Journal of the American College of Cardiology
Vol. 58, No. 4, 2011

Published by Elsevier Inc.
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.02.063

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

Roberto De Ponti, MD,* Raffaella Marazzi, MD,* Sergio Ghiringhelli, MD,* Jorge A. Salerno-Uriarte, MD,* Hugh Calkins, MD,† Alan Cheng, MD†

Varese, Italy; and Baltimore, Maryland

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.

From the *Department of Heart, Brain and Vessels, Ospedale di Circolo e Fondazione Macchi, University of Insubria, Varese, Italy; and the †Division of Cardiology, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland. The study was not sponsored; Biosense Webster supplied the transseptal simulators. Drs. De Ponti and Calkins are consultants for Biosense Webster. Dr. Cheng has received a research grant from Biosense Webster. All other authors have reported that they have no relationships to disclose.

Manuscript received November 15, 2010; revised manuscript received January 27, 2011, accepted February 15, 2011.

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.

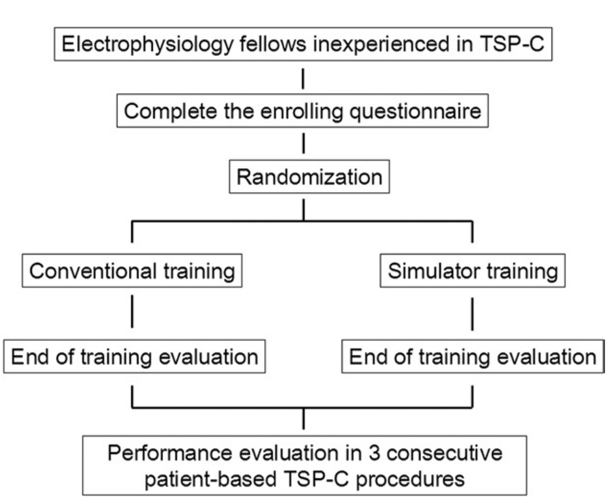

Figure 1 **Study Flowchart**

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

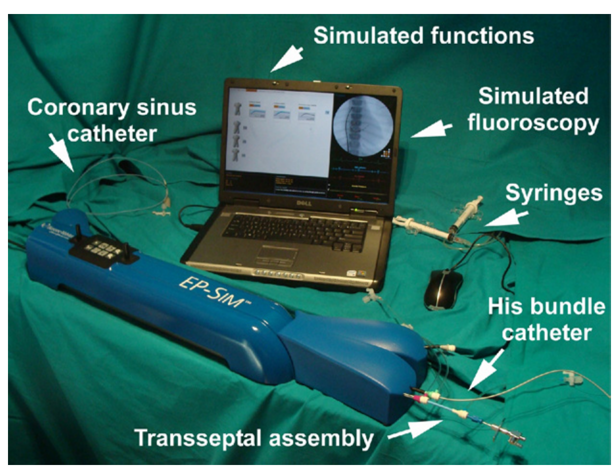

Figure 2 **Overview of the Transseptal Simulator**

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.

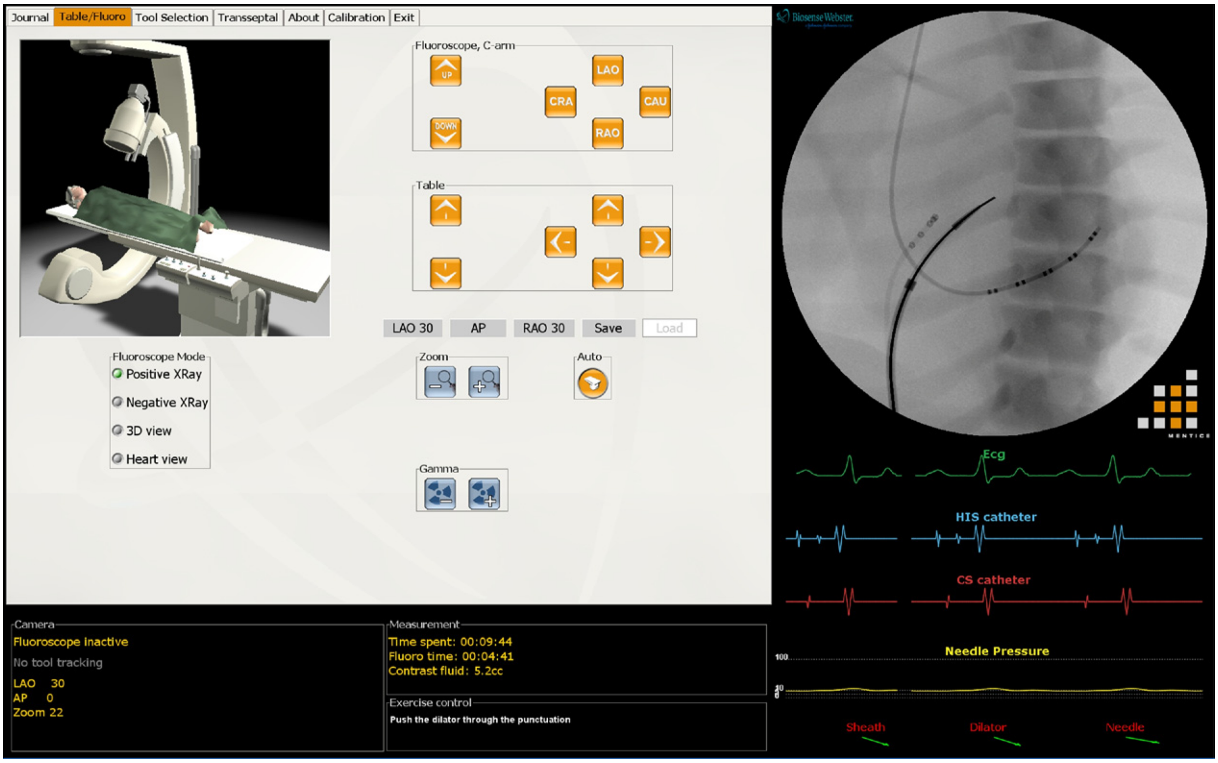

Figure 3 **Computer Screen of the Transseptal Simulator**

Computer screen during simulation. The **upper left-hand side** shows simulated functions such as fluoroscopy views and tool selection, whereas the **upper right-hand side** shows the simulated fluoroscopy. The **bottom** part of the screen shows procedure-related metrics **(left)** and **(right)** real-time surface electrocardiogram (ECG), His bundle and coronary sinus (CS) electrograms, pressure recording from the needle, and **arrows** showing the real-time orientation of the transseptal sheath, dilator, and needle, respectively. AP = anterior–posterior; CAU = caudal; CRA = cranial; LAO = left anterior oblique; RAO = right anterior oblique; 3D = 3-dimensional.

the trainee. Afterward, the trainee practiced independently without immediate tutor feedback. Procedural reports provided by the simulator were then reviewed by the tutor, and errors were extensively discussed with the trainee. At the end of this period, the trainee was evaluated on the simulator and assessed for the ability to perform a TSP-C independently. If the trainee failed to obtain at least 85 points on the composite score (Table 1), he/she was given an extended training period.

Evaluation of the post-training performance. During evaluation, the supervisor refrained from providing feedback. If the trainee was unable to complete the procedure or patient safety was being compromised, the supervisor took over and a score of 0 was assigned. As shown in Table 1, the maximum composite score is 100 points: 85 points are attributed to correct procedure performance (workflow) and 15 points assigned on the basis of other metrics (ability). The score corresponding to each procedural step was given only if the step was correctly accomplished by the trainee, in an "all or none" fashion, to assign the first 85 points objectively. The difficulty of patient-based TSP-C was also evaluated by the supervisor on a 0 to 5 scale according to pre-defined variables. Finally, recurrent errors were defined as errors in the same step in at least 2 of the 3 procedures.

Statistical analysis. Continuous variable are given as median (range). Categorical variables are given as percentages. Statistical analysis was performed with the Mann-Whitney *U* test with MedCalc (version 9.5.2.0, MedCalc Software, Mariakerke, Belgium).

Results

Study enrollment. Study enrollment began in June 2007 and ended in June 2010. During this period, 14 fellows were randomized, 7 in each arm. Both groups were well-matched in terms of demographic data and backgrounds (Table 2).

Training duration. As shown in Figure 4A, Conv-T lasted significantly longer than Sim-T (median 30 days, range 11 to

Table 2 **Characteristics of the Enrolled Fellows**

Variable	Conv-T	Sim-T	p Value
Age, yrs (median)	37	31	0.097
Male/female	7/0	6/1	0.490
Median of months in electrophysiology	15	14	1.000
Median of electrophysiology procedures in the previous month	20	20	0.623

Conv-T = conventional training; Sim-T = simulator training.

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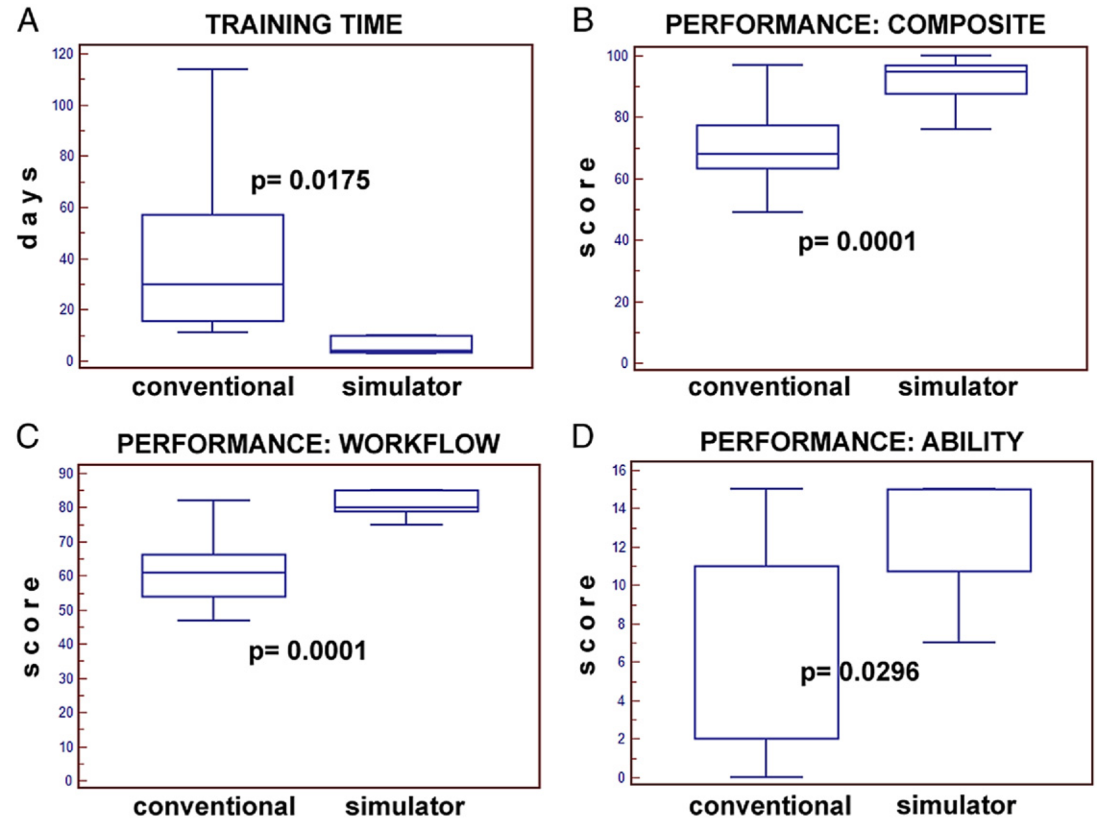

Figure 4 **Results: Training Time and Performance Scores**

Box-and-whisker plots of the training time **(A)** and performance scores **(B to D)** of the 21 patient-based procedures performed after training in each group.

114 days vs. median 4 days, range 3 to 64 days; p = 0.0175). Fellows assigned to Conv-T participated in 5 tutored TSP-Cs each and all demonstrated sufficient knowledge for independent performance at the first interview. In the Sim-T group, fellows performed a median of 43 (range 35 to 81) virtual procedures and, at the end of training, all qualified for patient-based performance with the maximum score.

Post-training performance. Forty-two TSP-Cs in 42 patients were performed and evaluated by the supervisors. Early or late complications were observed in none of the study procedures. One procedure performed by a Conv-T fellow was stopped by the supervisor for failing to aspirate the transseptal sheath before contrast injection. Case difficulty was well-matched between the groups (median 1 [range 0 to 4] in the Conv-T vs. median 2 [range 0 to 4] in the Sim-T group; p = 0.178).

The TSP-Cs performed by Sim-T fellows achieved higher composite scores (Fig. 4B), compared with those performed by Conv-T fellows (median 95 [range 76 to 100] vs. median 68 [range 0 to 96]; p = 0.0001). This difference was present even when workflow and ability scores were analyzed separately (Figs. 4C and 4D).

When the composite score was analyzed separately for each fellow (Fig. 5A), a greater variability in its value in the consecutive procedures was evident in the Conv-T group. Similarly, when the performance of the trainees was evaluated for each fellow as the average composite score of the 3 procedures (Fig. 5B), there was no overlap in the scores obtained in the 2 groups.

Finally, in the Conv-T group, all 7 fellows made recurrent errors (median 3, range 2 to 4), whereas in the Sim-T group, only 3 fellows made a single recurrent error (median 0, range 0 to 1; p = 0.0006).

Discussion

The results of this study demonstrate that fellows exposed to Sim-T had better TSP-C performance in patients, as compared with those undergoing Conv-T. Moreover, training time in Sim-T was significantly shorter than Conv-T, despite a higher number of virtual procedures in Sim-T. Interestingly, the composite performance score was less variable in the Sim-T group, and recurrent errors were sporadic. Because correct procedure performance (workflow) had the largest impact on the composite score, these data suggest that training with virtual reality allows improved understanding of the TSP-C steps, which are subsequently transferred more reliably in patient-based cases. Better performance after Sim-T is likely

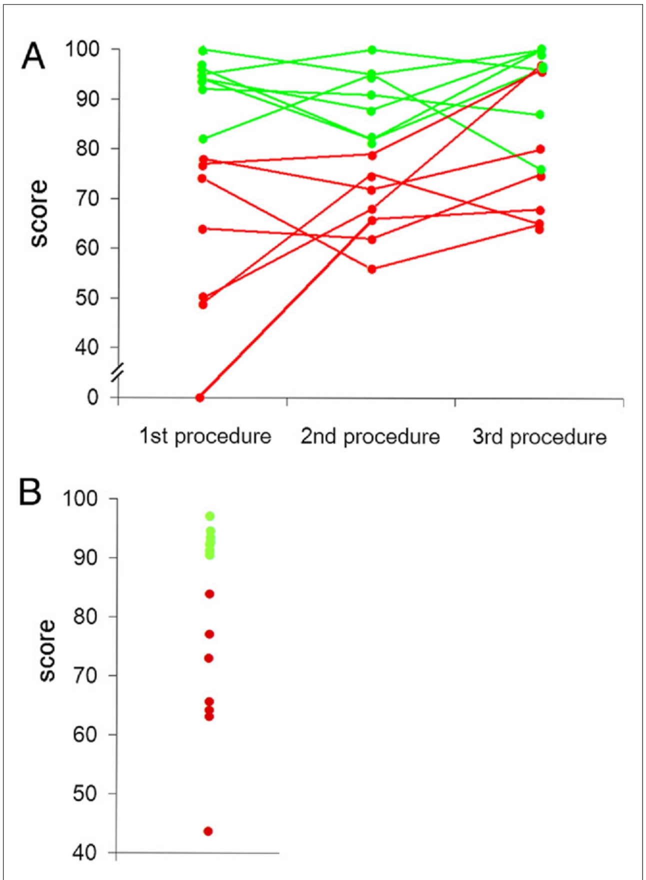

Figure 5 **Results: Individual Performance Scores**

Diagram of the individual composite scores shown sequentially as absolute values in the patient-based procedures **(A)** and as the average value of the 3 scores obtained by each fellow **(B)** in the conventional **(red)** and simulator **(green)** group.

the result of 2 factors: 1) exposure to a high number of procedures in a short amount of time; and 2) opportunity to test the independent performance of the trainee with subsequent correction of errors by the tutor on the basis of the report of the simulated procedure. None of these 2 aspects can be easily transferred to Conv-T for safety reasons or due to time constraints.

Finally, this simulator is not a stand-alone training modality. Experienced faculty instruction was instrumental in teaching the procedural steps, and the simulator served as a sophisticated tool to complement apprenticeship of trainees.

Study limitations. This was a pilot study involving 2 centers and a small number of trainees. Although these results should be confirmed in larger studies, our data demonstrate proof of concept that simulators have a role in cardiovascular training programs. Moreover, due to the small number of fellows at each institution every year, enrollment of a higher number of trainees in an acceptable time period would have required increasing the number of centers. This was practically impossible due to the limited resources available. Finally, this simulator does not incorporate other TSP-C techniques, including the use of intracardiac ultrasound. This feature might be included in future versions of the simulator.

Reprint requests and correspondence: Dr. Roberto De Ponti, Department of Heart, Brain and Vessels, Ospedale di Circolo e Fondazione Macchi, University of Insubria Viale Borri, 57, IT-21100 Varese, Italy. E-mail: rdeponti@alice.it.

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Key Words: atrial fibrillation ablation ▪ catheter ablation ▪ simulator training ▪ transseptal catheterization.

APPENDIX

For an accompanying video, please see the online version of this article.