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ORIGINAL RESEARCH

Randomized Trial of Conventional Transseptal Needle Versus Radiofrequency Energy Needle Puncture for Left Atrial Access (the TRAVERSE-LA Study)

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***Background*—**Transseptal puncture is a critical step in achieving left atrial (LA) access for a variety of cardiac procedures. Although the mechanical Brockenbrough needle has historically been used for this procedure, a needle employing radiofrequency (RF) energy has more recently been approved for clinical use. We sought to investigate the comparative effectiveness of an RF versus conventional needle for transseptal LA access.

***Methods and Results*—**In this prospective, single-blinded, controlled trial, 72 patients were randomized in a 1:1 fashion to an RF versus conventional (BRK-1) transseptal needle. In an intention-to-treat analysis, the primary outcome was time required for transseptal LA access. Secondary outcomes included failure of the assigned needle, visible plastic dilator shavings from needle introduction, and any procedural complication. The median transseptal puncture time was 68% shorter using the RF needle compared with the conventional needle (2.3 minutes [interquartile range {IQR}, 1.7 to 3.8 minutes] versus 7.3 minutes [IQR, 2.7 to 14.1 minutes], P=0.005). Failure to achieve transseptal LA access with the assigned needle was less common using the RF versus conventional needle (0/36 [0%] versus 10/36 [27.8%], P<0.001). Plastic shavings were grossly visible after needle advancement through the dilator and sheath in 0 (0%) RF needle cases and 12 (33.3%) conventional needle cases (P<0.001). There were no differences in procedural complications (1/36 [2.8%] versus 1/36 [2.8%]).

***Conclusions*—**Use of an RF needle resulted in shorter time to transseptal LA access, less failure in achieving transseptal LA access, and fewer visible plastic shavings.

***Clinical Trial Registration*—**URL: http://www.clinicaltrials.gov. Unique identifier: NCT01209260. **(*J Am Heart Assoc.* 2013;2: e000428 doi: 10.1161/JAHA.113.000428)**

Key Words: Brockenbrough needle • comparative effectiveness • left atrial access • radiofrequency energy needle • randomized controlled trial • transseptal puncture

Transseptal puncture is commonly performed to achieve left atrial (LA) access for a variety of common cardiac procedures, including catheter ablation of atrial fibrillation (AF),[1] accessory pathways and ventricular tachycardia,[2,3] LA appendage closure,[4,5] and mitral valve procedures.[6,7] Historically, a conventional Brockenbrough needle has been used to mechanically puncture the fossa ovalis, but adoption of a newer transseptal needle using radiofrequency (RF) energy applied to an insulated blunt-tipped electrode has increased despite a prospective trial comparing the 2 strategies. Although the conventional needle may provide more immediate tactile feedback and has a longer track record of success, the RF needle may be more effective in cases of an elastic, aneurysmal, or thickened interatrial septum.[8] In addition, safety concerns have been raised as more plastic particle shavings were observed after introduction of the Brockenbrough versus the RF needle through the dilator and sheath, suggesting that there may be a risk of plastic particle embolization with the conventional needle.[9] A large retrospective study found that the RF needle was faster, more effective, and safer in achieving LA access,[10] but a randomized prospective comparison to the conventional needle has not been performed.

The purpose of this study was to examine the effectiveness and safety of an RF needle compared with a conventional

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Brockenbrough needle for transseptal LA access in a prospective, randomized trial.

Methods

Trial Design and Patient Population

The Conventional Transseptal Needle Versus Radiofrequency Energy Needle Puncture for Left Atrial Access (TRAVERSE-LA) study was a single-blinded, randomized, controlled trial to compare the effectiveness and safety of transseptal puncture using an RF needle versus a conventional Brockenbrough in patients undergoing catheter ablation procedures requiring LA access.

Between January 2011 and November 2012, 72 patients were randomized in a 1:1, single-blinded fashion to 1 of 2 transseptal needle groups. Intraprocedural measurements were prospectively obtained at the bedside by study personnel. Patients undergoing catheter ablation procedures involving a planned transseptal puncture were included if they were ≥18 years of age and able to consent to the research study. Patients were excluded from the study if transesophageal echocardiography performed before the procedure revealed a patent foramen ovale large enough to alter the strategy for transseptal LA access (such as the planned use of the ablator to probe the interatrial septum). All patients provided informed, written, and witnessed consent. The study protocol was approved by the Committee on Human Research of the University of California, San Francisco.

Study Protocol and Transseptal Puncture

The transseptal puncture was performed by a cardiac electrophysiology fellow and attending electrophysiologist via right femoral venous access. Intracardiac echocardiography (ICE) using a 9-F Ultra ICE catheter (Boston Scientific) or an 8-F AcuNav ultrasound catheter (Biosense Webster) guided the transseptal puncture. Patients randomized to the RF needle group underwent transseptal puncture with a large, preformed curve 71-cm-C1 or 98-cm-C1 18-gauge NRG needle (Baylis Medical) through a 63-cm Fast-Cath SL1 sheath (St. Jude Medical) or a 71-cm large curl Agilis NxT Steerable Introducer sheath (St. Jude Medical). Sheaths were selected at the discretion of the operating physician prior to knowledge of treatment assignment. The RF needle diameter was 18 gauge proximally and 21 gauge distally and had a blunt distal uninsulated electrode tip for RF energy transmission. The needle was fully insulated throughout its course, except for the electrode tip. A grounding pad was placed on the left thigh. The RFP 100-115 RF Puncture Generator (Baylis Medical) was attached to the grounding pad and RF needle using a connector cable and was set to an output power of 10 W for 2 seconds. The generator produced continuous monopolar RF power output at a fixed frequency of ≈500 kHz. Patients randomized to the conventional needle group underwent transseptal puncture with either a large, preformed curve 71- or 98-cm 18-gauge BRK-1 needle (St. Jude Medical) through the same sheaths listed above. The BRK-1 needle had a shoulder 3 mm proximal to the introducer tip, designed to prevent the needle from advancing too far.

In preprocedural *ex vivo* testing of both needle groups, the transseptal needle and sheath were flushed with heparinized saline before use, and the transseptal needle was placed through the dilator and sheath until the tip of the needle could be visualized. The transseptal needles were not modified or manually shaped prior to placement through the dilator and sheath. In the conventional needle arm, the inner stylet was removed prior to advancement through the dilator and sheath. The transseptal needle was then removed, and the dilator and sheath were flushed again. Operators and study personnel looked for any evidence of grossly visible plastic particles, recorded as yes versus no (a "yes" answer required agreement between the operator and study personnel present).

The transseptal sheath and dilator were then advanced to the superior vena cava over a guidewire under fluoroscopic visualization. The guidewire was removed, and the contents of the dilator were evacuated and then flushed with heparinized saline. The transseptal needle was then flushed with heparinized saline, inserted into the dilator and sheath, and advanced under fluoroscopic guidance until the needle tip was located 2 to 5 mm proximal to the dilator tip. The needle, dilator, and sheath were pulled down as a unit (beginning of the time of measurement for the primary outcome) until tenting of the fossa ovalis was confirmed using ICE. Contrast injection and fluoroscopy were also used to verify the needle location. Holding the dilator and sheath still, the needle was then advanced out of the dilator, and contrast was injected. If LA access was not obtained after initial needle advancement in the conventional needle arm, the entire apparatus was advanced as a unit to puncture the septum with the needle; for the RF needle arm, RF energy was applied at 10 W for 2 seconds. If necessary, additional applications of RF energy were delivered to obtain LA access. LA access was confirmed by the operators on the basis of contrast media visualized in the LA under fluoroscopy and microbubbles observed in the LA with ICE. The dilator and sheath were then advanced over the needle into the LA under fluoroscopic and ICE visualization (end of the time of measurement for the primary outcome).

The initial study protocol allowed application of monopolar RF energy using an electrosurgical pencil (Covidien) or "bovie" set to "cut" at 35 W and applied to the proximal needle handle

of the BRK-1 needle in those who failed transseptal LA access with mechanical attempts.[11] However, the protocol was amended after enrollment of the 10th patient to exclude this practice after the publication of a study suggested that application of electrocautery to the BRK-1 needle may result in coring and embolizaton of septal tissue.[12]

Data Collection and Study Outcome Measures

The primary outcome was total time required for LA access for the first transseptal puncture, defined as time from the first pull-down of the needle/sheath/dilator apparatus in the superior vena cava to first entrance of the sheath into the left atrium. Secondary outcome measures included other efficacy measures (failure of the assigned needle type, time from interatrial septum engagement to sheath advancement, and time from needle advancement to sheath advancement) and safety measures (presence of visible plastic dilator shavings from needle introduction and any procedural complication plausibly related to transseptal puncture). Procedural complications plausibly related to transseptal needle puncture included aortic puncture, pericardial effusion, stroke or systemic embolization, and death. The assigned needle type was determined to fail when further attempts to achieve LA access were deemed to be either futile or unsafe per the discretion of the operator. All patients were monitored for both intraprocedural complications and postprocedural complications until discharge.

Statistical Analysis

We targeted a sample size of 72 (36 in each randomization group) in order to achieve 80% power to detect a 5-minute reduction in total transseptal puncture time (assuming a standard deviation of 7.5 minutes) using a 2-sided alpha level of 0.05. The primary analysis was performed on an intention-to-treat basis. An exploratory per-protocol analysis restricted to participants who maintained their initial needle assignment (ie, excluding crossover patients) was also performed. Normally distributed continuous variables are expressed as means and standard deviations, whereas continuous variables with skewed distributions are expressed as medians and interquartile ranges (IQRs). Baseline patient characteristics and outcome measures were compared between assigned needle groups using the χ^2 test for categorical variables and *t* tests or the Wilcoxon rank-sum test for continuous variables, as appropriate. A linear regression analysis using log-transformed transseptal time (due to right-skewed data) was used to identify predictors of transseptal time. Covariates were selected for inclusion in multivariable models if their univariate association with the outcome reached $P<0.20$. Statistical tests were 2-sided and considered significant if they yielded a $P<0.05$. Analyses were performed using Stata version 11.1 (College Station, TX).

Results

Baseline Characteristics

We enrolled a total of 72 patients undergoing planned LA access via a transseptal puncture; 36 patients were randomly assigned to the RF needle and 36 to the conventional BRK-1 needle (Figure 1). There were no significant differences in baseline patient demographic and clinical characteristics between the 2 study arms (Table 1). Twenty-two patients (30.6%) had a previous transseptal puncture a median of 536 days (IQR, 173 to 1167 days) before the index procedure. Contrary to the protocol, 3 conventional needle patients were initially unsuccessful and ultimately resulted in LA access only after electrocautery energy was applied to the proximal needle handle. These patients were included in all analyses as part of the conventional needle arm and were not considered failures or crossover patients.

Primary and Secondary Outcomes

As seen in Figure 2, the median transseptal puncture time was 68% shorter using the RF needle compared with the conventional needle (2.3 minutes [IQR, 1.7 to 3.8 minutes] versus 7.3 minutes [IQR, 2.7 to 14.1 minutes], $P=0.005$). In additional analyses, the mean transseptal puncture time trended toward a shorter overall time using the RF needle compared with the conventional needle (5.2 ± 10.2 versus 9.0 ± 8.2 minutes, $P=0.086$). Median transseptal puncture times were also shorter in the RF needle arm from engagement of the fossa ovalis to the long sheath in the LA and needle tip out of the long sheath to the long sheath in the LA (Table 2). Of the 36 patients randomized to the RF needle arm, 27 (75.0%) required RF application an average of 1.2 ± 0.6 times to achieve LA access. Per-protocol analysis (ie, excluding crossovers) showed statistically significantly shorter median transseptal puncture times in the RF needle arm from engagement of the fossa ovalis (1.3 minutes [IQR, 0.7 to 1.9 minutes] versus 2.4 minutes [IQR, 1.2 to 4.7 minutes], $P=0.003$) and from first advancing the needle out of the long sheath (0.8 minutes [IQR, 0.4 to 1.2 minutes] versus 1.5 minutes [IQR, 0.7 to 2.2 minutes], $P=0.012$).

Failure to achieve transseptal LA access with the assigned needle was less common using the RF needle compared with the conventional needle (0/36 [0%] versus 10/36 [27.8%], $P<0.001$). Although a larger proportion of patients with a previous transseptal puncture failed with the conventional needle, this did not reach statistical significance (4/10 [40%]

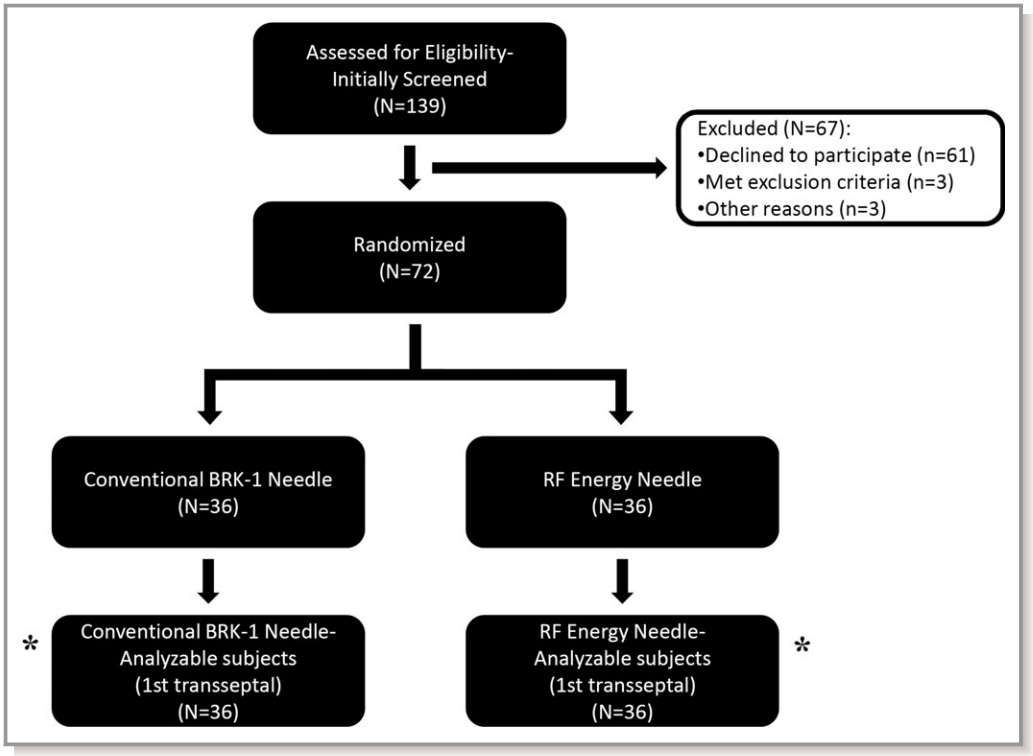

Figure 1. Subject flow in the study. *Patients available for analysis of the primary outcome of time of first transseptal puncture. There were no patients excluded from the analysis. RF indicates radiofrequency.

versus 6/26 [23.1%], P=0.31). In all 10 failures, crossover occurred because of an inability to puncture the interatrial septum despite forward pressure and tenting, leading to concern that further effort might lead to perforation of the free (lateral) LA wall. Of the 7 operators who enrolled patients in the study, 5 operators experienced failure of the assigned conventional needle. The 7 operators differed in their preference of and experience with each type of needle prior to study initiation (Table 3). In the RF needle arm, transseptal LA access was initially unsuccessful in 1 patient despite engagement of the interatrial septum and application of the RF pulse, resulting in crossover to the conventional needle. However, after failure of the conventional needle, the RF needle was attempted again, this time resulting in successful LA access after 1 RF pulse.

With *ex vivo* preprocedural testing involving advancement of the assigned transseptal needle through the plastic dilator and sheath, the RF needle created grossly visible plastic shavings less often than the conventional needle (0 [0%] versus 12/36 [33.3%], P<0.001). An example of plastic dilator shavings seen after introduction of the conventional needle through the dilator and long sheath is shown in Figure 3.

Procedural complications were no different between the RF and conventional needle groups (1/36 [2.8%] versus 1/36 [2.8%], P=1.000). In the RF needle arm, 1 patient was found to have a pericardial effusion detected by ICE after conclusion of the LA ablation procedure (3 hours after the transseptal puncture). In the conventional needle arm, 1 patient experienced a transient ischemic attack with brain magnetic resonance imaging consistent with embolic etiology.

Predictors of Transseptal Time

Multivariable linear regression analysis revealed that older patient age, increased attending physician experience, use of the conventional needle, and radial-view ICE were each significantly associated with longer transseptal time (Table 4).

Discussion

TRAVERSE-LA is the first randomized comparison of an RF versus conventional needle for transseptal puncture. The RF needle significantly reduced time to transseptal LA access, resulted in less failure of the assigned needle, and produced fewer visible plastic shavings from introduction of the needle through the dilator and sheath. Procedural complications did not differ between needle groups.

Transseptal puncture for LA access is becoming more common because of the growing adaptation of catheter ablation and structural heart procedures involving left-sided access.[1–7] However, the transseptal puncture procedure can be time consuming[13,14] and can result in important complications.[15,16] Prolonged transseptal procedures may increase

Table 1. Baseline Patient, Operator, and Procedural Characteristics

Characteristic	Conventional Needle Group (n=36)	RF Needle Group (n=36)	*P* Value
Patient demographic characteristics			
Age, y	61.1±11.7	59.9±11.3	0.668
Male sex	23 (63.9)	25 (69.4)	0.617
Race			0.392
White	33 (91.7)	33 (91.7)	
Black	1 (2.8)	0 (0.0)	
Asian	1 (2.8)	0 (0.0)	
Other	1 (2.8)	3 (8.3)	
Body mass index, kg/m^2	28.4±4.7	28.4±5.9	0.995
Hypertension	20 (55.6)	20 (55.6)	1.000
Diabetes	4 (11.1)	5 (13.9)	0.722
Coronary artery disease	4 (11.1)	5 (13.9)	0.722
Congestive heart failure	3 (8.3)	3 (8.3)	1.000
Previous stroke or transient ischemic attack	3 (8.3)	2 (5.6)	0.643
Atrial fibrillation	35 (97.2)	35 (97.2)	1.000
Atrial fibrillation type			0.563
Paroxysmal	27 (77.1)	29 (82.9)	
Persistent	7 (20.0)	6 (17.1)	
Long-standing persistent	1 (2.9)	0 (0.0)	
History of atrial flutter	6 (16.7)	9 (25.0)	0.384
History of atrial tachycardia	1 (2.8)	1 (2.8)	1.000
Wolff–Parkinson–White syndrome	1 (2.8)	1 (2.8)	1.000
Indication for transseptal puncture			1.000
Atrial fibrillation	35 (97.2)	35 (97.2)	
Accessory pathway	1 (2.8)	1 (2.8)	
Previous transseptal puncture	10 (27.8)	12 (33.3)	0.609
Left atrial size*			0.844
Normal	8 (29.6)	6 (25.0)	
Mildly enlarged	5 (18.5)	7 (29.2)	
Moderately enlarged	8 (29.6)	6 (25.0)	
Severely enlarged	6 (22.2)	5 (20.8)	
Operator-related characteristics			
Operator experience, days			
Fellow-in-training experience	395.2±169.4	433.3±165.4	0.337
Attending physician experience	3389.8±1377.3	3553.0±1458.3	0.627
Procedural characteristics			
Intracardiac echocardiography			0.759
Phased-array ultrasound	30 (83.3)	29 (80.6)	
Radial-view ultrasound	6 (16.7)	7 (19.4)	
Biplane fluoroscopy	33 (91.7)	31 (86.1)	0.453
Long sheath for transseptal needle			0.555
SL1 long sheath	35 (97.2)	34 (94.4)	
Agilis steerable long sheath	1 (2.8)	2 (5.6)	

Values are reported as mean±SD or n (%). RF indicates radiofrequency; SD, standard deviation.
*Proportions were calculated on the basis of patients with echocardiographic data available in each arm.

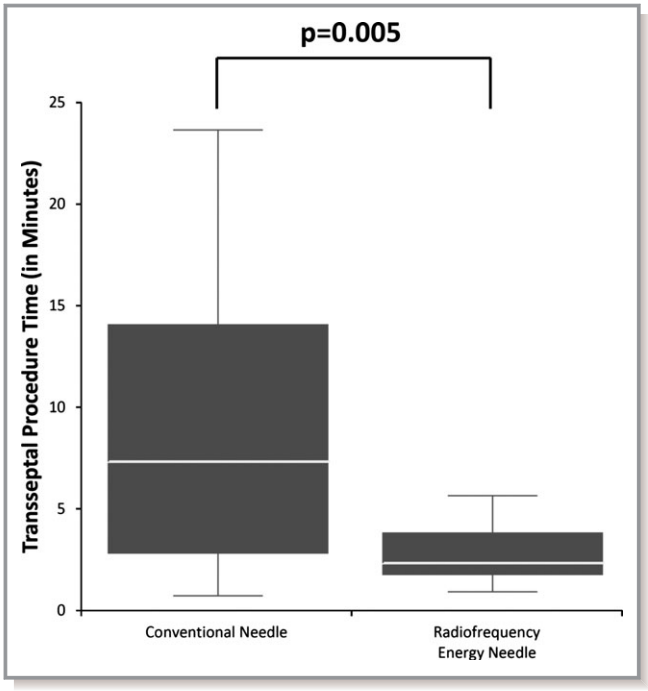

Figure 2. Total transseptal puncture procedure time by assigned transseptal needle. Box plots show the median (white line) and interquartile range (from top to bottom of the box plot). Each whisker represents the most extreme value within 1.5 times the interquartile range. Outlier values are not shown. Times are inclusive of crossover time.

total procedure times and ionizing radiation exposure to the patient and operator because of the high-intensity fluoroscopy that is often employed. Finally, personnel and electrophysiology laboratory time may become both clinically and financially relevant at the extremes of differences in transseptal time, particularly if it means staffing overtime is used or the "next case" is postponed for another day.

An observational study describing the initial experience using the RF needle reported a 97.2% success rate (35 of 36) in achieving transseptal access, but no comparator group was included.[17] Subsequently, a larger observational study suggested that the RF needle may result in shorter procedure times, better efficacy of achieving LA access, and decreased complications.[10] However, data were analyzed retrospectively, and patients were not randomized to needle therapy. As the RF needle was used more recently and therefore potentially in a more experienced electrophysiology laboratory, the results may have been biased in favor of the RF needle.

We found that RF compared with conventional needle use resulted in a 68% shorter median time to transseptal LA access; this amounted to an absolute 5-minute median difference and more than a 10-minute upper quartile difference in transseptal puncture time between the 2 arms. However, the absolute time difference may not be particularly large in light of the whole procedure. Indeed, we observed no difference in total procedure or fluoroscopy time between groups. Of note, the RF application itself was quite short; the 75% of patients who required RF usage for transseptal LA access needed an average of 1.2±0.6 applications, translating into an approximate mean of 2.4±1.2 seconds of total RF application time. Subanalyses examining several points during the first transseptal puncture, including time from fossa ovalis engagement to long sheath across and needle out of the sheath to long sheath across, found that the RF needle consistently resulted in shorter transseptal times in both intention-to-treat and per-protocol analyses. It is interesting to note that the variability of transseptal time appeared to be largest in the conventional group (as can be seen in Figure 2), suggesting that the timing differences were driven primarily by the more difficult cases in the conventional group versus a more uniform experience in the RF group.

To assess predictors of transseptal time, we constructed multivariable models with covariates plausibly associated with the outcome. After adjustment, use of the RF needle was one of the strongest predictors of a shorter transseptal time. Use of radial-view ICE was associated with longer transseptal

Table 2. Procedural Outcomes

Outcome	Conventional Needle Group (n=36)	RF Needle Group (n=36)	*P* Value
Transseptal-related procedural outcomes (minutes)*			
Time from pulling down from superior vena cava to sheath in LA	7.3 (2.7 to 14.1)	2.3 (1.7 to 7.3)	0.005
Time from interatrial septum engagement to sheath in LA	2.8 (1.4 to 8.5)	1.3 (0.7 to 1.9)	<0.001
Time from needle first out of dilator to sheath in LA	1.9 (0.8 to 7.6)	0.8 (0.4 to 1.2)	<0.001
Total procedure-related outcomes (minutes)			
Total procedure time	356.5±71.3	347.4±82.3	0.615
Total fluoroscopy time	52.6±18.8	54.1±21.0	0.747

Values are reported as median (IQR) or mean±SD. IQR indicates interquartile range; LA, left atrium; RF, radiofrequency; SD, standard deviation.
*Times are inclusive of crossover time.

Table 3. Operator Characteristics Before and During Transseptal Needle Study

Operator ID	Years of Experience With BRK-1 Needle Before Study	Years of Experience With RF Needle Before Study	Preferred Needle Before Study	Number of Patients in Study Randomized to BRK-1 Needle	Number of Patients in Study Randomized to RF Needle	Number of Crossover Patients From BRK-1 to RF Needle
1	18	1	BRK-1	4	5	3
2	10	0	BRK-1	2	6	1
3	10	0	BRK-1	4	0	0
4	8	2	RF	18	17	4
5	7	2	BRK-1	2	1	1
6	5	2	RF	5	7	2
7	1	1	RF	1	0	0

ID indicates identification; RF, radiofrequency.

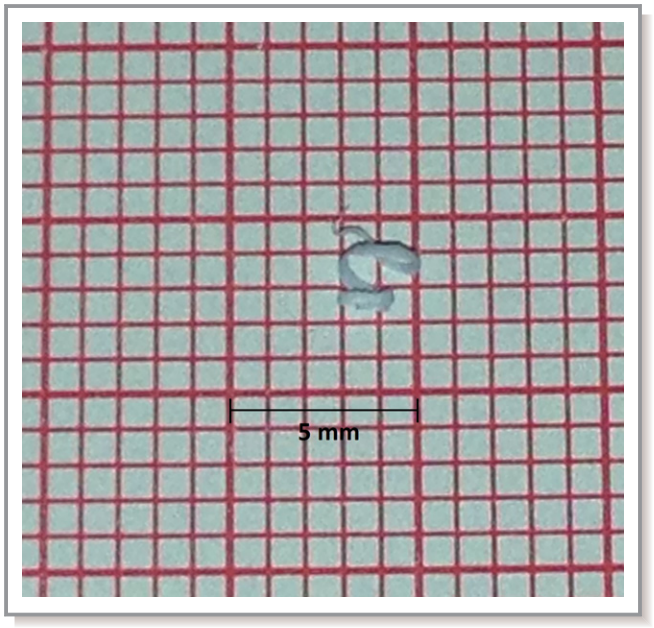

Figure 3. Pictured is an example of grossly visible particles that were produced after the introduction of a conventional needle through the dilator and long sheath. The particles are placed on conventional electrocardiography paper as a size reference.

times, suggesting that the higher-resolution view of the fossa ovalis obtained with phased-array ICE rather than the more global atrial view obtained with the radial-view system may be particularly useful during these procedures. Older patient age also predicted longer transseptal times, perhaps because of more distorted cardiac anatomy or more interatrial septal fibrosis. Counter to expectations, increased attending physician experience was also associated with longer transseptal times, perhaps related to a more cautious approach taken by experienced operators.

Randomization to the RF needle resulted in success in all patients, whereas randomization to the conventional needle resulted in 10 crossover patients, all of whom were subsequently successful using the RF needle. Because this was a single-blinded study and the operator made the final decision to crossover based on safety reasons, inadvertent bias may have occurred. However, we found that crossover of patients from the conventional to RF needle was distributed across operators, many of whom personally preferred to use the conventional needle prior to the study (Table 3). Therefore, it is not clear why bias (or lack of blinding) would not have similarly led to more crossovers from the RF to the conventional needle. Although the proportion of patients who failed transseptal puncture with the conventional needle was higher than reported in previous studies, it is noteworthy that all previous studies on the subject have been retrospective.[10,16] It is important to emphasize that this is the first study to prospectively enroll and then follow transseptal puncture patients with research personnel in the room before and throughout the case to carefully track successes and failures. It is possible that difficult or failed transseptal puncture attempts in previous retrospective studies were not included or missed. Finally, although not statistically significant, 40% of those who failed with the conventional needle (and succeeded with the RF needle) had a previous transseptal puncture, a previously established predictor of a difficult procedure.[13] However, given this large difference and previous evidence that repeat transseptal punctures are more challenging, the RF needle may be particularly preferred in the repeat transseptal puncture population. In fact, we used a conservative estimate when designating "failure" of the assigned transseptal needle: 3 additional patients assigned to the conventional needle had difficulty in achieving LA access despite forward pressure and tenting, and based on operator discretion, application of electrocautery to the conventional needle was performed against protocol, each time resulting in success. Although successful transseptal puncture has been described in the literature based on this technique,[11] we changed the study protocol to preclude this practice after the study was already under way based on

Table 4. Univariate and Multivariable Analyses of Predictors Associated With Transseptal Time

Variable	Univariate Analysis		Multivariable Analysis	
	Percent Increase in Transseptal Time* (95% CI)	*P* Value	Percent Increase in Transseptal Time* (95% CI)	*P* Value
Age (per 10-year increase)	15.4% (−5.1 to 35.9)	0.138	18.2% (1.6 to 34.8)	0.032
Previous transseptal puncture	34.1% (−16.6 to 84.8)	0.184	31.0% (−10.0 to 72.1)	0.136
Radial view intracardiac ultrasound	87.5% (29.6 to 145.3)	0.004	79.6% (29.6 to 129.7)	0.002
Attending physician experience (per 1-year increase)	9.8% (4.1 to 15.5)	0.001	8.3% (3.2 to 13.3)	0.002
Conventional needle	67.8% (23.3 to 112.2)	0.003	73.3% (35.8 to 110.9)	<0.001
Male sex	−22.0% (−71.9 to 27.9)	0.381	†	—
Congestive heart failure	−29.2% (−114.5 to 56.1)	0.497	†	—
Fellow physician experience (per 1-year increase)	−5.2% (−57.1 to 46.7)	0.842	†	—
Biplane fluoroscopy	34.8% (−39.9 to 109.6)	0.356	†	—

CI indicates confidence interval.
*The β coefficient from regression analyses represents the percent increase in transseptal time per unit increase of continuous predictor variables or as associated with individual categorical variables.
†Covariates failing to meet criteria for inclusion in the multivariable model (as described in the Methods section).

evidence of tissue coring and the theoretical risk of embolism that can occur with this technique.[12]

We found that the RF needle was less likely to produce visible plastic shavings after introduction into the dilator and sheath. The most plausible mechanism for this difference is that the conventional needle has a sharp tip, whereas the RF needle tip is blunt. Feld et al[9] reported that the production of plastic shavings measured by light microscopy occurred less commonly with RF needles than with conventional needles. Our study is the first prospective, randomized trial to confirm these findings and quantitate the prevalence of this phenomenon in a clinical setting. In the conventional needle arm, we performed *ex vivo* testing without the stylet in the needle, which is the standard of care at our institution. We performed shaving in this manner to mimic the course of the needle through the dilator/sheath outside the patient's body. In fact, our method of conventional needle introduction without the stylet and with forward flushing is the most common method employed in published reports,[10,13,16] and is reflected in the original report of shaved visible particles.[9] We acknowledge that the frequency of plastic shavings might be reduced if the stylet is left in place until the needle/stylet tip is close to the dilator tip; however, removing the stylet within the body may increase the risk of air embolism and does not preclude unseen shaving production from the unprepared distal portion of the dilator. Future studies are needed to evaluate whether plastic shavings are dislodged during transseptal procedures, even after the dilator and sheath are prepped in the absence of the stylet, potentially leading to clinical sequelae. Complications did not differ between the RF and conventional needle arms. It is important to emphasize that ICE was used to guide transseptal puncture in all cases in this trial and that risks may be higher if the RF needle is used in the absence of ICE.

Study Limitations

Several limitations should be acknowledged. First, this study included a relatively small number of patients. We calculated the sample size necessary to meet the primary outcome of the study a priori, and a lack of power should not result in spurious false-positive results. However, lack of power could result in failure to detect certain real relationships, such as important predictors of transseptal time in multivariable models. Second, the reasons for the high rate of LA access failure in the conventional needle study arm are unclear and could represent unique aspects of the patient population studied that may not be generalizable to general practice. Third, we only used the BRK-1 needle manufactured by St. Jude Medical in the conventional needle arm of this study. Conventional needles manufactured by different companies may have other characteristics that could affect transseptal puncture success. Fourth, our study did not involve other novel protocols in the event of conventional needle failure, such as use of electrocautery applied to a conventional needle or a nitinol guidewire (SafeSept, Pressure Products Inc) through the lumen of the conventional needle.[18] Finally, despite finding that use of the RF needle resulted in shorter transseptal puncture time, less failure, and fewer plastic shavings, the RF needle is generally more expensive than the conventional needle, suggesting that a formal cost-effectiveness study is warranted.

Conclusions

Use of an RF needle resulted in shorter time to transseptal LA access, less failure in achieving transseptal LA access, and fewer visible plastic shavings. There were no differences in clinically recognized complications.

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Disclosures

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