

# Operator learning curve for transradial liver cancer embolization: implications for the initiation of a transradial access program

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## PURPOSE

We aimed to analyze transradial access (TRA) learning curve on patients undergoing hepatic chemoembolization, investigating the relationship between procedural volumes and various benchmarks of procedural success.

## METHODS

We enrolled 60 consecutive patients who received two unilobar hepatic chemoembolizations within a 4-week interval performed by a single interventional radiologist, highly-trained in conventional transfemoral access (TFA) procedures, but without any previous practical experience in TRA procedures and with a preliminary 2-day theoretical training only. Consecutive patients were prospectively enrolled and analyzed in 3 groups: A (cases 1 to 20), B (cases 21 to 40), and C (cases 41 to 60). All patients underwent one hepatic chemoembolization using TRA and the other one using TFA in random order. All TFA procedures performed by the same operator in the same series of patients were considered as the control group. Primary endpoint was to analyze the relationship between TRA procedure operator experience and benchmarks of procedural success, to define the optimal procedural learning curve.

## RESULTS

Technical success was obtained in all patients, with a crossover rate (radial to femoral access) of 0%. An association between incremental TRA operator experience (in terms of performed procedures) and decrease of preparation, puncture, fluoroscopy, and total examination times was observed. Similarly, inverse associations between incremental TRA operator experience and contrast medium (CM) volumes ( $P < 0.001$ ) and radiation dose (RD) values (in terms of RAK - Reference Air Kerma) ( $P < 0.001$ ) were also observed. Compared with TFA, CM volumes and RD values were significantly higher only in group A (cases 1–20). Procedure success remained high in all TRA groups and no significant association between TRA incremental experience and postprocedural outcomes was found. Higher postprocedural complaints at the access route and more limitations in performing basic activities were recorded after TFA vs. TRA ( $P < 0.001$ ).

## CONCLUSION

TRA catheterizations can be safely performed in patients treated for liver cancer embolization after a relatively short training in controlled conditions and with a better performance in comparison with TFA. Operator proficiency improves with greater TRA experience, with a threshold needed to overcome the learning curve represented by about 20 procedures.

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In recent years transradial artery access (TRA) has been validated as an alternative to transfemoral artery access (TFA) for both cardiac and noncardiac vascular procedures. Several studies have shown that TRA can be used in the treatment of all patients and lesions, similar to more familiar and conventional TFA, with several advantages such as minimal vascular complication rates, no need for prolonged compression or closure devices, shorter postprocedural monitoring, earlier ambulation and less patient discomfort (1–8). Those advantages have been also confirmed in two recently published inpatient comparison studies for hepatic intra-arterial locoregional procedures (9, 10). Nevertheless, the perception of a higher technical complexity related to TRA and an associated significantly slower learning curve have resulted in a limited use of that approach in interventional radiology. Furthermore, the reported advantages of TRA by centers with high-volume radial operators cannot be transferred to most interventionalists, predominantly trained for the transfemoral approach.

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A deeper understanding of factors affecting TRA learning curve, therefore, would be useful in defining prerequisite volumes for adequate training, in order to optimize TRA results in terms of clinical benefits and for an unbiased comparison between experiences conducted by well-trained operators in each technique.

The aim of our study was to analyze TRA learning curve on patients undergoing hepatic chemoembolization, investigating the relationship between procedural incremental experience and various benchmarks of procedural success.

## Methods

### Study design

All patients with hepatic malignancies admitted to our Institution from October 2016 and September 2017 undergoing two consecutive lobar chemoembolizations within a 4-week interval were enrolled in our study. Indication for treatments was based on a multidisciplinary tumor board evaluation. Procedures were performed using both transradial and transfemoral accesses in a random order (TFA or TRA for the first and TRA or TFA for the second lobar hepatic chemoembolization, respectively). All patients were included in an observational prospective inpatient comparative single-center study designed to assess effectiveness and safety of TRA vs. TFA. This study was focused on the assessment of a single-operator learning curve. One interventional radiologist, highly-trained in conventional TFA (15 years of experience), but without any previous practical experi-

ence in TRA procedures and with a preliminary 2-day theoretical training only, was in charge of all procedures.

The study was compliant to the Declaration of Helsinki and the International Conference on Harmonization (ICH) Harmonized Tripartite Guideline for Good Clinical Practice (GCP), led under the approval of the local ethics committee and the institutional review board (IRB). All patients gave their informed consent to treatment via TRA. Inclusion and exclusion criteria for TRA are shown in Table 1.

### Study population

A total of 60 consecutive patients undergoing two chemoembolizations of a single hepatic lobe within 4 weeks over a 12-month period, were included in the study (46 males, 14 females; mean age, 66.03±7.05 years) (Table 2). In order to determine the impact of the learning curve, TRA volume was analyzed as a continuous variable for modelling.

Initially, the relationship between TRA procedure experience and angiographic and procedural variables was analyzed through generalized linear mixed mod-

els drawing plots to investigate curves for outcome versus TRA case volume, any given slope along the curve representing the rate of change in outcome with increasing TRA experience. The presence of potential inflection points along the relationship curves between case volume (per case increase) and outcomes was considered for the determination of possible threshold for overcoming the learning curve. Candidate knot points were chosen for testing based on visual inspection of curves. Finally, 3 consecutive patient study groups of the prospectively consecutively random-enrolled population were evaluated and compared: group A (cases 1 to 20; interval time for enrolment, 4 months), group B (cases 21 to 40; interval time for enrolment, 3 months), and group C (cases 41 to 60; interval time for enrolment, 5 months). We used all TFA procedures performed by the same operator in the same series of patients as control.

### End points

The following primary outcomes were chosen as markers of operator proficiency: intraprocedural conversion rate, defined as

**Table 1.** Inclusion and exclusion criteria

#### Inclusion criteria

- Patients over 18 years of age
- Histologically proven primary or secondary liver malignancy
- Indication to undergo two consecutive treatment sessions of unilobar hepatic chemoembolization within a 4-week interval
- Suitable transfemoral and transradial access route (normal Allen's and Barbeau's test)
- Performance status (ECOG) classified as 0-1
- Adequate hematologic function: ANC  $\geq 1.5 \times 10^9/L$ ; platelets  $\geq 40,000/\mu L$ ; INR  $\leq 1.3$  (If a patient was on anticoagulants, they had to be able to stop medication temporarily prior to transarterial chemoembolization and have INR  $\leq 1.3$  at the time of the procedure)
- Adequate renal function: serum creatinine  $\leq 2.0$  mg/dL and GFR  $\geq 60$  mL/min/1.73 m<sup>2</sup>

#### Exclusion criteria

- History of severe allergy or intolerance to any contrast media or chemotherapeutic drugs not controlled with medication
- Vascular status: absence of pulse in femoral or radial arteries, abnormal Allen/Barbeau test results, small radial artery (<3 mm), presence of a dialysis fistula or impending dialysis dependence, failed previous arterial access
- Patients who refused the transradial approach
- Patients who were unable to complete the study

ECOG, Eastern Cooperative Oncology Group; ANC, absolute neutrophil count; INR, international normalized ratio; GFR, glomerular filtration rate.

### Main points

- Transradial artery access (TRA) catheterization is a safe and suitable option for interventional procedures, with success rates strictly dependent on the operator experience, the learning curve, and the complexity of patient and disease.
- Ultrasound guidance seems to contribute to a more rapid gaining of an adequate proficiency in TRA, accelerating the learning curve, providing earlier and higher first-attempt success rates as well as fewer mean attempts to success and shorter mean times to success.
- For TRA, the threshold to overcome the learning curve seems to be around 20 procedures, at least for simple procedures. Present findings have implications both for operators looking to expand their skills and for defining further standards for training.

**Table 2.** Baseline and angiographic characteristics

	All (n=60)	Group A (Cases 1–20) (n=20)	Group B (Cases 21–40) (n=20)	Group C (41–60) (n=20)	P
Age (years)	66.03±7.05	65.35±6.31	67.35±5.76	65.4±8.85	0.132*
Height (cm)	167.1±8.5	166.3±7.2	168.3±8.3	167.5±6.3	0.143*
BMI (kg/m <sup>2</sup> )	28.38±1.29	27.85±1.22	28.4±0.99	28.9±1.45	0.159*
Male/Female	46/60 (76.7)	15/20 (75)	17/20 (85)	14/20 (70)	0.521**
Indication					
HCC	30/60 (50)	10/20 (50)	12/20 (60)	8/20 (40)	0.831**
mCRC	18/60 (30)	6/20 (30)	4/20 (20)	8/20 (40)	
pNET	7/60 (11.7)	2/20 (10)	3/20 (15)	2/20 (10)	
ICC	5/60 (8.3)	2/20 (10)	1/20 (5)	2/20 (10)	

Data are presented as mean ± standard deviation or n/N (%).  
 BMI, body mass index; HCC, hepatocellular carcinoma; mCRC, colorectal cancer liver metastases; pNET, peripheral neuroendocrine tumor; ICC, intrahepatic cholangiocarcinoma.  
 \*ANOVA; \*\*chi-square test.

**Table 3.** Secondary outcomes

Angiographic and procedural variables
Time of preparation: from the time the patient was placed in the supine position on the examination table until the time when the interventionist started the procedure
Time of puncture: from anesthetic administration at the site of vascular access until placement of the arterial sheath
Number of punctures
Fluoroscopy time: time recorded by the angiographic equipment at the end of each procedure
Mean radiation dose: in terms of RAK (as recorded by the angiographic equipment at the end of each procedure)
Total time of examination: from arterial sheath placement to its removal
Amount of contrast medium
Complaints related to the procedure
Pain during the puncture
General discomfort during the intervention
Discomfort after the procedure in the limb used for the access route
Limitations for the patient after the procedure in performing basic activities such as eating or physiological functions
RAK, reference air kerma.

the need for a second different access (also defined as crossover rate or change of access route) within the procedure and one-month later, and access site complication rate, major if blood transfusion or vascular repair were involved (11). Access site hematoma was assessed according to the criteria

of National Cancer Institute (NIH) (Common Terminology Criteria of Adverse Events) (12). Postprocedural neurologic events (i.e., transient ischemic attacks, stroke) were recorded.

Secondary outcomes were angiographic and procedural variables (Table 3). At the

end of the bed-rest period any complaint related to the procedure was recorded through a previously published questionnaire (9), compiled by a different investigator not involved in the procedure, based on a four-point scale (0: none, 1: mild, 2: moderate, 3: severe) (Table 3).

### Procedures

Patients underwent treatments in an angiographic room after antibiotic prophylaxis, under moderate sedation; in detail, fentanyl 50–150 µg IV or morphine 5–10 mg IV, and midazolam 1–5 mg IV were used to achieve moderate sedation.

Particles and drugs for chemoembolization were selected according to histology (as assessed by imaging and/or biopsy) and operator decision.

One operator, with the same devices and technique, led all TRA and TFA procedures.

For TRA, ultrasonography (US) guided puncture of the left radial artery was always performed, under local anesthesia with 1% lidocaine (4–5 mL), using a Seldinger technique (21-gauge needle).

A 5 F vascular introducer sheath (Glide-sheath Slender - Terumo Corp.) was inserted over a 0.021-inch microwire (Terumo Corp.), followed by insertion of 5 F arterial catheter - 110 cm Optitorque Multipurpose (Terumo Corp.), 4 cm long tip catheter for selective catheterization. Superselective catheterization and chemoembolization were performed using a coaxial technique, with a 2.7 F microcatheter (Progreat, Terumo Corp.). A mix of 2.5 mg of verapamil, 2 mL of 2% lidocaine (Xylocaine, AstraZeneca) and heparin 2000 IU was injected through the vascular sheath to prevent clots and vasospasm.

For TFA, a 5 F introducer sheath (Radifocus Introducer II, Terumo Corp.) was always placed in the right common femoral artery with selective catheterization performed with a 5 F diagnostic catheter, Cobra (Terumo Corp.) or Simmons II (Terumo Corp.). Superselective catheterization and chemoembolization were performed using a coaxial technique, placing the same 2.7 F microcatheter (Progreat).

In all patients the introducer sheath was removed at the end of the procedure and hemostasis achieved by compression (manual or with the application of a pressure bandage). After TFA, patients had a 6-hour bed rest, whereas after TRA they were only asked to avoid movements of the wrist joint. Patient discharge followed a short

**Table 4.** Angiographic and procedural variables

	All (n=60)			Group A (Cases 1–20) (n=20)			Group B (Cases 21–40) (n=20)			Group C (Cases 41–60) (n=20)					
	TRA	TFA	P *	A-B	A-C	B-C	TRA	TFA	P **	TRA	TFA	P **	TRA	TFA	P **
Time of preparation (min)	14.3±5.4	10.7±4.1	<0.001	0.022	0.025	0.078	20.9±3.9	11.4±3.5	<0.001	11.7±1.9	12.5±4.7	0.480	10.1±1.2	8.2±2.9	0.085
Time of puncture (min)	3.9±1.3	3.6±1.0	<0.001	0.024	0.028	0.592	5.2±1.0	3.2±0.8	<0.001	3.4±0.5	4.0±1.1	0.098	3.1±0.9	3.5±0.9	0.297
Number of punctures	1.4±0.6	1.3±0.5	0.140				1.7±0.7	1.3±0.5	0.057	1.1±0.4	1.3±0.6	0.214	1.3±0.5	1.2±0.5	0.577
Fluoroscopy time (s)	369.2±88.0	341.6±37.0	<0.001	0.015	0.021	0.671	450.3±44.6	361.0±25.9	<0.001	352.6±90.3	350.3±27.2	0.921	304.7±48.3	313.2±39.0	0.503
Mean radiation dose (RAK) (mGy)	393.2±229.8	323.3±269.7	<0.001	0.011	0.014	0.092	655.6±213.1	248.8±219.4	<0.001	275.6±87.2	504.4.6±349.8	0.004	248.3±43.3	216.5±53.5	0.058
Total examination time (min)	30.2±5.8	27±7.5	<0.001	0.012	0.018	0.552	36.3±6.0	26.2±5.0	<0.001	28.7±2	28.7±2.0	0.671	25.5±1.3	25.0±2.9	0.478
Contrast volume (mL)	81.9±23.2	78.6±30.2	0.023	0.029	0.021	0.424	103.7±25.7	80.4±30.4	0.017	65.8±5.7	68.2±31.4	0.746	76.1±13.1	87.1±26.9	0.171

TRA, transradial artery access; TFA, transfemoral artery access; RAK, reference air kerma.

\* ANOVA; \*\* paired Student t-test

complication-free observation period (at least 12 hours), as a rule, on the day following the procedure.

### Follow-up

Patients were re-evaluated after 4 weeks with physical examination, arterial pulse check, laboratory, and cross-sectional imaging.

### Statistical analysis

Descriptive statistics and inferential analysis were performed using Statistical Package for Social Science (SPSS v. 20.0, IBM Corp.) software and included the Kolmogorov-Smirnov test for normal distribution testing, parametric (ANOVA, paired Student t-test), nonparametric (Kruskal-Wallis, Wilcoxon test) and Fisher Freeman Halton tests, where indicated. A P value ≤ 0.05 was considered statistically significant.

### Results

A technical success for chemoembolization was observed in all patients (100%). There was no switch from TRA to TFA (cross-over rate, 0%). Angiographic and procedural/postprocedural outcomes are reported in Table 4.

An association between incremental TRA operator experience (in terms of performed procedures) and decrease of preparation, puncture, fluoroscopy and total examination times was observed. Similarly, inverse associations between incremental TRA operator experience and contrast medium (CM) volumes and radiation dose (RD) values (in terms of RAK - reference air kerma) were also observed. The presence of inflection points along the curves for angiographic and procedural variables was investigated with knot points around 20 TRA cases chosen for evaluation based on visual inspection of the plots (Fig.). This result was confirmed by analysis of different patient study groups. In particular, when compared to the TFA control group, CM volumes and RD values were significantly higher only in group A (Cases 1–20), with similar results for group B (Cases 21–40) and group C (Cases 41–60), respectively (Table 4). When considering qualitative evaluation, significantly higher intraprocedural discomfort was registered in group A (Table 5).

In contrast, procedure success remained high in all TRA groups and no significant association between TRA incremental expe-

**Table 5.** Patients' opinions regarding procedures

	All (n=60)						Group A (Cases 1–20) (n=20)			Group B (Cases 21–40) (n=20)			Group C (Cases 41–60) (n=20)		
	TRA	TFA	P*	A-B	A-C	B-C	TRA	TFA	P**	TRA	TFA	P**	TRA	TFA	P**
Pain during puncture	1 (0–3)	1 (0–2)	0.075				1 (0–3)	1 (0–2)	0.028	1 (1–1)	1 (1–2)	0.186	1 (0–1)	1 (0–1)	0.267
Intraprocedural discomfort	1 (0–2)	1 (0–3)	0.048	0.037	0.156	0.133	1 (0–2)	1 (0–2)	0.015	1 (1–2)	1 (0–2)	0.186	1 (0–1)	1 (0–3)	0.330
Postprocedural discomfort	0 (0–3)	1 (0–3)	0.001	0.023	0.028	0.838	1 (0–1)	1 (0–2)	0.069	0 (0–2)	2 (1–2)	<0.001	0 (0–1)	1 (1–2)	<0.001
Postprocedural limitations in performing basic activities	1 (0–3)	2 (0–3)	0.001	0.612	0.013	0.055	0.5 (0–2)	2 (1–3)	<0.001	1 (0–1)	2 (1–3)	<0.001	1 (0–1)	1 (1–2)	0.002

Data are presented as median (min–max). Patient evaluation was based on a 4-point scale (0: none, 1: mild, 2: moderate, 3: severe). TRA, transradial artery access; TFA, transfemoral artery access. \*Kruskal-Wallis test; \*\*Wilcoxon test.

rience and postprocedural outcomes was found. Higher limitations in basic activities were recorded after TFA vs. TRA procedures in groups (A–C) (Table 5).

In terms of postprocedural adverse events, no major vascular complications or neurologic events were registered. A total of 5 minor complications for TRA (1 local hematoma and 4 ecchymosis, 8.3%) and 6 for TFA (2 local hematoma and 4 ecchymosis, 10.0%) were observed ( $P = 0.5$ ), self-limited without any further interventions or clinical sequelae and without any association to TRA incremental experience. No radial artery occlusion or hand ischemia were recorded immediately or in the follow-up.

## Discussion

The concept of a learning curve, in which operator skills improve with increasing experience, has been observed for many procedures, including TRA in cardiac interventions (13–24), although to date there are no published papers focusing on the assessment of the association between TRA experience and operator proficiency, particularly for specialists highly experienced in TFA procedures. Determining the minimum threshold to overcome the learning curve could be important for fostering TRA adoption by interventional radiologists, given its advantages in clinical practice.

In our study we confirm that the learning curve seems to have a major influence on operator proficiency: the observed threshold for overcoming the learning curve was about 20 procedures, lower than previously reported for cardiac procedures. Specifi-

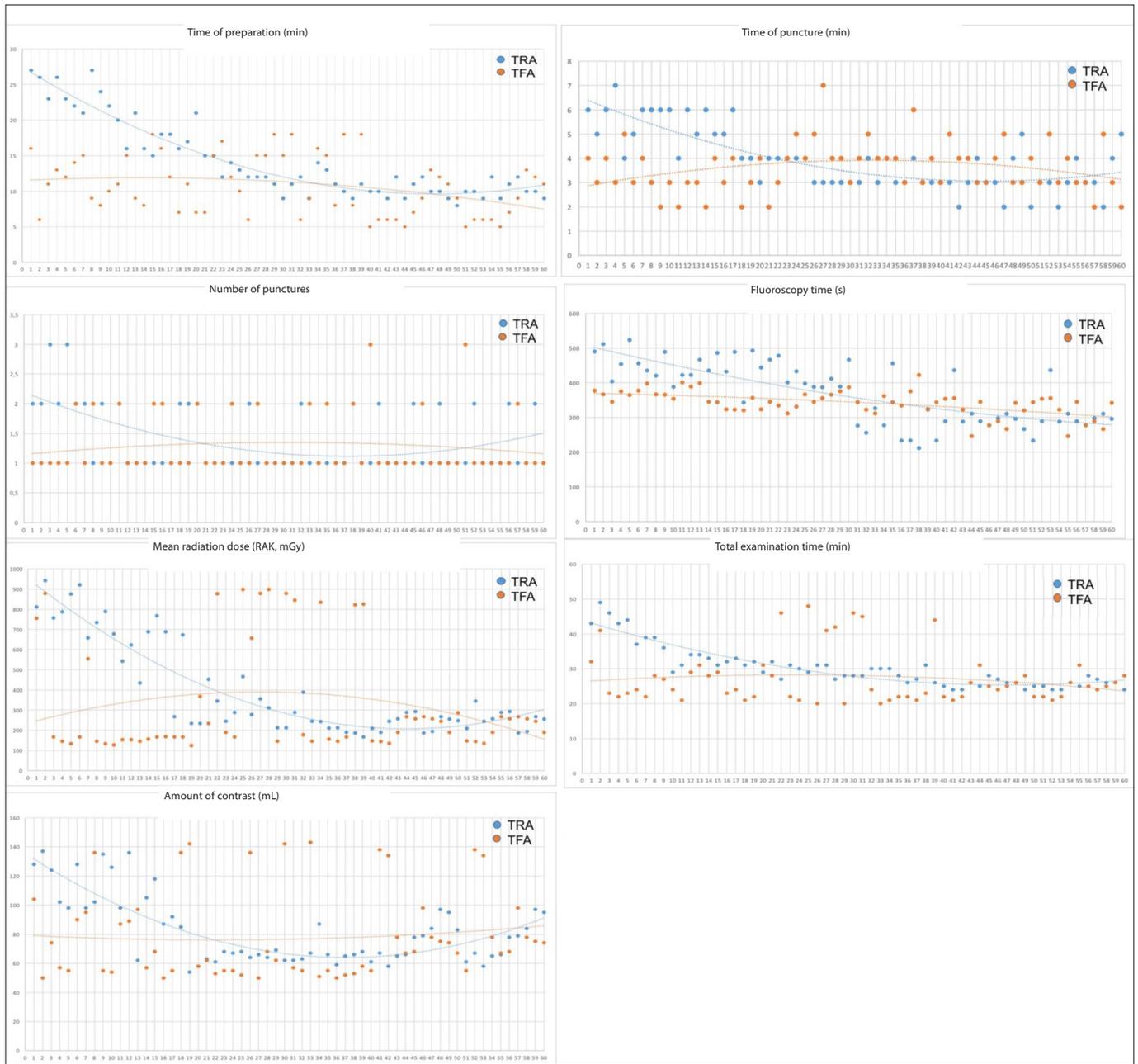
cally, a range of potential thresholds from 30–50 procedures were found in a previous study, obtained including 54 561 TRA procedures performed by 942 new TRA operators at 704 sites (14). A case-volume threshold of at least 50 TRA procedures was also reported in a learning curve analysis evaluating new TRA operators to achieve similar procedural outcomes as experienced TRA performers. Furthermore, Spaulding et al. (24) found that an annual procedural volume of >80 TRA procedures correlated with significantly lower rates of access failure and shorter overall procedure times for coronary angiography. Finally, Looi et al. (20) also registered improvement of proficiency when comparing results from operators' last 6-month experience to their first 6 months ( $n=82$  procedures) for inexperienced operators performing TRA diagnostic angiograms.

The discrepancy between our results and what is reported in the literature could have several explanations, one of them probably related to the use of US guidance for radial artery catheterization rather than the traditional palpation technique, generally preferred by cardiologists in previous papers. As also reported in a recent comparative study (25), US guidance could provide earlier and higher first-attempt success rates as well as fewer mean attempts to success and shorter mean times to success, eventually predicting anatomic variants. In comparison to cardiologists, interventional radiologists are usually well-trained in the use of US guidance for vascular and extravascular procedures as well, which can contribute to a more rapid gaining of an adequate proficiency in TRA, accelerating the learning curve.

Moreover, we usually use the same standard technique with dedicated radial devices, such as dedicated low-profile vascular introducer sheaths and a single-catheter technique, with a preformed shaped tip, for accessing thoraco-abdominal aorta as well as performing selective catheterization of hepatic arteries, with no need for catheter exchange. It is well-known that catheter exchanges increase procedural complexity, facilitate radial artery spasm, even prolonging procedure duration and increasing radiation exposure for both patient and operator. Multiple-catheter strategy could require longer learning curve and more operator training and experience.

Finally, we hypothesize that the observed early procedural proficiency could be related to the selection of technically simple procedures, based only on lobar hepatic catheterization.

The most important limitation in our study is that it is focused on the learning curve of a single operator on a single procedure (i.e., lobar chemoembolization). Data are therefore not applicable to all operators and/or other procedures and do not take into account individual operator variabilities and differences in procedure complexity, which could be addressed by further studies. Nevertheless, our experience shows that, under controlled conditions and with fixed prerequisites, it is possible to assess standards in the development of a learning curve, which can represent a reference point. Although TRA learning curve could be slower for complex hepatic interventions, needing superselective catheterizations and embolizations, and for patients with comorbidities,



**Figure.** Angiographic and procedural variables. RAK, reference air kerma; TRA, transradial artery access; TFA, transfemoral artery access..

ties such as obesity and old age, our data support that TRA competence could take advantage of starting with lower-risk and lower-complexity patients to achieve high procedural success rates early on and moving on to more complex cases later.

In conclusion, our study demonstrates that TRA catheterizations can be safely performed in patients requiring liver cancer embolization after a relatively short training in controlled conditions and with a better performance in comparison with TFA. The threshold to overcome the learning curve

seems to be around 20 procedures. Present findings have implications both for operators looking to expand their skills and for defining further standards for training.

**Conflict of interest disclosure**

The authors declared no conflicts of interest.

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