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Safety and Feasibility of Transulnar Catheterization When Ipsilateral Radial Access Is Not Available

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Objectives: We evaluated the safety and feasibility of transulnar approach when ipsilateral radial access was not available. Methods and Results: From March 2011 until February 2013, 476 consecutive patients who underwent transulnar catheterization were included in a single center prospective registry of effectiveness and safety. Diagnostic coronary angiography accounted for 42% of cases, percutaneous coronary intervention (PCI) for 38%, and 17% underwent carotid artery stenting. A subgroup analysis was done in 240 patients with documented ipsilateral radial artery occlusion (RAO). Procedural success was 97% with a crossover rate of 3% to transfemoral access. Hand ischemia was not observed in any patient on day 1 after procedure and on 1 month follow-up. None of the patients showed ulnar nerve injury. Two patients developed major forearm hematoma that resolved without clinical consequences. Minor access site hematoma occurred in 8%. Severe clinical spasm occurred in two patients. Asymptomatic ulnar artery occlusion at 1 month follow-up was detected in 3.1%. There was no difference between patients with or without RAO in terms of procedural success and any vascular complication. Conclusion: Transulnar approach is safe and feasible alternative wrist access when performed by experienced radial operators, providing high success rate and low incidence of vascular complications. © 2013 Wiley Periodicals, Inc.

Key words: transulnar approach; transradial approach; radial artery occlusion; percutaneous coronary intervention; carotid artery stenting

INTRODUCTION

The first effort at retrograde arterial catheterization of the left ventricle involved the use of ulnar artery cutdown for arterial access. Zimmerman et al. [1] used this approach for the first successful retrograde catheterization of the left ventricle in 1949 for 11 patients with aortic insufficiency.

Based on 2 decades of experience and data, a large European panel of experts has recommended radial access as the first choice for angiography and PCI when performed by operators experienced with the method [2].

Opposite to the transradial access (TRA), which is now rapidly becoming the preferred access site for coronary interventions worldwide, the transulnar artery approach (TUA) has received very little attention as a potential access for cardiac catheterization [3,4]. Reported technical failure for transradial procedures is between 1% and 7%, mainly related to the learning curve [4].

Furthermore, TRA has limitations in some conditions such as weak radial pulse after several previous TRA procedures, RAO [5,6], radial artery (RA) used for surgical grafts or fistulas, RA anomalies [7,8], RA spasm (RAS) [9,10], and procedures requiring large bore devices.

TUA has been described as a viable alternative wrist access for coronary diagnostic and interventional

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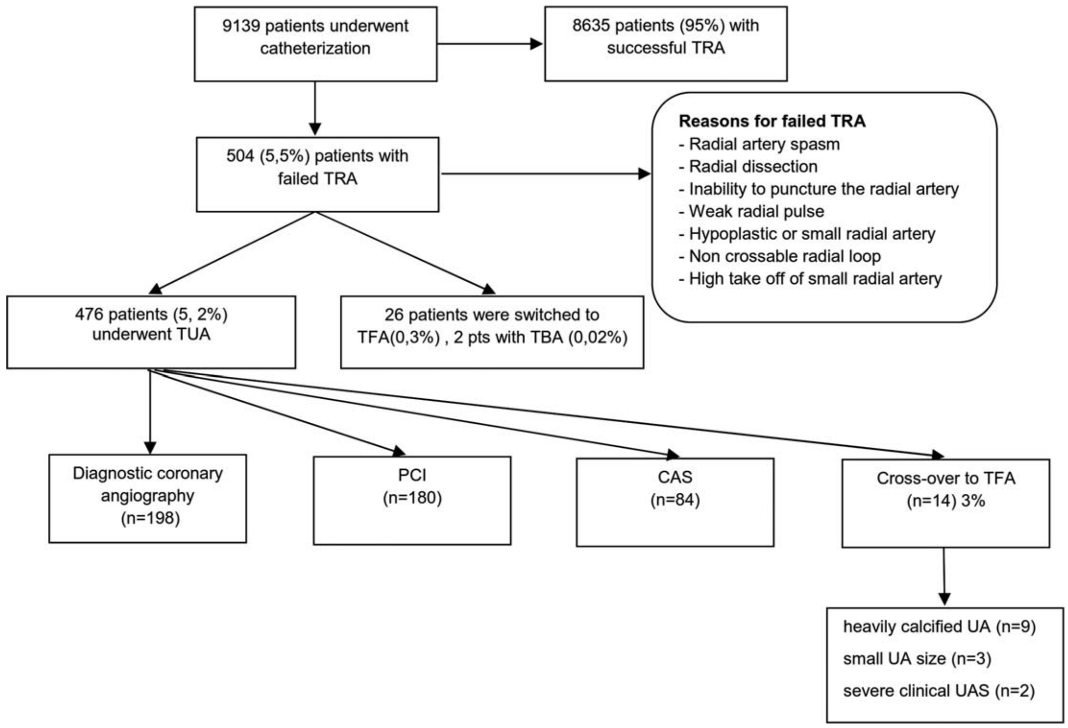

Fig. 1. Flow chart of the study.

procedures, with favorable results reported in small initial studies [11–16]. Larger studies has further confirmed the safety and effectiveness of TUA as an alternative approach to TRA for coronary procedures [17,18].

However, there are no large-scale studies on safety and feasibility of TUA for interventions with large bore devices and in patients with coexisting ipsilateral RAO. The main objective of this study was to further evaluate the safety and feasibility of TUA for cardiovascular procedures in a dedicated high volume TRA center, when ipsilateral radial access was not available.

METHODS

This study was designed as a single center prospective registry of effectiveness and safety, and data were collected in a dedicated database. All procedures were done by experienced high-volume operators performing more than 95% of all procedures through the TRA, ranging from 300 to 600 procedures annually per operator.

Patient Population

From March 2011 to February 2013, a total of 9,139 patients underwent TRA catheterization in our institution. The right radial access was the most common route (97%).

TRA was not available in 504 (5.5%) patients due to inability to puncture the RA, weak or absence of radial pulse, RAS and dissection, hypoplastic or small RA, noncrossable radial loop, and high take off of small caliber RA.

In 476 consecutive patients (5.2%), the procedures were performed through the ipsilateral TUA while only 26 patients were switched to femoral approach (0.3%) and 2 patients underwent ipsilateral brachial catheterization (0.02%). Crossover to femoral and brachial access was performed because ipsilateral ulnar artery was not available (absence of ulnar pulse, extensive UA calcifications). From 476 analyzed patients with TUA, diagnostic procedures accounted for 42% of cases, PCI for 38%, and 84 patients underwent CAS (17%).

Written, informed consent was obtained from each subject. This study has been approved by institutional review committee and the medical ethical committee. Study flow charts are shown in Figs. 1 and 2.

Ulnar Artery Cannulation and Preprocedural Ulnar Artery Angiography

The wrist was hyperextended and the skin was prepared with local anesthesia (1 ml lidocaine 2%) around

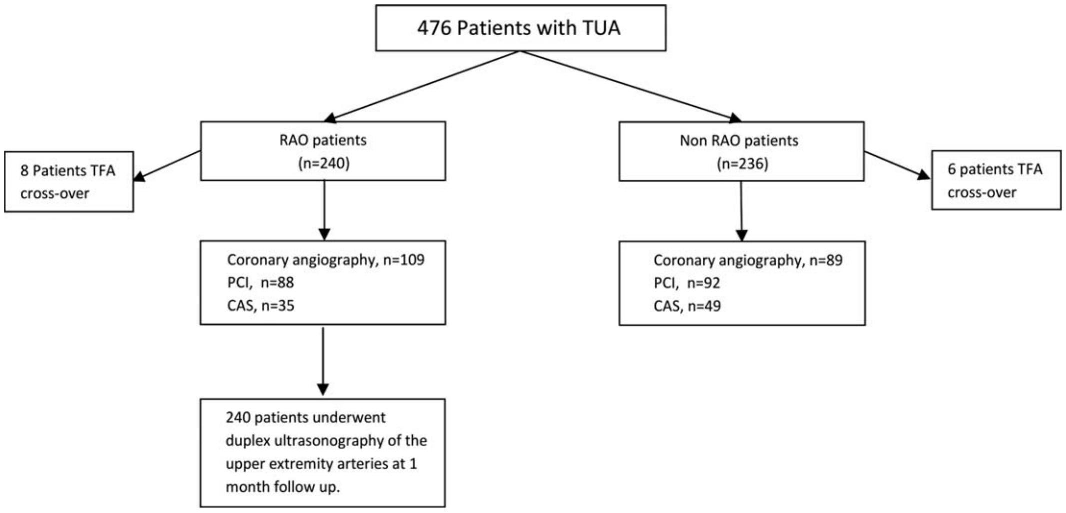

Fig. 2. Flow chart of patients with or without RAO.

0.5–3 cm proximal to the flexor crease skin fold along the axis with the most powerful pulsation of the UA.

The UA was accessed with a 20-G plastic cannula using the counter-puncture technique. The cannula-over-needle was inserted at a 45–60° angle along the vessel axis and from lateral to medial, thus avoiding the ulnar nerve. When a good arterial "back bleed" was obtained, the 0.025″ hydrophilic guidewire was advanced and the hydrophilic 5F or 6F sheath (Radifocus, Terumo, Tokyo, Japan) was introduced over the guidewire.

Intra-arterial vasodilator (5 mg verapamil) was injected to reduce ulnar artery spasm (UAS). Immediately after sheath insertion, intravenous unfractionated heparin (UH) was administered (50–70 μ/kg, up to 5,000 units).

UA angiography was performed through the cannula or sheath, before catheter insertion (Fig. 3). The forearm angiography defined the radial and UA anatomy from mid forearm to brachial/axilar anastomosis. A diluted solution of 3 ml of contrast mixed with 7 ml of blood was injected briskly and recorded. In cases with UAS, tortuosity and/or ulnar loops, and high take-off UA, we used a 0.014″ soft PCI guidewire under fluoroscopy guidance.

Fig. 3. Ulnar artery angiography through cannula with palmar arches.

Coronary Procedure

When ulnar access was provided and sheath was in place, the procedures were performed in the same fashion as from the TRA. Choice of diagnostic and guiding catheters, wires, balloons, and stents were left to the operator's discretion. For larger bore devices (>6F) used in complex PCI of bifurcations, left main stenting, chronic total occlusion, and when inserting a 7.5F sheathless guiding catheter (ASAHI INTECC, Aichi, Japan), a more supportive stiff Amplatz type .035″ 260-cm long guidewire was preferred (Fig. 4).

All diagnostic coronary angiogram patients received intravenous bolus of 5,000 IU UH. PCI patients already

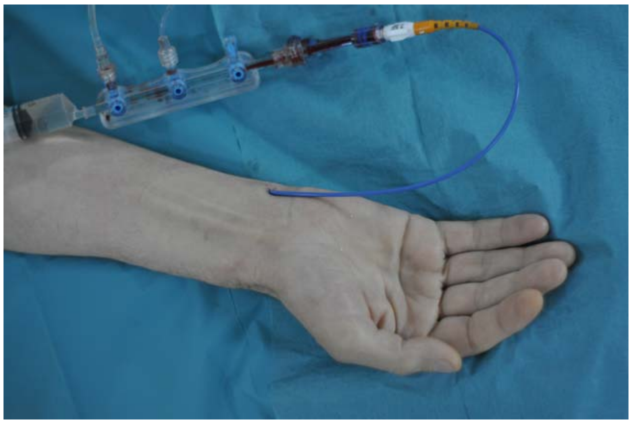

Fig. 4. Right TUA with 7.5F sheathless guiding catheter.

Fig. 6. Patient hemostasis after TUA.

Fig. 5. Right TUA for CAS using a 6F guiding sheath 90 cm.

receiving 100 mg aspirin were preloaded with 600 mg clopidogrel and received 100 IU/kg body weight of intravenous UH. Clinical and procedural variables were recorded in all patients.

Carotid Artery Stenting Procedure

Initial carotid angiography was performed through a 5F diagnostic catheter (predominantly Simmons 2). CAS was performed through a 5F or 6F, 90 cm guiding sheath: Shuttle sheath (Cook, Minneapolis, MN) or Destination sheath (Terumo, Tokyo, Japan) (Fig. 5) or through 7F or 8F guiding catheter. Compatibility with the guiding sheath diameter was determined by the UA size based on ulnar angiography. All procedures were performed with distal protection devices (Nav 6, Abbott Vascular, Temecula, CA). All patients were preloaded with 600 mg clopidogrel and maintained on 75 mg for at least 1 month and on 100 mg aspirin daily, indefinitely.

Arterial Sheath Management

UA sheath was removed immediately after the procedure, and hemostasis was achieved by TR band compression (Terumo, Tokyo, Japan). TR band was applied by inflating 15–18 ml of air at the puncture site. As UA is more deeply seated without nearby bone structure, hemostasis with initially higher pressure than TRA was necessary particularly after using larger bore devices. The pulse oximetry was used to confirm that hemoglobin oxygen saturation was more than 90% on the involved hand after hemostasis was obtained (Fig. 6). Compression was applied for approximately 2- to 3-hour period (depending on the sheath size) with gradual relaxation of compression after the first hour. Patients were discharged within the same day or the following days after a careful examination by the attending physician.

Study Endpoints

Primary endpoint of the study was procedural success. The occurrence of clinical UAS during the procedure, vascular access site and major vascular complications at 30 days were defined as the secondary endpoints of the study. A subgroup analysis was done in 240 patients with documented ipsilateral RAO (diagnosed from preprocedural ulnar artery angiography). Duplex ultrasonography of the upper extremity arteries was performed at 1 month in all patients with ipsilateral RAO by a dedicated vascular ultrasonographist who was blinded for the baseline characteristics and methodology of the study.

Definitions

Procedural success was defined as completion of the planned procedure through the initial access site [7]

TABLE I. Baseline Characteristics of Transulnar Procedures

Clinical variables	TUA ($N = 476$)
Age (years)	60 (32–82)
Male	310 (65%)
BMI (kg/m^2)	27 (21–47)
CAD risk factor	
Hypertension	336 (70.6%)
Diabetes mellitus	95 (20%)
Dyslipidemia	140 (29.4%)
Smoking	117 (24.6%)
STEMI PCI	19 (4.0%)
Prior RA interventions	301(63.2%)
Prior CABG	23 (4.8%)
PAD	14 (2.9%)
Prior stroke	18 (3.8%)
Length of stay < 2 days	380 (82%)
Same day discharged	219 (47.4%)

TABLE II. Procedural Characteristic of Transulnar Procedures

Procedural variables	Procedures ($N = 476$)
Procedure	
Diagnostic coronary angiography	198 (42%)
PCI	180 (38%)
CAS	84 (17%)
Right ulnar artery approach	462 (97%)
Left ulnar artery approach	14 (3%)
Ulnar anatomy	
Severe tortuosity	1 (0.2)
High take-off	4 (0.8)
Heavily calcified	17 (3.6)
Rudimented UA	3 (0.6%)
Sheath size	
5F	160 (33.6%)
6F	302 (63.4%)
7F	4 (0.8%)
7.5F Asahi Sheathless	9 (1.8%)
8F	1 (0.2%)
Long 90 cm guiding sheath 5/6F	18 (3.7%)/50 (10%)
5F (Shuttle sheath/Destination sheath)	12 (66%)/(34%)
6F (Shuttle sheath/Destination sheath)	31 (62%)/19 (38%)
Fluoroscopy time (minute)	
Diagnostic	3.6 (1–20)
PCI procedure	12 (2–46)
CAS	10 (6–43)
Procedural time (minute)	
Diagnostic	22 (10–50)
PCI procedure	36 (20–75)
CAS	25 (14–90)

BMI, body mass index; CAD, coronary artery disease; STEMI, ST segment elevation myocardial infarction; CABG, coronary artery bypass surgery; RA, radial artery; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; CAS, carotid artery stenting; UA, ulnar artery; F, French.

without associated in cath-lab major clinical complications (e.g., stroke, death, or coronary artery perforation) [19].

Clinical UAS was classified as grade I: minimal local pain and discomfort; grade II: significant local pain and discomfort, not precluding procedure completion; grade III: severe local pain and discomfort necessitating crossover; and grade IV: catheter entrapment with severe local pain and discomfort. These criteria correlate with clinical signs of radial artery spasm [20].

Vascular access site complications were defined as the occurrence of any of these conditions at the initial ulnar access: formation of an aneurysm or fistula, hematoma, loss of ulnar pulse, or ulnar nerve injury. Forearm hematoma was classified into five grades (grade I: local hematoma, superficial; grade II: hematoma with moderate muscular infiltration; grade III: forearm hematoma and muscular infiltration, below the elbow; grade IV: hematoma and muscular infiltration extending above the elbow; grade V: ischemic threat—compartment syndrome) [21].

Hand ischemia was defined as an inadequate blood supply to the hand resulting in pain, discoloration, frank ulcerations, tissue necrosis, and/or gangrene of fingers. Ulnar artery occlusion (UAO) was demonstrated by the absence of spectral and color Doppler signals in the interrogated vessel by color Doppler ultrasound imaging. Major vascular complications were defined as hemoglobin drop >3 g/dL and requiring intervention or surgery and/or blood transfusion [22].

Statistical Analysis

For normally distributed numeric variables, data were expressed as mean ± standard deviation and for continuous variables not fitting a normal distribution were expressed as median (minimum-maximum). Percentages were used to express categorical variables. χ^2 test was used to compare categorical variables, and Student's *t*-test or Mann-Whitney *U*-test was used to compare differences between two groups. A *P*-value of <0.05 was considered statistically significant. Statistical analysis were performed with SPSS 17.O for Windows (SPSS, Chicago, IL)

RESULTS

Baseline and procedural characteristics of patients are shown in Tables I and II. The median age of the patient was 60 years and 65% were male. Right UA was used in 97%, and hypertension was the most common risk factor. Most of the procedures were performed through a 6F catheter (63%). Majority of the patients (82%) were discharged within 2 days and for same day discharge was feasible in 47% of patients. The most frequently used technique for common carotid artery cannulation during CAS was anchoring and simple looped method, predominantly with a 6F guiding sheath—90 cm (64%) [23].

TABLE III. Study Endpoints

Variables	($n = 476$)
Procedural success	462 (97%)
Crossover to TFA	14 (3%)
Heavily calcified UA	9 (64.2%)
Small UA size	3 (21.5%)
Severe clinical UAS	2 (14.3%)
Clinical ulnar artery spasm	40 (8.4%)
Grade I	34 (7.1%)
Grade II	4 (0.08%)
Grade III	2 (0.04%)
Grade IV	0
Access site bleeding complications	39 (8.2%)
Hematoma grade 1	18 (3.8%)
Hematoma grade 2	10 (2.1%)
Hematoma grade 3	9 (1.8%)
Hematoma grade 4	2 (0.04%)
Hematoma grade 5	0
Major vascular complication at 30 days	0
Sign of hand ischemia at 30 days follow-up	0
Ulnar artery occlusion (UAO) at 30 days	15 (3.1%)

TFA, transfemoral approach; UAS, ulnar artery spasm; UAO, ulnar artery occlusion.

Study Endpoints

Procedural success was high (97%), with a crossover rate of 3% (14 cases) to transfemoral approach (TFA). Crossovers were due to heavily calcified UA in nine patients (1.9%), small UA size in three patients, and severe clinical UAS (grade III) in two patients (0.4%). Minor UAS (grade I) was detected in 34 patients (7%), and moderate UAS (grade II) was present in four patients (0.8%).

None of the patients showed ulnar nerve injury. Two patients (0.4%) developed major forearm hematoma (grade IV) that resolved without clinical consequences. Minor access site hematoma (grade I/II) occurred in 5.9%.In 15 patients, and there was asymptomatic UAO at 1 month follow-up (3.1%). No major vascular complication was found at 30 days clinical follow-up (Table III).

Subgroup analysis of 240 patients with documented ipsilateral RAO showed that this group of patients had a significantly higher rate of previous radial procedures ($P < 0.001$) and previous use of 6F sheath ($P = 0.001$) compared to the non-RAO patients (Table IV). There was no difference in procedural outcome as well as in clinically relevant spasm, hematomas, and major vascular complications between patients with or without ipsilateral RAO. There was no UAO at 30 days in a group with ipsilateral RAO (Table V).

None of the patients had clinical signs of hand ischemia at 30 day follow-up. Duplex ultrasonography

TABLE IV. Baseline Characteristics Between Ipsilateral RAO and non-RAO Group

Variables	IRAO group ($n = 240$)	Non-IRAO group ($n = 236$)	P value
Age (years)	60 ± 9.0	62.2 ± 9.6	NS
Male	162 (67%)	148 (62.7%)	NS
BMI (kg/m^2)	26.6 ± 3.3	26.5 ± 3.2	NS
CAD risk factor			
Hypertension	189 (78.7%)	147(62.3%)	NS
Dyslipidemia	77(32%)	63 (26.7%)	NS
Diabetes meliitus	49 (20.4%)	46 (19.5%)	NS
Smoking	60(25%)	57(24%)	NS
Previous transradial procedure	237(98.7%)	64 (27.1%)	<0.001
Previous sheath size used			
5F	29 (12%)	16 (6.8%)	NS
6F	206 (85.8%)	41 (17.4%)	<0.001
7F	0	2	NS
Previous sheathless guiding catheter used			
7.5F	2	5	NS
Currently used sheath			
5F	68 (28.3%)	92 (39%)	NS
6F	158 (65.8%)	144 (61%)	NS
7F	2	2	NS
8F	0	1	/
Currently used sheathless guiding catheter 7.5F	6	3	NS
Current fluoroscopy time (minutes)	8.6 ± 8.2	9.9 ± 8.1	NS
Current procedure time (minutes)	26 ± 15.2	29.2 ± 17.5	NS

IRAO, ipsilateral radial artery occlusion; BMI, body mass index; CAD, coronary artery disease; F, French; NS, nonsignificant.

TABLE V. Outcomes of Patients Based on Ipsilateral Radial Artery Status

Variables	IRAO group ($n = 240$)	Non-IRAO group ($n = 236$)	P value
Procedural success	232 (97%)	230 (97%)	NS
Clinical ulnar artery spasm	17 (7.0%)	17 (7.2%)	NS
Vascular access site complications			
Hematoma Grade I–V	19 (7.9%)	20 (8.4%)	NS
Grade 1	9 (3.7%)	9 (3.8%)	NS
Grade 2	5 (2.0%)	5 (2.1%)	NS
Grade 3	4 (1.6%)	5 (2.1%)	NS
Grade 4	1 (0.4)	1 (0.4)	NS
Grade 5	0	0	NS
Major vascular complication at 30 days	0	0	NS
Ulnar artery occlusion at 30 days	0	15 (6.3%)	<0.001

examinations performed at 1 month in all patients with ipsilateral RAO documented patent UA flow.

DISCUSSION

The most important finding in this study is that TUA is a safe and useful alternative wrist approach for cardiovascular intervention when ipsilateral radial access is not available. The procedure was safely performed in our study population with a low complication rate. However, TUA was not possible in 9% of all patients with failed TRA due to absence of UA pulse, extensive UA calcifications, and small caliber UA. Despite inclusion of complex procedures requiring large bore devices with high procedural success, our study showed a low incidence of clinically relevant UAS grade II/III (1.3%). This finding is lower compared to the reported incidence of RAS (6–12%) [22]. Vasospasm has been related to vessel size and mediated by α-receptors response to epinephrine. The UA, generally has a larger diameter (1.3:1) and straighter course; loops and curvatures are very rare (Fig. 7). UA is less prone to spasm with fewer α-receptors than the RA. That might result in a lower risk of vasospasm compared with TRA [24].

TUA was indicated for CAS in patients who had already undergone TRA carotid stenting for bilateral carotid stenosis or had several previous ipsilateral TRA procedures. Five and six French guiding sheaths (90 cm, the hydrophilic Shuttle sheath and semihydrophilic Destination) were predominantly used in this study (Fig. 5).

TUA carotid stenting (when RA is not available) could be particularly beneficial for patients with extensive peripheral vascular disease and with anatomical variations that make cannulation of the common carotid more difficult from the femoral approach. Early mobilization and reduction of access site bleeding and vascular complications are important additional advantages in women and the older population undergoing these procedures.

Fig. 7. Ulnar and radial artery angiography: clearly larger size UA.

Furthermore, there were 19 STEMI cases (4%) successfuly performed through the TUA after failed ipsilateral TRA. Adding the TUA expertise could further reduce the crossover rate to TFA and lower the intrinsic risk of bleeding and vascular complications associated with the femoral approach [16,25].

Vascular access site complications (hematoma grade I/II) were found in 7.6%. Only two patients had hematoma grade III (0.4%) that resolved without clinical consequences and none of the patients had major vascular complications.

In all 240 patients with documented ipsilateral RAO, preprocedural ulnar angiography demonstrated functional collaterals predominantly from anterior interosseous artery (Fig. 8). In those patients, UA pulse was considerably stronger than in patients with patent radial arteries. All patients with RAO underwent duplex ultrasonography which showed patent ulnar artery flow and none of them had signs and symptoms of hand ischemia at 30 day follow-up. It appears that the anterior interosseal artery supply to the wrist may under certain

Fig. 8. Right UA angiography with ipsilateral RAO and functional collaterals from anterior interosseous artery.

circumstances be adequate in maintaining the perfusion. This finding has further strengthened the safety of TUA and reconfirm the clinical irrelevance of the preprocedural Allen's test. Many high-volume operators around the world typically perform TRA procedures without the assessment of the dual hand circulation with excellent safety outcomes. Presumably, the presence of a rich collateral circulation is protective against hand ischemia even in the presence of an abnormal Allen's test and/or RAO. An abnormal result with any form of Allen's test carries low specificity for the prediction of severe hand ischemia and may wrongly exclude patients with abnormal results from TRA. Such exclusion exposes patients to the inherent vascular risk of TFA.

Patients with ipsilateral RAO had a significantly higher previous radial attempts and were more frequently associated with previous 6F sheath used compared to non-RAO patients. Other factors influencing the occurrence of RAO are high sheath to artery ratio [26], interruption of RA flow during or after the procedure, anticoagulation regimen, and duration of hemostatic compression [5]. Although the use of TRA has steadily increased, it is hypothesized that the future approach of previously accessed RA might be limited, particularly with larger bore devices.

In our practice, TRA remains the default access for almost all cardiovascular interventions. The indications of TUA in this population were weak or absence of RA pulsation, previously documented significant RA variations, several previous TRA procedures, complex PCI requiring larger bore devices in patients with previous TRA and contralateral carotid stenting in patients with previous CAS through ipsilateral radial approach. Crossover to TFA was very low (3%). However, there were no major vascular complications or hand ischemia even in patients with ipsilateral RAO at 30 day follow-up.

According to our experiences, some considerations for a successful TUA program are:

1. Preprocedural ulnar artery angiography through a cannula or small sheath provides road map for safe navigation thus preventing dissection and perforation. It may rule out severe atherosclerosis and calcifications and anatomical variations so devices could be selected based upon the UA size. In patients with relevant UAS and with severe tortuosity and high take off of small caliber ulnar artery, we recommend 0.014″ hydrophilic guidewire for safe navigation through the ulnar arteries. Small caliber catheters are preferred in cases with smaller sized ulnar arteries. However, in our study 3% were switched to TFA due to heavily calcified UA (nine patients), high take off of small caliber UA in three cases, and resistant UAS (two patients).
2. Hydrophilic catheters and sheaths including dedicated sheathless catheters (Fig. 4) could decrease UA injury and minimize mechanical stimuli on UA.
3. Excessive catheter manipulation should be avoided. This is more significant issue for operators going through the learning curve for the TRA.
4. The optimal hemostasis (patient hemostasis) and meticulous postprocedural care are of paramount importance.
5. Specific TRA and TUA expertise in elective PCI, ensuring procedural time and a success rate comparable to those with the TFA are strongly recommended before using this technique particularly in the emergency settings.
6. TUA in an extremity with previous RAO is feasible, likely safe, but should be reserved for patients where contralateral TRA is not available, especially when femoral access site complication risk is high.
7. Finally, homolateral TUA should be attempted only by very experienced high volume radial operators with expertise in UA cannulation.

STUDY LIMITATIONS

Several limitations of this study should be considered. First of all, this is a nonrandomized study involving consecutive patients. Second, diagnosis of UAS was subjective, based on clinical signs, as resistance during catheter maneuver, inability to freely manipulate the catheter, and/or difficulty in moving the catheter with concomitant forearm pain during the procedure.

Furthermore, all procedures were done by experienced and high-volume transradial and transulnar operators. All CAS procedures were performed by a single operator (SK) with extensive experience with both the TRA and CAS; the transradial learning curve may limit the implementation of the described techniques.

CONCLUSION

Transulnar approach is a safe and feasible alternative wrist access for patients undergoing cardiovascular interventions when ipsilateral radial access is not possible. With careful technique and experienced operators, the procedure can be performed with a high success rate and low incidence of vascular complications. However, further large-scale randomized studies are needed to reconfirm the role of TUA for cardiovascular procedures when ipsilateral radial is not available.

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