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Real-Time Ultrasound Guidance Facilitates Transradial Access

RAUST (Radial Artery Access With Ultrasound Trial)

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ABSTRACT

OBJECTIVES This study sought to assess the utility of ultrasound (US) guidance for transradial arterial access.

BACKGROUND US guidance has been demonstrated to facilitate vascular access, but has not been tested in a multicenter randomized fashion for transradial cardiac catheterization.

METHODS We conducted a prospective multicenter randomized controlled trial of 698 patients undergoing transradial cardiac catheterization. Patients were randomized to needle insertion with either palpation or real-time US guidance (351 palpation, 347 US). Primary endpoints were the number of forward attempts required for access, first-pass success rate, and time to access.

RESULTS The number of attempts was reduced with US guidance [mean: 1.65 ± 1.2 vs. 3.05 ± 3.4, $p < 0.0001$; median: 1 (interquartile range [IQR]: 1 to 2) vs. 2 (1 to 3), $p < 0.0001$] and the first-pass success rate improved (64.8% vs. 43.9%, $p < 0.0001$). The time to access was reduced (88 ± 78 s vs. 108 ± 112 s, $p = 0.006$; median: 64 [IQR: 45 to 94] s vs. 74 [IQR: 49 to 120] s, $p = 0.01$). Ten patients in the control group required crossover to US guidance after 5 min of failed palpation attempts with 8 of 10 (80%) having successful sheath insertion with US. The number of difficult access procedures was decreased with US guidance (2.4% vs. 18.6% for ≥5 attempts, $p < 0.001$; 3.7% vs. 6.8% for ≥5min, $p = 0.07$). No significant differences were observed in the rate of operator-reported spasm, patient pain scores following the procedure, or bleeding complications.

CONCLUSIONS Ultrasound guidance improves the success and efficiency of radial artery cannulation in patients presenting for transradial catheterization. (Radial Artery Access With Ultrasound Trial [RAUST]; NCT01605292) (J Am Coll Cardiol Intv 2015;8:283–91) © 2015 by the American College of Cardiology Foundation.

Transradial catheterization is associated with reduced access site complications and increased patient comfort compared with transfemoral catheterization (1). In patients with ST-segment elevation, there is a decrease in mortality associated with the transradial approach (1,2). However, despite increased interest, there is a significant learning curve to transradial catheterization and the proportion of transradial percutaneous coronary intervention (PCI) procedures performed is still low in the United States at approximately 16% (3).

Failure to access the transradial artery is the cause of 57% of all transradial PCI failures (4). The radial artery is small at 2.4 to 2.6 mm (5), which approaches the 2- to 4-mm 2-point discrimination limit of fingertip palpation (6). The radial artery may also be

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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

IQR = interquartile range

OR = odds ratio

PCI = percutaneous coronary interventions

PVD = peripheral vascular disease

US = ultrasound

diminutive, collapsible, calcified, mobile, or associated with anatomic anomalies or dilated radial veins. Difficulty or delays with radial access may contribute to the reluctance of operators in adopting transradial catheterization, particularly for primary PCI (2,7).

Real-time ultrasound (US) guidance has been demonstrated to facilitate safe and more efficient vascular access in central veins and in the femoral artery (8,9). Several previous small trials have demonstrated potential benefit in radial artery lines outside of the catheterization laboratory (10), but the technique has not been tested in a multicenter prospective study focused on transradial access for cardiac catheterization.

METHODS

STUDY DESIGN. RAUST (Radial Artery access with Ultrasound Trial) was a prospective, multicenter randomized controlled trial of transradial access with palpation or US guidance. The study was investigator-initiated and unsponsored. All patients provided written informed consent for the research study, and the study was approved by the Institutional Review Board of each institution. Adult patients presenting for planned transradial cardiac catheterization procedures were included in the trial, provided that a trained operator and working US machine were available. Patients with emergent procedures, chronic renal disease on hemodialysis, nonpalpable radial pulse, or abnormal hand collateral circulation (abnormal Allen test or Barbeau class D) were excluded from the study. Patients with previous ipsilateral radial puncture within the week prior to the procedure were also excluded.

EQUIPMENT. The study used US machines with a high-frequency linear array transducer capable of imaging and displaying at a depth of 2 mm with a screen of at least 12.1 diagonal inches. The machines included the M-Turbo with L25x or HFL38x 6 to 13 MHz transducer (Sonosite Inc., Bothell, Washington), the Site-Rite Vision with linear 5 to 10 MHz transducer (Bard Access, Salt Lake City, Utah), and the iU22 xMATRIX with L12-5 5 to 12 MHz transducer (Philips Healthcare, Andover, Massachusetts). Sterile probe covers and transducer gel were used for all US procedures. No needle guides were used for this study.

OPERATOR TRAINING. This study included operators experienced in transradial catheterization to minimize potential confounders. Participation in the study required a minimum of 100 previous radial artery catheterization procedures, with at least 15 US-guided procedures. Thirteen attending physicians and 3 advanced interventional fellows participated in the study across 6 sites.

RANDOMIZATION. Patients were randomized in a 1:1 fashion to either palpation or US guidance using sealed envelopes balanced in blocks of 50 to 80 generated at each center. Patients were not randomized until a single trained operator was assigned to their procedure.

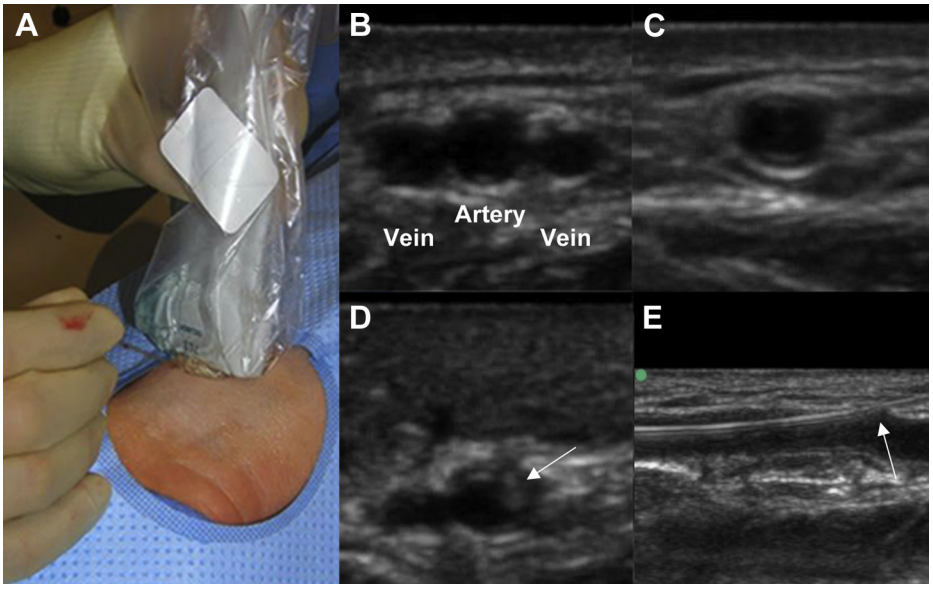
STUDY PROCEDURES. All patients received assessment of the hand circulation using either the Allen test or Barbeau test. All procedures were performed according to local standard and operator preference with the exception of palpation or US guidance. Patients received conscious sedation, 5-F or 6-F sheaths, and intra-arterial and/or subcutaneous lidocaine as per local practice. A minimum of 2,000 U of intravenous unfractionated heparin or bivalirudin was required for anticoagulation, and a minimum of either 2.5 mg of intra-arterial verapamil or 100 μg nitroglycerin for spasm prophylaxis.

Following administration of local anesthetic, radial access was obtained using a 21- to 22-gauge needle and short hydrophilic sheaths (Glidesheath, Terumo, Somerset, New Jersey). Single- or double-wall technique was used per operator preference. For US-guided procedures, the artery was imaged in the axial plane, and the artery lined up with the centerline of the probe. The needle was inserted at the center of the probe, and the needle tip was imaged by short wiggles of the needle if necessary (**Figure 1**, Online Video 1). Details of the technique have been previously described (11). The guidewire would then be inserted, the skin nicked per operator practice, and the sheath inserted over the guidewire and flushed. Palpation-guided procedures were allowed to cross over to rescue US guidance after 5 min of attempts.

Following the procedure, hemostasis was achieved with the TR Band (Terumo), the D-Stat Rad-Band (Vascular Solutions, Minneapolis, Minnesota), or manual compression. Patent hemostasis and removal of any bands following the procedure were according to local practice. Between 1 and 4 h following the procedure, patient pain levels at the point of radial access were measured using a 0 to 10 visual analog scale. Screening for radial artery occlusion or vascular complications occurred per local practice, including at minimum a pulse check.

Baseline patient demographics and comorbidities were recorded. Peripheral vascular disease (PVD) was defined as having a previous clinical diagnosis of atherosclerosis in a noncoronary vessel, including

FIGURE 1 Technique of US-Guided Radial Access



(A) Axial position of draped ultrasound (US) probe over the right radial artery. The needle is inserted just below the center of the probe when the artery is in the center of the image plane. **(B)** Visualization of radial artery and veins. **(C)** Compression causes closure of radial veins and reveals pulsatility of artery. **(D)** Visualization of the needle tip **(arrow)** compressing and puncturing the artery. **(E)** Confirmation of wire position **(arrow)** in the radial artery in longitudinal plane. See Online Video 1.

previous revascularization (e.g., carotid endarterectomy, peripheral vascular bypass), known >50% obstruction in a noncoronary vessel, or abdominal aortic aneurysm. Procedural details including number of attempts, time to access, medications, sheath size, type of procedure, access technique, hemostasis technique, and any access site crossovers were tracked.

ENDPOINTS AND POWER. The primary endpoints of the study were the first-pass success rate, the total number of attempts needed for access, and the time to access. Attempts were defined as forward passes separated by withdrawal of the needle, specifically excluding short wiggles needed to visualize the needle under US so long as these occurred in the skin or tissue above the plane of the artery. The number of attempts to access were verbally announced by the operator and confirmed by an independent technician. The time to access was measured from the point of the first application of the operator's fingers or US probe to guide access to successful sheath placement and flushing. The counting of attempts and measurement of time was not altered for patients who crossed over from palpation to US guidance. For patients randomized to US guidance, the probe was draped during the table setup, requiring approximately 15 to 30 s in our laboratories.

Secondary endpoints included the incidence of spasm, difficult procedures, bleeding complications, crossover to US guidance, and access site crossover. Spasm was defined and identified by the operator as any significant resistance or patient pain with catheter manipulation. Difficult procedures were prospectively defined as either requiring ≥5 attempts or ≥5 min. Bleeding was defined as a hematoma >2 cm or any bleeding requiring intervention.

The goal sample size of 400 patients was derived primarily from a desire to have multiple operators participate in the study, but it was also sufficiently powered to study each of the primary endpoints in isolation. The study had an estimated power of 97.5% with an alpha of 5% to detect the 17% absolute difference in first-pass success seen in previous trials (9), >95% power to detect a 30-s difference in time to access, and >99% power to detect a difference in number of attempts of 1.

STATISTICAL ANALYSIS. Baseline demographic, clinical, and procedural characteristics were examined for statistically significant differences between the 2 groups. Collected outcome data were analyzed

on an intention-to-treat basis. The Kolmogorov-Smirnov and Shapiro-Wilk tests of normality were used to examine the distribution of data from continuous variables. Outcome measures were reported using the median (interquartile range [IQR]) and compared with non-parametric tests when the normality assumption was not met. For comparison with other studies, the mean ± SD is also reported. The unpaired Student's *t*-test or Mann-Whitney *U* test was used for continuous variables, and the uncorrected Chi-squared or Fisher's exact test were used for proportions. Correlations between variables that were not normally distributed were assessed with the Spearman rank correlation coefficient. Multivariable analyses were undertaken using logistic regression. Two-tailed tests of significance are reported and p values <0.05 were considered statistically significant. Statistical analyses were performed using the SPSS statistical software program (version 16.0.2, SPSS, Chicago, Illinois).

RESULTS

Between December 1, 2011 and March 29, 2013, 698 patients were enrolled across 6 sites. They were randomized to palpation (n = 351) or US (n = 347) guidance. An interim analysis revealed that the first 225 patients from 2 sites (114 palpation, 111 US) had an extraordinarily high first-pass success rate (96.5% palpation, 97.3% US), and the number of attempts were found to have been incorrectly counted as the number of separate skin punctures rather than forward passes. These subjects were censored from the comparison of number of attempts, first-pass success rate, and multivariate analysis of attempts, but they were included for all other outcomes. Enrollment was extended following this analysis to ensure the goal sample size of 400 subjects having full procedural data was met.

There were no significant differences in the baseline characteristics of the patients (Table 1). Barbeau test was used in 47% of procedures and was not different between the 2 groups. There were also no significant differences in procedural characteristics (Table 2), including types or doses of medications administered. Approximately 20% of procedures were interventions. The majority of procedures were performed using single-wall technique. Closure was predominantly with the TR band, but the D-stat Rad-band was used in 1 site exclusively. Manual compression was used in <3% of procedures.

Our results showed a significant reduction in the number of attempts required to cannulate the radial artery with US versus palpation (mean: 1.65 ± 1.2 vs. 3.05 ± 3.4, p < 0.0001, median: 1 [IQR: 1 to 2] vs. 2 [IQR: 1 to 3], p < 0.0001). This correlated with an improved first-pass success rate [64.8% (95% confidence interval [CI]: 58.7% to 70.1%) vs. 43.9% (95% CI: 37.6% to 50.2%), p < 0.0001]. The mean and median times to access were reduced with US guidance (88 ± 78 s vs. 108 ± 112 s, p = 0.006 and 64 [IQR: 45 to 94] s vs. 74 [IQR: 49 to 120] s, p = 0.01) (Figures 2A to 2C). Subgroup analysis demonstrated a consistent benefit of US guidance in reducing the number of attempts and time required for access regardless of sex, body mass index, or access technique (single- or double-wall) (Figure 3). There was a significant interaction between double-wall technique and having a reduced number of attempts and time using US.

The number of difficult access procedures was reduced with US guidance (Figure 2D). Defined as any

TABLE 1 Baseline Patient Characteristics

	Palpation (n = 351)	Ultrasound (n = 347)	p Value
Age, yrs	62.3 ± 10.6	61.5 ± 11.5	0.80
Male	262 (75)	254 (73)	0.66
Outpatient	141 (40)	139 (40)	0.98
BMI	30.2 ± 7.2	30.4 ± 6.9	0.64
Obesity, BMI >30 kg/m^2	153 (44)	149 (43)	0.86
Hypertension	305 (87)	292 (84)	0.30
Hypercholesterolemia	265 (75)	254 (73)	0.49
Diabetes mellitus	151 (43)	149 (43)	0.98
Tobacco	107 (30)	128 (37)	0.07
PVD	16 (5)	14 (4)	0.73
Barbeau class B or C	54/149 (36)	56/149 (38)	0.81

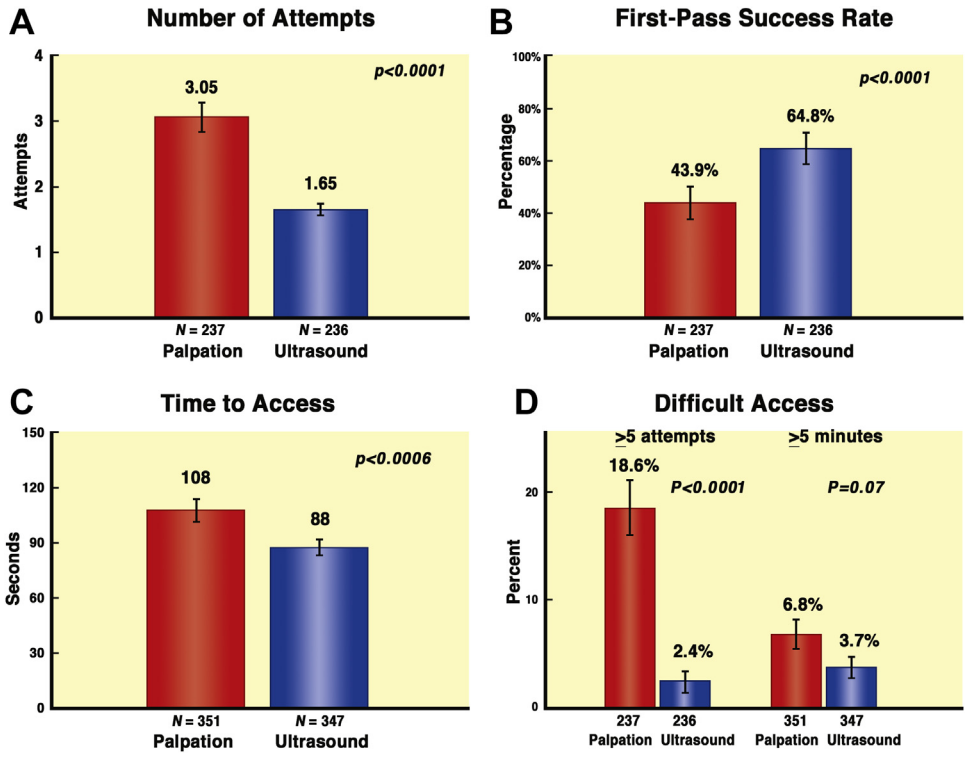
Values are mean ± SD, n (%), or n/N (%).
BMI = body mass index; PVD = peripheral vascular disease.

TABLE 2 Procedural Characteristics

	Palpation (n = 351)	Ultrasound (n = 347)	p Value
Intervention	63 (18)	73 (21)	0.30
5-F sheath	193 (55)	185 (53)	0.66
Single-wall technique	306 (87)	295 (85)	0.41
Right radial access	323 (92)	328 (95)	0.19
Verapamil, ≥2.5 mg	340 (97)	342 (99)	0.20
Nitroglycerin, ≥100 μg	271 (77)	278 (80)	0.35
Lidocaine IA, 5 mg	167 (48)	170 (49)	0.71
TR Band closure	225 (64)	229 (66)	0.60
D-stat band	114 (33)	111 (32)	0.89
Unfractionated heparin	322 (92)	321 (92)	0.71
GPIIb/IIIa	13 (4)	14 (4)	0.82
Bivalirudin	51 (15)	50 (14)	0.96
P2Y$_{12}$ inhibitor	193 (55)	200 (58)	0.48

Values are n (%).
GP = glycoprotein; IA = intra-arterial.

FIGURE 2 Palpation- Versus US-Guided Radial Access



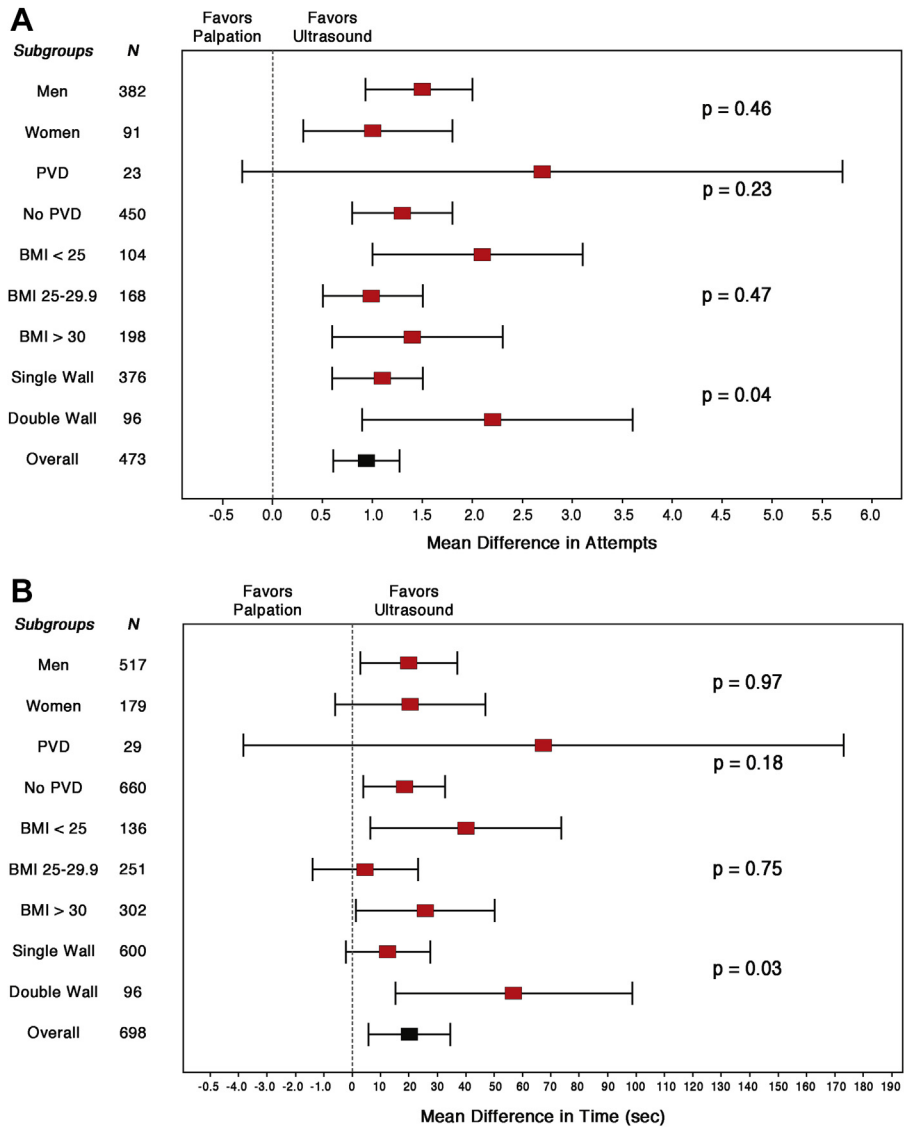
Comparison of palpation-guided and ultrasound (US)-guided radial access for the following: **(A)** number of attempts; **(B)** first-pass success rate; **(C)** time to access; **(D)** difficult access. Values are mean ± SE or ± 95% confidence interval for proportions.

procedure requiring 5 or more attempts, US reduced the number of difficult procedures from 18.6% to 2.4% ($p < 0.001$). Defined as requiring 5 min or more in time, US guidance showed a trend toward reducing the number of difficult procedures from 6.8% to 3.7% ($p = 0.07$).

There were no significant differences in clinical outcomes between the 2 groups (Table 3). Spasm and bleeding complications were reported equally and rarely in both groups, and patient-reported pain scores were low in both groups. Although US guidance was not used to screen for radial artery occlusion, symptomatic radial artery occlusion was not reported in routine clinical follow-up by any site. Ten patients in the palpation group required crossover to US guidance after 5 min, with US successfully rescuing the access in 8 cases. Crossover to another site (usually femoral) occurred occasionally following sheath insertion in both groups due to spasm, tortuosity, or insufficient guide support. Crossover to another site prior to sheath insertion (failed access) occurred numerically more frequently in the palpation group than the US group. Using a per-protocol analysis, failure of sheath insertion occurred with 15 patients with palpation alone compared with 3 with US ($p = 0.007$).

Univariable analyses revealed a significant but weak correlation between radial artery spasm and number of attempts (rho = 0.12, $p = 0.008$) and time to access (rho = 0.12, $p = 0.01$). Patients who experienced spasm had more attempts than patients without spasm (median: 3 [IQR: 1 to 5] vs. 1 [IQR: 1 to 3], $p = 0.008$) and required more time for access (99 [IQR: 58 to 271] s vs. 65 [IQR: 45 to 104] s, $p = 0.011$). PVD was also observed to be related to spasm, with 21.7% (6 of 23) of the patients with spasm having documented PVD versus 3% (18 of 450) of patients without spasm ($p = 0.003$). No other variables were found to be related to spasm. Multivariable logistic regression analysis using as predictors the randomized treatment, presence of PVD, and number of attempts, revealed that the presence of PVD (odds ratio [OR]: 6.4, 95% CI: 2.1 to 19.9, $p = 0.001$) and the number of attempts (OR: 1.15, 95% CI: 1.03 to 1.28, $p = 0.01$) were significant predictors of spasm. Univariable analysis found PVD to be the only baseline

FIGURE 3 Subgroup Analysis



Mean difference (± 95% confidence interval) in **(A)** number of attempts and **(B)** time to access (s) between ultrasound and palpation guidance. The p values for the interaction between the benefit of ultrasound guidance and sex, peripheral vascular disease (PVD), body mass index (BMI), and access technique are included.

variable that was predictive of multiple attempts at access. Patients diagnosed with PVD required significantly more attempts (median: 2 [IQR 1 to 6]) than patients without PVD (median: 1 [IQR 1 to 3]) ($p = 0.011$).

DISCUSSION

In this prospective, multicenter randomized controlled study, US guidance facilitated radial artery access compared with palpation as measured by the first-pass success rate, number of attempts, and time to access. US guidance was helpful in reducing the number of difficult access procedures and as a rescue technique when attempts using palpation alone failed. By improving the consistency and reducing the time of radial access, US guidance may be especially helpful in primary PCI procedures where the benefits of transradial catheterization are greatest, but where a 4% to 12.3% access site crossover rate

and a 1.5-min longer procedure time are typical (2), and a consensus statement recommends alternate access sites if transradial access is not achieved within 3 min (7).

These results suggest that "seeing" the small radial artery on US may be more accurate than "feeling" the artery, due to the 2- to 4-mm 2-point discrimination limit of fingertip palpation (6). US guidance is particularly useful in those patients with difficult access with palpation alone. A weak pulse may make palpation-guided access difficult, whether caused by a small artery, a deep artery, or hypotension. With hypotension, the arterial flashback in the needle may be slow or ephemeral if the posterior wall is punctured. With a small or muscular artery it may be difficult to maintain the optimal intraluminal needle position necessary for wire insertion by single-wall technique. With congestive heart failure and elevated venous pressures, the radial veins may dilate and be accidentally cannulated. With a calcified artery, the vessel may move away from the needle tip or require additional force to cannulate. With a clotted needle, successful cannulation of the artery may go unrecognized. US guidance potentially addresses all of these situations by visually confirming needle position above the artery before cannulation, compression and puncture of the arterial lumen, or position of the needle tip within the lumen.

The findings of this study are consistent with that of previous trials comparing real-time 2-dimensional US guidance for radial arterial line placement. Levin et al. (12) found in 69 adult patients requiring intraoperative monitoring an improvement in first-pass success rate from 34% to 62% ($p = 0.03$) with a mean number of attempts of 3.1 ± 2.4 versus 1.6 ± 1.0 ($p = 0.003$). Schwemmer et al. (13) found in 30 infants that the first-pass success rate was increased from 20% to 67% ($p < 0.05$). Shiver et al. (14) showed in 60 critically ill emergency room patients an improvement in first-pass success rate from 50% to 87% ($p = 0.005$) and a reduction in time from 314 s versus 107 s ($p = 0.0004$). In 1 trial, US did not have a benefit, which was felt by the investigators to be due to insufficient experience, with 94% of operators having <5 US-guided procedures (15). These findings are summarized in a meta-analysis, which suggested a 17% absolute improvement (26% to 43%) in first-pass success rate (10).

More recently, a single-operator experience with US guidance for transradial catheterization suggested that any benefit to US guidance was limited to patients with failed palpation-guided attempts (16). However, the study did not measure individual attempts, had a significant crossover rate of 13%, and did not specify the experience of the single operator with US procedures or definitions of failed access. This study did indicate that US guidance did permit radial access in 33% of patients with nonpalpable radial pulses compared with 0% success with palpation.

TABLE 3 Clinical Outcomes

	Palpation (n = 351)	Ultrasound (n = 347)	p Value
Spasm	12 (3)	15 (4.3)	0.56
Pain score, 0–10	0 (0–1)	0 (0–1)	0.67
Bleeding complication	4 (1.1)	5 (1.4)	0.75
Crossover to ultrasound rescue attempts after >5 min	10 (8 successful)	NA	NA
Crossover to another site after sheath insertion	5	2	0.45
Crossover to another site before sheath insertion/failed access	7	3	0.34
Failure of sheath insertion with original technique	15	3	0.007
Any crossover in access site or technique at any time	20	5	0.004

Values are n (%), median (interquartile range), or n.
NA = not applicable.

The present study was not adequately powered for clinical outcomes; therefore, the benefit of US guidance found was limited to procedural success and efficiency. The success rate for radial access was very high (>95%) in both groups, which is consistent with the experience of the operators participating in the study and the availability of US guidance as a rescue technique after 5 min. US guidance reduced the risk of failed radial access in a per-protocol analysis, which suggests that the need for alternative access sites (especially femoral) would be reduced with the use of US. Clinical complications from transradial access are rare in experienced laboratories using contemporary techniques, so a much larger sample size would be required to detect a difference in complications.

Spasm has been strongly and independently associated with multiple attempts at access, possibly due to increased injury to the vessel or surrounding tissue. Two studies found that unsuccessful access on first attempt was independently associated with 45% to 50% increased risk of radial artery spasm (17,18). In a large registry, Goldsmit et al. (19) found that the need for more than 1 puncture attempt was associated with an OR of 3.5 (95% CI: 1.9 to 6.3) of moderate/severe spasm. Regression analysis in this study confirmed an association between number of attempts and spasm. US guidance, by reducing the number of attempts and increasing the first-pass success rate, would presumably reduce the incidence of spasm. In the present study, clinically relevant spasm occurred only rarely (3% to 4%) and

equally in both groups. This is likely due to the high proportion of male patients in our population, and the use of only 5-F and 6-F sheaths. We cannot rule out that the benefit of US guidance on number of attempts would translate into a reduction of spasm if tested in a larger sample or if a more sensitive definition of spasm were used.

It is also possible that the correlation between multiple attempts and spasm is partly the result of a common factor such as radial artery size or calcification. Only in the study by Jia et al. (18) were both radial artery size and number of attempts assessed in multivariable analysis, and while the number of attempts remained an independent predictor of spasm (OR: 1.5), radial artery size was a stronger predictor (OR: 4.0). In our experience, we have observed that spasm is much more likely to occur when a relatively small or calcified radial artery is present, which is consistent with the observations of Saito et al. (20).

We did not use pre-procedure US to measure the size of the radial artery or screen for anatomical variations, which may be an additional benefit to its use (21). The incidence of radial artery anomalies such as high radial bifurcations, radial loops, or tortuosity approaches 10% (21) and has been associated with increased risk of spasm and failure (22). A high sheath to artery diameter ratio has been associated with radial artery spasm and occlusion (7,21). US screening for a small radial artery, calcification, occlusion, or anatomical variations may aid in the selection of sheath sizes or access site to minimize spasm or procedural failure.

These results should be generalizable to both the general population of patients and operators, as our subjects were unselected and operators with a wide range of experience with US were included. Although the majority of procedures were performed using single-wall puncture technique in this study, there was a nominally synergistic interaction between US guidance and the use of double-wall technique. Maintaining needle position for wire advancement in single-wall technique might be more difficult when the nondominant hand is releasing the US probe. Further studies may be needed to confirm this finding.

We believe that familiarity with US-guided access and imaging should be a part of the core curriculum for transradial training (7). Whether used routinely or as a rescue technique after several attempts at palpation-guided access have failed, US guidance will facilitate transradial catheterization and reduce the risk of transradial access failure. This benefit comes at a modest incremental cost ($6) of sterile drapes and gel and a fixed cost for an US machine that ranges from $15,000 to $25,000.

STUDY LIMITATIONS. Blinding of the operator or catheterization lab personnel to the use of US was not possible in this study. Despite the use of an observer and the lab timer, we cannot exclude a bias in the performance, measurement, or recording of the procedure or clinical data, although our first-pass and overall success rates are in line with previous studies. The time to prepare the US probe was not included in the time to access and may negate the average time benefit of US guidance if performed by the operator rather than by a technician. Consistent with the practice pattern in our institutions, we did not systematically screen for post-procedural radial artery occlusion with US.

CONCLUSIONS

In this multicenter randomized trial of transradial catheterization, US, compared with palpation, guidance increased the success and efficiency of sheath insertion. Familiarity with the technique will likely benefit transradial operators whether the technique is used routinely or as a rescue technique after initial palpation attempts fail.

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APPENDIX For an accompanying video, please see the online version of this paper.