Initial Clinical Experience of Transseptal Punctures Performed Using the SafeSept™ Transseptal Guidewire

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Background

Percutaneous transseptal puncture allows direct access to the left atrium (LA) and left ventricle by making a passage through the fossa ovale. Historically, TSP was used to perform hemodynamic studies, but this technique is now used predominantly by electrophysiologists for LA access to perform complex mapping and ablation procedures of the left cardiac chambers. In recent years, increasing numbers of TSPs have been carried out worldwide for catheter ablation therapy for atrial fibrillation.1

The area on the interatrial septum to perform the puncture safety is relatively small and the complexity of the procedure is influenced by anatomical variables between patients. Serious complications of up to 6% can arise from TSP,2,3 including potentially life-threatening complications such as perforation into adjacent great vessels, cardiac tamponade, and arterial thromboembolism. To reduce the risk of complications, transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE) can be used to visually guide the TSP.4,5 However, this requires additional skills, resources and cost. Furthermore, these imaging modalities may not be readily available in all centers.

Due to the growing demand for AF ablation, there will be increasing numbers of trainees and lower volume centers performing TSP. Significant numbers of patients will require ablations for recurrence of atrial arrhythmias, so increasing numbers of repeat AF procedures necessitating multiple TSP will be performed. It is now recognized that such cases are much more complex and associated both with higher risks of adverse events and increased failure rates due to fibrosis and thickening at the site of previous TSPs.6

To improve the success and safety of the TSP, a specially designed 0.014-inch diameter nitinol guidewire (SafeSept™ transseptal guidewire, Pressure Products Inc., San Pedro, CA) has been produced to facilitate safe access to the left atrium. The guidewire (Figure 1) is introduced through a standard transseptal apparatus allowing probing of the interatrial septum. During TSP, the wire is supported within the dilator, giving the sharpened tip of the wire column support and allowing it to cross the fossa, even if the fossa is thickened or fibrotic. Once across the fossa it is no longer supported and bends on itself, rendering the tip completely atraumatic and reducing the risk of perforating adjacent structures. When advanced into the pulmonary vein, the curved shape and floppiness of the wire tip will again not allow tissue damage.

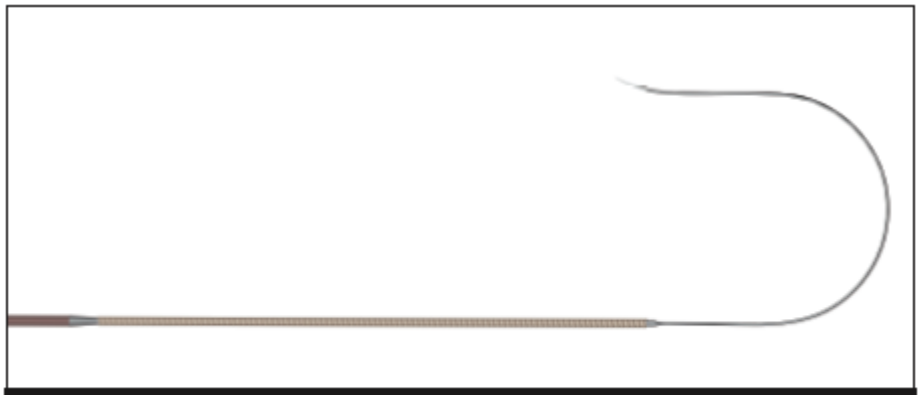

Figure 1. Close-up image of SafeSept™ transseptal guidewire (image courtesy of Pressure Products Inc., San Pedro, CA).

Guidewire Technique

A preferred right femoral venous access is used and a quadrapolar catheter is positioned in the coronary sinus for landmarking; other operators may also use a His bundle catheter to delineate the position of the aortic root. A standard transseptal sheath and Brockenbrough needle are positioned at the superior vena cava (SVC) and pulled down onto the right atrium under fluoroscopic guidance using LAO and RAO projections until a second distinct drop on to the fossa ovalis is seen (Figure 2a). The SafeSept transseptal guidewire is preloaded into the Brockenbrough needle via a hemostatic connector and advanced until it is 10 mm proximal to the needle tip. The Brockenbrough

needle is then advanced to the tip of the dilator but not exposed. With the fossa ovalis tented by the dilator tip, the SafeSept guidewire is advanced forward to puncture the septum. If passage through the septum into the LA is achieved, the guidewire passes effortlessly without resistance and usually cannulates the left superior pulmonary vein (Figure 2b). The platinum coil proximal to the guidewire's tip provides fluoroscopic confirmation that the guidewire has traversed the septum when seen in one of the pulmonary veins. The needle and then the dilator and sheath are passed into the LA using an over-the-wire technique (Figures 2c and 2d). The J wire over which the needle tip is passed prevents perforation of the posterior left atrial wall or any other structure by the needle. If the SafeSept guidewire fails to cross the septum, usually because the dilator tip is not in the correct anatomical position or not firmly against the interatrial septum, the guidewire merely crumples or is deflected on the septum. Further attempts in a different orientation can be made or a second pass taken with the sheath from the SVC again. Following successful transseptal access to the LA, the SafeSept guidewire can be retracted into the Brockenbrough needle for a second transseptal puncture if a double puncture is required.

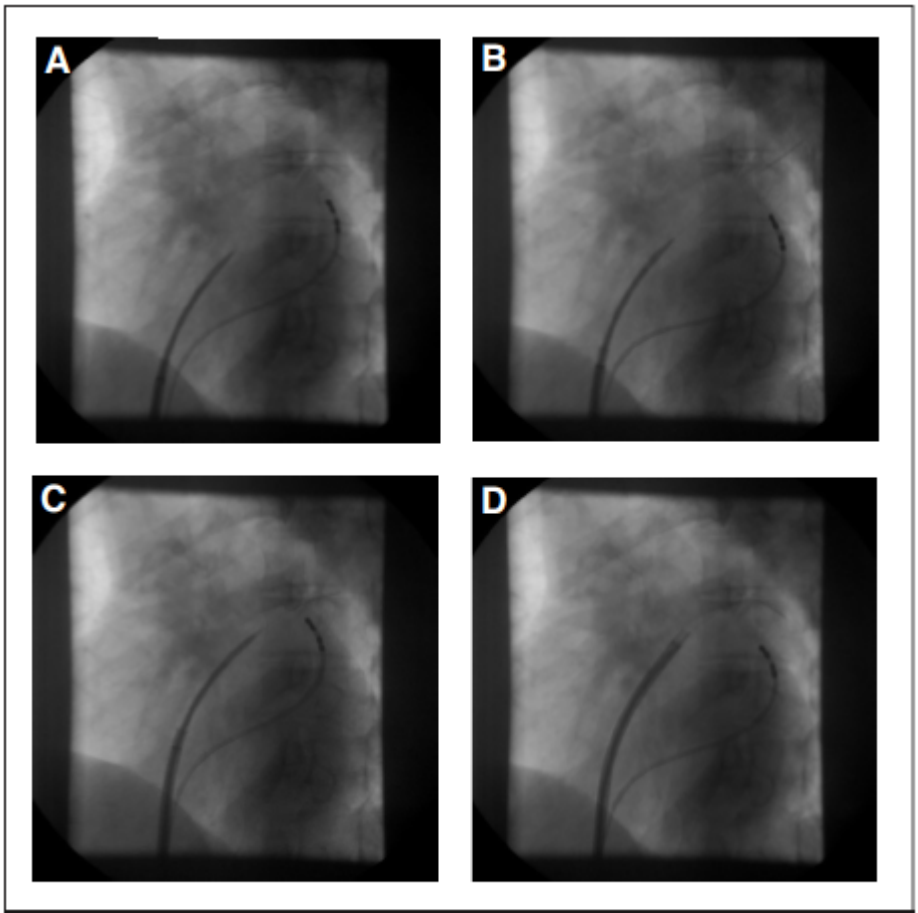

Figure 2. Fluoroscopic images at LAO projection of (A) apparatus prior to interatrial septal puncture. (B) SafeSept™ transseptal guidewire advanced across interatrial septum into left superior pulmonary vein. (C) Transseptal apparatus into LA using over the transseptal guidewire. (D) Sheath within LA.

Initial Clinical Experience

Our initial experience with the SafeSept transseptal guidewire was presented in May 2009 at the Heart Rhythm Society meeting in Boston.7 Fifty-six patients were evaluated over a six-month period, predominantly undergoing AF ablation but also including ablations of LA atrial tachycardias, left-sided accessory pathways and ventricular tachycardia. One-third of the patients evaluated had a previous history of TSP. Successful, uncomplicated LA access was achieved in 55 patients (98%) with no complications attributable to the SafeSept guidewire. The majority of these cases (83%) only required one pass with the SafeSept guidewire to cross the fossa ovalis, with no differences seen between patients undergoing their first TSP procedure or those undergoing a repeat procedure. Forty-eight percent of the TSPs using the SafeSept guidewire were performed by EP fellows, and the remainder by experienced senior operators.

The SafeSept guidewire was successful in two patients with previously difficult TSP and one patient with a failed TEE-guided TSP due to an aneurysmal septum. The SafeSept guidewire failed to achieve LA access in only one patient (2%). A subsequent attempt at the same sitting with a conventional pass using the Brockenbrough needle was also unsuccessful because of unusual anatomy. Since presenting our data, this patient has had a successful TEE-guided TSP using the SafeSept guidewire.

Our early experience indicates that the SafeSept guidewire can be used in both straightforward and complex TSP cases to safely access the LA without invasive imaging. Furthermore, as a teaching institution, our training fellows have found the SafeSept guidewire immensely helpful for safety and to gain confidence of this potentially difficult technique. Further evaluation in a larger cohort of patients is still required to fully validate the efficacy of this guidewire.

References:

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