Trans-Septal Catheterization in the Electrophysiology Laboratory
Data From a Multicenter Survey Spanning 12 Years

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OBJECTIVES
We report the data from the Italian Survey on trans-septal catheterization (TSP-C) for catheter ablation of arrhythmias in the left heart that covered 2003 and previous years.

BACKGROUND
Over the last decade the use of TSP-C in the electrophysiology laboratory has greatly increased. Recent data on number of procedures, accomplishment rate, and complications related to this procedure are lacking in a large cohort of patients.

METHODS
Thirty-three centers participated in the survey. The data collected retrospectively for 2003 included the number of procedures, indications, methods, and the number and reason for unaccomplished cases along with complications. Retrospective data collected for previous years included the annual number of procedures and cumulative data concerning indications, accomplishments, and complications.

RESULTS
Since 1992, 5,520 TSP-C procedures were used in arrhythmia ablation, with the peak increase in the use occurring in 2001. Trans-septal catheterization was performed for atrial fibrillation (AF) ablation in 78.3% of the procedures in 2003. The electrophysiologist independently performed the procedure in 29 of 33 centers. Trans-septal catheterization was successfully performed in 99.1% of the cases; the main reason for TSP-C not being performed was related to fossa ovalis/atrial septum anatomy. Complications were low both in 2003 and in the previous years (0.79% and 0.74%, respectively).

CONCLUSIONS
Trans-septal catheterization in the electrophysiology laboratory is associated with a high success and low complication rate. The use of TSP-C has progressively increased over the last decade and is currently used primarily for AF ablation. Although possible, severe complications were rare. (J Am Coll Cardiol 2006;47:1037–42) © 2006 by the American College of Cardiology Foundation

Since its introduction in clinical cardiology in 1959 by Cope and Ross (1,2), trans-septal catheterization (TSP-C) has been used for various purposes and applications (3–5). The methods used for this demanding procedure, however, may differ between centers and between operators (6–9). In recent years, the application of TSP-C has progressively moved from the field of interventional cardiology to clinical electrophysiology where it is used for catheter ablation in the left heart (10,11). The increasing number of cases using TSP-C is mainly related to the demand for atrial fibrillation (AF) ablation in the left atrium (12); however, recent data on methods, results, and complications of TSP-C in wide cohorts of patients are lacking. The purpose of this survey was to gather information on the TSP-C procedure performed for cardiac arrhythmia ablation from a nationwide retrospective data collection, the Trans-Septal Catheterization Italian Survey (TACIS).

METHODS
Data forms. The coordinating center (University of Insubria, Varese, Italy) prepared two forms for the purpose of this survey. The first form collected data concerning the TSP-C procedures performed during the year 2003 in the electrophysiology laboratory of a specified center. The overall number of procedures and the number of procedures for each treated arrhythmia was requested in the first section of this form. The TSP-C procedures employed for purposes other than ablation, such as dilation and stenting of post-ablation pulmonary vein stenosis, were excluded. Patients with a patent foramen ovale were also excluded. The sum of the procedures for all types of arrhythmia had to match the overall number of cases. Therefore, patients that had TSP-C performed for two different left-sided arrhythmias only had a single procedure counted; the arrhythmia reported was the one considered to be prevalent. Methods used to accomplish TSP-C were requested in the second form.
section of this form. In particular, the number of cases that had auxiliary tools—such as transesophageal echocardiogram, intracardiac ultrasound, positioning of the pigtail catheter in the aortic root, and measuring of intracavitary pressure—used during the procedure were requested. Moreover, every center had to report the number of cases in which dual TSP-C with two separate punctures was performed during the AF ablation in the left atrium. Dual TSP-C counted as a single procedure. Also the percentage of cases in which the electrophysiologist or the interventional cardiologist performed the procedure was obtained. Moreover, the anticoagulation policy at the time of atrial septal puncture and in the following phase of the procedure was requested. Finally, the results and the complications of TSP-C were requested. Specifically, the form requested the number of cases in which the procedure could not be accomplished and the reasons for this. Complications were defined as all events that were life-threatening, prolonged the hospital stay, and/or required immediate countermeasure management. Only complications that, at the physician’s discretion, were related to the TSP-C were considered, regardless of the timing of their occurrence.

In the second form, each center was required to provide data on TSP-C in the electrophysiology laboratory prior to the year 2003. Only basic data were requested in this form, owing to the obvious bias of retrospective data collection from past years. Specifically, the year when TSP-C use began was requested. Also, the number of procedures per year and the percentage of the arrhythmias requiring the TSP-C procedure were asked for in the form. Overall results and complications, as already defined, were requested. With the exception of the number of yearly procedures, all other data were pooled together for years prior to 2003.

**Data collection.** The files containing the two forms were sent as e-mail attachments to the address of the chief electrophysiologist of 38 hospitals on a national mailing list of centers performing TSP-C. The first e-mail explaining the aim of the study and containing the attachments was sent in March 2004; in cases of no response, another similar e-mail was sent 3 months and 6 months later. It was always clear that participation in the survey was voluntary and no objection was made for refusal to provide data. Preliminary data was presented at a national congress held on April 2004, and the survey information was made available so that any centers not previously contacted that were willing to participate could be included in the final survey. Only fully completed forms were accepted. In cases where data inconsistencies were found on the completed form, queries were generated by the coordinating center and sent to the participating center for clarification.

**Statistics.** Continuous variables are reported as mean ± SD. Categorical variables are expressed as proportions. Two-tailed confidence intervals were calculated by means of standard techniques. Comparison between groups was performed with the unpaired *t* test with previous logarithmic transformation of data.

**RESULTS**

**Participating centers.** Two centers among the 38 contacted claimed that TSP-C was not performed in their center. No center other than those initially contacted claimed to perform TSP-C for arrhythmia ablation. Therefore, the number of centers performing TPS-C in Italy in 2003 was restricted to 36. Among these, 33 centers (91.6%) participated in the survey and provided all the data requested in both forms. The remaining three centers did not respond or refused to participate. One high-volume center among the three non-participants claimed to have no complications related to TSP-C.

**Survey data from the year 2003.** A total of 1,764 TSP-C procedures were performed in the participating centers in 2003, according to the data collected from the first form. The mean was 53 ± 65 procedures per center with a wide range of 5 to 290 procedures. The distribution of the arrhythmias, in which the ablation indicated the TSP-C procedure, is shown in Figure 1. It appears that the prevalent indication for TSP-C is ablation of AF in the left atrium, followed by left atrial tachycardias and left-sided accessory pathways. Additionally, TSP-C was only episodically used for ventricular tachycardia ablation in the left ventricle, and in a single case it was performed for slow pathway ablation in an atrioventricular node re-entrant tachycardia, refractory to conventional ablation. Twenty-two centers reported the routine (>80% of the procedures) use of tools to assist the atrial septal puncture, with five centers reporting the routine simultaneous use of multiple tools. Figure 2 shows the number of centers that used the

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**Figure 1.** Proportion of arrhythmias that indicated trans-septal catheterization in the survey for the year 2003. AF = atrial fibrillation; APA = accessory pathway-mediated arrhythmias; AT, Afl = left atrial tachycardia/atrial flutter; AVNRT = atrioventricular node re-entrant tachycardia; VT = ventricular tachycardia.

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**Abbreviations and Acronyms**

- AF = atrial fibrillation
- TSP-C = trans-septal catheterization

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different types of tools. In contrast, in a relevant number of centers, 11 total, the procedure was performed according to a simplified method with no pressure recording or ultrasound imaging, previously described (7). There was no statistically significant difference regarding the volume of cases between these centers and those that used tools (60.2 ± 77.8 cases in the centers not using tools vs. 50.1 ± 60 cases in the other centers; p = 0.67). There was a slightly significant difference, however, in amount of TPS-C experience in centers not using tools (6.2 ± 3.6 years in the centers not using tools vs. 3.6 ± 2.2 years in those using tools; p = 0.049). Interestingly, among the centers that routinely used no tool to assist in TSP-C, four reported the occasional use of adjunctive technologies in selected cases. Specifically, two centers used intracavity or transesophageal ultrasounds in cases with a previous unsuccessful attempt of TSP-C, and the other two centers used pressure recordings and pigtail catheter positioning when peculiar anatomy was encountered, especially in patients with prior cardiac surgery.

Double TSP-C for AF ablation was routinely (≥80% of the procedures) performed in 9 of the 33 (27%) centers, in 521 procedures, which accounts for 37.6% of the overall number of procedures performed in 2003 for AF ablation. The electrophysiologist alone performed the TSP-C in all cases in the vast majority of the centers (29 of 33; 87.8%). In the remaining centers, it was performed by the interventional cardiologist alone (two centers) or in cooperation with the electrophysiologist (two centers).

All centers reported that if any anticoagulation was used before the procedure it had to be timely withdrawn so that the values of coagulation parameters were within normal range at the time of atrial septal puncture. After TSP-C accomplishment, intravenous heparin was administered to maintain the activated clotting time >250 s.

Trans-septal catheterization was accomplished in 1,748 of the 1,764 procedures (99%). Reasons for 12 centers not accomplishing the procedure in 16 cases are reported in Table 1. Twenty-nine centers reported a TSP-C success rate greater than 95% and the mean success rate was 98.3% (confidence interval 84.4% to 100%). Although suggestive,
the previous year was reported, although a continuous trend toward an increase in the number of procedures was observed in the following years as well (35% increase in 2002 and 60% increase in 2003). The increase in the number of procedures reported in 2001 correlated with the peak in the number of new centers starting the TSP-C reported in that year. Ten new centers began performing the procedure in 2001. Figure 4 shows the distribution of centers according to whether AF was an indication for TSP-C. The procedure was exclusively, 95%, or almost exclusively, between 80% and 94%, performed to treat AF by left atrial ablation in more than 50% of the centers. Overall, TSP-C was accomplished in 3,724 of the 3,756 procedures (99.1%). Twenty-seven centers reported a success rate 95% and the mean success rate was 99.1% (confidence interval 95.5% to 100%). Thirty-two procedures were not accomplished in 10 of the centers and the reasons are reported in Table 1. Similar to that observed in 2003, the reason for not accomplishing the procedure in the previous years was related to the inability to correctly localize the fossa ovalis or to penetrate the atrial septum in more than 50% of the cases. Fourteen centers reported complications related to TSP-C in 28 procedures (Table 2). One death due to cardiac perforation and tamponade during the TSP-C procedure was reported. This accounts for a mortality rate of 0.018% after pooling together the data from 1992 to 2002 and from 2003, when no mortality was reported. Among the six cases of arterial thromboembolism or air embolism (one in 2003 and five in the previous years), three developed signs and symptoms of cerebral transient ischemic attack and three had transient chest pain with electrocardiographic signs of acute myocardial ischemia, soon after atrial septal puncture. In the former ones, complete symptom regression was observed within 12 h and serial computed tomography scan excluded areas of permanent brain injury, whereas in the latter intraprocedure angiography showed no coronary artery disease and serial echocardiograms and blood samples ruled out permanent myocardial damage. Of interest, the 13 cases of needle puncture of the right free wall (4 in 2003 and 9 in the previous years) did not result in clinically relevant pericardial bleeding, whereas among the 5 cases of needle puncture of the aortic root (1 in 2003 and 4 in the previous years) only 2 showed no sequelae, whereas 3 resulted in signs and symptoms of aortic perforation. Similar to that observed in 2003, the two cases with transient ST-segment elevation reported in the previous years showed angiographically normal coronary arteries and no sign of permanent myocardial damage. Finally, the only case of pericarditis was observed after needle puncture of the right free wall and injection of a limited amount of dye in the pericardium through the needle.

**DISCUSSION**

In the present study, the results of an Italian survey on TSP-C are reported. To the best of our knowledge, this is the first nationwide multicenter survey specifically aimed at reporting on the methods, results, and complications of TSP-C in the electrophysiology laboratory. Previous reports on a large cohort of patients (13,14) date back to more than 10 years ago and refer to TSP-C performed for purposes other than electrophysiology. The results and complication rates of these previous studies cannot be extrapolated directly to the procedure currently performed for ablation in the left heart. In the present survey, every effort was made in preparing the forms to obtain only simple, basic data in order to favor participation and accuracy of the data collection. Yet, the results of the survey should have been specific enough to allow for solid conclusions. Data reported for 2003 were kept separated from those of the previous years both in the gathering and presentation of the data, because it was assumed that data concerning the previous year would have been more accurate than data from the years preceding 2003; only very basic data was requested for years preceding 2003.

The results of this survey indicate that the widespread use of TSP-C performed by the electrophysiologist for ablation purposes is associated with a high success rate and low complication rate. Both for 2003 and for the previous years, the cumulative percentage of accomplishment was around 99%, with the vast majority of the centers reporting a success rate greater than 95%. The fact that in the year 2003 the electrophysiologist was the physician in charge of the
procedure in almost all centers seems to be the result of specific training performed in the previous years by the interventional cardiologists or other electrophysiologists experienced in TSP-C. Trans-septal catheterization was performed without routine pressure recordings, use of ultrasound, or positioning of the pigtail catheter in the aortic root in one-third of the centers in 2003. These centers showed a slightly significant longer period of experience in TSP-C as compared with the others. It has been previously reported for a large cohort of patients undergoing catheter ablation in the left heart that this “simplification” of the TSP-C procedure in the electrophysiology laboratory does not compromise safety (7); however, auxiliary tools, such as transesophageal and intracavitary ultrasounds, were available and used in 4 of these 11 centers in selected cases. These were used when difficulties were expected or encountered during the procedure or in cases with a prior unsuccessful attempt at TSP-C. The reasons for not accomplishing TSP-C were mainly, if not exclusively, related to difficulties in localization and puncturing of the fossa ovalis, because its imprecise localization could be assumed in cases of needle puncture of the right free wall or of the aortic root. As already described (14,15), “needle-only” puncture might be uncomplicated and have no sequelae. According to our experience, this seems to apply predominantly to the needle puncture of the right free wall, which had no clinical sequelae, so that in these cases only procedure interruption, patient monitoring, and procedure rescheduling are required. In particular, procedure interruption seems mandatory in all cases in which prolonged anticoagulation is used and a lengthy procedure is expected, such as in AF ablation. Conversely, the majority (three of five cases) of needle punctures of the aortic root developed sign and symptoms of aortic perforation. This leads us to reconsider the benign course of needle punctures of inappropriate structures, which should be avoided in every case. Finally, it should be underlined that needle punctures of any kind are at high risk for evolution into severe complications. In fact, if the operator does not immediately recognize the wrong positioning of the needle and the whole assembly is advanced over the needle, this will likely result in cardiac perforation and tamponade.

The complication rate was invariably low, 0.79% and 0.74% in 2003 and in the previous years, respectively. Only a single case of death was reported and accounted for a mortality rate of 0.018%. Nevertheless, it has to be underlined that these figures express only the complications strictly related to TSP-C. Therefore, these do not indicate the overall complication rate related to catheterization/ablation in the left heart. Most of the complications, especially for complex procedures such as left atrial ablation for AF (16), might be related to a longer procedure duration, multiple radiofrequency energy applications, and prolonged catheter manipulation, which are all variables associated with the ablation phase of this procedure. It is noteworthy that five of the seven centers that reported
become familiar with the TSP-C approach that was not previously considered for treatment of other arrhythmias. **Study limitations.** This was a voluntary survey with a retrospective data collection. Thus, there are obvious limitations; however, this type of data collection might overcome the difficulties often encountered when a prospective study on complications is undertaken. The survey was limited to a single country; therefore, it involved a small community of electrophysiologists. In some ways, this might have limited the bias in data reporting. Regarding the non-accomplishment of the TSP-C procedure, no data were available on alternative strategies used to manage the cases, although this datum was not numerically important.

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**REFERENCES**


**APPENDIX**

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