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Research Article

Effect of Standard *versus* Radiofrequency Transseptal Puncture on Structural Heart Fellow Training: A Single Center Experience

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ABSTRACT

Background: A number of systems have recently been developed to assist in transseptal puncture for structural heart procedures. The effect of the systems on training newer operators is unknown.

Objectives: This was a single center experience of a Radiofrequency (RF) transseptal system utilization to determine if there were advantages in training as compared to standard needle-based systems.

Methods: Data was collected on 87 consecutive transseptal punctures for structural heart procedures involving structural heart fellows at a single institution. Data time points in crossing transeptal above a Z-score of two were excluded.

Results: Procedure types were evenly matched in each arm RF *vs.* BRK. Average time to transseptal puncture with wire or needle across septum was shorter in the RF arm at 203.7 seconds *versus* 281.9 seconds in the BRK arm (P value=0.0009). Average time for sheath across septum was shorter in the RF arm at 82.4 seconds *versus* 124.2 seconds in the BRK arm (P value=0.02). The attending physician had to perform judgment-based hands-on assist with septal crossing in 28% BRK cases *vs.* 7% RF cases (P value=0.02). No adverse events occurred in either arm.

Conclusion: Although both standard and RF transseptal puncture methods were associated with exceptional safety, use of the RF system allowed for a more independent, efficient hands-on training experience.

Keywords: Transseptal; Radiofrequency; Trainee; Structural heart

INTRODUCTION

Transseptal puncture has been available for over 60 years, initially developed for diagnostic purposes during left heart catheterization to measure left atrial pressure. It is now an integral part of many transcatheter structural heart procedures including Left Atrial Appendage Occlusion (LAAO) therapies, mitral valve interventions, pulmonary vein interventions, and percutaneous left ventricular assist devices, as well as left-sided atrial arrhythmia ablation procedures. Traditionally, the Brockenbrough needle (BRK, Abbott Vascular) has been utilized for direct mechanical puncture of the interatrial septum [1]. Imaging techniques including intraprocedural Transesophageal Echocardiography (TEE), intracardiac echocardiography, and fluoroscopy have improved our ability to safely cross the interatrial septum. The development of the Radiofrequency (RF) needle (Baylis Medical) has demonstrated efficacy and potential improvement in safety compared with traditional methods. As the field of structural heart interventions continues to rapidly expand, a new generation of structural heart operators are currently being trained throughout the United States and across the globe [2]. The ability to successfully train these new operators in a setting of rapidly expanding new technologies to safely and successfully treat the evermore complex patients that

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fall in the structural heart realm is of utmost importance [3]. In this single center experience, we set out to determine how the RF transseptal system affected total operator times, trainee learning independence, and complication rates when compared to the traditional mechanical transseptal puncture approach. We compared the use of a RF transseptal system (Baylis medical) with the mechanical transseptal puncture needle, BRK, and determined total duration of the transseptal procedure, the amount of attending physician input, and overall safety [4,5].

MATERIALS AND METHODS

Data was collected from November 2, 2022 to June 29, 2023 with a single operator as the attending of record and two structural fellows at the University of Alabama at Birmingham (UAB) Hospital. The patient population was an adult cohort (above 18 years of age) with proper indications for their respective procedure. All transseptal procedures performed including LAAO (Watchman (Boston Scientific), and Amulet (Abbott)), mitral TEER, mitral Valve in Valve (ViV), mitral paravalvular leak, and Percutaneous Balloon Mitral Valvuloplasty (PBMV) were included in the data collection. As standard protocol in the data collection registry in the structural heart section at UAB, patients were allocated prior to the start of procedure with coin toss into either the RF arm or the BRK arm for transseptal puncture. There was a single attending operator for the entirety of data collection [6-8].

Standard femoral venous access was performed using fluoroscopy and ultrasound guidance. Time zero was designated as wire in the superior vena cava and time to transseptal puncture with wire or needle across septum and subsequently, time to sheath across septum were measured in seconds. All aspects of procedure were done under TEE guidance. There was a total of 87 patients for which data was collected, 46 patients in the RF arm and 41 patients in the BRK arm. In order to account for outliers, data time points in crossing transseptal with wire or needle across the septum above a Z-score of two were excluded. There was one case in the RF arm and two cases in the BRK arm that were excluded based on this cutoff. Average and standard deviation time frames were determined, and statistical analysis was performed using a two tailed t-test in Microsoft Excel (Version 16.46). Data on extra support in each arm (direct attending judgement-based hands-on involvement) was collected and comparison was performed using a chi-squared test for independence [9].

RESULTS

The average time to transseptal puncture with wire or needle across septum was shorter in the RF arm at 203.7 seconds *versus* 281.9 seconds in the BRK arm (P value=0.0009). The average time for sheath across septum was shorter in the RF arm at 82.4 seconds *versus* 124.2 seconds in the BRK arm (P value=0.02) (Table 1). No adverse events occurred in either arm. The types of procedures were evenly matched in RF *versus* BRK: 32 LAAO *vs.* 29 LAAO; 11 mitral TEER *vs.* 12 mitral TEER. There was one mitral ViV, one mitral valve paravalvular leak, and one PMBV in the RF arm. The excluded procedures based on Z-score cutoff were one LAAO in the RF arm and one LAAO and one mitral TEER in BRK arm. The attending physician had to perform judgement-based hands-on assist with septal crossing in 28% BRK cases (11 out of 39 procedures) *versus* 7% RF cases (3 out of 45 procedures) (P value=0.02). There was one instance in the BRK arm where electrocautery assistance was utilized and attending physician input was involved.

	RF (45 total)	BRK (39 total)	P value
Wire or needle across septum	203.733 (sec)	281.897 (sec)	0.0009
Sheath across septum	82.378 (sec)	124.179 (sec)	0.02

Table 1: The average time for sheath across septum in the RF arm and BRK arm.

DISCUSSION

Our single center experience demonstrates a number of interesting findings. Under the supervision of an experienced attending, transseptal puncture led by structural heart fellows with use of either standard or RF needle was associated with an excellent safety profile with no complications seen in either group. The use of the RF system was associated with a more efficient transseptal puncture. Importantly, the use of the RF needle allowed for more independence with a significantly higher likelihood of structural heart trainees performing the entire transseptal puncture process [10].

Technically, the BRK needle requires coordination of the needle, sheath, and dilator for rotation and then forward pressure to be applied so that the needle that is tenting the interatrial septum can puncture it. From a rotation standpoint that may lead to a more difficult to control manipulation of anterior posterior motion, which is important when looking to perform site specific puncture as necessitated by structural heart interventions. As forward pressure is applied to the system to puncture the septum with the needle, there is an element of unknown regarding translation of that pressure that may cause the sheath to jump forward, particularly in the setting of an aneurysmal septum. With the RF needle there is no needle control necessity as part of the manipulation and therefore, theoretically, less coordinated manipulation required to achieve site specific septal tenting. From a technical perspective, once tenting occurs, there is no need to apply puncture force with the sheath and dilator, rather gentle contact is applied with the wire and the RF allows for a controlled wire crossing thus avoiding the potential uncontrolled forward system jump. These technical issues make the RF needle an attractive prospect particularly in the setting of a training program.

In terms of efficiency, it was clear that there were advantages to the RF system. The streamlined approach of a more straightforward technical manipulation and lack of needle removal with the RF system likely explain the faster time to puncture and also the time to sheath across septum. From a training perspective, there also appeared to be advantages to the RF system. The goal of training in transseptal puncture is to allow the development of independent skills in a supervised controlled manner by trainees while ensuring patient safety. The

RF system clearly allowed for a more independent trainee hands-on process with 93% of transseptal punctures performed entirely by the trainees as opposed to 72% of punctures in the BRK group. It is the opinion of the investigators from both a trainer and a trainee perspective, that the RF was associated with a more streamlined training process and the development of independent transseptal skills.

There are some limitations to our findings. Our structural heart training program has experience with thousands of structural heart procedures and high volume of transseptal procedures (>200/year) with dedicated cardiac anesthesiologists or experienced cardiac imaging physicians to perform TEE guidance, thus, these findings may not necessarily extrapolate to all programs. The decision of when the attending physician intervened on 'judgment' was subjectively based on whether the technical aspects of needle/catheter manipulation etc. warranted more experienced hands-on manipulation. Along with this, the team of technologists and nurses involved were also highly experienced including years of involvement in transseptal procedures and this may account for the 0% complication rate in either arm. It is very possible that if an absolute hands-off approach was taken then the complication rate and/or procedure times may have been higher. This single center experience included procedures that are relatively commonly performed such as LAAO and TEER; it is possible that with less commonly performed and site-specific punctures associated with less common procedures the benefits in term of efficiency would have been even more marked.

CONCLUSION

Although both standard and RF transseptal puncture methods were associated with exceptional safety, use of the RF system allowed for a more independent and efficient hands-on training experience for the structural heart fellows. This single center experience demonstrated that the RF needle showed significant improvement in procedural times in all aspects including the wire or needle across septum and sheath across septum. The amount of attending hands-on judgment-based assistance was significantly lower with the RF approach as well. As therapies for structural heart disease expand, an environment to allow trainees to expand their knowledge while delivering safe and efficient treatment to patients is paramount.

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