# **Argentine Registry of Transesophageal Echocardiography**

## Registro argentino de ecocardiograma transesofágico

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#### **ABSTRACT**

Background: There is currently no data regarding the utilization of transesophageal echocardiography in Argentina.

Objective: The main purpose of this study was to evaluate the complication rate of transesophageal echocardiography in our country. Other objectives were to identify the characteristics of the laboratories, the operators' training level, the rate of sedation and/or anesthesia and the main reasons for its request, and to analyze the suitability of the indications and the contribution of the method to the clinical management of patients.

Methods: A prospective, multicenter registry was conducted of all the transesophageal echocardiographies performed in 46 centers in Argentina between November 2016 and September 2018.

Results: A total of 2,562 transesophageal echocardiograms were analyzed. Patients' mean age was  $61.4~(\pm 16)$  years and 61% were men. Mean study duration was 14.5 minutes  $(\pm 11)$ . Ambulatory echocardiograms constituted 50.5% of cases. The rate of sedation was 28.7% and 8.4% were performed under anesthesia. The most frequent indications were: endocarditis 22.7%, embolic source 21.5%, heart valve disease 20.3% and atrial fibrillation/atrial flutter 17.2%. Minor complications were registered in 30 cases (1.17%) and respiratory or cardiovascular complications in 25 studies (0.98%). There was 1 case of gastric mucosal lesion (0.039%) without perforation. Clinically significant findings were reported in 1,296 studies (50.6%), additional information to transthoracic echocardiography was provided in 1,600 cases (62.5%), unsuspected findings were described in 282 studies (11%), and 82.7% of the studies had an adequate indication.

**Conclusions:** This is the first multicenter registry on transesophageal echocardiography in our country. The results highlight a high rate of adequate indication, a considerable diagnostic yield and low complication rate.

Key Words: Echocardiography, Transesophageal - Echocardiography, Transesophageal/complications - Diagnostic Techniques, Cardiovas-cular - Diagnostic Imaging - Registries

### **RESUMEN**

Introducción: No disponemos de datos nacionales que informen la realidad del uso de ecocardiograma transesofágico en nuestro país. Objetivos: El objetivo principal fue evaluar la tasa de complicaciones del ecocardiograma transesofágico en centros de nuestro país. Objetivos secundarios: Relevar características de los laboratorios, nivel de formación de los operadores, tasa de uso de sedación y anestesia, identificar los principales motivos de solicitud y analizar la pertinencia de las indicaciones y el aporte del método al manejo clínico del paciente.

Método: Registro prospectivo, multicéntrico, de todos los ecocardiogramas transesofágicos realizados en 46 centros de Argentina entre noviembre de 2016 y septiembre de 2018.

Resultados: Fueron analizados 2562 ecocardiogramas transesofágicos, la edad media fue de  $61,4~(\pm 16)$  años; el 61% de los pacientes era de sexo masculino. La duración media resultó de 14,5 min  $(\pm 11)$ . Los estudios ambulatorios constituyeron el 50,5%. La tasa de uso de sedación fue del 28,7% y el 8,4% se realizó bajo anestesia. Indicaciones más frecuentes: endocarditis: 22,7%, fuente embolígena: 21,5%, valvulopatía: 20,3% y fibrilación auricular/aleteo auricular: 17,2%. Se registraron complicaciones menores en 30 casos (1,17%) y complicaciones respiratorias o cardiovasculares, en 25 estudios (0,98%). Se registró 1 caso de lesión de mucosa gástrica (0,039%) sin perforación. Se reportaron hallazgos clínicamente significativos en 1296 estudios (50,6%); agregó información adicional al ecocardiograma transtorácico en 1600~(62,5%) y se describieron hallazgos no sospechados en 282~(11%), mientras que el 82,7% de los estudios tuvieron una indicación apropiada.

Conclusiones: Este es el primer registro multicéntrico sobre ecocardiograma transesofágico en nuestro país. Entre los resultados obtenidos, se destacan una alta tasa de indicación apropiada, un considerable rédito diagnóstico y la baja tasa de complicaciones.

Palabras clave: Ecocardiografía transesofágica - Ecocardiografía/complicaciones - Técnicas de diagnóstico cardiovascular - Diagnóstico por imagen - Sistema de registros

## **Abbreviations**

| TEE | Transesophageal echocardiography | TAVI | Transcatheter aortic valve replacement |  |
|-----|----------------------------------|------|--|--|
|-----|----------------------------------|------|--|--|

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#### INTRODUCTION

Transesophageal echocardiography (TEE) is a semiinvasive diagnostic procedure that allows the visualization of cardiac structures and large vessels from the esophagus and/or stomach by means of an ultrasound probe. Its availability has expanded in recent decades and is currently used both as a diagnostic tool, as well as for monitoring, control and guidance of surgeries and/or percutaneous procedures. Proper performance and interpretation require an advanced training level. (1, 2) The rate of major complications reported in the literature is low. (3-5) Even though it is considered a safe procedure, serious complications have been reported, mainly related to esophageal and gastric trauma during probe insertion and/or manipulation. (3) We do not have national registries that report the current use of TEE in our country, the complication rate, the appropriateness of the indications or the diagnostic yield in our setting.

#### **OBJECTIVES**

The main purpose of the study was to evaluate the rate of complications associated with TEE performance in Argentine centers. Secondary objectives were to examine the characteristics of the laboratories that perform this practice in Argentina, the operators' training level, the rate of sedation and/or anesthesia and to analyze the main reasons for the request, the appropriateness of the indications and the contribution of the method to the clinical management of the patient.

#### **METHODS**

A prospective, multicenter registry of all TEE performed in 46 centers in Argentina was conducted between November 2016 and September 2018.

Initially, a survey was implemented to collect only once information about the equipment used, monitoring availability (ECG, oxygen saturation), resuscitation devices, the staff assisting the responsible professional and the academic degree of the professional performing the procedures.

Subsequently, a prospective registry, based on an online form, was completed on a web portal protected by username and password. Demographic data, site of performance, general condition of the patient, use of anesthesia and/or sedation, operator's level of experience, and presence of relative contraindications were collected. Other data recorded concerned depth of the views acquired, significant findings, additional information to transthoracic echocardiogram, conduct modification based on the study results, study duration, complications, and suitability of the indication according to appropriate use guidelines published by Douglas et al. (6)

### Statistical analysis

Statistix 8.0 software package was used for the statistical analysis. Continuous variables are expressed as mean (±standard deviation) or median and interquartile range as appropriate. Discrete variables are expressed as percentages. The chi-square test was used for analysis of discrete variable association and Student's t test or ANOVA were used to compare means. In all cases a p value <0.05 was considered significant.

#### **Ethical considerations**

The registry protocol was approved by the Bioethics Committee of the Argentine Society of Cardiology and all the patients signed an informed consent form to carry out the study and for data collection.

#### **RESULTS**

Forty-six centers participated in the study, 33 (71.7%) of which belonged to the private sector and 13 (28.3%) to the public sector. The majority were inpatient centers (87%) and only 5 (11%) were outpatient diagnostic centers. Sixteen centers represented the Autonomous City of Buenos Aires, 10 the province of Buenos Aires, 4 Santa Fe, 2 Catamarca, 2 Córdoba, 2 Mendoza and 2 Río Negro. The provinces of Chubut, Corrientes, Entre Ríos, Jujuy, Misiones, Salta and San Luis were represented by 1 center. Regarding the type of probe, 39 (85%) had multiplanar probes, 4 (9%) biplanar probes and only 2% had pediatric probes. Fourteen institutions (30%) had 3D probes. The presence in the laboratory of cardioverter-defibrillator and cardiac arrest equipment was reported in 38 centers (83%), pulse oximeter in 43 (94%), and oxygen and aspiration in 37 (80%). Forty-two institutions (91.3%) had staff to assist the operator during the study (26% had technicians, 24% nurses, 12% nursing graduates and 25% specialists or physicians-in-training).

A total of 2,562 TEE were analyzed. Table 1 describes the characteristics of the population. Mean age was  $61.4 (\pm 16)$  years and 61% were male patients. The average duration of the study was 14.5 minutes (±11). Ambulatory studies had an average duration of  $14.8\pm7.6$ ) minutes. Studies of patients admitted to the ward or closed units had a shorter duration (12.8±8.2 minutes, p<0.0001) and studies performed in the operating room were significantly longer (36.4±39 minutes, p<0.0001). In 50.5% of cases TEE was conducted on an outpatient basis. Among studies performed during hospitalization, 527 (41.5%) were done in the general ward, 668 (52.6%) in closed units and 74 (5.8%) in the operating room. Most were programmed studies (79%), while 19% were considered urgencies and 2% emergencies. Only topical anesthesia was used in 63% of studies, while 28.7% was performed under sedation and 8.4% under general anesthesia. Hospitalization was associated with greater use of sedation and anesthesia compared with outpatients [sedation: 31% vs. 26%, OR: 1.43 (1.2-1.7), p=0.0001; anesthesia: 12.1% vs. 4.7%, OR: 3.1 (2.2-4.2) p < 0.0001]. The most commonly used sedation drug was midazolam followed by propofol. In the case of studies under anesthesia, the most commonly used drug was propofol followed by midazolam in combination with fentanyl. One hundred and seventy studies (6.6%) were performed with the patient under mechanical ventilation.

A cardiologist inserted the probe in 88.3% of cases, a physician-in-training in 10% and an anesthesiologist in 1.7% of cases. The participation of physicians-in-training was more frequent in ambulatory than in hospitalized patient studies [11.9% vs. 7.8%, OR: 1.5

| Table 1. Population characteristic | CS.   |       |  |  |  |
|------------------------------------|-------|-------|--|--|--|
| Total N                            | 2,562 |       |  |  |  |
| Age (mean±SD                       | 6140  | ±16   |  |  |  |
| Male Sex (N/%)                     | 1,553 | 61%   |  |  |  |
| Duration of the study (mean±SD)    | 14.5  | ±11   |  |  |  |
| ,                                  | N     | %     |  |  |  |
| Context of study performance       |       |       |  |  |  |
| Hospitalization                    | 1,269 | 49.5% |  |  |  |
| General ward                       | 527   | 41.5% |  |  |  |
| Critical care unit                 | 668   | 52.6% |  |  |  |
| Operating room/procedure guidance  | 74    | 5.8%  |  |  |  |
| Temporality                        |       |       |  |  |  |
| Programmed                         | 2,023 | 79.0% |  |  |  |
| Urgency                            | 489   | 19.1% |  |  |  |
| Emergency                          | 50    | 2.0%  |  |  |  |
| Sedation/Anesthesia                |       |       |  |  |  |
| Sedation                           | 735   | 28.7% |  |  |  |
| General anesthesia                 | 214   | 8.4%  |  |  |  |
| Mechanical ventilation             | 170   | 6.6%  |  |  |  |
| Probe insertion                    |       |       |  |  |  |
| Expert cardiologist                | 2,262 | 88.3% |  |  |  |
| Anesthesiologist                   | 45    | 1.8%  |  |  |  |
| Physician-in-training              | 255   | 10.0% |  |  |  |
| Depth of Views                     |       |       |  |  |  |
| Transgastric                       | 1,238 | 48.3% |  |  |  |
| Deep Transgastric                  | 521   | 20.3% |  |  |  |
| Relative contraindications         |       |       |  |  |  |
| Esophageal varices                 | 1     | 0.04% |  |  |  |
| Mediastinal radiation              | 1     | 0.04% |  |  |  |
| History of digestive hemorrhage    | 7     | 0.27% |  |  |  |
| History of dysphagia               | 7     | 0.27% |  |  |  |
| Hiatal hernia                      | 2     | 0.08% |  |  |  |

(1.16-1.97), p=0.002), while anesthesiologists participated mainly in hospitalized patient studies (3.2% vs. 0.31%, OR: 10.2 (3.6-28), p <0.0001). Physicians-intraining had more participation in general ward studies than in critical care unit studies [10.4% vs. 6.9%, OR: 1.56 (1.04-2.3), p <0.03]. Probe insertion was more frequently performed by anesthesiologists in the operating room (46% of cases) and their participation in the critical care unit or general ward studies was exceptional (<1% of the studies).

Transgastric views were performed in 1,238 cases (48.3%) and deep transgastric views were acquired in 521 cases (20.3%). Relative contraindications were recorded in 18 patients (0.7%), the most frequent being history of digestive hemorrhage (7), dysphagia (7), hiatal hernia (2), esophageal varices (1) and mediastinal radiation (1).

The most frequent indications for TTE were: endocarditis 22.7%, embolic source 21.5%, heart valve disease 20.3%, atrial fibrillation/atrial flutter 17.2%, congenital heart disease 7%, surgery or percutaneous procedure guidance 4% and aortic pathology 2.6% (Figure 1).

Minor complications were recorded in 30 cases (1.17%): presence of moderate or abundant blood in saliva 18 (0.7%), dysphagia 9 (0.35%), dysphonia 2 (0.078%) and vomiting 1 (0.039%). Respiratory or cardiovascular complications were reported in 25 studies: oxygen desaturation in 19 (0.74%), supraventricular arrhythmias in 4 (0.16%), and sinus bradycardia in 2 (0.08%). Table 2 shows the complications reported.

One case of gastric mucosal lesion (0.039%) without perforation was recorded in an inpatient, with indication of emergency TEE, performed under sedation. There were no cases of esophageal mucosal lesion or perforation.



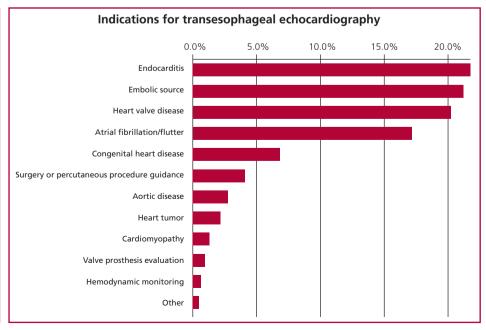


Table 2. Complications

|  | M  | 0/   |
|--|----|------|
|  | N  | %    |
| Minor complications                          | 30 | 1.17 |
| Moderate presence of blood in saliva         | 17 | 0.66 |
| Abundant presence of blood in saliva         | 1  | 0.04 |
| Dysphagia                                    | 9  | 0.35 |
| Dysphonia                                    | 2  | 0.08 |
| Vomiting                                     | 1  | 0.04 |
| Respiratory and cardiovascular complications | 25 | 0.98 |
| Oxygen desaturation                          | 19 | 0.74 |
| Supraventricular arrhythmias                 | 4  | 0.16 |
| Sinus bradycardia                            | 2  | 0.08 |
| AV block                                     | 0  | 0.00 |
| Ventricular arrhythmias                      | 0  | 0.00 |
| Digestive tube complications                 | 1  | 0.04 |
| Esophageal mucosal lesion                    | 0  | 0.00 |
| Esophageal perforation                       | 0  | 0.00 |
| Gastric mucosal lesion                       | 1  | 0.04 |
| Gastric perforation                          | 0  | 0.00 |
| Death unrelated to the procedure             | 3  | 0.12 |

Three deaths were recorded, none of them associated with the study. Two cases were deaths related to percutaneous aortic valve implantation (TAVI) and the remaining one was in the post-operative repair of a mechanical complication of infarction.

Transophageal echocardiography results reported clinically significant findings in 1,296 studies (50.6%), provided additional information to the transthoracic echocardiogram in 1,600 cases (62.5%), and described unsuspected findings in 282 cases (11%).

Transophageal echocardiography confirmed previous suspicion in 1,066 cases (41.6%), generated no change in patient management in 1,009 cases (39.4%), and a change in conduct was reported based on the result in 487 cases (19%).

The analysis of appropriate use criteria revealed that 82.7% of the studies had an appropriate indication, while 16.4% presented an inappropriate indication. The most relevant inappropriate TTE study decision corresponded to the instance when a transthoracic echocardiogram could have resolved the patient's diagnosis and management (45.49%), followed by studies to diagnose endocarditis in patients with low probability of having the disease (35.1%). TEE for surveillance over time of findings that do not imply a therapeutic change (18.7%) and use of the method even after reaching an anticoagulation and non-cardioversion decision (0.72%) were also inappropriate TEE studies. A total of 0.88% studies were observed with uncertain indications.

#### **DISCUSSION**

This is a federal registry with representation of the majority of the provinces of our country and a distribution of the number of centers according to the population. Regarding the setting in which the studies are carried out, we observe with satisfaction that a high proportion of laboratories have defibrillator, cardiac arrest equipment, oxygen, aspiration or suction devices and pulse oximeter. In this sense, achieving 100% availability is a goal to offer a safe procedure. Eight out ten laboratories have professionals with level 3 training on TEE according to ECOSIAC laboratory accreditation guidelines. (1) In 91% of the studies, the performing physician had assistance, most often performed by technical, nursing or physicians-in-training.

Among the negative aspects, centers without multiplanar probe availability, although in a low proportion (<10%), is still remarkable.

Half of the studies were performed in outpatients. Among inpatients, the studies carried out in the general ward were more frequent, followed by those in closed units. Only 5% of the studies were done in the operating room. Most of the studies were elective, in 19% of cases in the context of an urgency and only in 2% of cases during an emergency.

Among the technical aspects, it is noteworthy that 63% of cases was performed with topical anesthesia, 28.7% with sedation and only 8.4% under general anesthesia. It is important to point out that this registry does not include studies that could not be done, so we cannot draw conclusions about the effectiveness of using only topical anesthesia.

In line with a large majority of studies conducted in non-surgical settings and with low use of general anesthesia, most operators were cardiologists. In almost 90% of cases, an experienced cardiologist inserted the probe, in around 10% of studies a cardiologist-in-training and in less than 2% of cases an anesthesiologist. The latter participated almost exclusively in studies performed in the operating room.

Regarding the depth of the views and the windows used in the study, the esophageal views were, as expected, the most widely employed. It is noteworthy that in spite of the low use of sedation and anesthesia, transgastric windows were possible in 48% of the studies.

The average duration of the studies was  $14.5\pm11$  minutes. Even though there was a numerically significant difference between outpatients ( $14.8\pm7.6$  minutes) and inpatients ( $12.8\pm8.2$  minutes) (general ward and closed units), this does not seem clinically relevant. On the other hand, the studies performed in the operating room had 2.5 times longer duration, extending for  $36.4\pm39$  minutes.

The main reason for indicating the study was suspicion of infectious endocarditis, followed by evaluation of embolic source and heart valve diseases. The assessment of atrial fibrillation and atrial flutter prior to cardioversion was the fourth reason, a little behind the first three. There was apparently no predominant indication, but a group of four reasons, each comprising almost one fifth of the indications. The remaining 20% included the evaluation of congenital heart dis-

eases, surgery and procedure guidance, aortic diseases and others.

A high diagnostic yield was observed for TEE results, reporting clinically significant findings in half of the cases. Moreover, TEE provided additional information to transthoracic echocardiography in two thirds of the cases and unsuspected findings in 11%.

In most cases, the study was useful to confirm previous suspicion or generate a therapeutic conduct change. In contrast, in 40% of cases the study did not produce conduct changes, a proportion that seems high if its semi-invasive nature is taken into account. However, the evaluation of its appropriate use, according to the criteria published by the American Society of Echocardiography, (6) is satisfactory with 78.9% of studies with appropriate criteria.

Regarding aspects related to the safety of the method, the rate of minor complications was low (2.1%), the most frequent being oxygen desaturation, presence of moderate amount of blood in saliva and dysphagia. A single case of mucosal lesion was reported in the gastrointestinal tract and no deaths associated with the procedure were reported.

The rate of clinically significant complications in outpatients (non-surgical) varies between 0.2% and 0.5% in the literature and mortality has been estimated at <1: 10.000. (3-5, 7, 8) The Mayo Clinic, in a series published in 1994, recorded one death related to the procedure among 7,134 studies. (7) The multicenter study by Daniel et al. reported one death in 10,419 studies. (4) These figures are comparable to those of upper digestive endoscopy, for which the overall rate of non-fatal complications ranges between 0.08% and 0.13% and the reported mortality is approximately 0.004%. (3, 9, 10).

Intraoperative TEE has a theoretically higher risk profile since it involves the insertion and manipulation of the probe in intubated patients who are under anesthesia and cannot collaborate, nor warn about discomfort during probe placement. (3) However, the reported morbidity rate is similar to that of the outpatient setting and varies from 0.2% to 1.2%. (11-13) The largest published report (7,200 patients, single center) reported a morbidity of 0.2% and mortality of 0%. (12) In our registry, the proportion of intraoperative studies was low, so it was not possible to perform a subanalysis of the complications in that setting.

The estimated incidence of upper digestive tract perforation is between 0.01% and 0.04% in both perioperative and ambulatory patients, and represents a high mortality complication (10% to 56%). (3-5, 12, 14) In the series published by Min et al. in over 10,000 consecutive TEE, 3 perforations (0.03%) were reported: 2 at the level of the cervical esophagus and 1 in the hypopharynx. The authors noted that in all cases it was associated with difficult insertion of the probe and all were elderly patients (>75 years). (5)

There were no deaths or cases of digestive tract perforation in our series; this could be attributed to the operators' experience and good monitoring conditions, although the limited sample size and the possible subregistration due to lack of patient mid-term follow-up are limitations to be taken into account.

Major bleeding of the gastrointestinal tract caused by TEE is rare and generally due to disruption of the mucosa by direct trauma or laceration of friable tissues. The global incidence of major hemorrhagic complications after TEE has been estimated between 0.02% and 1.0%. (3, 4, 12, 14) Our series recorded a single case of gastric mucosal lesion, representing 0.039% of studies.

#### Limitations

Perhaps the main limitation of this registry has to do with the non-obligatory nature of participation. This could result in selection bias, explaining the low representation of studies performed in the operating room and hemodynamics lab.

In addition, the registry does not include failed attempts; therefore, not all the studies attempted in each center may be represented, thus altering the indication motives, the type of anesthesia and the rate of minor complications.

Finally, the low proportion of studies performed in the operating room or as procedure guidance makes it difficult to draw conclusions about this method in those scenarios.

## CONCLUSIONS

This study represents the first multicenter registry on the reality of transesophageal echocardiography in our country. It is an unprecedented study both locally and internationally. A large number of care centers with broad representation participated throughout the country according to our population distribution.

Results showed a significant high percentage of centers adequately prepared for the performance of this type of studies, both from technological and human resources viewpoints. The appropriate indication rate was high, which resulted in considerable diagnostic and clinical benefit. The complication rate was low and in all cases of little clinical relevance, expressing the safety of the method.

## **Conflicts of interest**

None declared.

(See authors' conflicts of interest forms on the website/

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#### **Appendix**

#### Task team

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