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Superiority of Simulator-Based Training Compared With Conventional Training Methodologies in the Performance of Transseptal Catheterization

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Objectives This study aims to compare the performance of electrophysiology fellows in transseptal catheterization (TSP-C) after conventional (Conv-T) or simulator training (Sim-T).

Background Current training for TSP-C, an increasingly used procedure, relies on performance on patients with supervision by an experienced operator. Virtual reality, a new training option, could improve post-training performance.

Methods Fellows inexperienced in TSP-C were enrolled and randomly assigned to Conv-T or Sim-T. The post-training performance of each fellow was evaluated and scored in 3 consecutive patient-based procedures by an experienced operator blinded to the fellow's training assignment.

Results Fourteen fellows were randomized to Conv-T (n = 7) or to Sim-T (n = 7) and, after training, performed 42 TSP-Cs independently. Training time was significantly longer for Conv-T than for Sim-T (median 30 days vs. 4 days; p = 0.0175). The Conv-T fellows had significantly lower post-training performance scores (median 68 vs. 95; p = 0.0001) and a higher number of recurrent errors (median 3 vs. 0; p = 0.0006) when compared with Sim-T fellows.

Conclusions The TSP-C training with virtual reality results in shorter training times and superior post-training performance. (J Am Coll Cardiol 2011;58:359–63) © 2011 by the American College of Cardiology Foundation

Despite increased application of simulators for training in various fields, training in many medical disciplines—including cardiovascular interventions—is still based on traditional models where trainees are exposed to procedures under the tutelage of an experienced physician (1). This methodology has several disadvantages, the most important of which involves exposing patients to trainees in the early phase of their learning curve. This is particularly crucial when it involves complex procedures such as transseptal catheterization (TSP-C). Although devastating outcomes including death have been reported in <1% of all cases (2), adequate training for TSP-C is essential (3) to limit potential increases in complication rates because of increasing demand for this procedure for atrial fibrillation ablation.

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We hypothesize that simulator training (Sim-T) is superior to conventional training (Conv-T) in instructing trainees on the performance of TSP-C. Hence, this randomized prospective 2-center study aims to compare the results of Conv-T versus Sim-T in TSP-C in the electrophysiology laboratory.

Methods

Study design. The study was approved by the ethical committee and the institutional review board in each center. All fellows provided signed informed consent. The study flowchart is shown in Figure 1. At each center, electrophysiology fellows with no exposure to TSP-C were randomized to the 2 different training modalities. After an end-of-training evaluation, each trainee was required to perform TSP-C as the primary operator in 3 consecutive patients. Each procedure was supervised and graded by an expert physician blinded to his/her training modality. The primary endpoint was to demonstrate a significant difference between the 2 training groups in the composite performance score attributed to each patient-based procedure by the supervisor (Table 1).

Transseptal simulator. The TSP-C simulator has been described in detail previously (4), and a virtual procedure is shown in Online Video 1. Briefly, it is a modified version of

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Abbreviations and Acronyms

Conv-T = conventional training

Sim-T = simulator training

TSP-C = transseptal catheterization

the Procedicus VIST (version 7.0, Mentice AB, Gothenburg, Sweden, in cooperation with Biosense Webster, Diamond Bar, California), which allows for catheters in the coronary sinus, the His-bundle area, as well as the TSP-C and a pig-tail catheter in the aortic root. This is a high-fidelity hybrid simulator in which a haptic device (the "virtual patient") is connected to a computer with a dedicated software interface (Fig. 2, Online Video 1). The software generates a 3-dimensional rendering of the human cardiovascular system. Through ports in the haptic device, catheters and a transseptal assembly can be inserted, manipulated, and positioned under virtual fluoroscopy, which appears on the computer screen (Fig. 3) when a pedal is pressed. For TSP-C, a 0.032-inch-long guidewire, an 8.5-F transseptal introducer (Preface 301803M, Biosense Webster), and a Brockenbrough needle (EP 003994S, Medtronic, Minneapolis, Minnesota) are used. Every tool is real in its proximal part, whereas the distal part is simulated. Injection of virtual saline or contrast through the TSP-C apparatus, recordings of the left atrial and aortic pressure, as well as tactile resistance to puncture of the fossa ovalis are also provided. The system automatically logs procedural errors.

Conventional and simulator training. The TSP-C methodologies have been reported elsewhere (5,6). Intracardiac ultrasound is not routinely used at either center.

The Conv-T included a detailed lesson given by the tutor on TSP-C. Afterward, the trainee participated in 5 patient-based TSP-Cs under the guidance of the tutor. This allowed the trainee an opportunity to experience and review extensively with the tutor all the aspects of the procedure.

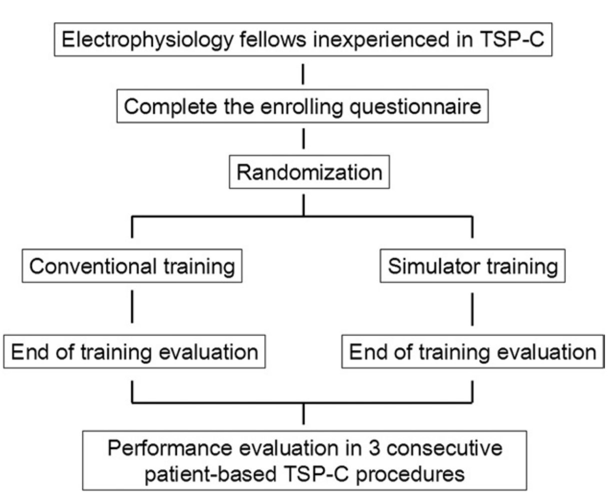

Figure 1 **Study Flowchart**

TSP-C = transseptal catheterization.

Table 1 **Score Table for Performance Evaluation**

Actions and Metrics	Score
Section 1: workflow	
Correct positioning of the guidewire in the superior vena cava	5
Correct advancement of the TSP assembly over-the-wire	7
Flush by saline of dilator lumen before needle insertion	6
Correct positioning of the needle inside the dilator	10
Correct rotation of the needle during assembly withdrawal	10
Correct rotation of the sheath and dilator during assembly withdrawal	5
Correct localization of the fossa ovalis	12
Use of oblique projections to verify correct engagement of the fossa ovalis	10
Check of pressure curve and/or contrast injection from the needle lumen	10
Correct needle advancement into the left atrium	6
Correct dilator/sheath advancement into the left atrium	4
Subtotal section 1	85
Section 2: ability	
Fluoroscopy time <5 min	4
Procedure time <10 min	4
Volume of radio-opaque contrast injected <20 cc	2
Number of attempts <2	5
Subtotal section 2	15
Composite score	100

TSP = transseptal.

At the end of this period, the ability to independently perform TSP-C was assessed by the tutor during an interview. If the trainee failed to demonstrate adequate knowledge, additional training was provided.

The Sim-T started with an explanation of TSP-C on the simulator with the tutor and the trainee performing the procedures together with detailed explanations of each step to

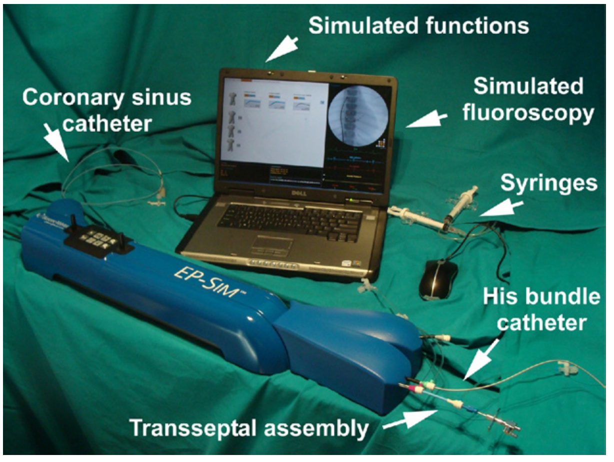

Figure 2 **Overview of the Transseptal Simulator**

Display of the simulator components. Coronary sinus catheter, His bundle catheter, and the transseptal assembly are inserted in a left venous subclavian port and 2 right femoral venous ports, respectively. Two separate syringes are for simulated injection of contrast and saline. Also see Online Video 1.