ORIGINAL ARTICLE

CME

Antithrombotic Strategies in Atrial Fibrillation. The XIX CONAREC Registry

Estrategias antitrombóticas en fibrilación auricular. Registro CONAREC XIX

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ABSTRACT

Background: Atrial fibrillation (AF) represents the most common sustained arrhythmia. Treatment has evolved since the last survey performed in our setting, with a marked trend towards the use of anticoagulation therapy, and the development of new anticoagulation drugs. However, Argentina lacks updated data about antithrombotic therapy or the use of new oral anticoagulants (NOAC).
Objective: The aim of the study was to assess antithrombotic strategies in AF patients admitted for cardiovascular causes in centers with cardiology residency.
Methods: Between September and November 2013, 927 patients with at least one episode of atrial fibrillation within the last 12 months and hospitalized for cardiovascular causes in centers with cardiology residency were enrolled in the study.
Results: Median values (interquartile range) of CHADS2 and CHA2DS2-VASc and HASBLED scores were: 2 (1-3), 3 (2-4) and 1 (1-2), respectively. At admission, only 54% of patients with history of AF without contraindication and CHADS2 1 (n=253) received anticoagulation therapy; 89% with dicoumarinic agents and only 26.5% in the therapeutic range. At discharge, anticoagulation rates increased up to 70%, and including all patients without contraindication, 59.74% received anticoagulation therapy at discharge. Aspirin as single strategy was used in 26% of patients. The major reasons for not prescribing anticoagulants included contraindications (36%), social limitations (21%) and unknown reasons (14.8%). Stroke [OR 2.18 (95% CI 1.02-4.67); p=0.04], age [OR 1.01 (95% CI 1-1.03); p=0.009], hypertension [OR 1.54 (95% CI 0.99-2.41); p=0.05], heart failure [OR 1.68 (95% CI 1.1-2.55); p<0.01] and severe ventricular dysfunction [OR 4.99 (95% CI 1.71-14.55); p=0.003] were independent predictors of anticoagulation. High level of education was a predictor for the use of NOAC (OR 1.84, 95% CI 1.08-3.14).
Conclusions: The population of this survey performed in centers with cardiology residency has moderate thromboembolic risk and low bleeding risk. The rate of oral anticoagulation increased during hospitalization and high level of education was associated with the indication of NOAC.

Key words: Atrial Fibrillation - Anticoagulation - Hemorrhage - Stroke

RESUMEN

Introducción: La fibrilación auricular (FA) representa la arritmia sostenida más frecuente. Desde el último relevamiento en nuestro medio, la concepción del tratamiento ha cambiado, con una marcada tendencia hacia la anticoagulación de los pacientes, y han surgido nuevas drogas anticoagulantes. No obstante ello, no existen datos actualizados en la Argentina sobre el tratamiento antitrombótico ni del uso de nuevos anticoagulantes orales (NACO).
Objetivos: Evaluar las estrategias antitrombóticas en la FA en pacientes internados por una causa cardiovascular en centros con residencia de cardiología.
Material y métodos: Entre septiembre y noviembre de 2013 se registraron 927 pacientes con al menos un episodio de FA en los 12 meses previos e internados por una causa cardiovascular en centros con residencia de cardiología.
Resultados: las medianas (rango intercuartil) de CHADS2, CHA2DS2-VASc y HASBLED fueron de 2 (1-3), 3 (2-4) y 1 (1-2), respectivamente. Al ingreso solo recibían anticoagulantes el 54% de los pacientes con antecedente de FA sin contraindicación y CHADS2

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1 (n = 253), con dicumarínicos el 89% y solo el 26,5% en rango terapéutico. En ellos, la tasa de anticoagulación al alta subió al 70%. Incluyendo a todos los pacientes sin contraindicación al alta, el 59,74% recibió anticoagulación. La aspirina como única estrategia fue empleada en el 26%. Los motivos para no anticoagular fueron contraindicaciones (36%), limitaciones sociales (21%) y no aclarados en el 14,8%. Fueron predictores independientes de anticoagulación en pacientes sin contraindicaciones: el accidente cerebrovascular [OR 2,18 (IC 95% 1,02-4,67); p = 0,04], la edad [OR 1,01 (IC 95% 1-1,03); p = 0,009], la hipertensión arterial [OR 1,54 (IC 95% 0,99-2,41); p = 0,05], la insuficiencia cardíaca [OR 1,68 (1,1-2,55); p < 0,01] y la disfunción ventricular grave [OR 4,99 (IC 95% 1,71-14,55); p = 0,003]. El alto nivel educativo fue predictor de NACO (OR 1,84, IC 95% 1,08-3,14).
Conclusiones: La población de este registro realizado en centros con residencia de cardiología presenta un riesgo tromboembólico moderado y un riesgo hemorrágico bajo. Durante la internación se observó un aumento de las tasas del uso de anticoagulantes orales y el nivel educativo fue un factor asociado con la indicación de NACO.

Palabras clave: Fibrilación auricular - Anticoagulación - Hemorragia - Accidente cerebrovascular

Abbreviations

AF	Atrial fibrillation	**ECG**	Electrocardiogram
AFL	Atrial flutter	**NOAC**	New oral anticoagulants

INTRODUCTION

Atrial fibrillation (AF) is the most frequent sustained arrhythmia. According to international registries it is estimated that about 1-2% of the world population suffers from this disease and its prevalence is even higher with increasing age, reaching 15% in the population over 80 years of age. (1, 2)

The presence of AF doubles mortality rate (3, 4) even adjusted for other causes, with a fivefold increase in the risk of stroke, which is often fatal. (5)

Due to the progressive increase in life expectancy, the prevalence of AF in the overall United States population could reach 5.6 billion people by 2050. (1)

In our setting, 13 years have elapsed since the publication of the last survey on AF management. (6) Thereafter, the concept of treatment has changed, and with the development of new anticoagulant drugs there is a marked trend towards patient anticoagulation. Moreover, ablation has gained a predominant role in the treatment.

The benefit of oral anticoagulation with vitamin K inhibitors for the prevention of thromboembolic events has been clearly demonstrated, with approximately 64% of stroke reduction and a clear relationship between adherence to treatment, time in therapeutic range and events. (7)

However, Argentina has no updated data on the characteristics of patients with AF, management strategies and oral anticoagulation.

Furthermore, new oral anticoagulants (NOAC) have emerged as an interesting option to consider in certain populations of patients with AF. Therefore, there is need of epidemiological data in the general population beyond large randomized trials.

The main aim of the XIX CONAREC registry is to survey the current status of AF in Argentina, focusing on the antithrombotic approach

METHODS

The XIX CONAREC registry is a multicenter, cross-sectional observational study conducted in cardiology services with residency affiliated to the Argentine Council of Residents in Cardiology (CONAREC). Patients ≥18 years hospitalized for cardiovascular causes and presenting with documented AF and/or atrial flutter (AFL) or a previous history of these conditions in the past 12 months (surface ECG, Holter, telemetry) were included in the study. Patients with AF/AFL in the postoperative period of cardiac surgery were excluded from the study. The primary end-point sought to identify the antithrombotic strategies adopted by the treating physicians during hospitalization in the cardiology service or coronary care unit. The secondary end-point sought to detect the strategies adopted to control rhythm and heart rate. Patient recruitment was consecutively performed from September 16 to November 16, 2013, and follow-up was limited to hospitalization. No patient personal data was registered.

Data collection and validation

Data collection for each patient was obtained through personal interviews during hospitalization and was in charge of a cardiology resident.

Data were loaded online through the www.conarec.org page in an electronic case report form (eCRF) specially designed with unique access via an individual password. Data were immediately and automatically incorporated into the central database.

The information was evaluated every 15 days and the officer in charge of the center was contacted in case of inconsistencies. Definitions have been previously published (8-9). The analysis of CHADS2, CHA2DS2-VASc thrombotic event and HASBLED bleeding risk scores was independently performed from their constitutive variables. Classification of AF type as a function of time of evolution and therapeutic strategy was independently adjudicated as defined in the protocol.

Cross-auditing was randomly performed to 20% of centers and those presenting with a loading rate <1 patient/month were excluded from the study.

Statistical Analysis

Patients with AFL were excluded from the analysis. Discrete variables are presented as percentage and continuous variables as mean±standard deviation if the distribution was normal or as median and interquartile range if they were

not normal. Variables were compared using Student's t test, Wilcoxon test, chi -square test or Fisher´s exact test, as appropriate.

A multiple logistic regression analysis was performed to determine which factors were independently associated with indication for anticoagulation and another to assess novel anticoagulant predictors. Variables that in the univariate analysis were associated with events with p <0.10 were incorpporated in the model. A p value <0.05 was considered as statistically significant and the Epi Info 2000® software package was used for statistical analysis.

Ethical considerations

The protocol was revised and approved by the Argentine Society of Cardiology Ethical Board

RESULTS

Patient Characteristics

The study included 927 AF patients from 59 centers, distributed in the following regions: Buenos Aires/CABA 55%, Center 28%, Argentine North 12%, New Cuyo 4% and Patagonia 1%. Patient baseline characteristics are listed in Table 1. Median age was 73 years (64-81) and 59% of patients were men. Atrial fibrillation showed no valvular etiology in 93% of cases. History of stroke was found in 9.8% of cases (84% with ischemic etiology) and transient ischemic attack in 3%. The estimated CHADS2 score for thromboembolic risk had a median of 2 (1-3) and the CHA2DS2-VASc score a median of 3 (2-4). In 9.5% of cases, no risk factor was detected by CHADS2 and this value was reduced to 4% using CHA2DS2-VASc. The risk of bleeding assessed by HASBLED presented a median of 1 (1-2).

Table 1. Baseline population characteristics

Age, years*	73	64-81
Weight, kg*	80	70-90
Heart rate, bpm*	106	76-140
	n	%
Female gender	382	41.2
Valvular AF	60	6.5
First episode of AF	261	41.6
Hypertension	724	78.4
Diabetes	153	16.9
AMI	140	15.3
Stroke	89	9.8
TIA	23	2.9
Heart failure	326	35.6
Moderate-severe LVEF	193	24.87
Peripheral vascular disease	114	12.6
Liver dysfunction	22	2.4
Alcohol consumption	73	8
Renal failure	138	15.1
Cancer	74	8.1
Dyspepsia	72	7.9
Anemia	156	17
Labile INR	32	4.2
Major bleeding	27	3
Mild bleeding	40	4.4
Hemorrhagic stroke	5	0.6
$CHADS_2$*	2	(1-3)
CHA_2DS_2-VASc*	3	(2-4)
HASBLED*	1	(1-2)

AF: Atrial fibrilation. AMI: Acute myocardial infarction. TIA: Transient ischemic attack. LVEF: Left ventricular ejection fraction. INR: International Normalized Ratio. *median (interquartile range)

Hospitalization

Patients had medical coverage insurance in 85% of cases: social security in 49%, prepaid coverage in 21% and PAMI in 15%. Eleven percent of patients had not completed primary education. The most frequent reasons for hospitalization were AF in 37% of cases, decompensated heart failure in 31% and coronary artery disease in 8.5%, with a median hospital stay of 4 days (1, 5-7). Transthoracic echocardiography was performed during hospitalization in 83% of patients, with estimated moderate to severe left ventricular systolic dysfunction in 25% of cases; 12% of patients underwent transesophageal echocardiography.

Eighty-seven percent of patients presented with symptoms (66% with EHRA III/IV). According to Gallagher´s AF classification, (10) first episode was found in 42% of cases, paroxysmal in 13.5%, persistent in 17.5% and permanent in 27%. Overall mortality was 6% and 0.4% in patients exclusively hospitalized for AF. In the admission electrocardiogram 85% of patients presented with AF, 13% with sinus rhythm and 2% with other ECG patterns.

Antithrombotic strategy

Patients with a history of non-valvular AF without contraindications and with CHADS2≥1 (n=253) were under anticoagulant therapy in 54% of cases (median CHADS2=2 [1-3]). They were mostly treated with dicoumarinic agents (89%, only 26.5% of which were in the therapeutic range on admission); the remaining 11% were treated with NOAC (dabigatran at doses of 110 and 150 mg every 12 hours, and rivaroxaban). At the time of this registry apixaban was not marketed.

In this selected population, anticoagulation rate increased significantly between admission and discharge from 54% to 70%, respectively [OR 1.98 (1.35-2.91)]; p <0.05] (Figure 1).

In 59.74% of cases, patients without contraindications received anticoagulant therapy at discharge (CHADS2 score of 0, 1 and ≥2 in 6.1%, 31.9% and 61.7% of these patients, respectively). Percutaneous

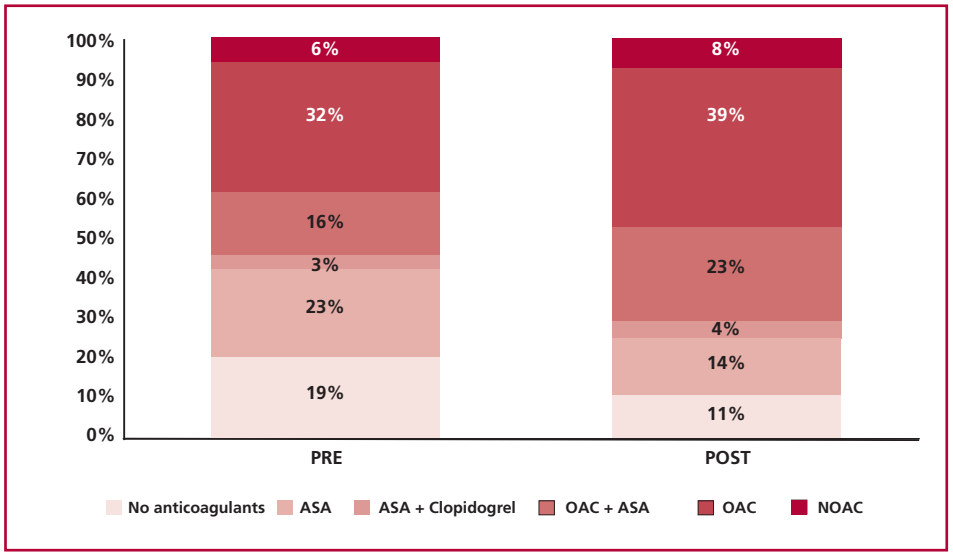


Fig. 1. Antithrombotic strategies in patients with history of atrial fibrillation with no contraindications and $CHADS_2 \geq 1$ (n=253). Significant increase of strategies, including anticoagulant agents, observed after hospitalization in a center with cardiology residency. (OR 1.98; p<0.01). OAC= Dicoumarinc agents. ASA=Aspirin, NOAC=New oral anticoagulants.

closure of left atrial appendage was made only in 0.4% of cases. The independent predictors associated with the use of anticoagulation in patients without contraindications were stroke, age, hypertension, heart failure and severe ventricular dysfunction (Table 2).

In our registry, the overall rate of ASA use at discharge was 26%, while only 23 patients (2.6%) received triple antithrombotic scheme.

New oral anticoagulants

Six percent of patients with history of AF received NOAC treatment. Several factors were associated with use of NOAC such as age, gender, renal dysfunction, weight, embolic risk, risk of bleeding, educational level, health coverage and concomitant use of aspirin. In the multiple logistic regression analysis (Table 3), adjusted by all the other factors, only high educational level was predictor of NOAC use (OR1.84, 95% CI 1.08-3.14). A strong association was also found between prepaid coverage and high educational level, the latter prevailing in the multivariate analysis. At discharge, the overall rate of NOAC was 16%, distributed in rivaroxaban (6.7%), and dabigatran 150 mg (5.7%) and 110 mg (3.5%).

No anticoagulation

Excluding patients who died in hospital, 351 patients (40%) were discharged without anticoagulation (Figure 2). The reasons were: contraindications (36%), social limitations (21%), and patient decision (8%). Nineteen percent of patients did not receive anticoagulation owing to low embolic risk score, and in 15% no reason was found for not indicating anticoagulation. A trend for not using anticoagulant therapy was observed in patients with coronary stent (see Table 2). No anticoagulation due only to old age was described as the most frequent relative contraindication.

Table 2. Multiple logistic regression analysis of predictors for anticoagulant use

	Odds Ratio	95% CI	p
Severe LVEF	4.99	1.71-14.55	0.003
Stroke	2.18	1.02-4.67	0.04
Heart failure	1.68	1.10-2.55	0.01
Hypertension	1.54	0.99-2.41	0.05
Renal failure	1.47	0.72-2.98	0.27
Diabetes	1.13	0.64-2.01	0.66
Female gender	1.07	0.7-1.63	0.72
Age	1.01	1-1.03	0.009
Stent	0.59	0.31-1.11	0.10

LVEF: Left ventricular ejection fraction

Supplementary data

Figure 3 shows anticoagulant therapy at discharge as a function of CHA2DS2-VASCc

DISCUSSION

The XIX CONAREC registry describes the updated characteristics of patients with AF hospitalized in centers with cardiology residency in Argentina. Moreover, this is the first Argentine registry including patients treated with NOAC.

As the registry was conducted in cardiology wards, it included patients with more comorbidities and with at least moderate thromboembolic risk as evidenced by median values of 2 and 3 in the CHADS2 and CHA2DS2-Vasc scores, respectively. However, anticoagulation rate in patients with prior AF and anticoagulant therapy indication was only 54%, increasing significantly to 70% at discharge. These results are superior to those obtained previously in our country

Table 3. Predictors of new anticoagulant indication

	Univariate analysis			Multiple regression analysis		
	OR	95% CI	p	OR	95% CI	p
Female gender	0.54	0.32-091	0.01			
CHA_2DS_2-VASc		.	<0.01			
HASBLED			<0.01			
Severe LVEF	1.91	1.06-3.57	0.018			
Aspirin	0.52	0.30-0.88	<0.01			
High educational level	1.82	1.1-3.01	<0.01	1.92	1.13-3.26	0.015
Old age	0.42	0.24-0.68	<0.01			
SevereCRF	0.37	0.11-1.23	0.04			

The only predictor in the multiple regression model was high educational level (complete secondary or university education). In a second adjustment after inclusion of health coverage, only educational level remained significant (see text). LVEF: Left ventricular ejection fraction. CRF: Chronic renal failure

Fig. 2. Main causes for not indicating oral anticoagulation (n=351). CI= contraindication.

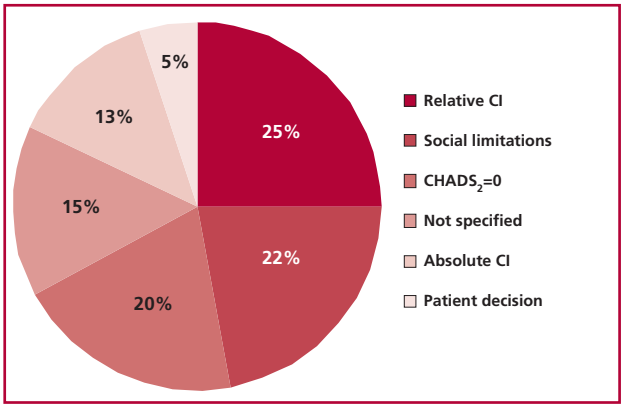
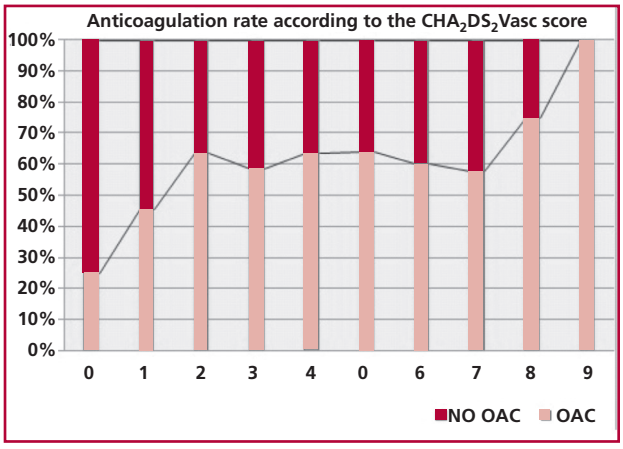


Fig. 3. Supplementary material. Anticoagulation at discharge according to the CHA2DS2Vasc score. OAC: Anticoagulation



with a total rate of 48.5% reported patients with anticoagulant use in the PENFACRA (6) registry, and are consistent with international data collected in registries such as the Euro Heart Survey on Atrial Fibrillation (11) but lower than in exclusively ambulatory AF registries such as the Orbit AF study. (12) This marks a clear trend favoring the use of antithrombotic strategies in AF in our country following current recommendations. On the other hand it shows the importance of hospitalization in a cardiology service, as previous registries have reported the relevant involvement of a cardiologist at the moment of indicating anticoagulant treatment compared to the intervention of a clinical or general practitioner. (6).

According to the present registry, the independent predictors to indicate anticoagulation in Argentina were: previous stroke, age, history of heart failure and left ventricular ejection fraction impairment, all of them contributing to thromboembolic risk scores used in daily practice, showing coherence and rationality in antithrombotic indications consistent with international data.

Of note, only 26% of patients with dicoumarinic anticoagulants were in the therapeutic range on admission, considering that this is a determinant factor of thromboembolism, bleeding and even death in patients treated with anticoagulant therapy (13). This result should be viewed with caution as it is a unique and defined value on patient admission and data were not collected during hospitalization or ambulatory follow-up. Most patients (49%) received acenocoumarol as vitamin K antagonist, whose pharmacokinetics and interactions are different from warfarin used in most registries and clinical trials.

In the last years, with the introduction of NOAC, the spectrum of possibilities has expanded turning the decision of indicating antithrombotic treatment even harder. As in the case of dicoumarinic agents, the rate of NOAC use increased after hospitalization in a cardiology ward. These drugs might be useful in specific groups, such as patients with difficulties in adherence or understanding the dicoumarinic scheme. However, the only independent predictor of NOAC at discharge was a high educational level, revealing a relationship between this variable and prepaid health coverage. It is possible that the current cost of these drugs has a

clear influence on prescription and that this distribution might change with time according to the economic and social situation.

Interestingly, despite the high thromboembolic risk, this was not a population at high risk of bleeding, presenting a median HASBLED of 1. This should favor the rate of anticoagulation. However about 35% of patients with no absolute contraindications and with CHA2DS2-Vasc≥2 and CHADS2≥1 are not anticoagulated despite having a net clinical benefit as demonstrated from these risk strata in favor of anticoagulation (14). Among the major causes of non-anticoagulation are social limitations and the patient's decision, barely modifiable from the cardiologist´s position.

However, excluding these two groups, there remains a considerable percentage of non-anticoagulated patients without absolute contraindications, old age being the most common cause in this group. As an isolated datum old age should not be a contraindication to anticoagulation, since the reduction of stroke risk exceeds the risk of bleeding (8-15), but there are different variables of a subjective nature such as fragility or unstable gait that in everyday practice lead to contraindicate anticoagulants.

Limitations

The XIX CONAREC registry exclusively included hospitalized patients evaluated in cardiology services. This entails three drawbacks; firstly the described population may not be representative of the general population of patients with AF in our country; secondly there is no patient follow-up data and thirdly it does not provide data on ambulatory patients exclusively with AF, who usually have fewer comorbidities, and hence, less risk. On the other hand, the inclusion of patients hospitalized for cardiovascular causes indicates that it is a heterogeneous population with a relatively high overall mortality not attributable exclusively to AF.

CONCLUSIONS

The XIX CONAREC registry provides updated information on the indication of oral anticoagulation therapy and the first results on the use of NOAC. The surveyed population has a moderate thromboembolic risk and low bleeding risk. Regarding previous data, the rate of anticoagulation in patients with high thromboembolic risk has increased. In turn, hospitalization in a center with cardiology residency has significantly raised the indication of anticoagulation in the population studied.

Nevertheless, a significant percentage of patients in Argentina are not anticoagulated without a clear justification.

Conflicts of interest

None declared

(See author´s conflicts of interest forms in the web / Supplementary Material)

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APPENDIX

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Sanatorio Güemes	Matias Grieco
Sanatorio Julio Mendez	Ignacio Garrido
Sanatorio Mitre	Diego Crippa
Sanatorio Sagrado Corazón	Carlos Luis Gonzalez
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Clinica Velez Sarsfield	Carlos Segura
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LA RIOJA	
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Instituto del Corazon - INCOR	Lisandro Ivan Metelsky
MENDOZA	
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Htal. el Carmen - Godoy Cruz	Soledad Tejera
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Sociedad Española de Socorros Mutuos	Saimon Sgarioni
NEUQUEN	
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SALTA	
Htal. San Bernardo	Julio Nuñez
SAN JUAN	
Hospital Marcial Quiroga	Alejandro Peñaloza Aviles
SANTA FE	
Clínica de Nefrologia y Enfermedades Cardiovasculares	Maria Jose Diez
Hospital Clemente Alvarez (Rosario)	Celeste Giuli
Hospital Español de Rosario	Ivan Gribaudo
Hospital Italiano Garibaldi de Rosario	Luciano Calvente
Hospital Provincial del Centenario (Rosario)	Rodolfo Leiva
Hospital Provincial de Rosario	Marcela Galuppo
Instituto Cardiovascular de Rosario	Miguel Hominal
Instituto De Cardiologia Dr. Sabathie (Rosario)	Marcos Cicerchia
IPC - Sagrada Familia	Mauro Storani
Sanatorio de la mujer	Claudio Marigo
Sanatorio Diagnóstico y Tratamiento	Victor Alfonso
Sanatorio Nosti (Rafaela)	Pamela Reyes
Sanatorio Mayo	Gonzalo Costa
Sanatorio los Alerces (Rosario)	Carolina Navarro
Sanatorio Los Arroyos (Rosario)	Romina Deganutto
Sanatorio Parque (Rosario)	Sabrina Juliá
Sanatorio Rosendo Garcia UOM (Rosario)	Valeria Cabrol
Sanatorio San Gerónimo	Santiago Vicario
Sanatorio Santa Fe	Marianela Colombo
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