bridge-to-SAVR and 12% palliative therapy. Technical success was achieved in all patients (100%). Hemodynamic success was achieved in 30 patients

(93.75%). Invasive max and mean gradients were reduced from 73±22 mm Hg and 49±22 mm Hg to 49±19 mm Hg and 20±13 mm Hg, respectively (p = <.001), with a mean pre-procedural LV ejection fraction of 50.22% (the majority of patients suffered from normal-flow, high-gradient AS). Clinical success was achieved in 29 patients (90.6%). Nineteen (59%) and 26 (81%) patients were mobilized within 12 and 24 hours, respectively. The mean fluoroscopy and procedural times were 9.10±6.9 minutes and 47±20 minutes, respectively. No intraprocedural or periprocedural deaths occurred. Neither major intra- or periprocedural complications (balloon entrapment or compartment syndrome requiring surgical intervention) nor bleeding complications occurred in the study population. These preliminary data show the safety and feasibility of DRA with larger catheters.

We also tested the role of DRA as secondary access in transcatheter aortic valve implantation (TAVI). The cohort comprised of 41 patients. TAVI was successful in all cases. Technical success was achieved in all patients (100%). Clinical success was achieved in 40 patients (97,5%). Hemodynamic success was achieved in all patients (100%). By hemodynamic investigation, the peak-to-peak mean gradient decreased from 76.8 ± 27.2 to 10.7 ± 5.1 mmHg (p=0.001). Balloon postdilatation was performed in 19 cases (46.3%),

and the crossover to urgent surgical aortic valve implantation was 0%. Secondary access was achieved through the left DRA only (100%) and the crossover rate to the femoral access site was achieved in 3 cases (7.31%) of major primary femoral access perforation. No complications occurred due to transradial access. Transfemoral vascular access site complications occurred in 7 cases (17.07%): 1 occlusion, 2 flow-limiting stenoses and 4 perforations of the common femoral artery. Three complications were successfully managed using balloon dilatation and balloon tamponade from the transradial access.

In the last study, a special role for DRA was investigated: the antegrade puncture and radial angioplasty for the proximal chronic RAO via DRA. This was a proof-of-concept study. From July 2016 to March 2022, we prospectively enrolled 30 consecutive patients with RAO. The mean age of the patients was 63 ± 11 years, and 15 patients (50%) were men. Almost the entire cohort was known to have coronary artery disease (n = 27, 90%). Among the study population, 21 patients (70%) received right DRA, and the most common indication for the procedure was percutaneous coronary intervention (PCI) (19, 63.2%). Most patients had asymptomatic RAO (n = 28, 93.3%); only two (6.6%) reported numbness in their hand.

The procedural characteristics and success rate of DRA RAO recanalization are listed in Table 9. Procedural success through retrograde wiring was 100% (n = 30), and all cases (n = 30, 100%) were performed by the “dottering” technique with the sheathless system. Moreover, there were no major vascular complications (0%); only two EASY 1–2 hematomas were described (10%), and one had an angiographically visible perforation (3%). The remaining dissections were several (n = 16, 53%) but were not flow-limiting. All patients had a good flow at the end of the procedure when a final upper limb angiography was performed by continuous injection while withdrawing the catheter. One case of periprocedural stroke was reported (3%) with onset immediately after the procedure (after sheath removal) and recovering 24 h later. As for efficacy endpoint, 27 of the radial arteries (90%) remained patent at the one-month follow-up.

In summary, transcatheter interventions are becoming increasingly complex, and the chronic nature of coronary artery disease forces patients to undergo repeated interventions throughout their lives. In this context, vascular access becomes as important as the intervention itself, and special attention must be paid to this part of the procedure and its education among the operators. Of course, RAO prevention remains desirable. Patent hemostasis should be

universally indicated, and ultimately, radial artery recanalization via DRA may reopen “closed doors” for selected patients. While head-to-head comparisons between PRA and DRA have been started, we believe randomized, controlled trials directly comparing DRA to PRA are not sine qua non with regard to juxtaposition between the two sites as one does not substitute the other. DRA represents an evolution and a complement of the developing nature of transradial access and nuances such as preservation of the common radial artery, easier hemostasis, and ergonomics play a role when choosing a specific entry site.

CONCLUSION

DRA is a safe and feasible vascular access, with great versatility among different transcatheter procedures. Reduction in the number of early and late radial artery occlusions, nerve damage, local hematoma, and major bleeding are distinct advantages of the DRA over the PRA. Mastering the technique expands the access options for operators and increases patient comfort. In our study, we found no evidence of increased risk of periprocedural or long-term adverse outcomes for DRA across all types of interventions. Furthermore, we demonstrated the personalized role of Doppler ultrasound in guiding DRA and showed different types of learning curve patterns. Even in

the hands of an experienced interventional cardiologist, questions remain regarding its routine use, especially in patients with acute coronary syndrome when it is necessary to minimize the time of puncture and catheterization of the access artery. Randomized studies would elucidate the impact of DRA on hard clinical endpoints such as severe bleeding or mortality.