Intracardiac Echocardiography Guided electrified J-wire trans-septal puncture: a prospective randomized controlled trial

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Abstract

Background: Application of electrocautery to a J-wire is used to perform transseptal puncture (TSP), but with limited evidence supporting safety and efficacy. We conducted a prospective randomized controlled trial to evaluate the safety and efficacy of this technique. Methods: 200 consecutive patients were randomized in a 1:1 fashion to either the ICE-guided electrified J-wire TSP group or a conventional Brockenbrough (BRK) needle TSP group. The TSP was performed with a 0.032” guidewire under 20W, “coag” mode and was compared to TSP using the BRK needle. The primary safety endpoints were complications related to TSP. The primary efficacy endpoints included the TSP success rate, the total TSP time, and the total procedure time. Results: All patients complete the procedure safely. The electrified J-wire TSP group had a significantly shorter TSP time than BRK needle TSP group. The total procedure time, number of TSP attempts required to achieve successful LA access, width of the intra-atrial shunt at the end of ablation were similar between the two groups. The incidence of new cerebral infarction detected by MRI were similar between the 2 groups (3/32 patients in the J-wire TSP group and 2/26 patients in conventional BRK TSP group, p=0.82). And no difference in the incidence of residual intra-atrial shunt (4.3% versus 6%, p=0.654) during the 3-month’s follow up. Conclusion: Using an electrified J-wire for TSP under the guidance of ICE appears to be as safe as and more efficient than conventional BRK needle TSP, which may be especially useful in the era of non-fluoroscopy AF ablation.

Introduction

Trans-septal puncture (TSP) is commonly used in atrial fibrillation (AF) ablation, left atrial appendage closure, percutaneous left ventricular assist device, and various cardiac valve disease procedures. Performing a safe and effective TSP is crucial to a successful procedure. The typical TSP performed in clinical practice is to push a Brockenbrough (BRK) needle mechanically across the fossa ovalis. However, physically pushing a BRK needle is prone to displacement of the desired puncture site, resulting in a suboptimal puncture, especially in patients with an aneurysmal or thickened or fibrosed fossa. The need to physically push the needle may also result in uncontrolled forward motion after the septum gives way, increasing the risk of free wall perforation, which may lead to puncture failure or complications¹,⁶,¹⁵. One of the methods developed to facilitate challenging TSP is to use a dedicated commercially available radiofrequency (RF) puncture needle²,³. However, the RF needle is not widely available, and it increases financial burden on patients and the health care system. A few studies with small sample size reported the electrocautery/RF assisted J-wire TSP technique but with equivocal results⁴,⁵.

In addition, the use of intracardiac echocardiography (ICE) during AF catheter ablation or other interventional cardiac procedures has become more prevalent. Zero/minimized fluoroscopy AF ablation has been performed safely in many electrophysiology labs¹¹,¹². We proposed that ICE could provide direct visual
guidance to further improve safety when using an electrocautery assisted J-wire TSP technique, especially during the process of delivering energy and initially crossing the septum. We designed this prospective randomized study to testify the safety and efficacy of using an electrified J-wire for ICE guided zero-fluoroscopy TSP.

Methods

This is a prospective, randomized, controlled study which included 200 consecutive patients. Inclusion criteria included patients undergoing AF catheter ablation procedures, age ≥18 years but <85 years, and being able to provide a written consent. This study excluded patients with patent fossa ovalis, atrial septal defect, or status post permanent pacemaker implantation. Patients were randomly assigned to the ICE-guided electrified J-wire TSP group or conventional BRK needle TSP group by 1:1 ratio.

The study design was compliant with the Helsinki agreement and was approved by the Ethics Committee of Sir Run Run Shaw Hospital.

Procedural Methods

Oral anticoagulation therapy was not interrupted during the peri-procedure period. During the procedure, patients were under conscious sedation; after local anesthesia with lidocaine, the femoral vein was punctured, followed by venous heparin administration with an ACT goal of 300 to 350s. The ICE catheter was advanced into the right atrium (confirming “Home view”). Left atrial thrombus was excluded using ICE, as previously described. Baseline pericardial effusion, fossa ovalis morphology and atrial septal shunts were assessed. Under ICE monitoring, a J-wire (0.032”) was advanced into the superior vena cava (SVC), followed by a steerable introducer sheath (Agilis NXT, St Jude Medical Inc.; Vizigo, Biosense Webster, et al.) along the J-wire into the SVC. Then, according to the study protocol, the following process was performed:

**The electrified J-wire TSP group:**

The J-curve of the guidewire was placed just at the sheath tip, and under ICE guidance, the sheath and the wire were slowly pulled down from SVC at 4 to 6 o’clock until the tip of the sheath dilator was seen slipping into the fossa ovalis, with a “tenting sign” of the fossa appreciated on ICE. At this point, under the guidance of ICE, the angle and height of the sheath was fine-tuned to confirm that it was located at an optimal puncture site per operator discretion. Gentle withdrawal of the “J” wire to expose just the tip (only about 1mm) out of the sheath dilator tip was performed. The electrocautery generator was set to electrocoagulation mode, with power at 20W. The cautery pen tip was placed in contact with the proximal portion of the guidewire and energy delivered to facilitate TSP. The electrocoagulation time of each energy delivery was limited to less than 2s. If the “white smoke” at the tenting site representing microbubbles could be seen in the left atrium by the ICE, the energy delivery was immediately stopped, even if application time was < 2s. Under the guidance of ICE, the J-wire was then advanced into one of the left pulmonary veins, and then the transseptal sheath was advanced along the wire into the left atrium. (Figure 2a)

**The conventional BRK needle TSP group:**

The J-wire was removed and the transseptal needle was inserted inside the dilator. Under the guidance of ICE, the assembly was carefully pulled back from the SVC to the fossa ovalis. The needle was pushed to crossing the septum to the left atrium after the assembly was correctly against the fossa ovalis with a visible “tenting sign”. After successful puncture, the puncture needle was withdrawn and exchanged for a J-wire. The J-wire was advanced into one of the left pulmonary veins, and then the transseptal puncture sheath was advanced into the left atrium. (Figure 2b)

All AF ablation was performed with a single transseptal approach. Ablation strategies included PV isolation, linear ablation, and non-PV trigger ablation, as previously described.

Post-procedure management
Oral anticoagulants were continuously administered to all patients for at least 3 months post procedure, with subsequent continuation based on patient stroke risk (CHA\textsubscript{2}-DS\textsubscript{2}-VASc score).

If patients with neurological deficiency symptoms post-operation or the asymptomatic patient agrees, a cerebral MRI was performed within 48 hours post procedure to assess for cerebral infarction in both groups.

Patient symptoms, 12-lead electrocardiograms (ECGs) and ambulatory monitoring were evaluated during each follow-up visit as described previously\textsuperscript{13}. An echocardiogram was scheduled at 3 months post-procedure to evaluate whether the iatrogenic atrial septal defect was closed.

Study endpoints

The total time of the TSP process and the total time of the whole procedure, number of puncture attempts were recorded prospectively during the procedure. The total time of the TSP process was defined as time from the pull-down of the needle/sheath assembly in the SVC to successful advancing of the sheath into the left atrium and removal of the dilator out of the body. At the end of the procedure, after all other catheters except for ICE were removed out of the body, the width of the iatrogenic shunt in the fossa ovalis was measured by ICE from the right atrium. The primary safety endpoints included severe complications definitely related to TSP, including aortic puncture, new or increased pericardial effusion, symptomatic stroke or systemic embolization, residual iatrogenic intra-atrial shunt and death. The primary efficacy endpoints included the TSP success rate and total puncture time.

Statistical analysis

We targeted a sample size of 200 (100 in each randomization group) in order to achieve 80% power to detect a 1-minute reduction (5min in Conventional BRK needle TSP group and 4min in electrified J-wire TSP group) in total transseptal puncture time (assuming a standard deviation of 2.5 minutes) using a 2-sided alpha level of 0.05. Continuous variables are expressed as mean ± SD if normally distributed or median (interquartile range [IQR]) if not normally distributed. Differences between two groups will be compared by student’s t-test (normally distributed data with equal variance) or Mann-Whitney U test (failed either normality or equal variance test). Categorical variables will be presented as percentages and compared by using the Chi-square test or Fisher’s exact test. The statistical significance for all tests will be accepted at P< 0.05.

Results

200 patients undergoing TSP for AF ablation in Sir Run Run Shaw Hospital from November 2021 to July 2022 were enrolled. The patients were randomized into the ICE-guided electrified J-wire TSP group or conventional BRK needle TSP group 1:1. ICE-guided electrified J-wire TSP group had a statistically higher LVEF (66.51±7.88% versus 63.45±9.72%, p=0.016). There was no significant difference in other baseline characteristics between the 2 groups (Table 1).

Procedure details

No left atrial thrombus was detected by ICE in any cases during the procedure. TSP was successfully achieved in all patients in both groups with ICE guided zero-fluoroscopy. Both groups had 3 patients with complex interatrial septum, including 1 small fossa ovalis, 2 interatrial septal aneurysm in the electrified J-wire TSP group and 1 severely dilated aortic root, 1 thick septum and 1 interatrial septal aneurysm in the conventional BRK needle TSP group, defined by operator visualization and discretion. The electrified J-wire TSP group had a significantly shorter total TSP time (221.73±146.65s versus 311.81±253s). The total procedure time, number of puncture attempts required to achieve LA access, width of the shunt in the atrial septum at the end of ablation were similar between the two groups (Table 2).

The incidence of fresh cerebral infarction detected by MRI (Fig 3) were similar between the 2 groups (3/32 patients in electrified guidewire group and 2/26 patients in conventional needle group, p=0.82). All of these patients reported no symptoms. As shown in Fig 4 and Fig 5, there was no significant difference between the 2 groups in the freedom from AF recurrence (79/86 versus 79/83, p=0.382) and the incidence of interatrial shunt (3/70 versus 4/66, p=0.640) during the follow up.
Discussion

Main findings

To our knowledge, this is the first and largest randomized study comparing the efficacy and safety between an electrified J-wire TSP and a conventional BRK needle TSP, both with guidance of ICE. Our study showed that the electrified J-wire TSP group had a much shorter total TSP time and did not increase the risk of stroke or iatrogenic atrial septal defect.

Safety

There were no severe complications related to TSP including aortic puncture, pericardial effusion, and death etc. There were several key steps in ICE-guided TSP in our procedure that ensured safety. They included: regularly assess for pericardial effusion with ICE before and during the procedure; ICE visualization of each catheter manipulation, especially anatomical relationship of the transseptal assembly to the intra-atrial fossa during the “tenting sign” and position of the tip of sheath, dilator, and needle tip to avoid perforation; monitoring lesion formation; systemic heparinization was given just after successful femoral vein access had been achieved.

Embolic Events

In this study, patients in both groups had similar rates of asymptomatic embolic events during the procedure and the 3-month follow-up period. Previous studies suggested that using electrocautery to perforate the interatrial septum may carry the risk of tissue charring and systemic embolism. However, these findings were in an ex-vivo porcine model, not in vivo. That study also showed that power > 20w did not significantly improve the success rate of TSP but only increased the risk. Therefore, a power setting of 20w and minimized delivery time was utilized in this study. Indeed, our results confirmed the power of 20w was as safe as BRK needle puncture during J-wire trans-septal electrocautery. Moreover, the J-wire we used was a solid structure instead of the tubular structure of the BRK needle tip, which may reduce the risk of tissue coring and embolic events.

Incidence of iatrogenic atrial septal defect post-procedure

In this study, the size of residual shunt at the interatrial septum level was similar between the two groups immediately at the end of the procedure. In most cases, any residual shunt was closed spontaneously by 3-month’s follow-up. Previous animal isolated heart experiments showed the diameter of damage area was usually less than 2mm with an electrified guidewire puncture when a steerable sheath(9F)was used, so that the width of the shunt at the interatrial septum was mainly determined by the profile of the steerable sheath, not the burning effect itself.

Efficacy

There was 100% success in achieving TSP and access to the LA in both groups. Compared with conventional BRK needle TSP procedures, electrocautery assisted TSP significantly reduced TSP time. Some possible reasons include: Firstly, the workflow of electrocautery assisted TSP was simplified, which did not require an exchange of the BRK needle to a J-wire and eliminated additional flushing steps. Secondly, The BRK needle usually requires a reshaping to achieve a more favorable TSP location, especially in some difficult cases. Although the J-wire was soft and not steerable, adjustment of the curve of the steerable sheath to achieve proper contact and direction was found to be effective. Thirdly, if the appropriate location on the fossa ovalis was not achieved during the pulldown from the SVC, with the conventional method (exchanging the needle back to a J-wire, advancing the J-wire back to the SVC, then re-exchanging the wire for the needle for pulling down again). In contrast, the J-wire could be pushed forward from the right atrium directly back to the SVC to re-attempt pulldown during the electrocautery assisted J-wire TSP process. Fourthly, after the needle or the J-wire crosses the septum, advancing the sheath across the septum may be easier in the electrocautery assisted J-wire TSP as the puncture site was potentially initially larger as a result of the
burn delivered. Lastly, in patients with complex septal anatomy such as aneurysmal, thickened, or fibrosed septum, TSP with only a mechanical push might result in the needle encountering resistance or slide away, which may result in a suboptimal TSP or multiple puncture attempts. Unlike the traditional method, the ICE guided electrified J-wire TSP, with adequate contact against the septum, the J-wire could easily cross the septum and more likely to puncture at an optimal site.

There are several modified strategies for TSP reported in the literature. Jaffar M. Khan et al reported 8 cases using a guidewire electrosurgery-assisted trans-septal puncture. They used an 0.014” coronary guidewire through the BRK needle, with the electrosurgery pencil was connected to the end of the guidewire instead of directly connected to the needle to avoid increased puncture size and surrounding tissue damage. De Ponti et al introduced a sharp-tip, J-shaped guidewire (SafeSept, Pressure Products, Inc.,San Pedro, CA, USA) to facilitate transseptal catheterization. Inohara et al recommended a dedicated RF wire (0.035” VersaCross RF System, Baylis Medical) which is also efficient and safe. However, among these strategies, our method is the simplest, which do not need to change wire during the whole TSP procedure. Besides, our method utilizes standard TSP equipment already used for the typical procedure, resulting in no additional cost. This strategy we used is especially fit for ICE guided zero-fluoroscopy AF ablation procedure.

Limitations
This was a single center study which need further widely validation. The use of ICE in both arms of the study may have resulted favorably in significant safety and efficacy of the TSP process, which may have minimized potential additional differences in the outcomes of both arms. Further randomized, multicenter study with larger sample size is warranted to verify our findings.

Conclusion
Using an electrified J-wire for TSP under the guidance of ICE appears to be as safe as and more efficient than conventional BRK needle TSP, which may be especially useful in the era of non-fluoroscopy AF ablation.

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References

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Electrified J-wire TSP group (N=100)</th>
<th>Conventional BRK needle TSP group (N=100)</th>
<th>P Value</th>
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<tr>
<td>Age (y)</td>
<td>62.78±10.64</td>
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<td>Male sex (n, %)</td>
<td>66</td>
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<td>Body mass index, kg/m2</td>
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<td>LA diameter (mm)</td>
<td>40.34±7.60</td>
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<td>LVEF(%)</td>
<td>66.51±7.88</td>
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<td>Paroxysmal AF(n, %)</td>
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Abbreviations:AF, atrial fibrillation; ICE, intracardiac echocardiography; LA, left atrium ; LVEF, Left Ventricular Ejection Fractions; TSP, transseptal puncture ; TSP, transseptal puncture.

Table 2. Procedural Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Electrified J-wire TSP group (N=100)</th>
<th>Conventional BRK needle TSP group (N=100)</th>
<th>P Value</th>
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<tr>
<td>Procedure time</td>
<td>165.53±56.24</td>
<td>171.21±45.38</td>
<td>0.444</td>
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</table>
Total TSP time         221.73±146.65     311.81±253     0.003
Number of puncture   attempts required   1.68±1.71       1.43±0.74       0.209
Puncture /RF time     4.43±6.03         30.83±80.19    0.002
Width of the shunt    1.63±1.30         1.71±1.46       0.71

Abbreviations:RF, radiofrequency;TSP, transseptal puncture.

Figure 1. Flow sheet in the study.

Figure 2a: Methods of electrifying a J-wire for transseptal puncture without fluoroscopy.
A: The sheath was in the desired position in the fossa ovalis with the “tenting sign”. The guidewire was not pushed into the tip of the sheath, the “double track sign” was seen by ICE(intracardiac echocardiography).
B: The guidewire was pushed into the tip of the sheath, the “double track sign” disappeared.
C: Position the cautery tip in contact with the proximal portion of the guidewire and delivers energy, the bubbles could be seen in the left atrium. Which means the puncture process is succeed.
D: The guidewire was advanced into the left atrial through the RF area.
E: The transseptal sheath was advanced along the wire into the left atrium. The second “tenting sign” was seen by ICE.
F: When the second “tenting sign” disappeared, pull out the dilator and guidewire, the “double track sign” was seen in the left atrium.

Figure 2b: TSP with a conventional transseptal puncture needle without fluoroscopy.

A: The sheath was in the desired position in the fossa ovalis with the “tenting sign”.
B: The tip of transseptal needle had crossed the septum and was inside the left atrium.
C: After a successful puncture, the needle was changed to a guidewire, the guidewire was advanced into the Left superior pulmonary vein or left inferior pulmonary vein.
D: The transseptal sheath was advanced along the wire into the left atrium. ICE(intracardiac echocardiography) showed the second “tenting sign”
E: The second “tenting sign” disappeared, which means the sheath had passed though the septum.
F: The dilator and guidewire was pulled out of the body, the “double track sign” was seen in the left atrium.
Figure 3. Incidence of fresh cerebral infarction detected by MRI (magnetic resonance imaging)

Figure 4. Incidence of interatrial shunt at 3-month post procedure
Figure 5. The rhythm status at 3-month post procedure