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a Multicenter Survey Spanning 12 Years**

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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 per-

formed 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

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Abbreviations and Acronyms

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

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 \pm 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 TSP-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

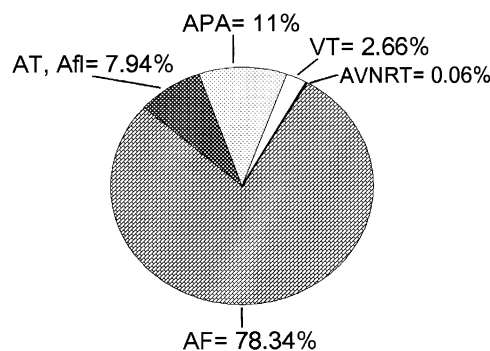


Figure 1. Proportion of arrhythmias that indicated trans-septal catheterization in the survey for the year 2003. AF = atrial fibrillation; APA = accessory pathway-mediated arrhythmias; AT, Afl = left atrial tachycardia/atrial flutter; AVNRT = atrioventricular node re-entrant tachycardia; VT = ventricular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

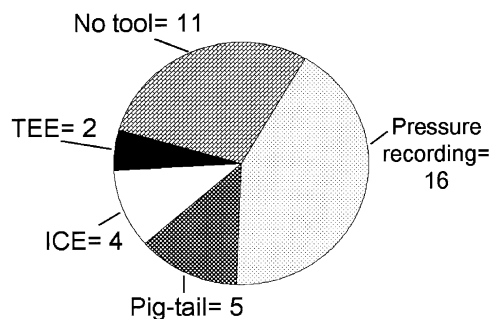


Figure 2. Number of centers routinely using auxiliary tools to assist in trans-septal catheterization. Eleven centers used no tool, whereas five centers routinely used multiple tools. ICE = intracardiac echocardiography; TEE = transesophageal echocardiography.

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 intracavitary 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 ($\geq 80\%$ 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,

Table 1. Reasons for Not Accomplishing Trans-Septal Catheterization

	2003	1992-2002
No. of procedures	1,764	3,756
No. of aborted procedures	16 (0.90%)	32 (0.85%)
Reasons		
Lack of localization of fossa ovalis	7	18
Resistant atrial septum	4	1
Needle puncture of right atrium	4	9
Needle puncture of aortic root	1	4

the differences in the volume of cases and in the years of experience between centers with a success rate $<95\%$ and those with a success rate $>95\%$ was not statistically significant (22.8 ± 15.8 cases vs. 57.7 ± 68.6 cases, respectively; $p = 0.20$) (2.3 ± 1 years vs. 4.8 ± 3 years, respectively; $p = 0.10$). Lack of statistical significance might be possibly related to the limited number of centers involved in the comparison. Interestingly, in the majority of the cases, 11 of 16 (69%), the inability to accomplish the TSP-C procedure was related to the inability to locate the fossa ovalis or to the atrial septum anatomy. Nine centers reported complications related to TSP-C in 14 procedures (Table 2), and no deaths were reported. Of the seven centers that reported the 10 cases of cardiac perforation or puncture by Brockenbrough needle of inappropriate structures, five claimed the routine use of auxiliary tools to assist TSP-C. Transient asymptomatic ST-segment elevation was reported without signs of permanent myocardial damage and with angiographically normal coronary arteries in three cases. There was no statistically significant difference in the volume of cases between centers with and without complications (55.2 ± 88.2 cases vs. 52.8 ± 57.0 cases, respectively; $p = 0.94$), whereas the difference was mildly significant as to the years of experience (2.3 ± 1.6 years for centers with complications vs. 4.0 ± 2.7 years for those without complications; $p = 0.045$).

Survey data for the years prior to 2003. A total of 3,756 TSP-C procedures were reported from 1992 to 2002 by the 28 active centers. The continuous increase in the number of procedures per year from 1992 to 2003 is shown in Figure 3. The most relevant increase in the number of yearly procedures was observed in 2001 when a 94% increase over

Table 2. Complications Related to Trans-Septal Catheterization

	2003	1992-2002
No. of procedures	1,764	3,756
No. of procedures with complications	14 (0.79%)	28 (0.74%)
Death	—	1
Aortic root perforation	—	3
Cardiac perforation	3	3
Cardiac perforation with tamponade	2	3
Needle puncture of aortic root	1	1
Needle puncture of right atrium	4	9
Arterial thromboembolism	1	3
Arterial air embolism	—	2
Transient ST-segment elevation	3	2
Pericarditis	—	1

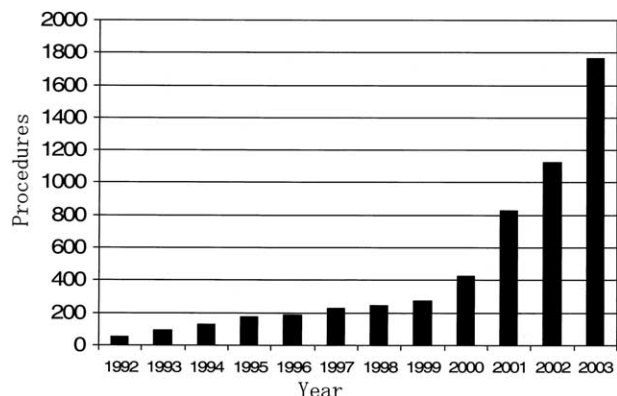


Figure 3. Cumulative number of yearly procedures performed between 1992 and 2003 in the participating centers.

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

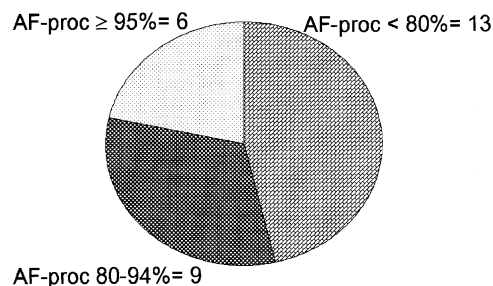


Figure 4. Distribution of centers according to the percentage of procedures performed for atrial fibrillation ablation between 1992 and 2002 in the participating centers. AF-proc = procedures for atrial fibrillation ablation.

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 ultrasounds, 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

cardiac perforation or needle puncture in 2003 routinely used auxiliary tools to assist the TSP-C procedure. This suggested that, although undoubtedly valuable in particular cases (9,17–19), routine use of pressure recordings, pigtail positioning, and ultrasound was not necessarily associated with a lower complication rate. Nevertheless, it is intuitive that particularly the use of ultrasound, by visualizing the correct positioning of the distal part of the assembly and the fossa ovalis “tenting,” could really be of help, especially in the early phase of the learning curve and whenever a peculiar anatomy is expected or encountered. The observation of transient ST-segment elevation in the inferior leads without chest pain, associated with hypotension, bradycardia, and the finding of a normal coronary artery has already been reported (20). This phenomenon has been considered a result of a Bezold-Jarisch-like vasovagal response, mediated by the mechanical effects of puncture on the vagal network located in the vicinity of the puncture site, and is reversed by atropine administration. Coronary embolism due to imperfect flush or management of the trans-septal sheath, when already placed in the left atrium, could be an alternative explanation of this phenomenon, although lack of chest pain seems to discriminate these cases from those with coronary thromboembolism or air embolism, at least in patients who are not under general anesthesia. Finally, the role of the common anticoagulation policy followed by all centers must be underlined. No case was under the effect of anticoagulants at the time atrial septal puncture was performed. This might have greatly contributed to minimize the effects of complications such as cardiac perforation or needle puncture, in case they had occurred.

The data presented in our survey also indicate that there has been a relevant increase in the number of TSP-C procedures per year, starting from about 100/year in the early 1990s to more than 1,700 in 2003. As expected, this was not only because of the increase in the number of the procedures in individual centers but was mainly related to a consistent increase in the number of centers performing TSP-C. The highest increase was observed in the year 2001. In 2001 the total number of procedures increased by 94% and 10 centers began performing TSP-C. In the following years, an unabated, although less relevant, increase in the number of TSP-C procedures was observed. The peak in 2001 might correlate with initiation or increase of ablation of AF in the left atrium, which was likely favored by the fact that new mapping tools for pulmonary vein electrical disconnection became commercially available in Italy. Although in a wide number of centers TSP-C was performed to treat various left-sided arrhythmogenic substrate, the majority of the procedures were aimed at AF ablation. It could be speculated that in Italy the widespread use of TSP-C was a phenomenon secondary to the ablation of AF in the left atrium. An increase in the early 2000s of ablation of AF in the left atrium might have stimulated several centers to

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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APPENDIX

In addition to the authors of this paper, the following physicians participated in TACIS: Emanuele Bertaglia (Mirano), Maria Grazia Bongiorno (Pisa), Nicola Bottoni (Reggio Emilia), Marcello Chimienti (Monza), Antonio Dello Russo (Roma), Maurizio Del Greco (Trento), Fabrizio Drago (Roma), Valentino Ducceschi (Vallo Lucania), Antonio Fusco (Peschiera Garda), Massimo Grimaldi (Bari), Stefano Grossi (Torino), Maurizio Landolina (Pavia), Raffaele Luise (Chieti), Roberto Mantovan (Treviso), Annibale Sandro Montenero (S.S. Giovanni), Renato Ometto (Vicenza), Giovanni Perego (Milano), Claudio Pratola (Ferrara), Alessandro Proclemer (Udine), Gaetano Senatore (Ciriè), Cesare Storti (Pavia), Claudio Tondo (Milano), Massimo Tritto (Castellanza), Pietro Turco (Maddaloni), Roberto Verlato (Camposampiero), Marco Zardini (Bergamo).

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