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Data Article

Dataset for the study of the effect of anticoagulation in the incidence of stroke and other outcomes in patients with left ventricular thrombus

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ABSTRACT

The optimal duration of anticoagulation in patients with left ventricular thrombus (LVT) is unknown. The data package herein presented contains the information used to assess the effect of duration of anticoagulation in the incidence of stroke in patients with left ventricular thrombus (LVT) in a tertiary hospital. In order to collect the required data, all transthoracic echocardiography studies at our institution from January 1st 2014 to December 31st 2021 with LVT were retrieved using dedicated software (Phillips Intellispace Cardiovascular; Koninklijke Phillips N.V., 2004-2020). Second, a dataset was designed ad hoc for this study in which the recruited data for the predefined objectives were obtained from electronic medical records. These data included clinical and demographic information including treatment choices

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(vitamin K antagonists [VKA] versus direct oral anticoagulants [DOAC]), duration of treatment, reason for interruption of treatment, occurrence of stroke, acute myocardial infarction, bleeding events, thrombus resolution, recurrence, and death. Retrieved data were stored in an excel sheet for analysis using the statistical package STATA (StataCorp v. 15.0, College station, TX). This methodology allows the reuse of these data for further analysis, in the context of the present study and also for future recruitment of additional patients from other institutions to increase statistical power.

Specifications Table

Subject	Health and medical sciences: Cardiology and Cardiovascular Medicine
Specific subject area	Left ventricular thrombus and incidence of stroke and other outcomes (acute myocardial infarction, bleeding and mortality)
Type of data	Chart with raw data
How the data were acquired	Data were acquired from a prospective database that comprises all transthoracic echocardiogram (TTE) exams performed at our institution. Using dedicated software (Phillips Intellispace Cardiovascular; Koninklijke Phillips N.V., 2004-2020) reports that were coded as having "intraventricular thrombus", "left ventricular thrombus", "intracavitary thrombus" or "apical thrombus" were selected. Clinical data were retrieved from the electronic medical records (EMRs).
Data format	Raw and analyzed
Description of data collection	The initial dataset consisted of 267 TTE exams identified as having left ventricular thrombus (LVT) obtained from a database that comprises all TTE exams performed at our institution. The studies from this first dataset were evaluated by two echocardiographers. Studies with unconfirmed diagnosis, thrombus location other than the left ventricle (LV) or duplicated studies were excluded. Thus, of the 267 studies, 44 were excluded because thrombus was unconfirmed (n=17) or present in locations other than the LV (n=27). In addition, from a total of 223 valid TTE exams, 122 were repeated studies (on the same patient), leaving a total of 98 patients. Then demographic, clinical and follow-up data were obtained from the EMRs. Data retrieved from the EMRs were those indicated in Tables 1–3, and the raw data is available on the attached dataset. Results are available in tables and supplementary files of the original article [1].
Data source location	Cardiology department. Hospital Universitario Ramón y Cajal Ctra de Colmenar Viejo, Km 9,100. 28034, Madrid Spain
Data accessibility	Analyzed data: in the original the article [1] Raw data: dataset is available at Zenodo repository. Lorente-Ros, A, & Zamorano Gómez, JL. (2022). Repository of Raw Datasets for the Study of Anticoagulation and the Incidence of Stroke and Other Outcomes in Patients with Left Ventricular Thrombus (Version 1) [Data set]. Zenodo. Direct URL to data: https://zenodo.org/record/7602176 DOI: https://doi.org/10.5281/zenodo.7602176
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1. Value of the Data

- The data contained in the clinical data sheet as described above are of great importance for this and future studies. It contains variables that can be related to the protective effect of anticoagulation treatment (and its duration) in the incidence of stroke. Current guidelines explicitly recognize the need for further investigation in this area [2]. The dataset represents a pure cohort of LVT, ensuring internal validity.
- The use of this dataset as a template for the inclusion of new patients (i.e., from other centers) will increase the power of the analysis. For instance, it seemed from our analysis that while long-term anticoagulation was largely associated with a lower risk of stroke, patients with lower embolic risk may not benefit from long-term anticoagulant treatment [1]. Subgroup analysis from other studies have also suggested a possible protective effect associated with longer anticoagulation periods [3]. A larger study could clarify this issue with the appropriate number of patients in the different groups.
- The availability of this dataset will be extremely useful for future studies to confirm the potential protective effect of long-term anticoagulant treatment in patients with LVT. Indeed, our single center study provided interesting results that should be confirmed in larger multicenter studies.
- Unanticipated findings, such as the protective effect of long-term anticoagulant treatment in the prevention of stroke also in patients in whom LVT was resolved could be clarified.
- In addition, larger databases, built based on ours, are necessary to more reliably analyze and compare the effects of the different anticoagulant treatments in different outcomes. For instance, it is not known if direct oral anticoagulants (DOAC) are superior to vitamin K antagonists (VKA) for thrombus resolution, prevention of stroke, or risk of bleeding.

2. Objective

The optimal duration of anticoagulation in patients that present with LVT is unknown. Current guidelines from both the American Heart Association and the European Society of Cardiology support anticoagulation for a definite period of time, with a low level of evidence and based on outdated studies [4–7].

This dataset was generated to retrospectively evaluate the incidence of adverse clinical events (stroke, acute myocardial infarction [AMI], bleeding and mortality) and the duration of anticoagulation in patients with LVT. This dataset facilitates future studies that are needed in this area and enables multi-center studies and meta-analyses.

3. Data Description

The raw data file presents the individual (anonymized) information of each patient: demographic and clinical characteristics as well as the appearance of different outcomes. Follow-up time and time-to-events are also provided. Recorded variables are those presented in Tables 1–4 and individual values can be consulted on the accompanying dataset.

Table 1 specifies baseline demographic and clinical characteristics that are recorded in the provided dataset, including age, sex, weight, height and baseline clinical variables such as the presence of cardiovascular risk factors, cardiovascular disease and other comorbidities (Table 1).

Table 2 presents the diagnoses at presentation (i.e., the underlying pathology that motivates the diagnosis of LVT such as AMI or stroke) and the different etiologies of cardiomyopathy recorded.

Table 3 presents the different outcomes that are recorded in the dataset, which enable the reproduction of the survival and regression analysis performed in the original work. Events such as stroke, AMI, bleeding complications, mortality or thrombus resolution are provided in the dataset along with the length of time until the occurrence of the primary outcome (Table 3).

Table 1
Baseline demographic and clinical characteristics recorded in the dataset.

Clinical Variables	Units	Dataset variable name
Baseline demographic and clinical characteristics recorded		
Age	(years)	age
Sex	(male/female)	sex
Weight	(Kg)	patientweight
Height	(cm)	patientheight
Hypertension	(yes/no)	htn
Dyslipidemia	(yes/no)	dysipedemia
Diabetes Mellitus	(yes/no)	diabetes
Coronary artery disease	(yes/no)	coronary_artery_disease
Peripheral artery disease	(yes/no)	pad
Atrial fibrillation (previous)	(yes/no)	previous_AF
History of heart Failure	(yes/no)	heart_failure
Previous stroke	(yes/no)	previous_stroke
Chronic Obstructive Pulmonary Disease (COPD)	(yes/no)	copd
GFR (Glomerular filtration rate)	(ml/min)	gfr
Cancer history	(yes/no)	cancer
LVT diameter (max, min)	(cm)	max_diam_lvt
LVEF (Teich and Simpson method)	(%)	lvef_teich; lvef_Simpsonbp
Treatment with DOAC	(yes/no)	doac
CHA_2DS_2-VASc	(value 0-9)	cha2ds2vasc
Follow up time	(months)	futime_months
Duration of anticoagulation	(months)	duration_ac_months

COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; LVT, left ventricular thrombus; LVEF, left ventricular ejection fraction; DOAC, direct oral anticoagulants; AMI, acute myocardial infarction.

Table 2
Diagnoses at presentation and etiologies of cardiomyopathy recorded in the dataset.

Diagnosis at presentation	Dataset variable name	
AMI	diagnosis_ami	(yes/no)
Stroke	diagnosis_stroke	(yes/no)
Other*	diagnosis_other	(yes/no)
Etiology of cardiomyopathy of the patients included		
Ischemic cardiomyopathy	ischemic_cm	(yes/no)
Idiopathic cardiomyopathy	idiopathic_cm	(yes/no)
Stress cardiomyopathy/ Tako-Tsubo Syndrome	stress_cm	(yes/no)
Non-compaction	noncompaction_cm	(yes/no)
Tachymiocardiopathy	tachy_cm	(yes/no)
Alcoholic cardiomyopathy	alcohol_cm	(yes/no)

*Other causes include incidental finding during hospital admission (for heart failure or other causes) or scheduled follow-up transthoracic echocardiography.
AMI, acute myocardial infarction.

Table 3
Outcomes recorded in the dataset.

Outcomes recorded	Dataset variable name
Stroke	stroke
Time-to-stroke (days)	stroke_fu_days
AMI	ami
Bleeding	bleeding
Thrombus Resolution	resolution
AF diagnosed during follow-up	post_AF
Thrombus Recurrence	recurrence_cm
Mortality	death

AMI, acute myocardial infarction; AF, atrial fibrillation.

Table 4
Variables used for subgroup analysis available in the dataset.

Subgroups used for secondary analysis
Age groups ($<$ 65 years of age; $\geq$ 65 years of age)
Ischemic risk groups (CHA2DS2-VASc $\geq$ 2; CHA2DS2-VASc $<$ 2; CHA2DS2-VASc $\geq$ 3; CHA2DS2-VASc $<$ 3)
Treatment groups (VKA, DOAC)
Diagnosis at presentation (AMI, Stroke, Other)
Presence of AF (AF at any time, no AF)
LVT resolution (resolved LVT or persistent LVT)

AMI, acute myocardial infarction; AF, atrial fibrillation; VKA, vitamin K antagonists; DOAC, direct oral anticoagulants; LVT, left ventricular thrombus.

In Table 4 we present the different variables that were recorded in order to permit secondary analysis: we performed subgroup analyses according to age, ischemic risk, treatment groups, diagnosis at presentation, presence of AF (which is an important embolic risk modifier) and LVT resolution (Table 4).

Dataset: The accompanying dataset provides individual values of the variables presented in Tables 1–4, which enable the reproduction of the analysis and potentially facilitate the enlargement of the sample size with data from other groups. The dataset is in excel format and the first row represents the variable name, as specified in Tables 1–4 ("Dataset variable name").

Analyzed data and results are those presented in the original manuscript [1].

4. Experimental Design, Material and Methods

Despite the serious embolic complications associated with LVT, the ideal duration of anticoagulant treatment remains uncertain [2,3]. The data presented in this study were derived from a cohort of consecutive cases at a single center. Initially, LVT-cases were identified from a prospective database of all echocardiographic exams conducted at our institution, including patient information and diagnosis codes recorded at the time of the study. Subsequently, relevant prespecified clinical information required for the analysis of predefined objectives was incorporated through a review of electronic medical records (EMRs).

4.1. Data Collection

The current study utilized a database comprising all transthoracic echocardiography studies conducted at our institution between January 1st, 2014, and December 31st, 2021 (totaling 130,558 studies), which were prospectively included. Utilizing specialized software (Phillips Intellispace Cardiovascular; Koninklijke Phillips N.V., 2004-2020), which provides advanced tools for organizing, processing and interpreting medical images, we identified exams featuring LVT. The data presented in this article originated from a retrospective review of clinical data pertaining to the selected patients with LVT from the aforementioned database, covering an 8-year period.

Two echocardiographers independently evaluated the studies and excluded studies with unconfirmed or doubtful diagnoses, thrombi outside the left ventricle (LV) and duplicate entries.

Second, a dataset designed ad hoc for this study was completed with data retrieved from EMRs. It encompassed clinical and demographic details, treatment selections (VKA or DOAC), treatment duration, incidence of stroke, acute myocardial infarction (AMI), bleeding events, thrombus resolution and recurrence, and mortality. The retrieved data were stored in an Excel sheet for analysis.

4.2. Statistical Analysis

Patients were categorized into two groups based on the duration of anticoagulation: the first group comprised individuals whose anticoagulation was terminated within 12 months of therapy initiation, while the second group included those who received anticoagulant treatment for over 12 months or did not discontinue anticoagulation during the follow-up period.

Categorical data were presented as percentages. Continuous data were summarized as medians with interquartile ranges or means with standard deviations. Chi-square or Fisher's exact tests compared variable distributions for categorical data, while ANOVA or Kruskal-Wallis tests were used for continuous data as appropriate. Generalized linear models estimated odds ratios and risk ratios. We conducted univariate and multivariate (Cox regression) analyses to demonstrate the relationship between the duration of anticoagulant treatment and the incidence of stroke. Also, the effect of the duration of anticoagulant treatment on other outcomes (AMI, bleeding, resolution and recurrence of the LVT, mortality) was analyzed by comparing the groups (Student's t test or Mann Whitney U test), and by logistic regression (and measured by the odds ratio and its 95% confidence interval). Finally, the relationship of the different outcomes was also compared between VKA and DOAC. A significance level of $p<0.05$ was applied. Data summaries and analysis were performed using the statistical software package STATA (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

4.3. Reproducibility of the Results

This methodology allows the reuse of these data for further analysis, in the context of the present study and also for future recruitment of additional patients from other institutions to increase statistical power.

Ethics Statement

The research was carried out in accordance with the Declaration of Helsinki and was approved by the local Ethics Committee (Hospital Ramón y Cajal, "Pronostic factors and use of direct oral anticoagulants in intraventricular thrombus, version 2.0, approved December 17, 2020; record 17/12/2020 ACTA 404). The study was compliant with patient confidentiality regulations, with anonymization of all data.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability

Repository of Raw Datasets for the Study of Anticoagulation and the Incidence of Stroke and Other Outcomes in Patients with Left Ventricular Thrombus (Original data) (Zenodo).

CRediT Author Statement

Álvaro Lorente-Ros: Conceptualization, Methodology, Data curation, Formal analysis, Writing – review & editing, Writing – original draft; **Marta Lorente-Ros:** Writing – review & editing; **Gonzalo L. Alonso-Salinas:** Supervision, Writing – review & editing; **Juan M. Monteagudo Ruiz:**

Methodology, Software, Formal analysis; **Covadonga Fernández Golfín:** Supervision, Data curation, Methodology, Writing – review & editing; **José L. Zamorano Gómez:** Supervision, Writing – review & editing.

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