# SPECIAL ARTICLES

# Spanish Registry on Catheter Ablation. 1st Official Report of the Working Group on Electrophysiology and Arrhythmias of the Spanish Society of Cardiology (Year 2001)

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**Background and objectives.** The information about the practice and results of catheter ablation of cardiac arrhythmias in Europe is limited and there is a lack of multicenter studies and registries. The Spanish Society of Cardiology developed a national registry to define the results of this procedure and the characteristics of the laboratories where it is performed.

**Methods.** A list of electrophysiology laboratories in Spain was prepared and questionnaires were sent to each of them. The questionnaires were completed with retrospective data about the characteristics of each center, their general activities, and ablation procedures performed during 2001. Data were collected on the results and complications in relation to the arrhythmic substrate or mechanism treated.

**Results.** Forty-three centers, out of a possible 48, voluntarily participated in the registry. A total of 4,374 ablation procedures were performed in 41 centers. The average number of procedures per center was  $106 \pm 84$  and the rates of success, major complications, and mortality were, respectively, 93%, 1.5%, and 0.1%. About 70% of the procedures were performed to treat patients with AV nodal reentrant tachycardias and accessory pathways or to abolish AV conduction.

**Conclusions.** The 2001 Spanish National Catheter Ablation Registry is one of the largest reported series of ablation procedures. The results of the registry demonstrate a high success rate and low complication and mortality rates in the practice of catheter ablation in Western Europe.

**Key words:** *Catheter ablation. Electrophysiology. Statistics. Registries.* 

#### Full English text available at: www.revespcardiol.org

## INTRODUCTION

Catheter ablation is now a well-established therapy in cardiology.<sup>1</sup> Recommendations have been published on its indications and the minimum technical and per-

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#### Registro Español de Ablación con Catéter. I Informe Oficial de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología (Año 2001)

Introducción y objetivos. El conocimiento sobre la práctica y los resultados de la ablación con catéter de arritmias cardíacas en Europa es limitado, sin apenas estudios multicéntricos o registros importantes. La Sociedad Española de Cardiología, a través de su Sección de Electrofisiología y Arritmias, ha elaborado un registro nacional con objeto de definir los resultados de este procedimiento y las características de los laboratorios que lo realizan en España.

**Métodos.** Se elaboró un censo de los laboratorios de electrofisiología cardíaca de España. A todos ellos se les envió un cuestionario en el que se recogieron retrospectivamente las características de cada laboratorio, su actividad general y los procedimientos de ablación llevados a cabo durante el año 2001, detallando los resultados y las complicaciones en función del sustrato o mecanismo arrítmico tratado.

**Resultados.** Cuarenta y tres centros, de un total de 48 posibles, contestaron el cuestionario. El número de procedimientos de ablación fue de 4.374 (41 centros), con una media de 106 ± 84 procedimientos por centro y con porcentajes de éxito del 93%, de complicaciones mayores del 1,5% y de mortalidad del 0,1%. El 70% de los procedimientos de ablación se realizó sobre taquicardias por reentrada intranodal, sobre vías accesorias o para abolir la conducción auriculoventricular, con un porcentaje de éxito del 93%.

**Conclusiones.** El Registro Nacional de Ablación con Catéter del año 2001 recoge una de las mayores muestras hasta ahora publicadas de procedimientos de ablación. La eficacia de este procedimiento en nuestro medio es elevada, y los porcentajes de complicaciones mayores y de mortalidad, escasos.

**Palabras clave:** Ablación con catéter. Electrofisiología. Estadísticas. Registro.

sonnel requirements that a laboratory of cardiac clinical electrophysiology must satisfy in order perform this procedure.<sup>2-5</sup> However, little information on the practice of this technique and its results in Spain has been available until now. Only information about the number of centers and number of therapeutic procedures performed have been published, without specifying the results.<sup>6.7</sup> An exception was the recently presented Registry of Catheter Ablation of the Working Group on Arrhythmias of the Sociedad Andaluza de

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## ABBREVIATIONS

RN: registered nurse.NASPE: North American Society of Pacing and Electrophysiology.SEC: Sociedad Española de Cardiología (Spanish Society of Cardiology).

Cardiología (Andalusian Society of Cardiology),<sup>8</sup> which, nevertheless, had the limitation of offering information from a limited geographic area of Spain.

This article presents the results of the National Registry on Catheter Ablation of the Sociedad Española de Cardiología (SEC) of 2001, prepared by the society's Working Group on Electrophysiology and Arrhythmias, with the participation of most of the electrophysiology laboratories in Spain. This is the first reference of the activity and results of catheter ablation in this country.

# **METHODS**

A census of cardiac electrophysiology laboratories in Spain was made using information available from the working group and its members, as well as facilitated by the catheter ablation manufacturing industry. All the laboratories were sent a questionnaire (Annex 1) as a hard copy and, in some cases, electronic mail. The questionnaire was also made public and could be obtained on the web page of the working group (www.arritmias.org).

The first part of the questionnaire collected general information on the hospital center, the service responsible for ablations, the availability of cardiovascular surgery at the center, the population attended by the center, and the number of patients on the waiting list at the end of 2001. Later, information was collected on the human resources of the laboratory (number of staff physicians, physicians working full-time at the laboratory, research fellows, resident physicians, registered nurses (RN), assistant nurses, and radiology specialists). Information was requested on the characteristics of the radiology laboratory where the procedures were carried out and what activities aside from ablation were performed there, such as implantation of pacemakers, defibrillators or electrical cardioverters. Information was obtained on available technological resources, like the polygraph system or the availability of special mapping techniques (non-fluoroscopic intracardiac navigation systems and intracardiac echography) or therapeutic techniques (cryoablation, ultrasound).

Later, the questionnaire asked about the total number of diagnostic electrophysiological studies, ablation procedures, patients treated by ablation, successful ablation procedures, and complicated ablation procedures performed in 2001. The number of pacemaker and defibrillator implantation and replacement procedures performed in 2001 was investigated. The last item in this section recorded the policy of each laboratory with respect to the prophylaxis of thromboembolism or the time interval before a procedure was considered definitively successful.

Finally, in the last item the number of procedures was recorded and the results were noted in accordance with the arrhythmic substrate or mechanism treated. Ten substrates or mechanisms were contemplated: intranodal tachycardia, accessory pathways, atrioventricular conduction, focal atrial tachycardia, cavotricuspid isthmus, macroreentrant atrial tachycardia or atypical atrial flutter, atrial fibrillation, idiopathic ventricular tachycardia, reentrant ventricular tachycardia associated with a myocardial infarction scar, and reentrant ventricular tachycardia unrelated with a myocardial infarction scar. For each substrate/mechanism, the total number of procedures and patients treated, and the number of procedures performed in patients treated successfully, were recorded. The number of procedures performed with catheters other than the conventional distal 4-mm electrode catheter was also noted (8-mm, irrigated tip, or other).

Success was defined as elimination of the substrate, not just modification of its properties. However, in the case of tachycardia due to intranodal reentry, suppression of the capacity to induce tachycardia was required and the maximum number of permissible inducible nodal echoes at the end of the procedure was recorded. Likewise, the following major complications were recorded: unintended atrioventricular block requiring definitive pacemaker implantation; cardiac tamponade or pericardial effusion that prolonged the hospital stay, whether or not it was evacuated; venous or arterial vascular complication that required a clinical or surgical intervention or prolongation of the hospital stay; cerebrovascular accident or transient ischemic accident, unstable myocardial infarction of recent appearance or unstable angina that required a clinical intervention or prolongation of the hospital stay; the appearance or exacerbation of heart failure related to the procedure, which motivated a clinical attitude or prolongation of the hospital stay, and other complications like pulmonary thromboembolism, pneumothorax, or infections. With respect to mortality, immediate deaths and peri-procedure deaths secondary to clinical or surgical procedures or other complications attributable to ablation were noted.

Finally, in the last substrate/mechanism item, information on some aspects previously mentioned was requested, detailed according to the different variants of the substrate/mechanism. Consequently, intranodal tachycardia was divided into common (I) and uncommon types (II); accessory pathways were classified by the presence or absence of pre-excitation, and in right, left, or perihisian; atrioventricular conduction, the access was noted, either venous or arterial; focal and macroreentrant atrial tachycardias were classified as right or left; cavotricuspid isthmus according to whether the patient presented counterclockwise, clockwise, or inferior vena cava atrial flutter; atrial fibrillation according to whether a right atrial or left atrial approach was used, as well as focal, isolation of pulmonary veins, or linear: idiopathic ventricular tachycardia according to its origin in the right ventricular outflow tract. left ventricular outflow tract, fascicular, or other location; postinfarction ventricular tachycardia according to whether the patient had an anterior or inferior scar, and ventricular tachycardia unrelated to a postinfarction scar, according to whether the patient had arrhythmogenic right ventricular dysplasia, dilated cardiomyopathy or another cardiomyopathy, and the presence or absence of a branch-to-branch reentry mechanism. The location of the atrioventricular accessory pathways and classification of the atrial arrhythmias were made using the new definitions of the Working Group on Arrhythmias of the European Society of Cardiology.9,10

The completed questionnaires were sent to the Secretariat of the Working Group on Electrophysiology and Arrhythmias, where administrative personnel assigned them a number (center code) and removed the upper part of the first page, which contained the information identifying the center. This information was filed separately to safeguard the confidentiality of the information submitted. The rest of the form was sent for data analysis to the registry coordinator (M. Álvarez).

## Statistical analysis

Numerical results are expressed as mean±standard deviation. The qualitative variables and proportions were analyzed using the  $\chi^2$  test, and the Fisher test, when necessary. The quantitative variables were analyzed by means of the Student t test. The success rates and complication rates were calculated in relation to the number of patients. A value of *P*<.05 was considered statistically significant. The statistical analysis was made with the SPSS 9.0 statistical program.

# RESULTS

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## Infrastructure and resources

Forty-three (Annex 2) out of 48 possible centers completed the questionnaire, which was 90% of the centers that were invited to participate. The characteristics of the participating centers are shown in Table 1.

Table 1. Characteristics of participating hospitalcenters in the National Registry of Catheter Ablationin 2001

Characteristics	Number (%)
University hospital	33 (77)
Level	
Tertiary	33 (77)
Secondary-local	3 (7)
Not specified	7 (16)
Health care system	
Public	37 (86)
Private	6 (14)
Department responsible	
Cardiology	41 (96)
Other	1 (2)
Pediatric center	1 (2)
Cardiac surgery	32 (74)

Among the material resources of the electrophysiology laboratories, it is significant that 33% of the centers (n=14) had a digital radiology room. This room was dedicated exclusively to performing electrophysiology procedures in 58% (n=25) of laboratories. The median number of days of the week dedicated to electrophysiology was 3 days (range, 1 to 5 days). In more than half of the rooms, definitive pacemaker (60%; n=26) and automatic defibrillator (56%; n=24) implantations were scheduled. On the other hand, in 58% of the rooms (n=25), scheduled external electrical cardioversions were performed. In 3 rooms, scheduled internal electrical cardioversions were carried out, in 8, implantation of event recorders, and in 7, tilt-table studies.

Intracavitary signals were recorded on digital polygraphs in all laboratories. Nevertheless, only 26% of the centers (n=11) had non-fluoroscopic intracardiac navigation systems,<sup>7</sup> CARTO<sup>®</sup> systems,<sup>3</sup> LOCALISA<sup>®</sup>, and 1 ENSITE<sup>®</sup>. Four laboratories also had intracardiac echocardiography. Catheter ablation was performed in all laboratories by radiofrequency, and there was a cryoablation center.

Human resources differed depending on whether the center was private or public. Private centers, with the exception of one, did not have research fellows or resident physicians, and the mean number of staff physicians was  $1.8\pm0.7$  (range, 1-3). The human resources of the publicly financed centers are shown in Table 2. In public centers, the mean number of physicians working in the electrophysiology laboratory was  $2.2\pm0.6$  (range, 1-4). Nevertheless, the number of physicians who worked full-time in the electrophysiology laboratory was lower ( $1.6\pm0.9$  per center). In 63% of the centers (22 of 35 that completed this item), two or more full-time staff physicians worked in the electrophysiology laboratory. Eleven centers also had research fellows. As far as auxiliary personnel are concer-

Table 2. Human resources of the laboratories of
public hospital centers participating in the National
Registry of Catheter Ablation of 2001

	Mean	Range	Sum	
Physicians (n=37)	2.2±0.6	1-4	80	
Full-time (n=35)	1.6±0.9	0-4	57	
No. of research fellows (n=37)	0.6±1.3	0-7	21	
No. of resident physicians (n=35)	1±1.5	0-2	36	
No. of RN (n=36)	1.5±0.5	1-2	54	
No. ARS (n=2)			2	
No. of auxiliary RNs (n=29)	0.7±0.5	0-2	22	

N indicates number of centers that responded; RN, registered nurses; ARS, assistant radiology specialist.

ned, the mean number of nurses was  $1.5\pm0.5$  per center, and 20 centers had at least two nurses working; the mean number of assistant nurses was  $0.7\pm0.5$ , and only 2 centers had a radiology specialist.

#### Laboratory practices and general results

Most of the laboratories (n=39) used heparin anticoagulation in the ablation procedures that were carried out by an arterial and/or transeptal approach, whereas only 3 used it in ablation procedures carried out by a venous approach, and 2 in diagnostic electrophysiological studies. The mean interval after an effective radiofrequency application in which a procedure was considered successful was  $27\pm6$  min, in 30 laboratories the interval was at least 30 min, and in 9 laboratories, less than 30 min (10, 15, or 20 min).

The total number of diagnostic electrophysiological studies made in 2001 and reported by 36 centers was 6480, a mean of 185±131 studies per center (median, 152; range, 9-725). The total number of ablation procedures performed in 2001 and reported by 41 centers was 4374 (results obtained in 41 centers), which is equivalent to 106±84 procedures per center (median, 89; range, 6-496). The distribution of the number of procedures per laboratory is shown in Figure 1. The overall success rate of catheter ablation procedures was 93%, the complication rate was greater than 1.5%, and the mortality rate was 0.1% (n=4). Two patients died after an ablation procedure on the atrioventricular conduction system, one of them after ablation of the cavotricuspid isthmus and the other after ablation for postinfarction ventricular tachycardia.

#### Results by arrhythmic substrate/mechanism

Thirty-six centers reported information on results by arrhythmic substrate or mechanism treated, involving 3829 patients who underwent a total of 3969 ablation procedures. The substrate treated (Figure 2) was intranodal tachycardia, followed by accessory pathways,



Fig. 1. Number of electrophysiology laboratories in the National Registry in relation to the number of catheter ablation procedures carried out in 2001.



Fig. 2. Relative frequency of different arrhythmic substrates/mechanisms treated by catheter ablation in Spain in 2001. CTI indicates cavotricuspid isthmus; AVN, atrioventricular conduction/node; AT, macroreentrant atrial tachycardia-atypical atrial flutter; INT, intranodal tachycardia; VT, ventricular tachycardia; ACP, accessory pathways.

cavotricuspid isthmus, and ablation of the atrioventricular conduction system. Less frequent procedures, performed in similar percentages of patients, were ablation of focal atrial tachycardia, idiopathic ventricular tachycardia, and postinfarction ventricular tachycardia. The substrates treated least frequently were atrial fibrillation, macroreentrant atrial tachycardia/atypical atrial flutter, and ventricular tachycardia due to structural heart disease without previous myocardial infarction. The mean number of different types of substrates/mechanisms treated in a single center (Figure 3) was  $7\pm2$  (median, 7; range, 3-10). Only 6 centers (17%) treated all the substrates analyzed. The rates of success and major complications in relation to the arrhythmic substrate/mechanism treated are shown in Table 3 and in Figures 4 and 5.

#### Intranodal tachycardia

One thousand three hundred and twenty-seven ablation procedures were performed in 1303 patients at 35 centers, a mean of  $37\pm32$  patients per center (range, 4-187). The peak number of inducible nodal echoes finally used to define a procedure as successful was  $1.5\pm0.7$  (range, 0-3). All procedures were performed with conventional ablation catheters, except for two in which an 8-mm distal electrode catheter was used.

The number of patients successfully treated was 1291 (99%). Eight patients (0.6%) suffered major complications, half of them (0.3%) due to unintentional atrioventricular block. No deaths occurred. All the centers had a success rate of more than 90%. In 22 centers (63%), a success rate of 100% with no complications was achieved, whereas 26 centers (74%) reported either a 110% success rate or no complications.

#### Accessory pathways

Thirty-four centers reported 1140 ablation procedures in 1084 patients, a mean of  $32\pm24$  patients per center (range, 4-136). The most frequent accessory pathway location was the left free wall (n=547; 54%), followed by the lower paraseptal region (n=245; 24%), right free wall (n=139; 14%), and perihisian region (n=78; 8%). Unconventional catheters were used in 42 procedures (8-mm distal electrode catheter in 15 patients, irrigated-tip catheter in 24 patients), and a non-fluoroscopic navigation system in 3 procedures.

The intervention was successful in 1007 patients (93%) and major complications occurred in 17 (1.6%), the most frequent being vascular arterial complications (n=9). There were no deaths. The success rates in relation to accessory pathway location were 97% in the left free wall; 87% in the lower paraseptal; 93% in the right free wall, and 81% perihisian. A success rate of 90% or more was achieved in 23 centers (68%), no complications occurred in 22 centers (65%), and 16 centers (47%) had success rates of 90% or more without complications.

#### Cavotricuspid isthmus

Thirty-five centers performed 758 procedures in 718 patients, a mean of  $20\pm20$  patients per center (range, 1-79). The type of flutter treated was differentiated in 32 centers: counterclockwise in 567 patients, clockwise in 78 patients, and inferior vena cava in 22 patients.



Fig. 3. Number of electrophysiology laboratories of the National Registry in relation to the number of different arrhythmic substrates/mechanisms treated by catheter ablation in 2001.



Fig. 4. Success rate of catheter ablation in Spain according to the arrhythmic substrate/mechanism treated in 2001. AF indicates atrial fibrillation; FAT, focal atrial tachycardia; VT-I, idiopathic ventricular tachycardia; VT-AMI, reentrant ventricular tachycardia associated with post-myocardial infarction scar; VT-NAMI, reentrant ventricular tachycardia not associated with post-myocardial infarction scar; other abbreviations as in Figure 2.

An unconventional ablation catheter was used in 590 procedures, generally an 8-mm distal electrode catheter (n=423), followed by an irrigated-tip catheter (n=150). A non-fluoroscopic navigation system was used in 12 patients.

The procedure was successful in 670 patients (93%) and complications occurred in 9 (1.2%). The most frequent complication was cerebrovascular accident/transient ischemic event (n=4), followed by 2 vascular

	Success rate			Complication rate		
	Mean	Median	Range	Mean	Median	Range
INT	99±2	100	94-100	0.76±1.6	0	0-5.9
ACP	91±7	92	67-100	2.4±4.2	0	0-16.6
AVN	98±7	100	67-100	1±3.5	0	0-20
СТІ	93±9	100	68-100	0.8±2.5	0	0-12
FAT	80±29	100	0-100	0		
AT	48±11	53	0-100	11±27	0	0-100
AF	57±47	84	0-100	31±43	10	0-100
VT-I	76±34	87.5	0-100	1.7±9	0	0-50
VT-AMI	70±28	72	0-100	3.8±13	0	0-60
VT-NAMI	69±34	71	0-100	6±15	0	0-50

Table 3. Results of catheter ablation according to the arrhythmic substrate/mechanism treated in the National
Registry of Catheter Ablation of 2001. The mean of each center is averaged

CTI indicates cavotricuspid isthmus; AF, atrial fibrillation; AVN, atrioventricular conduction/node; AT, macroreentrant atrial tachycardia-atypical atrial flutter; FAT, focal atrial tachycardia; INT, intranodal tachycardia; VT-I, idiopathic ventricular tachycardia; VT-AMI, reentrant ventricular tachycardia associated to post-myocardial infarction scar; VT-NAMI, reentrant ventricular tachycardia not associated to post-myocardial infarction scar; ACP, accessory pathways.



**Fig. 5.** Rate of major complications of catheter ablation in Spain in relation to the arrhythmic substrate/mechanism treated, in 2001. Abbreviations as in Figure 4.

complications, complete atrioventricular block, and pericardial effusion. One patient died after the procedure. A success rate of 90% or more was obtained in 23 centers (66%) and there were no complications in 29 (85%). Eighteen centers (53%) had a 90% or better success rate without complications.

#### Atrioventricular conduction

Ablation of the atrioventricular conduction system was attempted in 218 procedures in 211 patients in 31 centers. In each center,  $6\pm5$  patients were treated (range, 1-18). In 17 patients, an unconventional catheter was used (in 15, an 8-mm distal electrode, and in 2, an irrigated-tip catheter).

The procedure was successful in 208 patients (98%) and there were 3 (1.4%) major complications: 2 deaths

and 1 vascular complication. A success rate of 100% was obtained in 29 centers (93%) and there were no complications in 27 centers (93%). Twenty-six centers (90%) had 100% success without complications.

#### Focal atrial tachycardia

One hundred thirty-seven procedures were performed in 124 patients ( $4\pm3$  patients per center; range, 1-16) at 30 centers. An irrigated-tip catheter was used in 3 patients and an 8-mm distal electrode catheter in 1 patient. A system of non-fluoroscopic navigation was used in 1 patient.

The procedure was successful in 102 patients (82%) and no major complication occurred. Successful results were obtained in 83% of the tachycardias located in the right atrium (n=95), versus 71% of the tachycardias located in the left atrium (n=21)(*P*=NS).

# Macroreentrant atrial tachycardia/atypical atrial flutter

Ablation of this substrate was attempted in only 14 centers, where 45 procedures were carried out in 43 patients, equivalent to  $3\pm 3$  patients per center (range, 1-9). In 30 patients, the right atrium was treated, and in 14, the left atrium. Eleven centers reported the presence of heart disease (n=19) and/or previous cardiac surgery (n=14) in some of their patients. In 22 procedures, an unconventional ablation catheter was used (in 14, an 8-mm distal electrode catheter and in 2, an irrigated-tip catheter). A non-fluoroscopic navigation system was used in 6 patients.

The procedure was successful in 20 patients (46%) and complications occurred in 5 (12%). The success rate was 57% for tachycardias located in the right atrium and 21% for tachycardias in the left atrium (P<.05). The most frequent complications were vascu-

lar (arterial in 2 patients and venous in 1). One patient had a cardiac tamponade and 1 patient had an embolism.

#### Atrial fibrillation

This substrate was treated in 10 centers, although only 8 contributed sufficient data for analysis. Fortysix procedures were performed in 43 patients ( $5\pm7$  per center; range, 1-21). The left atrium was treated in 43 procedures and the right atrium in 3.

The procedure was successful in 33 patients (77%) and complications occurred in 7 (16%), in 2 cases cerebrovascular accident/transient ischemic accident and in 2, infarction/transient myocardial ischemia.

#### Idiopathic ventricular tachycardia

In 30 centers, 125 procedures were carried out in 115 patients, equivalent to  $4\pm 2$  patients per center (range, 1-12). The right ventricular outflow tract was the most frequent location (76%; n=88), followed by fascicular (14%; n=16), left ventricular outflow tract (4%; n=4), and other locations (6%; n=7). In 3 procedures, 8-mm distal electrode catheters were used, and in 2, irrigated-tip catheters.

The procedure was successful in 90 patients (78%), with a single pericardial effusion as the only major complication (0.8%). The success rate was 74% in tachycardia of the right ventricular outflow tract and 81% in tachycardia fascicular.

# Ventricular tachycardia associated with postinfarction scar

This substrate was treated in 24 centers, where 125 procedures were performed in 99 patients ( $4\pm3$ ; range, 1-13). In 21 procedures, 8-mm distal electrode catheters were used, and in 20, irrigated-tip catheters. A non-fluoroscopic navigation system was used in 27 procedures.

The procedure was successful in 70 patients (71%) and complications appeared in 4 patients (4%): 2 arterial vascular complications, 1 heart failure, and 1 death after a procedure.

# Macroreentrant ventricular tachycardia not associated to postinfarction scar

This substrate was treated only in 16 centers, with 48 procedures performed in 43 patients,  $3\pm1$  patients per center (range, 1-6). Fifteen ventricular tachycardias due to a branch-branch reentry mechanism were treated. Seventeen patients had dilated idiopathic cardiomyopathy and 12 patients had an arrhythmogenic right ventricular dysplasia in the 12 centers that com-

pleted this data field.

The procedure was successful in 29 patients (67%) and complications appeared in 2 patients (5%): 1 arterial vascular complication and 1 atrioventricular block.

## DISCUSSION

A national registry of catheter ablation has diverse uses. The first, and probably the most evident, is that it is the most useful reference for an electrophysiology laboratory to evaluate its activity, because registries are usually more representative of local reality than studies published by one or more centers, which often are biased in favor of the procedure. On the other hand, obtaining data from a large number of procedures made over a limited period of time allows us to more accurately understand the possible influence of technological innovations on results. Finally, information from registries can and should be useful for health care managers to confirm how and with what results a given therapy is being used for the needs of health care planning.<sup>11,12</sup> These uses have been recognized by the SEC, which has long prepared annual registries of activity through the Working Groups on and Hemodynamics, Heart Transplantation, Pacemakers, which are published in the REVISTA ESPAÑOLA DE CARDIOLOGÍA.

## Comparison with previous registries

Information available on catheter ablation in Spain has been limited until now. In 1994, a panel of experts of the Working Group on Electrocardiology and Arrhythmias of the SEC reported<sup>6</sup> on the number of electrophysiology laboratories in Spain (n=12) and the number of ablation procedures (n=600) that were carried out in 1992. The report also indicated that the number of centers could be insufficient in the future, given the expectations for growth in other countries. Later, the first registry of the activity of the Working Group on Electrocardiology and Arrhythmias for 1995 was published.<sup>7</sup> This registry was prepared by distributing a questionnaire where the number of ablation procedures was recorded, but not their results. The registry showed that in 1995 there were 29 centers in Spain, both public and private, which carried out a mean of 78±66 ablation procedures per center. Finally, the Working Group on Arrhythmias of the Sociedad Andaluza de Cardiología prepared a retrospective registry of four centers that inquired about the activity and results obtained in 2000.8 However, the activity of a significant number of centers in this autonomic community (33%) was not recorded in the study.

On the other hand, information available on catheter ablation in other countries is limited. As usual, the most complete information comes from the U.S., where the North American Society of Pacing and Electrophysiology (NASPE) has been compiling retrospective registries since 1989, although only two of them have information about results.<sup>13,14</sup> In 2000, NASPE published the first and, until now, the only prospective national registry of catheter ablation.<sup>15</sup> In Europe, the Portuguese Society of Cardiology recently reported the number (n=456) and type of ablation procedures performed at 9 centers, although it does not indicate what percentage of the overall number of centers this figure represents.<sup>16</sup> This registry did not report the success or complication rates. Finally, other registries have been published that evaluate the ablation of a specific substrate, like the atrioventricular node,<sup>17</sup> or ablation in a particular group of patients, like children and adolescents.<sup>18</sup>

The success of a registry arises fundamentally from the degree of participation of the hospital centers where the procedure under study is carried out. On the other hand, a registry in which results are analyzed is more useful than one that only reports on the number of procedures. Participation in the National Registry on Catheter Ablation in 2001 was 90%, much greater than in the two retrospective registries of the NASPE mentioned above (which had a participation of about 10% and 7%, respectively).<sup>13,15</sup> In the registries of the Section in 1995<sup>7</sup> and the registry of the Portuguese Society of Cardiology,<sup>15</sup> it is not clear that participation was total, since they did not report on whether all the centers that made ablations had completed the survey. For this reason, it can be concluded that the results of the National Registry on Catheter Ablation of 2001 is representative of the true situation of this procedure in Spain.

# Material and human resources

The radiology room where ablation procedures were performed was also used to carry out another type of non-electrophysiological procedures in just under half of the centers (42%). This proportion has not varied significantly since 1995.<sup>7</sup> This circumstance is probably related with the mean number of days per week assigned for electrophysiological procedures, which was  $3.6\pm1.4$ . Only 16 centers carried out electrophysiological procedures every day of the week. Both variables—exclusive use of the radiology room for electrophysiology and days assigned to it—are positively related with a larger number of ablation procedures.

The polygraph equipment has improved with time because all of the centers had digital equipment in 2001, whereas fewer than half did in 1995.<sup>7</sup> Nonetheless, few centers have non-fluoroscopic intracardiac navigation systems, which facilitate the ablation of complex substrates like atrial fibrillation and ventricular tachycardia.<sup>19</sup>

Most of the public centers, 22 of the 35 (63%) that completed this item, had two or more physicians wor-

king full-time, a small increase with respect to the 10 of 21 centers (48%) that met this condition in 1995. Nonetheless, the mean number of physicians working full-time in laboratories of electrophysiology and arrhythmias was  $1.6\pm0.9$ , a figure that practically has not changed since 1995 ( $1.6\pm0.7$ ).<sup>7</sup>

# **Results and substrates treated**

This registry is important because the number of patients included (n=3783) is similar to that of the largest registries that have been published, like the prospective NASPE registry (n=3357)<sup>15</sup> and the MERFS study (n=4398).<sup>20</sup> However, as has been noted, it is more representative than either or these registries because most of the centers in Spain participated.

The success rate of catheter ablation in the present registry (93%) was similar to that reported in other registries and varied, as in other registries, with the substrate treated. More specifically, the success rate (97%) for ablation procedures performed on traditional «substrates» (intranodal tachycardia, accessory pathways, and atrioventricular conduction) was similar to that of the NASPE registry<sup>14</sup> of 1998 and the prospective study of Calkins et al.<sup>21</sup> The proportion of complex substrates treated can be considered relatively low.<sup>22</sup> Thus, nearly 70% of the ablation procedures were performed to treat tachycardias due to intranodal reentry by ablating accessory pathways or atrioventricular conduction. The success rate of ablation of the cavotricuspid isthmus was 90% or greater, similar to the results of most of the series that have been published. The generalized use of 8-mm distal electrode and irrigated-tip catheters (in more than 70% of procedures) could be an important factor.<sup>23,24</sup> The success rate of the ablation intervention was slightly higher than 80% in focal atrial tachycardia, slightly lower in atrial fibrillation, and appreciably lower in other atrial arrhythmias. These success rates are not comparable to those of other registries because this distinction was not made in other registries and because the present registry was developed using the new classification proposed by the Working Group on Arrhythmias of the European Society of Cardiology.<sup>10</sup> The success rate of the ablation of ventricular tachycardia was 73%, and varied with the type of tachycardia (67%-77%). In general, these results were similar to those of the NASPE registry<sup>15</sup> and to those of the prospective registry of ablation of ventricular tachycardia with irrigated-tip catheters in patients with heart disease.25

The rate of major complications was acceptable (1.5%), similar to that obtained in other registries and lower than in the MERFS study (5.1%).<sup>20</sup> Some of the complications were associated with the type of substrate treated, such as atrioventricular block, in which

4 of the 6 complications took place while attempting the ablation of an intranodal tachycardia. The incidence of this complication in the ablation of this substrate was 0.3%, slightly lower than in the NASPE registry (0.7%) and clearly lower than in the MERFS registry (5.1%). It was significant, however, that atrioventricular block did not occur in any patient who underwent ablation of a perihisian accessory pathway. Arterial vascular complications (9 of 14 patients) and pericardial effusion/cardiac tamponade occurred more frequently (4 of 7 patients) in ablation procedures on accessory pathways. Ablation procedures for cavotricuspid isthmus and atrial fibrillation were the only ones that presented transient cerebrovascular or ischemic accidents, whose determinant factors could be the catheterization technique and peri-procedure anticoagulation policy. Likewise, the occurrence of coronary ischemic events in ablation procedures for atrial fibrillation was noteworthy, as this complication did not occur in attempted ablation of other substrates. Although the causes can vary, the most probable cause could be an inadequate technique in the management of vascular sheaths and catheters in the left atrium, since this complication has also been described in percutaneous closure of atrial septal defects.<sup>26</sup>

The mortality (0.1%) was slightly higher than in the NASPE registry<sup>15</sup> (0.03%) and similar to that of the MERFS registry (0.1%).<sup>20</sup> The study by Calkins et al<sup>21</sup> revealed the existence of three predictors of the risk of death: presence of structural heart disease, impaired left ventricular ejection fraction, and ablation of the atrioventricular conduction system were predictors present in the patients of this registry who died. Finally, it is important to note the absence of mortality in ablation procedures performed on substrates that are usually not associated with structural heart disease, like intranodal tachycardia, accessory pathways, focal atrial tachycardia, atrial fibrillation, and idiopathic ventricular tachycardia.

## Limitations

The main limitation of any registry is participation, which can limit its representativity. Nevertheless, the representativity of the present registry is ensured by a participation of about 90% of possible centers. However, some centers with a smaller volume of work did not participate in the SEC registry, probably because the procedures were carried out by physicians who were not specialists in cardiology in most of them.

# CONCLUSIONS

The National Registry of Catheter Ablation of 2001

has compiled one of the largest samples to be published in the international literature on ablation procedures and can be considered representative of the activity and results of this procedure in Spain. The effectiveness of this procedure in Spain is high (93%), and the rate of major complications (1.5%) and mortality (0.1%) is low.

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# ANNEX 1. National Registry on Ablation 2001

		Cod	le of center:		
Hospital:					
Demographic data					
Address:					
Province:	Zip c				
Telephone:	Extension:			Fax:	
Responsible physician, data:					
National Registry on Ablation 2001 Code of center:					
Autonomic community:					
Hospital type*: University / Tertiary / Secondary- Public / Private / Military Department: Cardiology department / Cardiology Cardiovascular surgery at center:			epartment) / Intensi	ve care / Other	
No. of inhabitants in the hospital district: No. of patients on ablation waiting list on 31/12/01:					
No. of patients outside district on ablation waiting list	on 31/12/01:				
*Circle all applicable options.					
Laboratory personnel					
No. of staff physicians*:		of full-time staff ph	ysicians*:		
No. of research fellows/grant holders/year:					
No. of resident physicians/year:		one every 6 mont	hs would be: 1/year	·)	
No. of assistant nurses/RNs:					
No. of ARS:					
No. of auxiliary assistant nurses/RNs:					
*To avoid counting the same physician in more than one center ( $\mu$ (e.g., two physicians, one of which also works in a private center:		vity), indicate in parent	thesis the number of phy	ysicians already counter	d in another center
Laboratory information					
Number and type of radiology rooms		Conventional _	/ Digital		
Room dedicated exclusively to electrophysiology/pace	makers:		Yes / No		
Days of week used for electrophysiology:					
Are pacemakers implanted in the room?			Yes / No		
Are automatic defibrillators implanted in the room?			Yes / No		
Is scheduled cardioversion performed in the room?			Yes / No		
Other procedures performed in the room:					
Digitized polygraph:			Yes / No		
No. of recording channels:					
Polygraph make and model:					
Pacer brand and model:					
Special techniques available					
Non-fluoroscopic intracardiac navigation:	🗆 Carto	🗆 Ensite	🗆 Localisa	□ Other	
Describe:					
Intracardiac echography:			Yes / No		
Cryoablation:			Yes / No		
Ultrasound ablation:			Yes / No		
Others:					
Diagnostic activity					
Total no. of diagnostic electrophysiology procedures*	:				
No. of electrophysiological studies for syncope/bradya					
No. of electrophysiological studies for supraventricula					
No. of electrophysiological studies for supraventicular tach					
No. of other electrophysiological studies for ventricular tach	yourula.				
No. of studies to evaluate defibrillation by implantable	automatic dofi	hrillator:			
		simulor.			
*Procedures performed before ablation are considered diagnostic					

The annex continues in next page

#### ANNEX 1. Continuation

Therapeutic activity	
Total no. of patients treated by ablation:	
Total no. of ablation procedures:	
No. of ablation procedures aside from first attempt:	
No. of substrates treated by ablation:	
Total no. of successful ablation procedures:	
Total no. of procedures performed for recurrence:	
Total no. of complications:	
No. of pacemaker implantations/replacements:	/
No. of automatic defibrillator implantations/replacements:	/
No. of cardioversions scheduled in EPS room/elsewhere:	/
Laboratory policy	
IV heparinization for diagnostic electrophysiology studies:	Yes / No
IV heparinization for transvenous ablation:	Yes / No
IV heparinization for arterial/transeptal ablation:	Yes / No
Usual delay after successful radiofrequency application:	

#### Comments

Ablations by substrate (complete an item for each of the following substrates: intranodal tachycardia, accessory AV pathways, AV conduction, focal atrial tachycardia, cavotricuspid isthmus, atypical atrial flutter/macroreentrant atrial tachycardia, atrial fibrillation, idiopathic ventricular tachycardia, macroreentrant ventricular tachycardia by postinfarction scar, macroreentrant ventricular tachycardia unassociated with postinfarction scar)

1.	No. of patients/procedures:	/
	No. of substrates treated by location:	/ / //
2.	No. of first procedures/successful non-first procedures:	/ No. of patients with successful outcome: _
	No. of successful procedures by location:	///
З.	No. of procedures in which a nonstandard ablation catheter was used:	
	a. 8-mm	
	b. Irrigated-tip	
	c. Cryoablation	
	d. Other (describe)	/
4.	No. of complications:	
	a. AVB requiring pacemaker	
	b. Venous/arterial vascular complications	/
	c. Pericardial effusion/cardiac tamponade	/
	d. Embolism/CVA/TIA	/
	e. AMI or ischemia	
	f. Congestive heart failure or pulmonary artery stenosis	
	g. Peri-procedure death	
	h. Other (describe)	
5.	No. of patients with recurrences:	Patients reviewed (approximation):%
6.	Comments:	

Write «0» in all numeric fields in which no procedure was performed or patient treated.

1. No. of patients/no. of procedures (proced.): number of patients undergoing one or more ablation procedures on each substrate/number of procedures performed on each substrate, including those performed for recurrences. No. of ACP/VT indicates number of accessory pathways/ventricular tachycardias in which ablation was attempted.

2. No. of first proced./successful non-first proced.: number of ablation procedures, differentiating between first procedures and successful procedures performed after failure of a first procedure or recurrence.

No. of patients with successful outcome: number of patients in which substrate ablation was finally successful without known recurrences. 3. No. of patients with recurrences: number of patients with a known clinical or electrocardiographic recurrence on a previously treated substrate (including patients successfully treated in later procedures).

No. of reviewed patients: approximate percentage of patients for which a reliable evaluation of procedure results at 6 months is available.

# ANNEX 2. Electrophysiology laboratories by autonomic communities and provinces participating in the National Registry on Catheter Ablation – 2001

**Comunidad Valenciana** 

#### Andalucía

Córdoba Hospital Reina Sofía Granada Hospital Virgen de las Nieves Málaga Hospital Virgen de la Victoria Sevilla Hospital de Valme Hospital Virgen del Rocío

#### Aragón

Zaragoza Hospital Clínico de Zaragoza Hospital Miguel Servet

Asturias Hospital Central de Asturias

#### Baleares

Hospital Son Dureta

#### Canarias

Gran Canaria Hospital Insular

#### Castilla-La Mancha Toledo

Hospital Virgen de la Salud

#### Castilla y León

León Hospital de León Valladolid Hospital Río Hortega Salamanca Hospital de Salamanca

#### Cataluña

Barcelona Ciudad Sanitaria de Bellvitge Hospital Clínic de Barcelona Hospital del Mar Hospital de la Santa Creu i Sant Pau Hospital Vall d'Hebron Centro Cardiovascular Sant Jordi\* Clínica Sagrada Familia\* Hospital Sant Joan de Deu\* Alicante Hospital General de Alicante Valencia Hospital General de Valencia Hospital Clínico de Valencia Galicia La Coruña Hospital Clínico de Santiago de Compostela Hospital Juan Canalejo Pontevedra Hospital Xeral Cies Madrid Clínica Puerta de Hierro Hospital 12 de Octubre Hospital de Alcorcón Hospital Clínico San Carlos Hospital de Getafe Hospital Gregorio Marañón Hospital La Paz Hospital Ramón y Cajal Clínica USP San Camilo\*

#### Murcia

Hospital Virgen de la Arrixaca

Clínica de la Zarzuela\*

#### Navarra

Clínica Universitaria de Navarra\* Hospital de Navarra

## País Vasco

Hospital de Basurto Hospital de Cruces

\*Centers with Principally private care.