Evaluation of radial artery occlusion in patients undergoing diagnostic and therapeutic coronary procedures via distal radial access. A retrospective observational study (RDISTAL DOR)

Avaliação de oclusão da artéria radial em pacientes submetidos a procedimentos coronários diagnósticos e terapêuticos pelo acesso radial distal. Um estudo observacional retrospectivo (RDISTAL DOR)

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ABSTRACT – Background: The use of the distal radial access for invasive coronary procedures has been rapidly adopted by the medical community, but with no evaluation of efficacy and safety outcomes of this approach. The objective was to evaluate the rate of radial artery occlusion involved in this technique, using Doppler ultrasound. **Methods:** This was an observational, retrospective study involving patients undergoing invasive diagnostic or therapeutic coronary procedures via distal radial access, with assessment of the radial artery patency by Doppler ultrasound. The primary outcome analyzed was the rate of radial artery occlusion. **Results:** Between July and December 2020, 51 patients underwent procedures via distal radial access, with assessment of the radial artery patency, out of a total of 603 patients seen during this period. Patients were aged 58 ± 10.8 years, 68.6% were male, 26.9% had diabetes mellitus, and 68.6% were diagnosed with acute coronary syndrome. Diagnostic procedures were performed in 68.2% of sample, and 23.5% of patients had undergone a previous use of the ipsilateral proximal radial access. Doppler ultrasound was performed over a mean period of 24 hours, and no occlusion of the radial artery was observed, with mean time for sheath insertion of 1.9 minutes. There was no major vascular complication. In two patients, pain was observed at the access point; another two had a small subcutaneous hematoma, and, one patient, presented with moderate spasm. **Conclusion:** The use of distal radial access was associated with a low rate of hemorrhagic complications in the access route, and absence of occlusion of the radial artery by Doppler ultrasound assessment.

Keywords: Diagnostic techniques and procedures; Radial artery; Cardiovascular surgical procedures; Diagnostic techniques, cardiovascular; Hemorrhage

RESUMO – Introdução: A utilização do acesso radial distal para procedimentos coronários invasivos tem tido uma rápida absorção pela comunidade médica, entretanto, sem avaliação dos resultados de eficácia e segurança dessa abordagem. O objetivo deste estudo foi avaliar a taxa de oclusão da artéria radial nessa técnica, por meio do ultrassom Doppler. **Métodos:** Estudo observacional, retrospectivo, envolvendo pacientes submetidos a procedimentos coronários invasivos diagnósticos ou terapêuticos pelo acesso radial distal com avaliação da perviabilidade da artéria radial pelo ultrassom Doppler. O desfecho primário analisado foi a taxa de oclusão da artéria radial. **Resultados:** Entre julho e dezembro de 2020, 51 pacientes realizaram procedimentos pelo acesso radial distal com avaliação da perviabilidade da artéria radial, de um total de 603 pacientes durante esse período. A idade foi de $58 \pm 10,8$ anos, sendo 68,6% do sexo masculino, 26,9% diabéticos, e o diagnóstico de síndrome coronária aguda se deu em 68,6%. Procedimentos diagnósticos foram realizados em 68,2% da amostra, e em 23,5% dos pacientes com uso prévio do acesso radial proximal ipsilateral. O ultrassom Doppler foi realizado num período médio de 24 horas, não se observando qualquer oclusão da artéria radial, com tempo médio para inserção da bainha de 1,9 minuto. Não ocorreu complicação vascular grave.

Em dois pacientes, observou-se dor em local do acesso; outros dois tiveram hematoma subcutâneo pequeno, e, em um paciente, espasmo moderado esteve presente. **Conclusão:** A utilização do acesso radial distal foi associada com baixa taxa de complicações hemorrágicas na via de acesso e ausência de oclusão da artéria radial por meio da avaliação pelo ultrassom Doppler

Descritores: Técnicas e procedimentos diagnósticos; Artéria radial; Procedimentos cirúrgicos cardiovasculares; Técnicas de diagnóstico cardiovascular; Hemorragia

INTRODUCTION

The use of distal radial access (DRA), through the structure known as the anatomical snuffbox or through the back of the hand, has recently emerged as a potential vascular access alternative for diagnostic and therapeutic procedures, namely, coronary angiography (CAG) and percutaneous coronary intervention (PCI).¹⁻⁵

Radial artery cannulation in its distal course, via the back of the hand, allows the patient to keep the forearm pronated and facilitates crossing of the left hand over the right hip during a left radial approach. In addition, the distal puncture preserves the radial segment of the proximal forearm for future interventions or as a conduit for arterial graft. This is a crucial aspect, since a radial artery occlusion may prevent the future use of the vessel for preparing a hemodialysis fistula, performing a myocardial revascularization surgery, a reconstructive surgery or, most importantly, repeating the access through this artery.

The most important benefit of the conventional or proximal radial approach (PRA) stems from a reduction in vascular complications and vascular access-related bleeding.⁶ The most frequent and important complication is radial artery occlusion (RAO), with an incidence of 7.5% in the first 24 hours, and a reduction of up to 5.5% in a 30-day follow-up.^{7,8} Radial artery occlusion rate using the distal radial approach is shown to be lower in non-randomized studies,^{2,9,10} with rates below 5%. This increases the potential for expansion of this new access route, although the complications of the procedure and the clinical outcomes of DRA have not been systematically assessed, therefore the safety of this approach remains unknown.¹¹

In the present study, the objective was to investigate the impact of DRA on RAO, and post-procedure hemorrhagic events in three centers with an increasing experience in the technique.

METHODS

This was an observational, retrospective study, including patients who underwent CAG and PCI procedures via DRA, and had the radial artery patency assessed by arterial Doppler ultrasound (USD) during hospitalization, from July to December 2020. The USD was performed only on

patients who remained hospitalized in our hospitals, excluding from this sample those who underwent the procedure via DRA, but were not submitted to USD, such as elective patients or those from external hospitals with no cath lab, who underwent the exam and returned to their hospitals shortly after its completion. Clinical, procedural and USD data were obtained from the analysis of a dedicated database and hospital records.

The DRA procedure was performed after palpating the radial pulse to identify a point of puncture in the anatomical snuffbox, and in the dorsal region of the hand. A distal radial artery puncture is similar to a conventional radial artery puncture performed at wrist level: the patient's right arm is placed along the patient's body, in a neutral position, on a support plate or a dedicated device, with its lateral side turned up. To favor a shift of the distal radial artery to the surface, the patient is asked to grasp his or her thumb under the other four fingers or hold a roll of gauze. In the case of access from the left side, the same technique is used, with the operator also on the left side of the patient. After a subcutaneous injection of lidocaine, the distal radial artery around the bone surface is punctured with a 21-gauge metal needle, at an angle of 30° to 45° and medial orientation, avoiding transfixing the vessel. After a successful puncture, a 0.021" flexible, linear metallic guidewire is inserted through the needle. Then, a hydrophilic sheath with a reduced external diameter of 10cm is inserted into the distal radial artery (Glidesheath Slender® 6F, Terumo, Tokyo, Japan). A solution containing 5,000IU of heparin sulfate and 0.2mg of nitroglycerin is infused through the sheath extension. If a PCI is planned, 100IU/kg body weight of unfractionated heparin is administered.

After the procedure is finished, the sheaths are removed immediately, and compression is applied using an adapted TR Band device (Terumo, Tokyo, Japan). Its rigid acrylic support needs to be removed, rendering it more flexible and allowing a suitable adaptation to the anatomy of the hand and the snuffbox. The removal of the wristband started after 1 hour, for diagnostic procedures, and after 2 hours, for therapeutic procedures. The distal pulse of the hand and changes in skin color were monitored during compression.

The main objective of the analysis was to assess the patency of the radial artery using USD during hospitalization. Radial artery occlusion was defined as absence of flow on color Doppler or absence of pulse wave on pulsed Doppler. Additional analyses included time to obtain vascular access (from the initiation of local anesthesia to the insertion of the sheath), access route bleeding rate according to the Early Discharge after Transradial Stenting of Coronary Arteries Study (EASY) criteria,¹² vascular complications of the procedure (hand ischemia, vascular perforation, formation of pseudoaneurysm or radial arteriovenous fistula, infection and need for vascular repair) at the puncture site, and spasm rate using a subjective scale (slight, moderate, and important). In this evaluation period, the operators had already performed at least 30 procedures via DRA.

For categorical variables, absolute and relative frequencies were calculated and, for numerical variables, summary measures (mean and standard deviation). This study was approved by the Ethics Committee of *Hospital e Maternidade São Luiz*, and registered at *Plataforma Brasil* (CAAE: 43964621.2.0000.0087). The research was exempt from the Informed Consent Form, but it was conducted in accordance with the principles of the Declaration of Helsinki.

RESULTS

Between July and December 2020, a total of 603 patients underwent diagnostic and therapeutic procedures to assess and/or treat coronary heart disease (Figure 1). Of this total, 51 patients who underwent DRA procedures with assessment of radial artery patency by USD during hospitalization, and had complete information in medical records and dedicated database, were evaluated in three operating hospitals. The procedures were performed by two operators with experience in the distal radial technique.

The clinical characteristics of the study population are shown in table 1. The mean age was 58 years, 68.6% were male, and 26.9% had diabetes mellitus. Unstable clinical

presentations accounted for most indications (68.6%). Diagnostic procedures were performed in 62.7% of sample, with the use of 5F sheaths (type Slender® 6F) in all procedures (Table 2), and the right side access was used in most cases (98.1%). About a quarter of the patients had undergone previous procedures via ipsilateral PRA, and two patients (3.8%) had been submitted to procedures via ipsilateral DRA. A selective compression wristband was used in all cases for hemostasis.

Doppler ultrasound was performed over a mean period of 24 hours (Table 3), and no occlusion of the radial artery was observed, with mean time for sheath insertion of 1.9 minute.

All patients were evaluated at the time of hospital discharge, with no complications found, such as hematoma with extension to the forearm and hand, perforation, dissection, pseudoaneurysm, arteriovenous fistula, ischemic injury, functional deficit and paresthesia. In two cases, the pain reported in the region of the puncture resolved with analgesia; in two other cases, there were small subcutaneous hematomas (2cm), classified as type I, according to the EASY study, and in one case, moderate spasm was observed, without any further complication.

CAG: coronary angiography; PCI: percutaneous coronary intervention; USD Doppler ultrasound.

Figure 1. Study flowchart.

Table 1. Clinical features

Variables	
Age, years	58±10.8
Male	35 (68.6)
Body mass index, kg/m ²	29±4.40
Diabetes mellitus	14 (26.9)
Hypertension	32 (62.7)
Dyslipidemia	20 (39.2)
Smoking habit	32 (62.7)
Family history of CAD	6 (11.8)
Prior MI	6 (11.8)
Previous percutaneous coronary intervention	8 (15.7)
Previous coronary artery bypass graft	0
Previous stroke	0
COPAD	2 (3.9)
Chronic renal failure	1 (1.9)
Clinical indication of the procedure	
Silent ischemia	9 (17.6)
Stable angina	7 (13.7)
NSTE-ACS	34 (66.7)
STEMI	1 (1.9)

Results expressed as mean±standard deviation or n (%).

CAD: coronary artery disease; MI: myocardial infarction; COPAD: chronic obstructive peripheral arterial disease; NSTE-ACS: non-ST-segment elevation acute coronary syndrome; STEMI: ST-segment elevation myocardial infarction.

Table 2. Angiographic characteristics and procedures

Variables	
Type of procedure	
Coronary angiography	32 (62.7)
PCI	5 (9.8)
<i>Ad hoc</i> PCI	14 (27.4)
Access side	
Right	50 (98.1)
Left	1 (1.9)
Severity of CAD	
Absence of obstructive lesions	20 (39.2)
Single vessel	21 (41.2)
Multivessel	10 (19.6)
Sedation/analgesia	51 (100.0)
Prior conventional radial access	12 (23.5)
Prior distal radial access	2 (3.8)
Procedure duration, minutes	31.9±20.2
Fluoroscopy time, minutes	8.1±6.6
Contrast volume, mL	77.5±44.52
Type of hemostasis	
Selective compression wristband (TR Band)	51 (100.0)

Results expressed as n (%) or mean±standard deviation.

PCI: percutaneous coronary intervention; CAD: coronary artery disease.

Table 3. Vascular complications at the puncture site and serious adverse events during the in-hospital period

Variables	
Radial artery occlusion by US Doppler	0
Time to perform the US Doppler, hours	24±11
Sheath insertion time, minutes	1.9±1.3
Bleeding in the access route (EASY criteria) ¹¹	2 (3.8)
Severe bleeding (BARC 3 and 5)	0
Vascular complications	0
Local pain after the procedure	2 (3.8)
Spasm rate	1 (1.9)
Complications in the access route	0
Neurological complications in the access route	0

Results expressed as n (%) or mean±standard deviation.

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

DISCUSSION

In this observational, retrospective sample, there was no case of RAO assessed by USD during hospital stay, which was performed mostly in the first 24 hours. In this small group, there was also no bleeding complication extending to the forearm and hand, nor major vascular complications, except for the presence of pain in the puncture site after the procedure in two patients, two small subcutaneous hematomas and one case of moderate spasm.

Radial artery occlusion, as the most frequent post-procedure complication, limits the use of repeated transradial procedures on the same wrist. The incidence of RAO is high in the first 24 hours, and decreases in the following months. Minimizing the risk of early RAO should be one of the main targets of a successful radial program in all PCI centers. In a meta-analysis conducted in 2016, the rate of early RAO was 7.7% in all studies (n=24), involving almost 11 thousand patients; and also when only randomized studies (n=12) were evaluated, including more than 5 thousand patients.⁷ Although the occurrence of RAO depends on several factors, including heparin dose, sheath size, use of vasodilators and hemostatic events, recent studies have suggested that damage to the arterial wall and subsequent changes, including medial dissection, intimal rupture and thrombus formation, are predominantly observed at the puncture site.^{13,14} This can contribute to the subsequent formation of a retrograde thrombus leading to total occlusion of the radial artery.

Distal radial access is considered to have the potential to maintain the integrity of the radial artery of the forearm and preserve it for future cannulation attempts. Mizuguchi et al. evaluated 228 patients undergoing CAG and PCI, with a RAO rate observed in only one patient (0.4%) by USD assessment and with no hematoma on the forearm.¹⁰ In a meta-analysis with five studies (four observational and one randomized) and 6,746 patients, Hamand et al. compared the clinical results of DRA *versus* PRA in CAG and PCI, and demonstrated

lower RAO with DRA (2.30% *versus* 4.86%; $p=0.004$), as compared to PRA,¹¹ with no significant difference in success rates, hematoma in the access site, spasm or dissection of the radial artery. This result was corroborated by a recent systematic review, including a total of 19 studies and 4,212 patients who underwent DRA procedures, with a success rate of 95.4%, and complications in 2.4% of cases, primarily bleeding and hematoma (18,2%), and a RAO rate of 1.7%, with a shorter compression time for hemostasis.¹⁵ Eid-Lidt et al., in a randomized study including 282 patients, compared the RAO rate by USD between DRA and PRA, 24 hours and 30 days after coronary procedure. In the intention-to-treat analysis, the RAO rates in 24 hours and 30 days were 8.8% and 6.4%, respectively, for PRA, and 1.2% and 0.6% in the DRA group (24 hours: $p=0.003$; 30 days: $p=0.007$).¹⁶

It is believed that the anatomic characteristics of the distal radial artery contribute to this low rate of occlusion in the radial artery of the forearm. In the DRA, the puncture site is located between the branch that irrigates the superficial palmar arch proximally and the short pollicis artery distally. Consequently, the antegrade flow through the superficial palmar arch can be maintained even after occlusion at the puncture site. This reduces the risk of retrograde thrombus formation in the radial artery of the forearm.² Therefore, the distal radial puncture can prevent RAO of the forearm.

Puncturing the distal radial artery in the anatomical snuffbox region is challenging and, like any technique, it has a learning curve. In a large prospective study, Lee et al. showed that the learning curve for the puncture time stabilized after approximately 150 cases.⁹ The identification of the smaller DRA lumen may explain this technical challenge.^{17,18} Ultrasound-guided access can collaborate for a better patient selection and a successful arterial cannulation, and also avoids potential injuries to the terminal vessels of fingers. Selecting the appropriate size of the sheath may be important, because a larger sheath size and a smaller artery diameter are well-known predictors of ar-

terial occlusion.^{7,19-21} In our study, 5F hydrophilic sheaths, type 6F Slender®, with thin-walled sheaths, which increase its internal lumen by more than 1F, were used for all patients, corroborating the low RAO rate.

DRA was first introduced in our services in 2017,⁵ with a progressive increase in its use and adoption by the physicians of the team. The puncture time in our analysis was 1.9 minutes, *i.e.*, similar to that found by Andrade et al. In no case was the USD used to guide the puncture. Currently, in one of the services provided, DRA is the preferential access in CAG and PCI procedures (Figure 2).

Although DRA clearly has several advantages, in terms of vascular complications, some specific issues must be noted. Among them is the impact of this approach on the blood supply of the scaphoid bone, which still needs to be studied, but which is not expected to be a point of concern, since the blood supply of the scaphoid bone is much more complex and extensive than previously thought.²² A low occurrence of neuropathy was described in only two studies (<2%).^{9,10} A branch of the superficial radial nerve is located in the anatomical snuffbox, and this can induce lesion to the nerve, which rarely occurs in the radial artery of the forearm, and may be the result of a needle injury during the puncture, or a long compression time. In our analysis, there were no cases of paresthesia or any other motor changes, but two patients had pain in the puncture site, which was relieved with analgesia and without the need for late follow-up.

There are several limitations to this study. This was an analysis of a retrospective observational registry. Although the current study was conducted in three centers, the sample set was relatively small, the observation period was short, there was no control group, and the RAO rate assessment by USD was conducted only in part of the total sample. In addition, the need for access-site cross-over rates were not assessed in this study, since the completion of the procedure via DRA was a requirement for inclusion. Further long-term studies, with larger sample sizes, are warranted for a more accurate assessment of the complications related to the procedure.

Figure 2. Temporal evolution of the use of distal radial access between January 2020 and January 2021.

CONCLUSION

Distal radial access was associated to a low rate of hemorrhagic complications in the access route and to absence of radial artery occlusion, by arterial Doppler ultrasound assessment, during hospital stay, when performing invasive coronary procedures. Future large-scale studies are needed to further elucidate our findings.

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None.

DECLARATION OF CONFLICTS OF INTEREST

The authors declare having no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: MT; data collection: MT and MHO; data interpretation: MT, VE and MHO; text writing: MT; approval of the final version to be published: MT, PBA, VE, SK, EMS, CNZ, FM and MHO.

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