fortune Journals

Research Article

CARDIOLOGY AND CARDIOVASCULAR MEDICINE

ISSN: 2572-9292

Prevalence of Brief Atrial Fibrillation in Ischaemic Stroke and Transient Ischaemic Attack - The MY-ATRIA Study: Rationale and Design

Salinas-Martínez Ricardo[1,4,*], Zaniboni Anna[2], Piccolo Laura[2], Migliaccio Ludovica[2], Rubini Lorenza[2], Riva Letizia[3], Fiorani Ambra[4], Paolucci Matteo[2], Gentile Mauro[2], Forlivesi Stefano[2], Pergolini Francesco[3], Carinci Valeria[3], Bugani Giulia[3], Brancaleoni Laura[2], Naldi Federica[2], Gentile Luana[2], Sandberg Frida[1], De Bie Johannes[4,5], Marzocchi Nicoletta[4], Casella Gianni[3], Zini Andrea[2]

Abstract

Background: Recent studies suggest that brief atrial fibrillation~(BAF, episodes shorter than 30 seconds) comprises 52% of all newly detected atrial fibrillation~(AF) in patients with ischaemic stroke~(IS) and transient ischaemic attack~(TIA) without AF history. However, variations in monitoring strategies could have led to under- or overestimating the prevalence of BAF.

Objective: Our study seeks to improve detections rates by adhering to recommendations from previous research, including prolonged cardiac monitoring, initiating monitoring shortly after ischaemic event and increased sample size.

Methods: The MY-ATRIA study is a single-center observational and transversal prospective study aiming to determine the prevalence of BAF episodes in patients with recent IS or TIA (indexing event) without AF history by performing 7-day Holter cardiac monitoring.

Results: We screened 637 patients with mean age of 70.3 ± 13.8 years, male predominance (58.9%, 375/637), and the majority with IS (96.5%, 615/637). The mean time interval from indexing event to enrollment was 2.29 ± 1.62 days and Holter monitoring started as soon as possible and no later than 7 days after indexing event.

Conclusion: This study will contribute to measuring the prevalence of IS or TIA patients with BAF episodes and the proportion of BAF episodes among all detected AF episodes. This is a step forward in determining whether BAF episodes represent an independent risk factor for thromboembolism and whether they warrant the same treatment as clinical AF.

Registered on ClinicalTrials.gov (NCT04963647)

Keywords: Prevalence; Brief Atrial Fibrillation; Paroxysmal Atrial Fibrillation; Ischaemic Stroke; Transient Ischaemic Attack; Ictus; Cerebral Infarction; Atrial Fibrillation Detected After Stroke; Holter ECG; Ischemic

Affiliation:

[1]Department of Biomedical Engineering, Lund University, Lund, Sweden

[2]IRCCS Istituto delle Scienze Neurologiche di Bologna, Department of Neurology and Stroke Center, Maggiore Hospital, Bologna, Italy

[3]Cardiology Department, Maggiore Hospital, Bologna, Italy

[4]Baxter International Inc. – Mortara Instrument Europe, Bologna, Italy

[5]Department of Electrical, Electronic, and Information Engineering, University of Bologna, Italy

***Corresponding author:**
Salinas-Martínez Ricardo, Department of Biomedical Engineering, Lund University, Lund, Sweden, Baxter International Inc. – Mortara Instrument Europe, Bologna, Italy

Citation: Salinas-Martínez Ricardo, Zaniboni Anna, Piccolo Laura, Migliaccio Ludovica, Rubini Lorenza, Riva Letizia, Fiorani Ambra, Paolucci Matteo, Gentile Mauro, Forlivesi Stefano, Pergolini Francesco, Carinci Valeria, Bugani Giulia, Brancaleoni Laura, Naldi Federica, Gentile Luana, Sandberg Frida, De Bie Johannes, Marzocchi Nicoletta, Casella Gianni, Zini Andrea. Prevalence of Brief Atrial Fibrillation in Ischaemic Stroke and Transient Ischaemic Attack - The MY-ATRIA Study: Rationale and Design. Cardiology and Cardiovascular Medicine. 10 (2026): 102-109.

Received: April 05, 2026
Accepted: April 13, 2026
Published: May 11, 2026

Ricardo S, et al., Cardiol Cardiovasc Med 2026
DOI:10.26502/fccm.92920489

Abbreviation	Meaning
AF	Atrial Fibrillation
AFDAS	Atrial Fibrillation Detected After Stroke
AFL	Atrial Flutter
BAF	Brief Atrial Fibrillation
CRF	Case Report Form
DNSC	Department of Neurology and Stroke Center
ECG	Electrocardiogram
ICF	Informed Consent Form
IS	Ischaemic Stroke
PAF	Paroxysmal Atrial Fibrillation
TIA	Transient Ischaemic Attack

Introduction

Stroke is a leading cause of mortality and disability worldwide [1]. The Global Burden of Disease study reported that stroke was the second-leading cause of death globally and that ischaemic stroke~(IS) constituted 62.4% of all incident strokes [1]. Atrial fibrillation~(AF) is a risk factor for IS, diagnosed in 20-30% of all IS patients [2]. This association motivated guidelines [3-5] to recommend cardiac monitoring in IS and transient ischaemic attack~(TIA) patients without AF history to identify AF and improve personalized treatment. The 2024 Guidelines for the management of AF recommended oral anticoagulation in patients with clinical AF to reduce the risk of secondary stroke [5]. Clinical AF was defined in the 2020 Guidelines for the management of AF [6] as an AF episode lasting at least 30 seconds detected in continuous electrocardiogram~(ECG) recordings or an AF episode present for 10 seconds in standard 12-lead ECG recordings. The 2024 Guidelines [5] refined this definition by acknowledging that the minimum duration required to diagnose clinical AF in ambulatory ECG monitoring is not clear and depends on clinical context. The 30-second threshold was first mentioned in the 2006 American Heart Association Guidelines [7] and has been carried forward in subsequent guidelines for the management of AF [2,5,6,8-10] without further explanation. However, this threshold remains controversial among stroke physicians [11,12] since it is uncertain whether AF episodes shorter than 30 seconds, hereinafter brief atrial fibrillation~(BAF), independently increase the risk for thromboembolism [5,12-14]. Consequently, the optimal management and treatment of IS and TIA patients with BAF episodes remains unclear [5,13]. Several studies have investigated the prevalence of BAF in IS and TIA patients. A 2015 systematic review by Sposato et al [14] estimated the prevalence of BAF in IS and TIA patients without AF history. The analysis included nine studies and reported that 7.6% of the patients that underwent cardiac monitoring after the ischaemic event had only BAF episodes and 5.7% had only clinical AF [14]. However, the review highlighted significant variability in study designs, including the time interval from the indexing event to initiating cardiac monitoring (median 29 days, range 1-90) and monitoring duration (median 21 days, range 1-435) which may have contributed to heterogeneous results [14]. A subsequent review by Sposato et al [15] in 2022 incorporated nine additional studies into the analysis and found that the overall AF detected after stroke~(AFDAS) shorter than 30 seconds, i.e. BAF, comprised 52% (95% CI, 36%-66%) of all newly detected AF. Thirteen studies in the review reported results based on ECG recordings from mobile outpatient telemetry and Holter monitoring [16-28] while five used loop recorders [29-33]. Among the telemetry and Holter studies, five performed monitoring for a median of 1.6 days (range 1-3.5) [24-28] six initiated monitoring months after the indexing event [22,23,30-33] five included small study cohorts (less than 70 patients) [23,28,29,32,33] and ten recorded only one [27,29,31,33] or two [19-23,26] leads. Although findings suggest that BAF may be more prevalent than clinical AF in IS and TIA patients, variations in monitoring strategies could have led to under- or overestimating its true prevalence. To address these limitations and determine the prevalence of BAF episodes in IS and TIA patients, additional studies following monitoring recommendations are needed. Evidence suggests that prolonged ECG monitoring (7 days or more) significantly enhances detection rates of BAF [13-15] and AF [12,34]. For example, a 2024 study suggested that prolonged cardiac monitoring doubles AF detection incidence compared to short-term monitoring (less than 7 days) [35]. Furthermore, initiating ECG monitoring within the first days after IS or TIA event has been shown to improve detection rates [12,14]. To the best of our knowledge, additional studies investigating the prevalence of BAF in stroke patients haven't been published after 2022. The MY-ATRIA study aims to determine the prevalence of BAF episodes in patients with recent IS or TIA without AF history. This study seeks to improve detections rates by adhering to recommendations from previous research, including prolonged cardiac monitoring, initiating monitoring shortly after indexing event and increased sample size. This paper presents the rationale, study design, and results of the enrollment process.

Patients and Methods

Study design

The MY-ATRIA study is a single-center observational and transversal prospective study conducted at the Department of Neurology and Stroke Center~(DNSC) at the Ospedale Maggiore in Bologna (Italy), registered on ClinicalTrials.gov (NCT04963647). The study aims to determine the prevalence of BAF episodes in patients with recent IS or TIA without AF history. All consecutive IS or TIA patients admitted to

Citation: Salinas-Martínez Ricardo, Zaniboni Anna, Piccolo Laura, Migliaccio Ludovica, Rubini Lorenza, Riva Letizia, Fiorani Ambra, Paolucci Matteo, Gentile Mauro, Forlivesi Stefano, Pergolini Francesco, Carinci Valeria, Bugani Giulia, Brancaleoni Laura, Naldi Federica, Gentile Luana, Sandberg Frida, De Bie Johannes, Marzocchi Nicoletta, Casella Gianni, Zini Andrea. Prevalence of Brief Atrial Fibrillation in Ischaemic Stroke and Transient Ischaemic Attack - The MY-ATRIA Study: Rationale and Design. Cardiology and Cardiovascular Medicine.10 (2026): 102-109.

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DOI:10.26502/fccm.92920489

the DNSC from June 16, 2021 to January 25, 2024 were evaluated for eligibility based on the criteria described in Figure~1. Patients meeting the eligibility criteria were enrolled to undergo Holter monitoring for 7 days. The first 24 hours of monitoring were performed using the Welch Allyn® H12+™ Digital Holter Recorder which records 12 leads at 1000 samples per second. The subsequent 6 days using the Welch Allyn® H3+™ Digital Holter Recorder, which records 6 limb leads and precordial lead V1 at 180 samples per second. Ambu® BlueSensor VL electrodes were placed on the body surface using the modified Mason-Likar ECG limb and standard precordial electrode positions, see Figure~2. Holter monitoring was initiated as soon as possible and no later than 7 days after indexing event. Enrolled patients could be discharged after completing the first 24 hours of monitoring, completing the remaining 6 days at their discharge destination. Once the monitoring was finished, the recorder was returned to the DNSC. Patients were removed from the study if the 12-lead Holter recording did not acquire the limb leads and precordial leads V1 and V2 for at least 16 hours or all the 12 leads for at least 10 hours. Removed patients did not undergo the 7-lead Holter monitoring. Similarly, patients were removed if the 7-lead Holter recording did not acquire 1 limb lead for at least 4.5 days and all the 7 leads for at least 1 day. Enrolled patients who were not removed due to any of these conditions hereinafter will be referred to as screened patients. Demographic, symptoms, comorbidity, and clinical parameters at baseline were documented in the case report form~(CRF) for all screened patients. The 12-lead Holter recordings were analyzed by cardiologists from a certified external provider using the Welch Allyn® Web Upload™ software. Diagnosed AF episodes were notified to treating physicians at the DNSC for necessary adjustments in secondary prevention treatment. The study workflow is depicted in Figure~3.

Study outcomes

All outcomes will be evaluated using collected data from screened patients. Paroxysmal AF~(PAF) refers to AF episodes lasting 30 seconds or more but less than 7 days [5]. The study outcomes are listed in Figure~4. For all the outcomes of the study, in case of detection of episodes of atrial flutter~(AFL) they will be considered as AF episodes since they both have similar risk factors and therapy [5,6,36]. Additionally, all episodes of AFL and AF shorter than 30 seconds will be considered as BAF. Detection of AF episodes will be performed using a hyper-sensitive AF detector, e.g. based on rhythm irregularity and/or P-wave absence scores. These scores are frequently used for discriminating AF from other arrhythmias with irregular rhythm. All PAF and BAF detections will be reviewed by expert ECG-readers and confirmed by cardiologists. Only confirmed episodes will be used for evaluating the study outcomes.

Inclusion criteria:

I. Patients diagnosed with IS or TIA. The diagnosis is confirmed through standardized clinical practice which may include one or more of the following diagnostic tests:
   1. Neuroimaging assessment with non-contrast computed tomography +/- computed tomographic angiography,
   2. Neuroimaging assessment with magnetic resonance imaging +/- magnetic resonance angiography,
   3. Cerebral flow assessment such as cerebral angiography.

II. IS or TIA within 7 days of the clinical episode.
III. Informed consent obtained (signed and dated).
IV. Adult patients (over 18 years of age).

Exclusion criteria:

I. Pacemaker or implanted cardioverter defibrillator.
II. Hemorrhagic stroke.
III. Cardiac surgery performed in the 30 days prior to enrollment.
IV. More than 7 days between the IS or TIA episode and patient enrollment.
V. AF diagnosis based on resting ECG performed at the time of enrollment.
VI. Any AF history (permanent, persistent or paroxysmal).
VII. Previous enrollment in this clinical study.
VIII. Pregnancy.

Figure 1: Eligibility Criteria of the study.

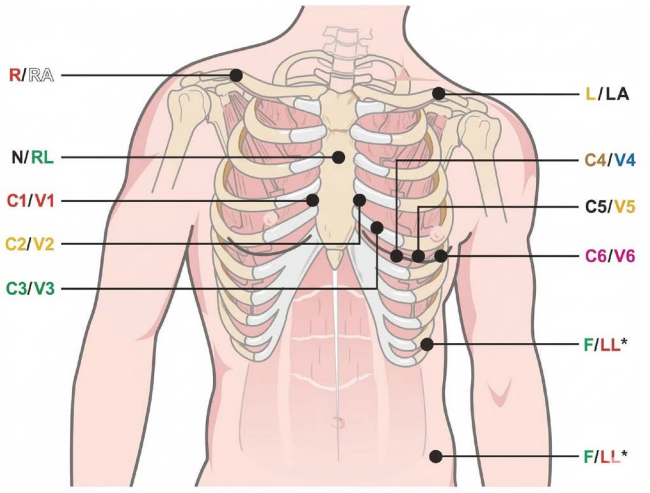

Figure 2: Modified Mason-Likar ECG limb and precordial electrode position.

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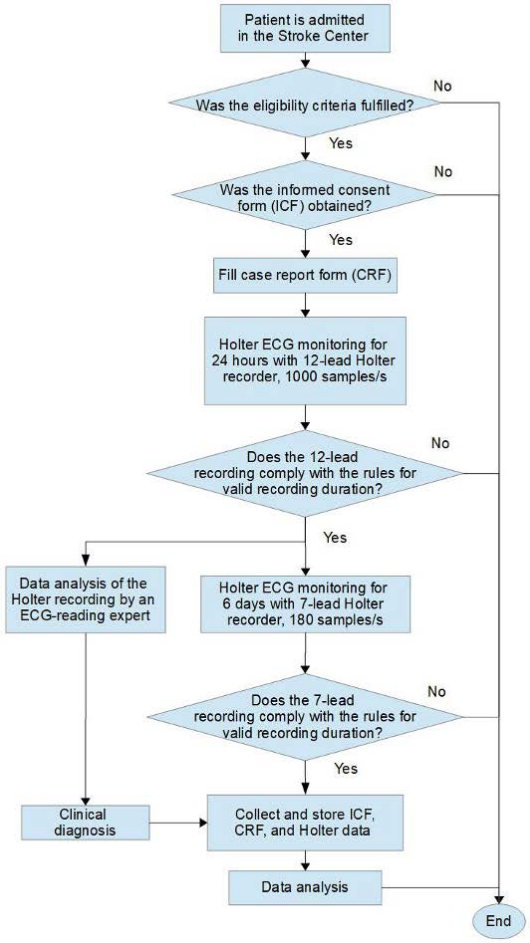

Figure 3: Diagrammatic representation of the workflow of the MY-ATRIA study.

Primary Outcome :

- Prevalence of patients with only BAF episodes in patients with recent IS or TIA without AF history, calculated as the number of screened patients having only BAF episodes divided by the number of screened patients.

Secondary Outcomes :

- Prevalence of PAF episodes in screened patients, calculated as the number of screened patients having PAF episodes divided by the number of screened patients.
- Proportion of patients with only BAF episodes, calculated as the number of screened patients having only BAF episodes divided by the number of screened patients having BAF or PAF episodes.
- Proportion of detected BAF episodes, calculated as the number of detected BAF episodes in screened patients divided by the number of detected BAF or PAF episodes in screened patients.
- Cumulative number of BAF episodes detected after 24-hour, 72-hour, and 7-day Holter monitoring.
- Cumulative number of patients with detected BAF or PAF after 24-hour, 72-hour, and 7-day Holter monitoring.
- Cumulative number of patients with detected PAF after 24-hour, 72-hour, and 7-day Holter monitoring.

Figure 4: Outcomes of the study.

Statistical analysis

Collected data will be summarized with respect to demographic variables and baseline characteristics. Exploratory analysis of demographic, symptoms, comorbidity, and clinical parameters at baseline will be carried out using descriptive statistics and represented using tables, graphs, and histograms. Continuous data will be presented in terms of mean, median, standard deviation, and dichotomous variables in terms of absolute number and percentage.

Univariate and multivariate analyzes will be performed using logistic regression to compare variables. For the multivariate analysis, only factors associated with AF in the univariate analysis will be considered. Baseline characteristics between patients with and without BAF will be compared using different statistical tests including the Wilcoxon test or the t-test for continuous variables and the Fischer's exact test or the chi-square test for dichotomous variables. Additionally, the odds ratio calculation will be used to measure the strength of the association between events. Outcomes with p-value lower than 0.05 will be considered statistically significant.

Sample size calculation

Sample size calculation for this study was based on a binomial distribution model, using the formula [37]:

$$n = \frac{Z^2 P(1-P)}{d^2}$$

where n is the sample size, Z is the statistic corresponding to level of confidence, P is the expected prevalence, and d is the precision. With an expected prevalence of BAF episodes in screened patients of 7% [14], a sample size of 626 patients is needed for the study to have a 95% level of confidence and a 2% precision. Assuming a dropout and exclusion rate of 10%, at least 689 patients fulfilling the eligibility criteria should be enrolled.

Ethical considerations

This study was conducted in compliance with Good Clinical Practice guidelines, the Declaration of Helsinki

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DOI:10.26502/fccm.92920489

and national and international regulations governing clinical trials. The protocol, informed consent form~(ICF), CRF and all study materials were approved by the Comitato Etico di Area Vasta Emilia Centro della Regione Emilia-Romagna with code-ID 605-2020-OSS- AUSLBO - SIRER ID 247 on September 16, 2020. All collected data were anonymized and stored in compliance with the current General Data Protection Regulation. Devices used in this study have CE mark and FDA approval, are market-released, and were used in accordance with their intended use.

Results

During the early enrollment phase, we observed an actual dropout and exclusion rate of approximately 20%, twice our initial assumption. To maintain statistical power and ensure clinical significance, we prospectively adjusted our sample size calculation to account for 20% dropout and exclusion rate. Upon this modification, at least 752 patients fulfilling the eligibility criteria should be enrolled. This proactive adjustment ensured adequate power to detect the expected BAF prevalence while accommodating real-world clinical challenges in prolonged cardiac monitoring studies. Of all IS or TIA patients admitted into the DNSC from June 16, 2021 to January 25, 2024, 792 met the eligibility criteria and were enrolled. Enrolled patients had a mean age of 70.6 ± 13.7 years, with male predominance (58.3%, 462/792), and the majority presented with IS (96.5%, 764/792). Following enrollment, 19.5% of patients (155/792) were removed due to insufficient Holter recordings duration. Some reasons for insufficient recordings duration included non-collaborative or agitated patients, early discharged to another destination, and patient's will. The validity of Holter recordings was checked using an automated algorithm that analyzed ECG lead fail, further exclusions could be necessary after assessing the quality of the signals. The final cohort comprised 637 screened patients who completed the full monitoring protocol. This cohort maintained similar baseline characteristics to the enrolled population, with a mean age of 70.3 ± 13.8 years, and comparable male predominance (58.9%, 375/637). The proportion of IS (96.5%, 615/637) also remained consistent. Among screened patients, the mean and median time interval from indexing event to enrollment was 2.29 ± 1.62 days and 2 days, respectively, and Holter monitoring started as soon as possible and no later than 7 days after indexing event.

Discussion

The aim of the MY-ATRIA study is to determine the prevalence of BAF episodes in patients with recent IS or TIA without AF history. For this purpose, we designed the study protocol in compliance with monitoring recommendations from previous studies, emphasizing early monitoring after indexing event, prolonged monitoring duration and increased sample size population to enhance detection rates. Prolonged 7-day Holter monitoring was performed using two recorders. The first 24 hours using the H12+™ and the subsequent 6 days using the H3+™. This strategy was selected to comply with the standard clinical routine in the DNSC for patients with IS or TIA of unknown etiology performing Holter monitoring for 24 hours. Furthermore, this strategy aligns with recommendations from previous studies showing that prolonged monitoring for 7 days or more significantly enhances detection rates of BAF [13–15] and AF [12,34,35]. Some studies using mobile cardiac outpatient telemetry [19,22,23] for 3 weeks or more have reported high detection rates of BAF. However, prolonged use of electrodes can cause skin discomfort, leading patients in some studies to discontinue monitoring before completion [22,23,30,31]. The 7-day Holter monitoring employed in our study represents a practical compromise between detection efficiency and patient comfort, ensuring feasibility for clinical implementation. A key methodological feature of the MY-ATRIA study is the initiation of monitoring within 7 days after indexing event. This decision is supported by evidence suggesting that the yield of AF detection is highest in the immediate post-event period [12,14]. Among the studies reviewed by Sposato et al. [15], only six studies [16,18,20,25,28,29] reported time to monitoring shorter than 7 days, while the median time to monitoring of the remaining studies was 49 days (range 16 to 93). The MY-ATRIA study's protocol ensures that monitoring begins as soon as possible after the event, increasing the likelihood of capturing clinically relevant arrhythmias. Sample size is another critical factor influencing the robustness of study findings. Previous studies have large variability in sample, ranging from 24 to 1507 patients. Notably, five have sample size smaller than 100 [23,28,29,32,33], and four of the studies with the largest sample size monitored patients for only one [20,24,26] or two days [25], potentially limiting their ability to detect episodes of BAF. Several studies have recommended that future research should aim for larger sample size to provide generalizability of findings [16,19,29,32,33]. This study tries to address this need by monitoring 637 patients to ensure statistical power and provide more robust estimates of BAF prevalence. The predominant definition of BAF refers to AF episodes shorter than 30 seconds [16,18–23,25,26,30,32,33] but some variations to this definition have been used. For example, Higgins et al. [29] defined BAF as a non-sustained PAF episode of at least 6 conducted ventricular complexes but shorter than 20 seconds, while Yetim et al. [24] considered supraventricular runs with more than 3 beats, lasting less than 30 seconds with absolutely irregular RR interval and no distinct P-waves as BAF. Alves et al. [28] defined BAF as supraventricular arrhythmias with a minimum duration of 10 seconds. The 2024 Guidelines [5] do not specify a particular terminology for AF episodes shorter than 30 seconds but acknowledge the need for validation of the 30-second

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threshold in the definition of clinical AF and its relevance to AF-related outcomes.

Detection of BAF episodes is particularly important in IS or TIA patients since BAF episodes are likely to progress into clinical AF [13,38,39]. Previous studies investigating the prevalence of clinical AF in IS or TIA patients [12,36] and in the elderly population [13,39] have highlighted the needed for a standardized approach to detecting and treating BAF episodes, particularly in elderly populations and those with additional stroke-related risk factors. Results from the MY-ATRIA study aim to provide robust data on the prevalence of BAF in IS and TIA patients that may contribute to the development of future guidelines and treatment strategies. Despite its strengths, the MY-ATRIA study has certain limitations. The exclusion of patients with insufficient monitoring duration may introduce selection bias, potentially underestimating the true prevalence of BAF in the study population. Another significant limitation is that the study is a single-center study conducted in Italy. Single-center studies may be influenced by local patient demographics and clinical practices, which may not be representative of general populations. Future studies should aim to include more diverse patient populations and explore the long-term implications of BAF detection on stroke recurrence and patient outcomes.

Conclusion

The MY-ATRIA study performed 7-day Holter monitoring on patients with recent IS or TIA without AF history to investigate the prevalence of BAF episodes. This study was designed as a single-center observational and transversal prospective clinical study. Results from this study will contribute to measuring the prevalence of IS or TIA patients with BAF episodes and the proportion of BAF episodes among all detected AF episodes. However, further research is needed to determine whether BAF episodes represent an independent risk factor for thromboembolism and whether they warrant the same treatment as clinical AF.

Acknowledgements

Contributorship

RSM, NM, AF, JDB, FS, AZan and AZin conceived the study. RSM and AF researched literature and drafted the protocol. RSM, AF, JDB and AZin were involved in ethical approval. AZan, LP, MG, SF, FN, MP, LB, LG and AZin were involved in patient enrollment. LM and LRu were involved in Holter data acquisition. LR, FP, VC, GB and GC were involved in cardiological assessment and Holter data quality control. RSM wrote the manuscript. RSM and NM edited the manuscript. RSM, NM, FS and AZin reviewed the manuscript. All authors approved the final version of the manuscript.

Statements and declarations

Ethical considerations

The protocol, ICF, CRF and all study materials were approved by the Comitato Etico di Area Vasta Emilia Centro della Regione Emilia-Romagna with code -ID 605-2020-OSS- AUSLBO - SIRER ID 247 on September 16, 2020.

Consent to participate

Participants provided written informed consent prior to participating. All collected data were anonymized and stored in compliance with the current General Data Protection Regulation.

Consent for publication

Not applicable.

Declaration of conflicting interest

AZin reports consulting and speaker fees from Bayer, Boehringer-Ingelheim, Alexion, Daiichi Sankyo, Pfizer, PIAM, Amgen, fees for Advisory Board from Boehringer-Ingelheim, Daiichi Sankyo, Bayer and Astra Zeneca, not related to this study.

RSM, NM, AF, JDB declare that they worked for Baxter International Inc. – Mortara Instrument Europe during their contribution to the study.

Funding

This study is framed inside MY-ATRIA consortium which received funding from the European Union's Horizon 2020 research and innovation program Marie Skłodowska-Curie [grant No.766082] and is governed by an agreement between Mortara Instrument Europe, now a subsidiary of Baxter International Inc., and Local Health Authority of Bologna – IRCCS Institute of Neurological Sciences of Bologna. Based on the agreement, Mortara Instrument Europe granted the IRCCS Institute of Neurological Sciences of Bologna the free loan of the equipment needed to acquire and upload data, and carried out the reports for 12-lead Holter recordings through a certified external provider. The publication fees for this article are covered by Baxter International Inc. – Mortara Instrument Europe.

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Citation: Salinas-Martínez Ricardo, Zaniboni Anna, Piccolo Laura, Migliaccio Ludovica, Rubini Lorenza, Riva Letizia, Fiorani Ambra, Paolucci Matteo, Gentile Mauro, Forlivesi Stefano, Pergolini Francesco, Carinci Valeria, Bugani Giulia, Brancaleoni Laura, Naldi Federica, Gentile Luana, Sandberg Frida, De Bie Johannes, Marzocchi Nicoletta, Casella Gianni, Zini Andrea. Prevalence of Brief Atrial Fibrillation in Ischaemic Stroke and Transient Ischaemic Attack - The MY-ATRIA Study: Rationale and Design. Cardiology and Cardiovascular Medicine.10 (2026): 102-109.

Ricardo S, et al., Cardiol Cardiovasc Med 2026
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