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Review Article

Transradial access for coronary diagnostic and interventional procedures: Consensus statement and recommendations for India Advancing Complex CoronariES Sciences through TransRADIAL intervention in India – ACCESS RADIAL™: Clinical consensus recommendations in collaboration with Cardiological Society of India (CSI)

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ABSTRACT

Radial access for cardiac catheterization and intervention in India has been growing steadily over the last decade with favorable clinical outcomes. However, its usage by interventional cardiologists varies greatly among Indian operators and hospitals due to large geographic disparities in health care delivery systems and practice patterns. It also remains unclear whether the advantages, as well as limitations of transradial (TR) intervention (as reported in the western literature), are applicable to developing countries like India or not. An evidence-based review involving various facets of radial procedure for cardiac catheterization, including practical, patient-related and technical issues was conducted by an expert committee that formed a part of Advancing Complex CoronariES Sciences through TransRADIAL intervention (ACCESS RADIAL™) Advisory Board. Emerging challenges in redefining TR management based on evidence supporting practices were discussed to formulate these final recommendations through consensus.

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1. Introduction

The proportionate mortality due to cardiovascular disease (CVD) has increased from 20.6% deaths in 1990 to 29.0% in 2013 as per Indian demographics.¹ The age-standardized death rate due to CVD stands at 272 per 100,000 population.² Paralleling this increased morbidity and mortality, the treatment of CVD has also witnessed revolutionary changes with about 51% increase in the total percutaneous coronary intervention (PCI) between 2014 and 2015.³

Following the first transradial (TR) coronary angiography (CAG) in 1992 by Kiemenij, this technique with fewer vascular complications has repeatedly proven more beneficial compared to other approaches and has spread worldwide.^{4–6} Several studies have shown that early ambulation with radial access may improve clinical outcomes and reduce morbidity and mortality among patients with myocardial infarction and stroke.⁷ However, higher radiation exposure more so during the operator’s learning curve, radial artery occlusion (RAO) and limitations in guide catheter (GC) size flexibility could be some of the limitations with transradial intervention (TRI).⁷

With increasing usage of TRI in western countries, India has also shown a similar trend of increasing TRI practice and acceptance over the last decade. While European Society of Cardiology (ESC) and The Society for Cardiovascular Angiography and Interventions (SCAI) have published recommendations for best TRI practices, similar guidelines relevant to Indian scenario are lacking both for diagnostic and interventional procedures.^{8,9}

1.1. Need for the consensus recommendations

Concomitant with the surge in radial access there has been a proliferation of research and practice-based studies that have examined various technical issues and outcomes in TR procedures. Although data strongly support the use of TRI as the default method for coronary intervention, it is important to review the limitations of this technique and the supporting evidence in favor. Moreover, given

the differences in health care delivery systems and practice patterns among various countries, it remains unclear whether the advantages, as well as limitations of TRI (as has been published in western literature), could be generalized to India and the developing world at large. Importantly, changing practice from the transfemoral intervention (TFI) to the TRI will, in most cases, result in increased procedure time, contrast use and radiation exposure to operator and patient during the learning curve for new operators.

Hence, an Indian consensus document defining best practices, practical issues (e.g. training and experience of operators), patient issues (e.g. challenging arterial anatomy) and technical issues (e.g. size limitation for the GC) covering various facets of TR procedures should be developed. This could also help to standardize clinical practices, minimize complications, and bring out areas that need further study.

1.2. Methodology

The scientific advisory board named as Advancing Complex CoronariES Sciences through transRADIAL intervention (ACCESS RADIAL™), decided upon the topics to be selected for the present “best practices” statement by consensus. The decision was guided by patient-level and operator-level outcomes as well as the amount and quality of evidence to guide a specific practice. The core committee members of ACCESS RADIAL™ advisory board met to discuss current status, emerging challenges and redefined TR management guidelines for India. The main topics discussed were:

- i Issues and challenges of TRI in the Indian setting.
- ii Consensus on clinical benefits of TRI in India.
- iii Learning curve and transitioning to TRI as the standard of care practice.

The extensive literature review was done, and the members discussed the available evidence supporting practices related to each topic and the final recommendations were formulated

through a consensus. After an exhaustive discussion on each facet, the proposed consensus statements were derived as deemed necessary by agreement.

The writing plan has been structured into (i) the available SCAI/ESC guidelines, (ii) the current literature available on each subject to back up the guidelines and (iii) consensus statements/recommendations made at the end of each section.

2. Consensus recommendations from ACCESS RADIAL™ advisory board

2.1. Patient selection

Approximately 90% of patients can undergo TRI for PCI using a “radial first” approach.¹⁰ Both ESC and SCAI guidelines recommend hemodynamically stable patients with the palpable radial pulse as an ideal characteristic for patients undergoing TRI.^{8,9}

TRI is the preferred strategy over TFI for obese patients as it is difficult to locate the common femoral artery and control the post-procedural major bleeding in these patients.¹⁰ In 2012, Hibbert et al. retrospectively reviewed 564 consecutive coronary procedures in extremely obese patients [body mass index (BMI) > 40], of whom 203 (36%) underwent radial and 361 (64%) were subjected to femoral angiography. A significant decrease in major bleeding [3.3% versus 0.0%, odds ratio (OR): 0.12, 95% confidence interval (CI): 0–0.71, $p = 0.015$] and access site injuries (4.7% versus 0.0%, OR: 0.08, 95% CI: 0–0.48, $p = 0.002$) were observed following TRI as compared to TFI.¹¹

TRI may be preferred for older patients as well as patients with higher risks of bleeding.¹² Females, due to smaller radial artery lumen (2.43 ± 0.38 mm), may however pose a technical challenge to TR operators.¹³ Issues in elderly and female patients have been addressed separately in Section 2.5 entitled “TRI in high-risk groups”.

Recommendations (Table 1)

- ESC and SCAI guidelines recommend patient selection criteria to be followed except for age criteria and dual blood supply testing.
- Adequacy of collateral circulation should be assessed by new radialist using Allen’s or Barbeau’s test but is not mandatory for experienced operators.
- TRI can be used safely and effectively even in patients who are:
 - 85 years or older.
 - Obese.
 - Females.
 - At high risk of bleeding complications.
- Identification of arteries that could accommodate larger size sheaths should be based upon
 - Pre-procedural manual palpation.
 - Color Doppler Ultrasound sizing of the artery.

2.2. New radialist and learning curve

Studies have shown that operator efficiency improves with greater TRI experience. ESC recommends a caseload of at least 80

Table 1
Patient’s selection criteria and contraindication for TRI.

Selection criteria	Contraindications
A palpable large radial artery with a strong pulse	Absent radial pulse
Age \leq 85 years	Arteriovenous shunt for renal dialysis on the procedure forearm
Hemodynamic stability	Raynaud’s phenomenon
No history of prior ipsilateral brachial or transradial procedure	The potential use of the radial artery as a conduit for aortocoronary bypass

cases/operator in a year, to maintain skill levels and achieve best outcomes.⁹ The learning steps are shown in Fig. 1.⁹

However, SCAI guidelines do not provide any specific cut off for competency in TR procedures. Hess et al. found that more than 50 TRI procedures are needed for new radial operators to achieve outcomes compared to experienced radial performers (>300 TRIs).¹⁴ Louvard et al. reported 10% operator failure in the first 50 cases which dropped to 3–4% after additional 500 cases were performed.¹⁵

Recommendations

- Radial access should be the default approach but femoral access exposure during training is desirable and mandatory.
- Learning curve and case selection to be adopted as per ESC guidelines.
- A new radialist during learning curve should avoid cases having
 - Absent or diminished radial artery pulse.
 - Complex or difficult anatomies, including bypass grafts, unprotected left main stenosis, complex bifurcations, chronic total occlusions (CTO) and patients with peripheral vascular lesions en route.
 - Hemodynamically unstable patients.
 - Young females or elderly patients (>70 years old).
 - Any requirement of more than 6-French (Fr) size catheter for any reason.

2.3. Procedural details, device and hardware selection

2.3.1. Right or left radial artery

Right radial artery (RA) is considered more convenient for manipulating devices, including GCs. As per both ESC and SCAI guidelines, the right side is ergonomically more suitable for the majority of the operators.^{8,9} However, ESC recommends the choice of right or left RA to remain a matter of operator preference only.⁹ However, considerations favoring the choice of left RA include the presence of a left internal mammary artery (LIMA) graft and a short aortic arch. Post-bypass settings, the presence of severe tortuosity in right subclavian or a retro-oesophageal right subclavian (RORSA) makes the performance of TRI more difficult by using right RA.

Bertrand and his coworkers found that almost 90% of interventional cardiologists used the right RA as a first access route.¹⁶ However, recently published meta-analyses^{17–19} recommended the use of left RA for the diagnostic or interventional coronary procedures as right RA showed a small but statistically significant increase in fluoroscopy times [5.8 ± 4.4 min versus 5.3 ± 4.2 min, standard deviation (SD) of the mean = 0.157, $p < 0.001$] and contrast use (84 ± 35 ml versus 82 ± 34 ml, SD of the mean = 0.082, $p = 0.003$).¹⁷

Recommendations

- Right RA should be the default for both diagnostic and interventional procedures.
- The choice could be based on operator preference (e.g. a left-handed operator may prefer left RA).
- Use of left RA for TRI may reduce the challenge for operators in patients with any of the following in isolation or in combination:
 - Severely tortuous right subclavian artery.
 - RORSA.
 - PCI in calcific tortuous or shepherd crook right coronary.
 - LIMA and saphenous bypass grafts.

2.3.2. Pre-procedural preparation

A well-informed patient is less anxious and more cooperative. ESC guideline suggests puncture site disinfection with shaving limited to the wrist quadrant where the final bandage is applied

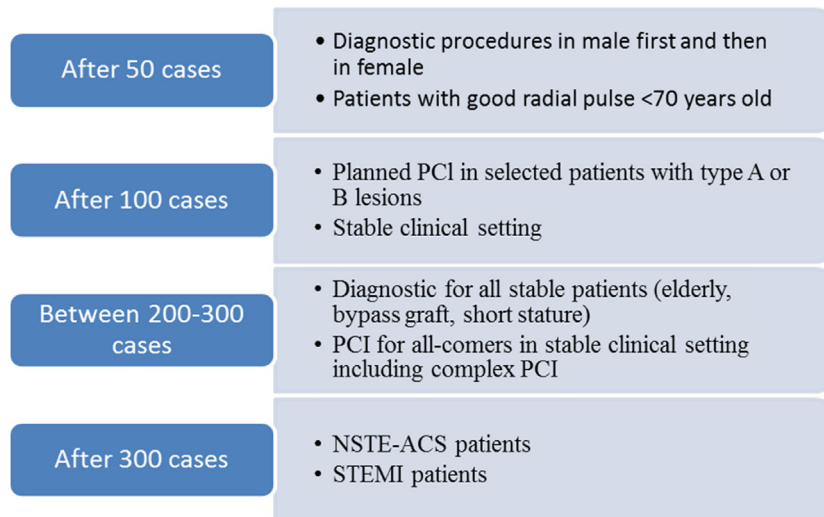


Fig. 1. Learning steps and type of cases.

NSTEMI-ACS- non-ST-segment elevation acute coronary syndromes; STEMI- ST segment elevation myocardial infarction; PCI- percutaneous coronary intervention.

after compression. The wrist is stabilized and kept parallel to the table all through the procedure, palm up, with slight hyperextension at the time of the puncture.⁹ SCAI guidelines further suggest establishing pre-procedural intravenous (IV) access on the contralateral arm. This prevents access site from getting impeded once a hemostatic device is placed.⁸

A non-invasive blood pressure (NIBP) cuff should be placed on the contralateral arm to monitor blood pressure (BP). Arm abduction at 70° angle on an arm board with the hand in a “palm-up” position has been used for sheath insertion.⁸ Prone position CAG via left TRI has also been described for patients with chronic back pain who are unable to lie down in a supine position.²⁰

Recommendations

- Counseling and appropriate premedication should be used in patients to avoid anxiety induced radial artery spasm (RAS).
- Right forearm and both groin (for standby alternative access of femoral artery and/or vein) must be prepared.
- Puncture site disinfection with shaving limited to the wrist quadrant.
- Establish pre-procedural IV access on the contralateral arm. BP cuff on contralateral arm for NIBP.
- Use radial arm board with the rolled towel or support pad for the appropriate positioning of the patient’s arm and a good working angle.
- Arm abduction at 70° angle to improve visualization for the RA puncture. While the same must be kept parallel to table all through the procedure for better catheter support and pushability.
- A pulse oximeter could be placed on the thumb or forefinger of the wrist being accessed.

2.3.3. Anesthesia, puncture and cannulation

Topical application of an anesthetic agent and proper selection of the puncture kit may improve patient comfort and can reduce the risk of RAS and cannulation failure. As per ESC guidelines, the ideal site for puncture is 2–3 cm proximal to the styloid process. The choice between a bare needle and venous cannula techniques is operator-dependent, with neither techniques being clearly superior to the other.⁹

In addition, SCAI guideline recommends a subcutaneous (SC) injection of lidocaine and nitroglycerin (NTG) at the puncture site

to promote RA dilatation. The RA can either be punctured directly (anterior) using a short (1.5 cm) 21-gauge direct access needle and a small caliber wire (0.018”–0.025”) passed through or using a needle with sheath via through-and-through puncture (double wall) technique. For the latter technique, the sheathed needle is usually held at a 30–45° angle to the horizontal plane.⁸

Although a direct puncture is ideal, it is usually not possible to achieve in some cases, and a “through and through” puncture is often required.²¹ Administration of about 2 ml local anesthesia cocktail (4 ml 2% Lignocaine + 1 ml NTG 500 µg) closer to the puncture site can increase the RA palpability. Midazolam should be co-administered with fentanyl and local anesthesia to reduce anxiety and prevent RAS.²² Deora et al. described modified RA puncturing technique (Patel and Shah’s modification) by using 20-gauge Teflon-coated needle at an angle of about 60–70° to the skin. This prevents rolling movement of the artery with better fixation.²¹ Ludwig suggested combining bare needle and venous cannula techniques for better skin penetration while maintaining the soft insertion of the cannula. Though time-consuming, the main advantage is the ability to perform angiography and locally administer drugs, prior to sheath insertion.²¹

Recommendations

- Use SC injection of lidocaine before puncture.
- Sheath covered needle is recommended for radial puncture.
- Double wall puncture technique should be preferred.
- Ideal RA cannulation site is about 2–3 cm proximal to the styloid process.
- In case of unsuccessful attempt to puncture, a complete removal of the needle and a reattempt of subsequent puncture just proximal to the initial site may be done.
- With the transient loss of pulse, waiting period of 10 min is sometimes helpful so as to relieve the spasm.

2.3.4. Sheath size

The introducing sheath is used to gain arterial access and facilitate the exchange of multiple catheters and wires while maintaining hemostasis. Sheath size: RA mismatch initiates the cycle of radial spasm and subsequent RAO. Both ESC and SCAI guidelines recommend 5-Fr or 6-Fr sheaths with a highly tapered tip for smooth transition.^{8,9} ESC cautions the use of 8-Fr sheaths at the possible cost of increased late RAO rate.⁹ In addition, SCAI also suggests the use of hydrophilic sheaths due to their added benefits

of less intimal trauma, increased patient comfort and possibly higher long-term arterial patency.⁸ However, the small size of the RA remains an important limitation for the use of large-bore guiding catheters (>6-Fr), restricting the treatment of highly complex lesions through the TR approach. Glidesheath slender[®] (GSS, Terumo) is a newly dedicated radial sheath with a thinner wall and hydrophilic coating – For e.g.: 7-Fr GSS combines an inner diameter (ID) compatible with any 7-Fr guiding catheter and an outer diameter (OD) smaller than current 7-Fr sheaths.

A recent meta-analysis comparing safety of 5-Fr and 6-Fr arterial sheaths in TRI-based coronary procedures, found 5-Fr sheath to be safer in patients with higher bleeding propensity or renal injury as it limits bleeding complications [OR = 0.58 (0.38–0.90), $p = 0.02$] and contrast volume administration [mean difference (MD) = –22.20 (–36.43 to –7.96), $p < 0.01$], without compromising procedural outcome [OR = 0.95 (0.53–1.69), $p = 0.86$].²³ In the Leipzig registry, RAO occurred in 13.7% and 30.5% of patients after 5-Fr and 6-Fr sheath use, respectively ($p < 0.001$).²⁴ Generally, the 10 cm length of 5-Fr or 6-Fr sheath is used for diagnostic angiography and PCI.²⁵

Recommendations

- Use smaller size radial sheath with the hydrophilic coating to reduce the risk of RAO.
- The usual practice is to use 5-Fr sheath for diagnostics and 6-Fr sheath for PCI.
- 7-Fr sheaths and guiding could be used but only if RA size is confirmed to be ≥ 2 –3 mm on ultrasound.

2.3.5. Adjunctive pharmacological therapy

Intra-arterial (IA) calcium channel blockers (CCBs) and/or nitrates are routinely utilized after vascular access to reduce radial vascular tone and prevent RAS. Both ESC and SCAI guidelines recommend NTG and CCBs as the most common components of the spasmolytic radial cocktail. Proper heparinization (unfractionated heparin 50 IU/kg or 5000 IU in bolus administered IA or IV) is also important to prevent RA thrombosis.^{8,9} SCAI guidelines also recommend cocktail dilution with either blood or saline.⁸

A prospective study by Spaulding et al. has shown a significant correlation between heparin therapy and post-procedural RAO. Asymptomatic RAO was noted in 71% of untreated patients, 24% of patients receiving 2000–3000 IU of heparin and only in 4.3% of patients receiving a dose of 5000 IU of heparin ($p < 0.05$).²⁶ In 2011, similarly, 5000 IU of heparin was found to reduce the incidence of RAO from 5.9% (observed with use of 2000 IU of heparin) to 2.9% ($p = 0.017$).²⁷ Also, IA administration of NTG with ($p = 0.001$) or without verapamil ($p = 0.003$) immediately after sheath insertion showed a significant reduction in RAS as compared to the placebo group.²⁸ Lack of pre-treatment has been found to be associated with RAS in up to 30% of the cases.²⁹

Recommendations

- NTG and CCBs (verapamil/diltiazem) should be injected IA after sheath placement to reduce the incidence of RAS.
- Proper heparinization with 5000 IU is important to prevent RA thrombosis.
- Dilute the cocktail (especially heparin) with blood before administering.

2.3.6. Guidewire

ESC guideline recommends a 0.014" polymer-jacketed wires or standard angioplasty wires to be placed under fluoroscopic guidance in presence of radial or brachial loops while SCAI guideline recommends a steerable 0.035" wire to be placed under fluoroscopy in case resistance is felt during advancement of the 0.035" J-tip wire.^{8,9}

In a retrospective study, Aminian et al. achieved successful completion of the significant amount of TR procedures with the use of a 0.014" hydrophilic coronary guidewire (GW) in challenging anatomical conditions.³⁰ However, the choice of wires may vary from standard 0.035" straight or J-tipped stainless steel to 0.014" hydrophilic coronary GW.³¹ Regardless of the type of wire, advancement should be guided under fluoroscopy while crossing the subclavian artery and the brachiocephalic trunk.

Recommendations

- Use of small-caliber wires and catheters are recommended in order to ensure optimal safety.
- Routinely a 0.035" regular wire or Baby J wire gives good trackability.
- In difficult cases where resistance is felt using a standard wire, use of 0.035" soft hydrophilic wire under fluoroscopy guidance is recommended.
- In case of radial loops and bends, a 0.014" Percutaneous Transluminal Coronary Angioplasty (PTCA)-GW can also be used to navigate and then exchange for a smaller diagnostic catheter, followed by guiding catheter on a 0.035" exchange-length wire.

2.3.7. Diagnostic catheter

As of today, there are no standard defined for the optimal choice of radial catheters in daily clinical practice. However, the ESC guideline suggests Judkins right or Amplatz right for right coronary artery (RCA), Judkins left for left coronary artery (LCA) and special multipurpose catheters like Tiger II as further options.⁹ However, the universal catheters suggested by SCAI guideline for TR diagnostics and interventional cases include Kimny, Optitorque[®] (Terumo) Tiger and Jacky, Sones, Barbeau, MAC 30/30 and PAPA.⁸

To evaluate the practice of TRI, Bertrand et al. conducted a survey among 1107 interventional cardiologists in 75 countries between August 2009 to January 2010 and found the use of 44.9% Judkins left 3.5 and 21.6% Judkins left 4.0 for LCA and 58.8% Judkins right 4.0 for RCA. In addition, Judkins right remained the most frequently used catheter shape for angiography of the left (48.6%) or right bypass grafts (46.8%). However, the left bypass (11.5%) or Amplatz left (22.6%) catheters were used for left venous bypass grafts and Amplatz left (12.0%) or multipurpose (23.8%) catheters were used for right bypass grafts. Tiger II (Terumo) catheters were found to be most popular in India.¹⁶

Recommendations

- The diagnostics catheter is same for both TR and TF angiography, only downsizing of the catheter is required for TRI.
- For TR diagnostic angiographic procedure, the Tiger catheter is a standard catheter, but if it fails to hook, then Judkins or Amplatz diagnostic catheter can be used (Table 2).
- The ideal catheter should be atraumatic, easy to use, able to deliver a set volume of contrast at an adequate flow rate reliably, seat well and remain stable during coronary injection.

2.3.8. Guide catheter

Issues in GC selection include both GC shapes and Fr size. SCAI guidelines suggest the use of universal GCs of 5-Fr (to minimize arterial injury as well as to provide adequate back-up) and 6-Fr sizes for complex PCI and 7 or even 8-Fr size for patients with a large stature.⁸ The choice should be based on the risk of expected RAO, the diameter of sheaths and catheters used, and the need for adequate backup and device sizes to be tracked.

The large majority of operators use extra back-up (EBU) GCs for LCA during TRI. However, 20% still prefers to use Judkins left. For RCA PCI, Judkins right or Eric Cohen Right (ECR) remains the most popular choice, probably due to their ease in getting intubated into the vessel and gain additional support, if required.^{16,32} 5-Fr guiding

Table 2
Catheter shapes for transradial diagnostic procedures.

Universal diagnostic	Diagnostic
Tiger II (Tig)	Judkin left 3.5
Kimny	Judkin right 4.0
Jacky	Amplatz

catheters have been associated with increased patient comfort and reduced risk of RAO but remains to be used less frequently because of poor support.³³ Although 5-Fr GCs allow most interventions to be performed, in complex cases, 6-Fr GCs would be needed because of limitation of the ID. Larger (7- or 8-Fr) GCs or sheathless catheters may be useful in selected cases³⁴ at the expense of higher rates of RAS and RAO. Further, Japan recently developed miniaturized devices/sheaths called “slender systems” to overcome the limitation in GC size with bigger ID but smaller external sheath sizes.¹⁶

Recommendations

- The choice of GC should be operator dependent. However, for routine use, prefer to choose 6-Fr GC.
- Ultrasound sizing of the RA is not required with 6-Fr GC.
- In selected patients of large stature, 7-Fr GCs can be considered (only after ultrasound-based RA diameter confirmation).
- PCI of the left coronary system should be accomplished with extra support (XB) or EBU catheters whereas, for right coronary, ECR or Short Amplatz left (SAL¹) may be used. Common GC shapes for TRI procedures are shown in Table 3.
- During TRI, the GC curve should be downsized by 0.5 as compared to the femoral route. For example, while a JL 3.5 may be appropriate for the femoral route, it would be too large for the right radial route and a JL 3.0 would be the right choice.
- If using EBU family to hook the artery, it is recommended to use Judkin Left or Amplatz shapes.
- Ikari left 3.5 (IL 3.5), a single TR GC, appears to be safe and feasible for both right and left CAG and intervention.

2.3.9. Radial artery anomalies

Anatomic variations of the RA is an important factor responsible for TR procedure failure.³⁵ ESC guidelines recommend angiographic assessment, use of specific GW and caution while advancing the wire for the successful TRI in case of anatomical variations.⁹ SCAI guidelines further recommend leaving the 0.035" GW in the catheter while torquing it into place in cases of subclavian/innominate artery tortuosity.⁸

A study from China reported that normal anatomy population showed higher procedural success rate with TRI than anatomical variation group (97.6% versus 93.0%, $p < 0.001$).³⁶ Similar findings were reported by Lo et al. where patients with anomalous anatomy had a greater procedural failure rate than patients with normal anatomy (14.2% versus 0.9%, $p < 0.001$).³⁷ The reasons of procedural failure were high radial bifurcation (4.6%), radial loop (37.1%), severe radial tortuosity (23.3%) or other anomalies (12.9%).³⁷ This study also suggested the use of hydrophilic wire to traverse a radial loop. Patel et al. suggested the use of balloon-assisted tracking

Table 3
Common guide catheter shapes for Transradial intervention.

Universal Guide	Guide (left)	Guide (right)
MAC 30/30	EBU/XB 3.5	ECR, short tip Amplatz
Kimny	Judkin left	Judkin right 4.0
	Amplatz left	Amplatz right
	IKARI left	IKARI right

EBU- extra backup; XB- extra support.

(BAT) technique in their review article to decrease the procedural failure rate³⁸ while Garg et al. recommended pigtail assisted tracking of GC for navigating the difficult radial loop or bend.³⁹

Recommendations

- Prefer 0.035-in. hydrophilic wire in case of radial tortuosity and guide the same under fluoroscopic/angiographic guidance.
- If resistance is met in advancing the 0.035-in. J-tip regular wire, then replace it with PTCA-GW.
- Let the catheter rotate along with as required by the RA anatomy. Preventing the rotation of the catheter will produce spasm.
- Use of BAT technique or pigtail assisted tracking of GC is recommended in case of difficulty in the tracking of GC to access loops or bends in the RA.

2.4. Complications

2.4.1. Radial artery hemostasis

Favorable anatomical features of the RA allow for successful hemostasis through compression against the bony structure, thus minimizing TRI-associated bleeding complications.⁴⁰

Both ESC and SCAI guidelines recommend the use of radial compression devices, which deliver non-occlusive pressure on access site in achieving hemostasis. Compression pressure should be released gradually over a period of two hours.⁹ Additionally, SCAI guideline recommends to decrease the pressure of compression device to the point of mild pulsatile bleeding and evaluate RA patency by using the reverse Barbeau's test.⁴¹

After the procedure, manual compression can be safely performed once the anticoagulant effect of heparin has dissipated (activated clotting time [ACT] < 150–180 s).^{42,43} A recent systematic review found a significant lower rate of RAO with biopolymer dressing (Chitosen) as compared to the hemostatic device (OR 2.20; 95% CI 1.20, 4.02).⁴⁴ However, a Prevention of Radial artery Occlusion-Patent Hemostasis Evaluation Trial (PROPHET) found lower incidence of RAO with a patent strategy using the TR Band[®] (Terumo) as compared to traditional hemostasis strategy (using fully occlusive technique) at 24 h (5% versus 12%) and 30 days (1.8% versus 7.0%).⁴⁵ Similarly, PROPHET II also showed a significant reduction in the rate of RAO with patent hemostasis and prophylactic ulnar compression as compared to standard patent hemostasis (0.9% versus 3.0%; $p = 0.0001$) using TR Band[®] (Terumo).⁴⁶

Recommendations

- Use manual compression for patients of diagnostic angiography.
- Use TR band[®] in patients who have undergone the interventional procedure.
- To achieve hemostasis, maintain compression for 2–3 h or until ACT falls below 180 s.
- Radial artery patency should be evaluated by using reverse Barbeau's test, before discharge and during initial post-procedure follow-up visit.
- SCAI guidelines on the steps of patent hemostasis should be followed (Table 4).⁴¹

2.4.2. Radial artery occlusion

RAO is the most significant problem after RA catheterization, with prevalence ranging from 2% to 18%.⁴⁷ The risk factors associated with RAO include hardware size, artery diameter, anticoagulation dose, hemostatic compression method and time.⁴⁸ Both ESC and SCAI guidelines recommend the use of heparin during procedure and assessment of RA patency following procedure to prevent RAO. Although spontaneous recanalization occurs within a month in up to 50% of the cases of RAO, the usual

Table 4

Steps in the patent hemostasis process after transradial procedure.

-
- Step 1: Withdraw the arterial sheath 2–3 cm.
 Step 2: Apply the hemostatic device proximal to the puncture site and tighten or inflate it.
 Step 3: Remove the sheath.
 Step 4: Decrease the pressure of the hemostatic device to the point of mild pulsatile bleeding at the skin entry site. After 2–3 cycles of pulsatile bleeding, retighten the hemostatic compression device gradually to eliminate this pulsatile bleeding.
 Step 5: Evaluate radial artery patency by using the reverse Barbeau's test
-

treatment includes immediate compression of the ulnar artery for 1 h and/or low molecular weight heparin for 4 weeks.^{8,9}

Plante et al. compared bivalirudin versus heparin on the occurrence of RAO and found no significant difference (3.5% bivalirudin versus 7.0% heparin, $p=0.18$) 4–8 weeks after the procedure.⁴⁹ A recently published systematic review and meta-analysis by Rashid et al. found that higher doses of heparin significantly decreased the incidence of RAO (risk ratio 0.36, 95% CI: 0.17–0.76). Also, when these patients with RAO were treated with compression of the homolateral ulnar artery for 60 min, the incidence of RAO was reduced from 5.9% to 4.1% and 2.9% to 0.8% ($p=0.03$) in the low-dose and high-dose heparin group, respectively.⁵⁰ In 2014, Jaradat et al. showed successful treatment of RAO with balloon angioplasty and a 90-s intra-thrombus infusion of abciximab.⁵¹

Recommendations

- Use small size hardware, adequate anticoagulation and patent hemostasis technique during the procedure (Table 5).
- Avoid prolonged high-pressure compression following the procedure.
- Assess RA patency after the procedure.
- Use RA pulse, reverse Barbeau test and duplex ultrasonogram to confirm the diagnosis of RAO.
- Treat asymptomatic RAO with observation alone as spontaneous recanalization occurs with time.
- Compress ulnar artery and use heparin for 4 weeks in case of symptomatic RAO.

2.4.3. Radial artery spasm

RAS is reported to occur in 15–30% of patients after RA catheterization.⁵² The risk factors include small artery diameter, old age, female gender, diabetes, repeated multiple puncture attempts, pain, and low BMI.⁵³ However, it can be prevented by the use of proper local anesthesia, spasmolytic cocktail, hydrophilic arterial sheaths and/or catheters, gentle and balanced movement of catheters, and antianxiety medication as recommended by ESC and SCAI guidelines (Fig. 2).^{8,9}

Recently, it has been shown that RA pulse grading ≤ 2 together with female sex and GC usage are independent predictors of RAS (OR: 8, 95% CI: 1.8–36.2, $p=0.007$, OR: 10.6, 95% CI: 2.2–51.2, $p=0.03$ and OR: 25.8, 95% CI: 6.1–108.5, $p < 0.001$, respectively).⁵⁴ In addition, RA size to sheath mismatch is also a strong predictor of RAS (OR 4.7, 95% CI: 1.4–16.5, $p=0.012$).⁵⁵ Rafael et al. found that the routine use of spasmolytic cocktail significantly decreased the

Table 5

Strategies to reduce the risk of radial arterial occlusion.

-
- Small size hardware (appropriate sheath length and diameter)
 Adequate anticoagulation
 Patent hemostasis technique (avoid prolonged high-pressure compression)
 Reduce the number of attempts at the same radial artery
 Radial cocktail to reduce spasm
-

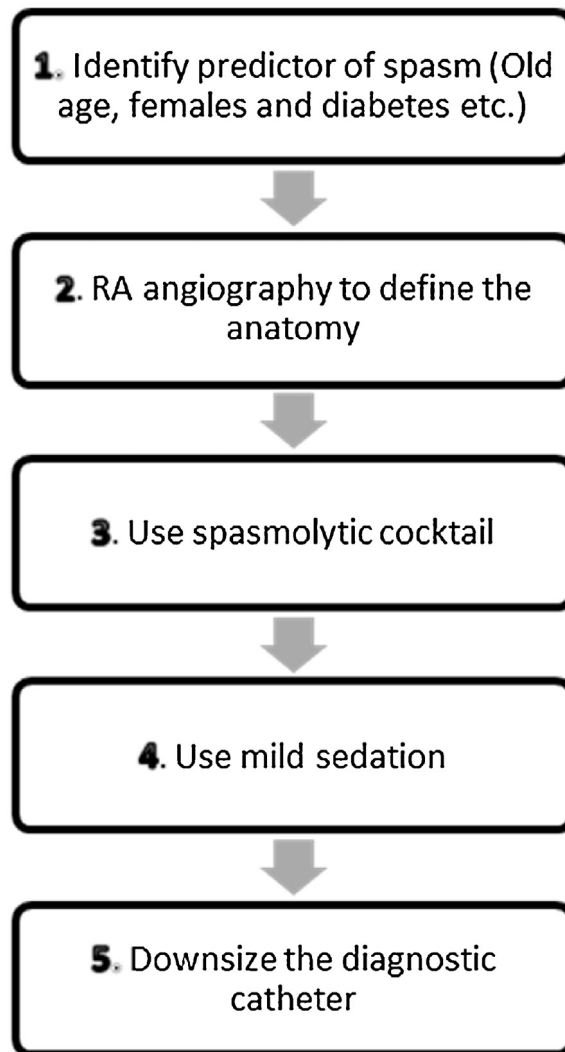


Fig. 2. Steps to prevent radial artery spasm.

incidence of RAS but no significant difference was observed in the occurrence of RAS between the cases where non-hydrophilic sheath ($n=18$) versus hydrophilic sheath ($n=4$) was used (20% versus 33%, $p=0.25$).⁵⁶ However, contrary findings were reported by Kiemeneij et al. where hydrophilic coating markedly decreased sheath induced spasm.⁵⁷ In 2013, Deftereos et al. found a significant reduction in the rate of RAS with the use of low doses of fentanyl and midazolam combination as compared to the control group ($p < 0.001$; OR: 0.29).⁵⁸ However, Astarcioğlu et al. found no difference in the occurrence of RAS between midazolam treatment group (20%) and the control group (21.3%).⁵⁹

Recommendations

- Prevent RAS with
 - Mild sedatives such as midazolam.
 - Routine use of hydrophilic hardware (5–6-Fr sheath).
 - Routine use of spasmolytic cocktail.
 - Antithrombotic strategy.
- Wait for a couple of minutes without handling the catheters as most vasospasms are temporary and resolve spontaneously with time.

2.4.4. Radial artery avulsion

It could occur during forceful removal of entrapped sheaths with intense RAS ongoing. SCAI guidelines recommend adequate time for the relaxation of the spasm artery.⁸

Excision of the avulsed RA without significant clinical sequelae has been reported in a number of cases.^{60,61} A case report showed successful treatment of RA avulsion with surgical ligation and resection.⁶² During RA avulsion, treatment should include IA administration of vasodilators, patient sedation and/or analgesia and reinsertion of the introducer. In case of severe RAS, adequate time should be given to completely resolve the RAS.⁶³

Recommendations

- Do not forcefully remove catheters or sheaths entrapped in a diffuse and severe RAS.
- Give time and local anesthesia until you start getting pressure from the side arm of the sheath.
- Refractory cases may need axillary nerve block or general anesthesia for catheter removal.

2.5. TRI in high-risk groups (ST-elevation myocardial infarction/elderly/female)

2.5.1. Female/elderly patients

ESC guideline do not recommend the use of more aggressive combinations of anticoagulants and antiplatelet agents in females during radial procedure, given that females remain at higher risk for non-access-site bleeding.⁹

Insights from Radial Vs. femoral access for coronary intervention (RIVAL) trial by Pandie et al. showed that women randomized to radial access were twice as likely to be crossed over to FA as compared with men (11.1% in women and 6.3% in men). This was due to the higher rates of RAS in women (9.5% in women versus 3.3% in men; $p < 0.001$).⁶⁴ However, recently a study published by Jin et al., from China ($n = 1216$ women) found significant lower incidence of post-PCI bleeding (adjusted OR: 0.46, 95% CI: 0.30–0.71) and major adverse cardiovascular events (MACE) (adjusted OR 0.35, 95% CI 0.19–0.63) in women undergoing TR-PCI compared with TF.⁶⁵

In 2004, Louvard et al. conducted a prospective multicenter study to compare the incidence of vascular events delaying hospital discharge after CAG and PCI between the radial approach ($n = 192$) and the FA ($n = 185$) in octogenarians (the OCTOPLUS study). A significantly lower number of vascular complication events were found in the radial group (1.6% versus 6.5%, $p = 0.03$).⁶⁶

Recommendations

- No extra recommendations are made except compliance with good standard puncture and procedure techniques.

2.5.2. Patients with STEMI/ACS

Both ESC and SCAI guidelines recommend radial approach for primary PCI in patients with STEMI as this is associated with better outcomes and less access site-related bleeding complications.^{9,41} In addition, SCAI also suggest FA site preparation routinely in patients with STEMI.⁴¹

The RIVAL trial examining the appropriateness of radial approach or FA in patients with acute coronary syndromes (ACS) found radial approach to be associated with a fewer large hematoma (hazard ratio [HR] 0.40; 95% CI 0.28–0.57, $p < 0.0001$) and pseudo-aneurysms (HR 0.30; 95% CI 0.13–0.71, $p = 0.006$).⁶⁷

The Minimizing Adverse Hemorrhagic Events by TR Access Site and Systemic Implementation of AngioX (MATRIX) trial also found 33% relative risk (RR) reduction in major bleeding unrelated to coronary artery bypass grafting (CABG) ($p = 0.013$) and 28% RR reduction in all-cause mortality ($p = 0.045$) using the radial approach, particularly in patients with ACS.^{68,69} In 2016, a meta-analysis conducted by Ando and Capodanno also arrived at the similar conclusions that radial approach significantly reduced mortality (RR: 0.73; 95% CI: 0.60–0.88; $p = 0.001$), major bleeding

(RR: 0.60; 95% CI: 0.48–0.76; $p < 0.001$), and MACE (RR: 0.86; 95% CI: 0.77–0.95; $p = 0.005$) as compared to FA in patients with ACS.⁷⁰ Similarly, a subsequent meta-analysis, including patients with entire spectrum of coronary artery disease, found a significantly lower risk of all-cause mortality (OR: 0.71; 95% CI: 0.59–0.87; $p = 0.001$), MACE (OR: 0.84; 95% CI: 0.75–0.94; $p = 0.002$), major bleeding (OR: 0.53; 95% CI: 0.42–0.65; $p < 0.001$), and major vascular complications (OR: 0.23; 95% CI: 0.16–0.35; $p < 0.001$) with radial approach.⁷¹

Recommendations

- TR-PCI can be safely performed in elderly and female patients with a good pulse and radial palpability.
- In patients with ACS/STEMI undergoing PCI, the radial approach should be the preferred approach for experienced radial operators.
- Operators still on the learning curve of radial access may avoid the same in initial 50–100 cases.

2.6. Transradial in complex percutaneous coronary intervention

2.6.1. TRI PCI (bifurcations)

Coronary artery bifurcation lesions account for approximately 15%–20% of PCI procedures.⁷² Conventionally TR procedures are done using 6-Fr guides or less. Size of the RA usually restricts the arterial sheath to 6-Fr. The increased inner lumen of GCs (0.7") combined with the decreased profile of balloons and stents and improved bifurcation technique has led SCAI to allow TRI for complex PCI.⁸ A two-stent strategy which requires >1 stent at a time, including crush and double kissing crush can be performed easily using any 6-Fr GC. For 2 simultaneous stents usually, a 7-Fr GC is required.

The Left Main Bifurcation Oxford-Rome (LABOR) study noted a significant increase in the use of TRI for left main bifurcation disease from 9% in 2005 to 91% in 2013.⁷³ In the Coronary Bifurcation Stenting (COBIS) II registry, no significant difference was found between TR and TF in terms of procedural success rate in the main vessel (98.6% versus 99.7%; $p = 0.07$) and side branches (90.6% versus 94.4%; $p = 0.05$). However, the rate of bleeding events was less in TR group than in the TF group (2.4% versus 9.4%; $p = 0.01$).⁷⁴

Recommendations

- An ideal approach for the treatment of bifurcation lesions is summarized in Fig. 3.⁷⁵
- 6-Fr should be used as a standard for bifurcation lesions.
- 7-Fr sheath could be used with ultrasound sizing of the artery in select situations requiring 2 simultaneous stents.
- 8-Fr sheath is not recommended.

2.6.2. Chronic total occlusion

As per ESC guideline, an over-the-wire (OTW) approach is mandatory in CTO recanalization with use of microcatheters as a need for catheter exchanges. 6-Fr GC accepts all thin OTW microcatheters and can be exchanged with a second monorail balloon using anchoring/trapping technique. Two thin microcatheter Finecross[®], (Terumo) could also work through a 6-Fr guide system. However, it can only be used in isolation via a 6-Fr GC⁹ as trapping the same for exchange is not possible for which a 7-Fr GC is needed as a bare minimum. Also use of Crusade[®] (Kaneka) double lumen catheter exchange with trapping technique and intravascular ultrasound with Corsair[®] (Asahi) needs minimum 7-Fr guide system. Trapping of a Stingray[®] (Boston Scientific) balloon (OTW) using the CrossBoss[®] (Boston Scientific) system in ADR (Anterior Dissection and Re-entry) requires minimum 8-Fr GC.

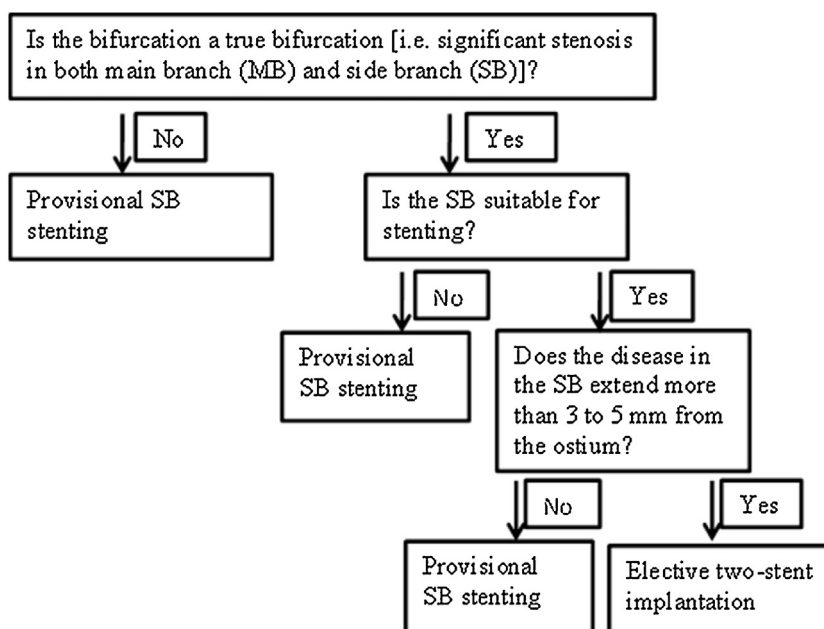


Fig. 3. Algorithm for treating bifurcation lesions.

In a systematic review and a meta-analysis of radial approach versus FA for CTO-PCI, Burzotta et al. noted <1% vascular access site complications and 0–3.8% in-hospital major adverse events with radial approach. Also, significant improvement in PCI success was observed between the first and the later period of the practice (OR, 95% CI: 0.30, 0.39–0.51; $p < 0.001$).⁷⁶ A retrospective review and analysis showed 98.7% procedural success rate of 7-Fr TR complex PCI.⁷⁷

Recommendations

- TRI can be successfully used for CTO-PCI.
- Identify the favorable and unfavorable factors affecting the success of CTO interventions (Table 6).⁷⁸
- Routine CTO cases can be safely performed using 6-Fr GCs but the operator should know the limitations with the system.
- Upgrade to a 7-Fr system could be done using guidance on GC depicted in Section 2.3.4.
- 8-Fr cannot be used through radial approach.
- In selected cases, a standard sheath with 6-Fr OD providing 7-Fr ID can be used.

Table 6
Factors affecting success of chronic total occlusions interventions.

Favorable characteristic	Unfavorable characteristic
Short segment Tapered tip	Calcification (strongest correlation with failure) Target vessel tortuosity/bending at occlusion • Long occlusive duration/unknown duration
No side branches or bridging collaterals	Long segment
Straight segment	Blunt stump
Functional CTO (Faint channel visualized present)	Flush ostial CTO
	Bridging collaterals Side branches Post CABG/CKD/DM Left circumflex artery CTO • Absence of antegrade flow

CABG- coronary artery bypass grafting; CKD- chronic kidney disease; DM- diabetes mellitus; CTO- chronic total occlusions.

2.7. When to discharge

For diagnostic PCI, early hospital discharge within first 2–3 h of procedure is recommended by ESC guideline for stable patients. In addition, stable patients with an optimal PCI result without post-procedural cardiac or vascular complications can be discharged within 4–6 h as per ESC guidelines.⁹

American College of Cardiology/SCAI guidelines recommend same-day discharge (SDD) only for elective, stable patients undergoing single-vessel PCI without complications and comorbidities.⁷⁹

Current standard United States practice involves overnight in-hospital observation post-PCI. However, international literature has validated the feasibility and safety of SDD after uncomplicated TR-PCI. Brayton et al. performed a meta-analysis of 37 studies (7 randomized trials and 30 observational studies) that encompassed 12,803 patients and found no difference in death, MI and complication rates between SDD and routine overnight observation (OR: 0.90; 95% CI: 0.43–1.87; $p = 0.78$) and low rate of major complications among the observational cohort (95% CI: 0.35%–1.32%).⁸⁰ Recently, a study conducted by Amin et al. showed an average total cost savings of approximately \$3689 per patient using TRI with SDD in comparison to patients using TFI with non-SDD.⁸¹

Recommendations

- Early discharge after 2–3 h of observation is feasible and safe in stable patients who undergo TR diagnostic procedures without complications.
- Stable PCI patients without cardiac or vascular complications during or 4–6 h after the procedure can be considered for discharge on the same day in high volume centers.
- Early follow-up visits and hospital readmission is required for patients with post-discharge complications.

2.7.1. Radial lounge

Radial lounge is a dedicated facility that is able to accommodate patients in an attractive environment that minimizes the feeling of “hospitalization” and enhances the recovery of the patients as well

as reduces the need of the hospital beds. A recent study observed SDD in 78.5% patients who underwent diagnostic angiography/PCI after the implementation of a radial lounge facility.⁸² Similarly, Brewster et al. found SDD in 84.7% of patients after PCI and 97% of patients after angiography that was managed in the radial lounge.⁸³

Recommendations

- Radial lounge facility should be promoted as it enhances the comfort and recovery of the patient.

2.8. Paramedical staff (nursing and technical staff)

Staff expertise is a key factor in the management of radial approach, before, during or after the procedure. Paramedical staff must be able to recognize potentially serious as well as rare complications early and at all times.⁹

Recommendations

- Pre-procedural and post-procedural management, site preparation and maintenance of the patency of the RA are the responsibility of paramedical staff.
- Dedicated training courses and workshops should be organized for paramedical staff to expand their knowledge and skill in this area.

2.9. Reducing radiation exposure

Both ESC and SCAI guidelines recommend giving specific attention towards radiation exposure and protection while using the radial approach.⁹ Low-intensity fluoroscopy and standard shielding for both patients as well as operators is suggested to reduce radiation exposure during radial approach. This is especially important during the learning phase via right RA.

In 2015, a meta-analysis was conducted to compare radiation exposures between TRI and TFI. The results showed small but a significant increase in fluoroscopy time with TRI for both diagnostic CAG (weighted MD, fixed effect: 1.04 min, 95% CI 0.84–1.24; $p < 0.0001$) and PCI (1.15 min, 95% CI 0.96–1.33; $p < 0.0001$).⁸⁴ Tewari et al. also noted similar findings and observed the mean fluoroscopy time taken as 4.40 ± 3.55 min for TR and 3.30 ± 3.66 min for TF-CAG ($p < 0.001$) while mean fluoroscopy time as 13.53 ± 2.53 min for TR and 12.61 ± 9.524 min for TF-PTCA ($p < 0.001$).⁴² However, an Indian study conducted by Sinha et al. found no significant difference in radiation dose as dose area product (24.2 ± 4.21 versus 22.3 ± 3.46 Gy cm²; $p = 0.43$) and fluoroscopy time (2.46 ± 1.22 versus 2.83 ± 1.31 min; $p = 0.32$) between TRI and TFI, respectively.⁸⁵

Recommendations

- The magnitude of the radiation exposure is largely determined by the experience and radiation protective technique followed by the operator, although the closer the radiation source, the higher is the exposure. However, this disadvantage must be balanced against the benefits of decreased access site complications and bleeding.
- SCAI guidance for reducing radiation exposure should be followed (Table 7).⁴¹
- The National Council on Radiation Protection and Measurements suggestion on substantial radiation dose level should be followed (Table 8).⁸⁶

2.10. Conclusion

A large body of evidence has shown that TRI reduces all-cause mortality and MACE as well as access site complications. Proper

Table 7

SCAI guidelines to reduce radiation exposure during transradial procedure.

- General measures
- Increase distance from image intensifier
- Use low-intensity fluoroscopy and low-frame rate for cine acquisitions whenever possible
- Utilize standard shielding (lead gown/vest, drape, lead shield, thyroid collar)
- Specific measures for trans radial procedures
- Use of a radial-specific radiation drape
- Use of a radiation board
- Avoid routine fluoroscopy/cine angiography of upper arm
- Utilization of the left radial access
- Under table leaded flaps

Table 8

Suggested values for first and subsequent notifications and substantial radiation dose level.

Dose metric	SRDL
$D_{\text{skin,max}}$	3 Gy
$K_{\text{a,r}}$	5 Gy
P_{KA}	500 Gy cm ^{-2d}
Fluoroscopy time	60 min

$D_{\text{skin,max}}$ -Peak skin dose; $K_{\text{a,r}}$ -Total air kerma at the reference point; P_{KA} -Air kerma-area product; ^d-Assuming a 100 cm² field at the patient's skin.

training, suitable hardware, pre and post procedure precautions and adjunctive pharmacotherapy are very important for the success of TRI. Although literature continues to emerge and evolve, the recommendations of this document are based on the widely cited evidence, as well as clinical experience of the board members, at the time of its development. We believe these guidelines will help to translate best evidences into the best practice.

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Conflicts of interest statement

The authors have no conflicts of interest to declare.

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