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Diagnosis of atrial fibrillation in postoperative thoracic surgery using a smartwatch: an open-label randomized controlled study (THOFAWATCH Trial)

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Strengths and limitations of this study

- The trial will be a prospective, bicentric, randomized trial and will include 202 adult patients undergoing major thoracic surgery (pneumonectomy or lobectomy).
- The intervention that is being investigated is the use of a smartwatch-based monitoring to detect the occurrence of postoperative atrial fibrillation (POAF) following thoracic surgery.
- No study have yet evaluated the effectiveness of smartwatches in detecting POAF after thoracic surgery.
- The primary endpoint will be the incidence of POAF within seven days post-surgery
- The secondary endpoints will include the rate of asymptomatic POAF, cardiovascular prognosis evaluated at 2 and 6 months (composite MACE outcome), feasibility of smartwatch usage (device usage time and success rate of single-lead ECGs), and recurrence or management of AF at follow-up

Introduction

Postoperative atrial fibrillation (POAF) affects approximately 20% of patients undergoing thoracic surgery and is associated with severe complications such as stroke, myocardial infarction, heart failure, and increased mortality. Early diagnosis is critical to mitigate these risks, but conventional monitoring is limited in detecting asymptomatic episodes. Smartwatches equipped with single-lead ECG and atrial fibrillation (AF) detection algorithms offer a novel approach for early POAF detection. This study aims to evaluate the effectiveness of smartwatch-based monitoring compared to standard care in identifying POAF following thoracic surgery.

Methods and Analysis

The THOFAWATCH trial is a randomized, bicentric open-label study enrolling 202 adult patients undergoing major thoracic surgery (pneumonectomy or lobectomy) with one-lung ventilation. Eligible patients will be randomized into two groups: (1) the “Smartwatch Monitoring” group, where participants will undergo rhythm monitoring using a smartwatch, and (2) the “Conventional Monitoring” group, receiving standard care without smartwatch monitoring. In the intervention group, any smartwatch-detected POAF episodes will be confirmed by 12-lead ECG. The primary outcome is the incidence of POAF within seven days post-surgery. Secondary outcomes include the rate of asymptomatic POAF, cardiovascular prognosis evaluated at 2 and 6 months (composite MACE outcome), feasibility of smartwatch usage (device usage time and success rate of single-lead ECGs), and recurrence or management of AF at follow-up. Inclusion criteria include adults (>18 years) undergoing scheduled thoracic surgery and able to use the smartwatch device. Exclusion criteria encompass patients with prior atrial fibrillation, those requiring telemetry, or undergoing reoperations. Statistical analysis will assess the primary outcome using chi-square or Fisher's exact test (α = 5%), while secondary outcomes will include descriptive and inferential statistics, with analysis conducted using SAS version 9.4.

Ethics and Dissemination

Ethical approval for this study has been granted by the appropriate institutional review board. The trial is registered under ClinicalTrials.gov (ID: [NCT06724718]). Results will be disseminated through peer-reviewed publications and scientific conferences to inform clinical practice regarding POAF detection and management following thoracic surgery.

Trial registration: NCT06724718 (Clinical trial)

Introduction

Postoperative atrial fibrillation (POAF) occurs in approximately 20% of patients undergoing major thoracic surgery and is associated with increased risks of heart failure, stroke, myocardial infarction, and death, leading to higher morbidity, prolonged hospital stays, and elevated healthcare costs (1) (2). POAF episodes are often paroxysmal and asymptomatic, raising the likelihood of developing permanent atrial fibrillation within five years by 4–5 times(1). Most episodes occur between 2 and 5 days post-surgery, primarily in conventional surgical units without continuous cardiac monitoring, unlike critical care units where rhythm monitoring is routine(2). The absence of monitoring in these settings leaves asymptomatic cases undiagnosed, exposing patients to greater risks of adverse outcomes(4). Treatment often involves bradycardic agents and, in cases exceeding 48 hours, anticoagulation therapy based on thromboembolic and bleeding risk scores(1).

Smartwatches equipped with single-lead ECG capabilities and algorithms for atrial fibrillation detection provide a promising solution for identifying POAF(5). These devices utilize photoplethysmography (PPG), a non-invasive optical technique to analyze blood volume changes in superficial tissues, enabling heart rhythm monitoring and oxygen saturation measurement(6,7). The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) recommend their use to detect atrial fibrillation, aiming to reduce its economic impact (8). However, no studies have yet evaluated the effectiveness of smartwatches in detecting POAF after thoracic surgery. Their use could address the unmet need for continuous monitoring in conventional units, enabling early detection and management of POAF.

We hypothesize that the use of smartwatches in patients undergoing elective major thoracic surgery with lung exclusion could significantly enhance the early detection of postoperative atrial fibrillation (POAF) compared to conventional monitoring and improve diagnostic performance during the hospital stay.

METHODS AND ANALYSIS

Study design

This is a randomized, prospective, multicenter (2 centers), open-label study.

Study population

The inclusion criteria are as follows:

- Patients with more than 18 years old
- Patients undergoing major elective thoracic resection surgery with pulmonary exclusion (one-lung ventilation) within the past 48 hours.
- Elective pneumonectomy or Lobectomy surgery.
- Post-surgery transfer to a conventional care unit.
- Patients with motor and cognitive ability to perform single-lead ECGs using the smartwatch.
- Social security coverage.
- Written informed consent from patient or next of kin.

The non-inclusion criteria are as follows:

- History of atrial fibrillation.
- Need for telemetry monitoring for atrioventricular block and/or rapid supra- or ventricular arrhythmias.
- Dependence on atrial or ventricular pacing from a pacemaker.
- Inclusion in another interventional clinical trial affecting POAF incidence.
- Mediastinal surgery (e.g., mediastinal mass resection or mediastinoscopy).
- Chest wall surgery (e.g., lymph node biopsy or wall repair).
- Pleural surgery (e.g., pneumothorax or pleurisy management).
- Reoperation of the surgical site (early or delayed).
- Surgery conducted >48 hours prior.
- Pregnancy
- Coexisting illness with a high probability of death (inferior to 6 months)

Study protocol

Randomization

Patients will be randomized into two parallel groups. Randomization will be conducted using the Ennov Clinical® software implemented by a data manager. Randomization will occur within 48 hours post-surgery (up to the 48th hour) while the patient is hospitalized, provided there are no prior rhythm disturbances or indications for intensive care with telemetry monitoring. The result of randomization will be displayed as “Conventional Monitoring” or “Smartwatch Monitoring” (Figure 1). The randomization will be stratified based on the following criteria: age over 65 years, diabetes, and open thoracotomy approach. The diagram of the study process is shown in Figure 2.

Intervention

In the “Smartwatch Monitoring” group, POAF will be identified using a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >20 seconds recorded by a single-lead ECG or POAF detected via PPG signals and/or a 12-lead ECG. More specially, the smartwatch detects episodes of POAF using its artificial intelligence algorithm. Confirmation is then required, either through a 1-lead ECG recorded by the smartwatch or a 12-lead ECG.

Patients will return the smartwatch at day 7 after surgery or the day of hospital discharge during the second follow-up visit (V2). The main difference in this group lies in the fact that, in addition to conventional monitoring, the patient can perform an 12-lead ECG independently, either on demand or in the presence of symptoms.

The smartwatch used in this study will be the ScanWatch 42mm, which is CE-marked (CE 1282) for the diagnosis of atrial fibrillation (AF). The smartwatch allows for heart rate monitoring (Continuous monitoring via PPG using three integrated LEDs), Single-lead ECG recordings (The smartwatch allows patients to perform 20-second ECG recordings by placing one hand on the watch's case) and data integration (The device is equipped to record and transmit data and ECG tracings via Bluetooth to the Health Mate app). Data from the smartwatch will be retrieved via the Health Mate app by the investigator during follow-up visits (V1 and V2). The smartwatch will be collected from the patient during the second follow-up visit (V2, Day 7).

Standard procedures

In the " Conventional Monitoring " group, patients in both centers (Amiens University hospital and Clinic Victor Pauchet) will be screened for POAF using a 12-lead ECG based on routine monitoring protocols

Specifically, in the “Conventional Monitoring” group POAF will be diagnosed with a 12-lead ECG which will only be carried out in the event of clinical symptoms and/or significant variations in heart rate observed by medical or paramedical staff.

All patients will receive standardized postoperative monitoring. This includes regular checks conducted every four hours. These checks will encompass the following parameters: non-invasive blood pressure, heart rate, oxygen saturation (SpO_2).

In both groups, the management of POAF will involve several essential steps:

- Assessment of hemodynamic stability: Evaluate hemodynamic tolerance and perform cardioversion in cases of poor tolerance.
- Correction of coexisting disorders: Address underlying issues such as hypoxemia, postoperative complication, sepsis or electrolyte imbalances.
- Treatment of atrial fibrillation: Implement rhythm control strategies and initiate antiarrhythmic therapy.
- Decision on curative anticoagulation: In accordance with guidelines, anticoagulation decisions should be based on several factors, primarily the patient's thromboembolic risk as assessed by the CHA2DS2-VASc score and the absence of significant hemorrhagic risk.
- Follow-up consultation: Provide a prescription and schedule a cardiology follow-up appointment after discharge.

Outcome measures

Primary endpoint

The endpoints and definitions are presented in Table 1.

The primary outcome measure will be the occurrence of POAF after major elective thoracic surgery within 7 postoperative days.

POAF is defined according to the 2020 ESC recommendations (1).

- POAF diagnosed by a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >20 seconds recorded by a single-lead ECG or POAF detected via PPG signals.

- POAF diagnosed in the standard care group will be confirmed using a 12-lead ECG.
- POAF diagnosis will be confirmed through interpretation of single-lead or 12-lead ECGs by a cardiologist.

Secondary endpoint

The secondary endpoints will be:

- Asymptomatic POAF prevalence, assessed by the number of patients presenting with postoperative POAF without symptoms. Symptoms will be evaluated using the EHRA score (Appendix).
- Cardiovascular prognosis, assessed using a composite endpoint of postoperative cardiovascular complications (MACE criteria) as defined by ESA and ESCIM standards (9). MACE criteria will be analyzed at 2 months and 6 months and validated in the presence of one of the following:
    - *Stroke:* Hemorrhagic or ischemic stroke with persistent sensory, motor, or cognitive deficits (e.g., hemiplegia, hemiparesis, aphasia, memory impairment).
    - *Myocardial infarction:* Elevated cardiac markers (e.g., myoglobin, troponin I) above the 99th percentile per lab standards; ischemic symptoms; ST-segment changes or left bundle branch block on ECG; Q waves; or evidence of coronary thrombus via angiography or autopsy
    - *Congestive heart failure:* New in-hospital signs or symptoms of dyspnoea or fatigue, orthopnoea, paroxysmal nocturnal dyspnoea, increased jugular venous pressure, pulmonary râles on physical examination, cardiomegaly or pulmonary vascular engorgement.
    - *Mesenteric ischemia*: Mesenteric ischemia confirmed by imaging or exploratory laparotomy, and/or ischemic colitis confirmed by digestive endoscopy or laparotomy.
    - *Resuscitated cardiac arrest*: Loss of mechanical cardiac activity confirmed by the absence of clinical signs of circulation.
    - *Cardiovascular death.*

- Feasibility of monitoring POAF using a smartwatch after thoracic surgery: Evaluated based on device wear time and the completion rate of patient-performed single-lead ECGs in case of POAF detection.
- Recurrence and management of POAF: Rhythm status (AF yes/no) at 2 and 6 months, treatment for cardioversion (e.g., electrical cardioversion, ablation, or medication).

Data collection and outcome definitions

The following data will be collected: age (years), gender, body mass index (kg m^{-2}), usual medication, medical history (coronary disease, peripheral vascular disease, stroke, smoking, diabetes, dyslipidemia, chronic obstructive pulmonary disease, hypertension, chronic kidney disease, creatinine clearance, blood creatinine levels, surgery type, neurological conditions (stroke, transient ischemic attack (TIA), dementia), deep vein thrombosis/pulmonary embolism, electrocardiogram, $CHAD_2S$-$VASC_2$ score, and HASBLED score.

Also, the following perioperative data will be collected : date of surgery, nature of the surgical procedure performed, surgical approach: minimally invasive surgery with video thoracoscopy, robot-assisted surgery, conversion to thoracotomy, duration of anesthesia, type of regional anesthesia performed, perioperative administration of blood products and the amount administered, total dose of phenylephrine, ephedrine, norepinephrine, nicardipine, dobutamine, adrenaline administered, administration of a beta-blocker or amiodarone during surgery.

Postoperative data include duration of orotracheal intubation, duration, type, and total dosage of catecholamines, postoperative VIS score, transfusion of blood products (type and quantity), total thoracic drain output (ml), reoperation, reintubation, MACE criterion, respiratory, infectious, neurological, and renal complications, duration of stay in continuous care, duration of hospital stay. Biological data will be recorded (Plasma hemoglobin, serum creatinine, urea, sodium, potassium, calcium, phosphorus, troponin US, leukocytes, CRP, TSH, BNP). During hospitalization, the following clinical parameters will be recorded: general hemodynamic parameters (heart rate, systolic, diastolic, and mean blood pressure, oxygen saturation, oxygen therapy administered), and the MACE criterion.

For the “Smartwatch Monitoring” group: number of single-lead ECGs performed, presence of POAF, duration of smart watch usage, clinical symptoms (EHRA), duration of POAF, and treatment provided for POAF.
For the “Conventional Monitoring” group: 12-lead ECGs performed, presence of POAF, clinical symptoms (EHRA), duration of POAF, and treatment provided for POAF.

2 months after surgery and 6 months after surgery, the following data will be collected: MACE criterion occurrence, the recurrence of POAF and management of POAF: rhythm status (AF yes/no), treatment for cardioversion (external electrical shock, ablation, pharmacological treatment). The recurrence of AF will be recorded in the hospital by performing an electrocardiogram if the patient is hospitalized. If the patient is not hospitalized, the data will be collected through a phone call to the patient and by reviewing the medical record (consultation for cardioversion, cardiology follow-up, follow-up for other conditions).

Endpoints will be assessed after thoracic surgery. Adverse events will be declared and notified in the eCRFs.
Standard definitions of postoperative outcomes established by the European Society of Anesthesia will be used (9). Cardiac arrest is defined as the cessation of cardiac mechanical activity, as confirmed by the absence of circulation signs. Stroke is defined as an embolic, thrombotic, or hemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g. hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) diagnosed on a cerebral scanner. Acute kidney injury is defined according to Kidney Disease Improving Global Outcomes (KDIGO) criteria as an increase in serum creatinine of over 27 µmol/L within 48 h or diuresis lower than 0.5 mL/kg/h (10). Myocardial injury is diagnosed by the characteristics presentation, serial changes on 12-lead electrocardiographic suggesting infarction, and arise in cardiac troponin, with at least one value above the 99th percentile of the upper reference limit (11). Mesenteric ischemia will be confirmed by imaging or exploratory laparotomy and ischemic colitis will be confirmed by gastrointestinal endoscopy or exploratory laparotomy.

Intention-to-treat analysis

Patients with serious adverse events will be analyzed according to their assigned group following the intention-to-treat principle.

Statistical method and Sample size calculation

In recent studies, the incidence of POAF in the studied population was 20%, with AF predominantly occurring within the first 4 postoperative days. The percentage of POAF at Day 7 is not precisely known, but since most cases occur relatively early, we estimate this percentage to be around 20%. Based on these assumptions, we would need 286 evaluable patients (142 per group) to detect an absolute difference of 12% (20% vs. 8%) in the incidence of AF with a two-sided alpha risk of 5% and a power of 80%. Anticipating 5% of non-evaluable patients, we will randomize 302 patients (151 per group).

Primary Endpoint (incidence of POAF) will be compared between the two groups using either a chi-squared test or Fisher's exact test, with a significance level set at 5%.
Regarding secondary endpoints, the percentage of asymptomatic POAF in the " Smartwatch Monitoring " group will be calculated with a 95% confidence interval. The percentage of major adverse cardiovascular events (MACE) at 6 months among patients diagnosed with asymptomatic POAF in the " Smartwatch Monitoring " group will also be calculated with a 95% confidence interval. In the " Smartwatch Monitoring " group, the duration of MI use will be expressed as mean ± standard deviation or median [range]. The percentage of patients performing a single-lead ECG in the case of POAF will be calculated with a 95% confidence interval. A p value of 0.05 will be considered as significant. No intermediate analysis is planned in the trial. Statistical analyses will be performed using SAS software version 9.4.
"Conventional Monitoring" or "Smartwatch Monitoring".

Data management and monitoring

Registration

Data will be collected and registered using electronic case report forms (eCRFs) by a dedicated local research technician. A research coordinator will centralize and verify the data.

Record keeping

Consent forms and eCRFs will be retained for 15 years at the University Hospital of Amiens in accordance with French law.

Study organization

The study promotion is performed by the University Hospital of Amiens, France. The Victor Pauchet Clinic is an associated investigator center.

Duration and timeline

Patients from Amiens university hospital and Victor Pauchet clinic can be included during a 2-year period beginning from January 2025.

The processes of developing the protocol, obtaining approval from the ethical committee, obtaining financial support, and developing the eCRFs occurred in 2024. The database should be closed after all participants have been included, followed by data analysis, manuscript writing and submission for publication.

ETHICS AND DISSEMINATION

The institutional review board (IRB) of the University Hospital of Amiens (*Comité de Protection des Personnes sud-ouest et outre-mer 1, 21050 Toulouse, France*) approved the study (Registration number ID RDB: 2022-A02028-27 in November 2024). The THOFAWATCH study will be conducted in accordance with the Declaration of Helsinki and French law on clinical research (12) and was registered on the 05th of december 2024 on the ClinicalTrials.gov website with the trial identification number NCT06724718. THOFAWATCH trial follows CONSORT Statement - CONSORT diagram is given in Figure 1 (13). Written informed consent will be obtained from all participants or next of kin.

Authors will be involved in disseminating research findings (through attending conferences and co-authoring results 'papers).

Patients or public involvement

Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research. Written informed consent will be obtained from all participants or next of kin.

Discussion

The hypothesis suggests that utilizing smartwatches for patients undergoing planned major thoracic surgery may notably enhance the detection of postoperative POAF compared to traditional monitoring methods.

POAF after thoracic surgery arises due to a combination of autonomic imbalance, systemic inflammation, and atrial remodeling. The surgical stress response activates the sympathetic nervous system, which, along with inflammation from tissue injury and oxidative stress, contributes to electrophysiological instability(14–16). These factors interact dynamically during the perioperative period, leading to the development of transient or sustained atrial fibrillation episodes(17).

Postoperative atrial fibrillation (POAF) is a recurrent issue following major surgery, particularly in thoracic surgery(1). Smartwatches have demonstrated good diagnostic performance, with high sensitivity and specificity, in non-surgical settings(8). The key challenge lies in detecting arrhythmias and diagnosing asymptomatic or highly transient AF episodes postoperatively. Most arrhythmias are paroxysmal, and a standard 12-lead ECG often fails to identify these episodes. Thus, we designed this study to evaluate the value of continuous smartwatch monitoring to overcome this limitation.

A recent study by Monteiro et al. on 108 patients showed that smartwatches, compared to conventional monitoring, provided improved monitoring, early arrhythmia detection, and better patient outcomes (18). However, no study to date has focused on this topic after thoracic surgery. We hypothesize that continuous smartwatch use can enhance AF detection following thoracic surgery.

To limit the scope, smartwatch monitoring is restricted to a maximum of 7 days, as POAF predominantly occurs early in the postoperative period.

This study holds several key strengths. It represents the first exploration of atrial fibrillation detection in the specific context of postoperative thoracic surgery, addressing a critical gap in the existing literature. Furthermore, its multicenter design ensures diverse patient representation and robust data collection, while the inclusion of a significant sample size enhances the reliability and generalizability of its findings.

This study aims to enable early diagnosis of AF, reduce economic and hospitalization burdens, and improve patient outcomes through tailored care and remote monitoring protocols.

Trial status

The trial is not yet recruiting.

List of abbreviations

AF: Atrial fibrillation

EACTS: European Association for Cardio-Thoracic Surgery

ECG: *Electrocardiogram*

EHRA: European Heart Rhythm Association

ESC: European Society of Cardiology

E-crf: electronic case report form

IRB: institutional review board

KDIGO: Kidney Disease: Improving Global Outcomes

LED: Light Emitting Diode

MACE: Major Adverse Cardiovascular Events

POAF: *Postoperative atrial fibrillation*

TIA: Transient ischemic accident

PPG: photoplethysmography

VIS: Vasoactive-inotropic score

Declarations

Ethics approval and consent to participate

The institutional review board (IRB) of the University Hospital of Amiens (*Comité de Protection des Personnes sud-ouest et outre-mer 1, 21050 Toulouse, France*) approved the study (Registration number ID RDB: 2022-A02028-27 in November 2024). The THOFAWATCH study was registered on the 05th of december 2024 on the ClinicalTrials.gov website with the trial identification number NCT06724718. We will obtain informed, written consent from all participants in the study.

Consent for publication

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article because no datasets were generated or analyzed during the current study. However, data from the study will be made available at the end of the trial, on request.

Competing interests

The authors declare that they have no competing interests.

Funding

The THOFAWATCH trial is sponsored by Amiens Hospital University.

Author contributions

PH and CB participated in the design of the study and helped to write the manuscript. OAA, AI, GH, MG, TL, HD and YM participated in the design of the study. MD will perform the statistical analysis. All authors read and approved the final manuscript.

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Monitoring of adverse events:

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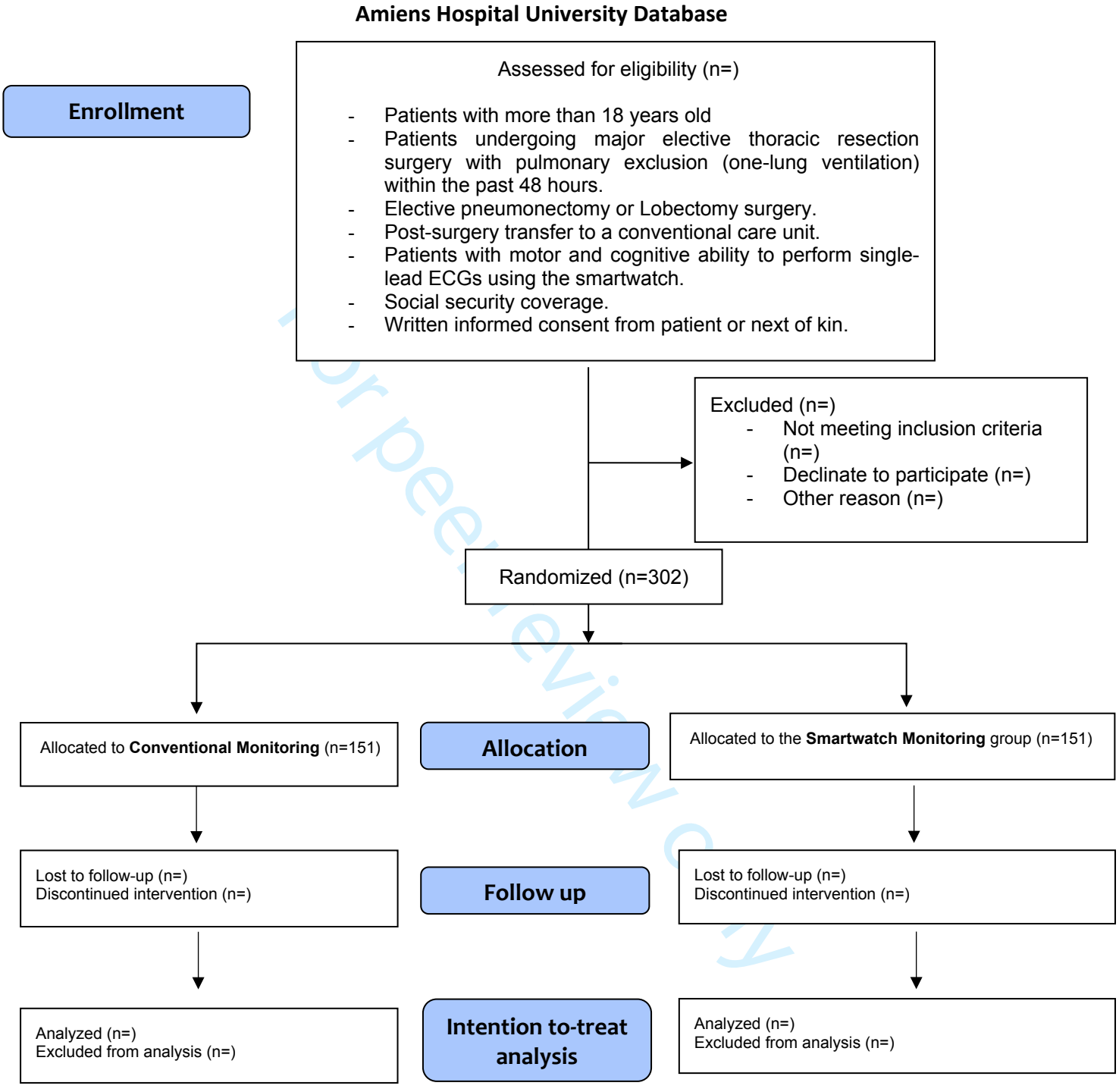
Figure 1. CONSORT diagram



ECG: Electrocardiogram;

Figure 1. Diagram of the study process

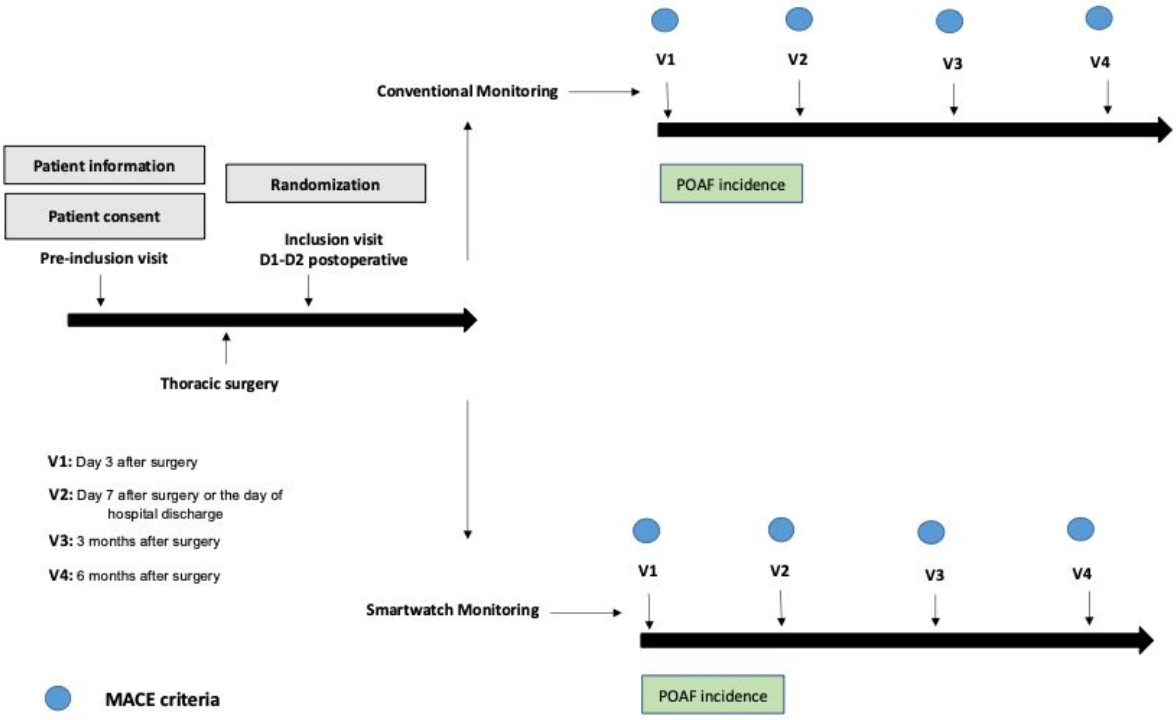


Table 1. Endpoints and definitions

Endpoints	*Definitions*
Primary endpoint	
Occurrence of POAF after major elective thoracic surgery within 7 postoperative days.	POAF is defined according to the 2020 ESC recommendations. - POAF diagnosed by a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >30 seconds recorded by a single-lead ECG or POAF detected via PPG signals and confirmed by a 12-lead ECG. - POAF diagnosed in the standard care group will be confirmed using a 12-lead ECG. - POAF diagnosis will be confirmed through interpretation of single-lead or 12-lead ECGs by a cardiologist.
Secondary endpoints	
Asymptomatic POAF prevalence	- Number of patients presenting with postoperative POAF without symptoms. Symptoms will be evaluated using the EHRA score (Appendix).
Major Cardiovascular and Cerebral Event (MACE)	One of the following criteria (Definitions above): - Stroke - Myocardial infarction - Acute kidney injury - Mesenteric ischemia - Successful resuscitated cardiac arrest
Stroke	An embolic, thrombotic, or hemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) diagnosed on a cerebral scanner
Myocardial infarction	Myocardial infarction was diagnosed by the characteristics presentation, serial changes on 12-lead electrocardiographic suggesting infarction, and arise in cardiac markers, preferably cardiac troponins, with at

	least one value above the 99th percentile of the upper reference limit
Congestive heart failure	New in-hospital signs or symptoms of dyspnoea or fatigue, orthopnoea, paroxysmal nocturnal dyspnoea, increased jugular venous pressure, pulmonary râles on physical examination, cardiomegaly or pulmonary vascular engorgement.
Mesenteric ischemia	Mesenteric ischemia confirmed by imaging or exploratory laparotomy and/or ischemic colitis confirmed by gastrointestinal endoscopy or exploratory laparotomy
Resuscitated cardiac arrest	Cessation of mechanical cardiac activity confirmed by the absence of clinical signs of blood flow.
Feasibility of monitoring POAF using a smartwatch after thoracic surgery	Evaluated based on device wear time and the completion rate of patient-performed single-lead ECGs in case of POAF detection.
Recurrence and management of POAF	Rhythm status (AF yes/no) at 3 and 6 months, treatment for cardioversion (e.g., electrical cardioversion, ablation, or medication).

AF: Atrial Fibrillation**, EHRA:** *European Heart Rythm Association,* **POAF:** Postoperative atrial fibrillation.

EHRA score	Symptoms
EHRA I	None: No symptoms.
EHRA II	**IIa:** Mild: Moderate symptoms not affecting daily life.
	IIb: Intermediate: Moderate symptoms not affecting daily life but causing discomfort for the patient.
EHRA III	Severe: Severe symptoms affecting daily life.
EHRA IV	Disabling: Symptoms necessitating the interruption of daily activities.

European Heart Rhythm Association score: Evaluation of symptomatology of patients with Atrial Fibrillation

BMJ Open

Diagnosis of atrial fibrillation in postoperative thoracic surgery using a smartwatch: an open-label randomized controlled study (THOFAWATCH Trial)

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Diagnosis of atrial fibrillation in postoperative thoracic surgery using a smartwatch: an open-label randomized controlled study (THOFAWATCH Trial).

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Introduction

Postoperative atrial fibrillation (POAF) affects approximately 20% of patients undergoing thoracic surgery and is associated with severe complications such as stroke, myocardial infarction, heart failure, and increased mortality. Early diagnosis is critical to mitigate these risks, but conventional monitoring is limited in detecting asymptomatic episodes. Smartwatches equipped with single-lead ECG and atrial fibrillation (AF) detection algorithms offer a novel approach for early POAF detection. This study aims to evaluate the effectiveness of smartwatch-based monitoring compared to standard care in identifying POAF following thoracic surgery.

Methods and Analysis

The THOFAWATCH trial is a randomized, bicentric open-label study enrolling 302 adult patients undergoing major thoracic surgery (pneumonectomy or lobectomy) with one-lung ventilation. Eligible patients will be randomized into two groups: (1) the “Smartwatch Monitoring” group, where participants will undergo rhythm monitoring using a smartwatch, and (2) the “Conventional Monitoring” group, receiving standard care without smartwatch monitoring. In the intervention group, any smartwatch-detected POAF episodes will be confirmed by 12-lead ECG. The primary outcome is the incidence of POAF within seven days post-surgery. Secondary outcomes include the rate of asymptomatic POAF, cardiovascular prognosis evaluated at 2 and 6 months (composite MACE outcome), feasibility of smartwatch usage (device usage time and success rate of single-lead ECGs), and recurrence or management of AF at follow-up. Inclusion criteria include adults (>18 years) undergoing scheduled thoracic surgery and able to use the smartwatch device. Exclusion criteria encompass patients with prior atrial fibrillation, those requiring telemetry, or undergoing reoperations. Statistical analysis will assess the primary outcome using chi-square or Fisher's exact test (α = 5%), while secondary outcomes will include descriptive and inferential statistics, with analysis conducted using SAS version 9.4.

Ethics and Dissemination

Ethical approval for this study has been granted by the institutional review board (IRB) of the University Hospital of Amiens (Comité de Protection des Personnes sud-ouest et outre-mer 1, 21050 Toulouse, France, registration number ID RDB: 2022-A02028-27 in November 2024). The trial is registered under ClinicalTrials.gov (ID: [NCT06724718]). Results will be disseminated through peer-reviewed publications and

scientific conferences to inform clinical practice regarding POAF detection and management following thoracic surgery.

Trial registration: NCT06724718 (Clinical trial)

Strengths and limitations of this study

- The trial will be a prospective, bicentric, randomized trial and will include adult patients undergoing major thoracic surgery (pneumonectomy or lobectomy).
- The intervention that is being investigated is the use of a smartwatch-based monitoring to detect the occurrence of postoperative atrial fibrillation (POAF) following thoracic surgery.
- No study have yet evaluated the effectiveness of smartwatches in detecting POAF after thoracic surgery.
- The primary endpoint will be the incidence of POAF within seven days post-surgery
- The secondary endpoints will include the rate of asymptomatic POAF, cardiovascular prognosis evaluated at 2 and 6 months (composite MACE outcome), feasibility of smartwatch usage (device usage time and success rate of single-lead ECGs), and recurrence or management of AF at follow-up

INTRODUCTION

In patients undergoing major non-cardiac surgery, postoperative atrial fibrillation (POAF) is a common and significant complication associated with increased risks of heart failure, stroke, myocardial infarction, and death, leading to higher morbidity, prolonged hospital stays, and elevated healthcare costs [1] [2] [3]. POAF episodes are often paroxysmal and asymptomatic, raising the likelihood of developing permanent atrial fibrillation within five years by 4–5 times[2]. Most episodes occur between 2 and 5 days post-surgery, primarily in conventional surgical units without continuous cardiac monitoring, unlike critical care units where rhythm monitoring is routine(2). The absence of monitoring in these settings leaves asymptomatic cases undiagnosed, exposing patients to greater risks of adverse outcomes[5]. Treatment often involves bradycardic agents and, in cases exceeding 48 hours, anticoagulation therapy based on thromboembolic and bleeding risk scores[2].

Smartwatches equipped with single-lead ECG capabilities and algorithms for atrial fibrillation detection provide a promising solution for identifying POAF with high accuracy [6, 7]. These devices utilize photoplethysmography (PPG), a non-invasive optical technique to analyze blood volume changes in superficial tissues, enabling heart rhythm monitoring and oxygen saturation measurement[8, 9]. The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) recommend their use to detect atrial fibrillation, aiming to reduce its economic impact [10]. However, no studies have yet evaluated the effectiveness of smartwatches in detecting POAF after thoracic surgery. Their use could address the unmet need for continuous monitoring in conventional units, enabling early detection and management of POAF.

We hypothesize that the use of smartwatches in patients undergoing elective major thoracic surgery with lung exclusion could significantly enhance the early detection of postoperative atrial fibrillation (POAF) compared to conventional monitoring and improve diagnostic performance during the hospital stay.

METHODS AND ANALYSIS

Trial design

This is a randomized, prospective, multicenter (2 centers), open-label study.

Study population

The inclusion criteria are as follows:

- Patients more than 18 years old
- Patients undergoing major elective thoracic resection surgery with pulmonary exclusion (one-lung ventilation) within the past 48 hours.
- Elective pneumonectomy or Lobectomy surgery.
- Post-surgery transfer to a conventional care unit.
- Patients with motor and cognitive ability to perform single-lead ECGs using the smartwatch.
- Social security coverage.
- Written informed consent from patient or next of kin.

The exclusion criteria are as follows:

- History of atrial fibrillation.
- Need for telemetry monitoring for atrioventricular block and/or rapid supra- or ventricular arrhythmias.
- Unstable condition requiring prolonged hospitalization in a critical care unit with continuous telemetry.
- Dependence on atrial or ventricular pacing from a pacemaker.
- Inclusion in another interventional clinical trial affecting POAF incidence.
- Mediastinal surgery (e.g., mediastinal mass resection or mediastinoscopy).
- Chest wall surgery (e.g., lymph node biopsy or wall repair).
- Pleural surgery (e.g., pneumothorax or pleurisy management).
- Reoperation of the surgical site (early or delayed).
- Surgery conducted >48 hours prior.
- Pregnancy
- Coexisting illness with a high probability of death (inferior to 6 months)

Study protocol

Randomization

The randomization will be performed using a list with fixed-size random blocks. The randomization will be stratified, and the stratification criteria will include: Age > 65 years, Diabetes, Surgical approach via thoracotomy (as opposed to a minimally invasive video thoracoscopy approach). The study is open-label, with an intention-to-treat analysis. Randomization will be conducted using the Ennov Clinical® software implemented by a data manager. Randomization will occur within 48 hours post-surgery (up to the 48th hour) while the patient is hospitalized, provided there are no prior rhythm disturbances or indications for intensive care with telemetry monitoring. The result of randomization will be displayed as “Conventional Monitoring” or “Smartwatch Monitoring” (Figure 1). The diagram of the study process is shown in Figure 2.

Intervention

In the “Smartwatch Monitoring” group, POAF will be identified using a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >20 seconds recorded by a single-lead ECG or POAF detected via PPG signals and/or a 12-lead ECG. More specifically, the smartwatch detects episodes of POAF using its artificial intelligence algorithm. Confirmation is then required, either through a 1-lead ECG recorded by the smartwatch or a 12-lead ECG.

During the second follow-up visit (V2), patients will return the smartwatch on day 7 after surgery or the day of hospital discharge. The main difference in this group is that, in addition to conventional monitoring, the patient can perform a 12-lead ECG independently, either on demand or in the presence of symptoms.

The smartwatch used in this study will be the ScanWatch 42mm, which is CE-marked (CE 1282) for the diagnosis of atrial fibrillation (AF). The smartwatch allows for heart rate monitoring (Continuous monitoring via PPG using three integrated LEDs), Single-lead ECG recordings (The smartwatch allows patients to perform 20-second ECG recordings by placing one hand on the watch's case) and data integration (The device is equipped to record and transmit data and ECG tracings via Bluetooth to the Health Mate app). Data from the smartwatch will be retrieved via the Health Mate app by the investigator during follow-up visits (V1 and V2). The smartwatch will be collected from the patient during the second follow-up visit (V2, Day 7).

"Conventional Monitoring" Group Postoperative Care

In the "Conventional Monitoring" group, patients from both centers (Amiens University Hospital and Clinic Victor Pauchet) will be screened for postoperative atrial fibrillation (POAF) using a 12-lead ECG, according to standard monitoring protocols. Specifically, POAF will be diagnosed using a 12-lead ECG, which will only be performed if clinical symptoms and/or significant heart rate variations are observed by medical or paramedical staff. No routine daily ECG will be conducted in the absence of such symptoms. Additionally, all patients (from both groups) will undergo standardized postoperative monitoring, which includes regular assessments every four hours throughout the hospital stay. These assessments will include the following parameters: non-invasive blood pressure, heart rate, and oxygen saturation (SpO_2).

In both groups, the management of POAF will involve several essential steps:

- Assessment of hemodynamic stability: Evaluate hemodynamic tolerance and perform cardioversion in cases of poor tolerance.
- Correction of coexisting disorders: Address underlying issues such as hypoxemia, postoperative complications, sepsis, or electrolyte imbalances.
- Treatment of atrial fibrillation: Implement rhythm control strategies and initiate antiarrhythmic therapy.
- Decision on curative anticoagulation: In accordance with guidelines, anticoagulation decisions should be based on several factors, primarily the patient's thromboembolic risk as assessed by the CHA2DS2-VASc score and the absence of significant hemorrhagic risk.
- Follow-up consultation: Provide a prescription and schedule a cardiology follow-up appointment after discharge.

Endpoints

Primary endpoint

The endpoints and definitions are presented in Table 1.

The primary outcome measure will be the occurrence of POAF after major elective thoracic surgery within 7 postoperative days.

POAF is defined according to the 2020 ESC recommendations [2].

- POAF diagnosed by a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >20 seconds recorded by a single-lead ECG or POAF detected via PPG signals.
- POAF diagnosed in the standard care group will be confirmed using a 12-lead ECG.
- POAF diagnosis will be confirmed through interpretation of single-lead or 12-lead ECGs by a cardiologist.

Secondary endpoint

The secondary endpoints will be:

- Asymptomatic POAF prevalence, assessed by the number of patients presenting with postoperative POAF without symptoms. Symptoms will be evaluated using the EHRA score (Appendix).
- Cardiovascular prognosis, assessed using a composite endpoint of postoperative cardiovascular complications (MACE criteria) as defined by ESA and ESCIM standards [11]. MACE criteria will be analyzed at 2 months and 6 months and validated in the presence of one of the following:
    - *Stroke:* Hemorrhagic or ischemic stroke, defined by objective criteria including clinical assessment (persistent sensory, motor, or cognitive deficits), neuroimaging, and standardized scales (NIHSS or mRS) [12] [13].
    - *Myocardial infarction:* Elevated cardiac markers (e.g., myoglobin, troponin I) above the 99th percentile per lab standards; ischemic symptoms; ST-segment changes or left bundle branch block on ECG; Q waves; or evidence of coronary thrombus via angiography or autopsy
    - *Congestive acute heart failure:* Clinical syndrome characterized by symptoms and/or signs resulting from a structural and/or functional cardiac abnormality, accompanied by elevated natriuretic peptide levels and objective evidence of pulmonary or systemic congestion [14][15].

- *Mesenteric ischemia*: Mesenteric ischemia confirmed by imaging or exploratory laparotomy, and/or ischemic colitis confirmed by digestive endoscopy or laparotomy.
- *Resuscitated cardiac arrest*: Loss of mechanical cardiac activity confirmed by the absence of clinical signs of circulation.
- *Cardiovascular death.*

- Feasibility of monitoring POAF using a smartwatch after thoracic surgery: Evaluated based on device wear time and the completion rate of patient-performed single-lead ECGs in case of POAF detection.
- Recurrence and management of POAF: Rhythm status (AF yes/no) at 2 and 6 months, treatment for cardioversion (e.g., electrical cardioversion, ablation, or medication).

Data collection and outcome definitions

All collected variables are summarized in Table 2. The following data will be collected: age (years), gender, body mass index (kg m^{-2}), usual medication, medical history (coronary disease, peripheral vascular disease, stroke, smoking, diabetes, dyslipidemia, chronic obstructive pulmonary disease, sleep apnea syndrome, hypertension, chronic kidney disease, creatinine clearance, blood creatinine levels, surgery type, neurological conditions (stroke, transient ischemic attack (TIA), dementia), deep vein thrombosis/pulmonary embolism, heart failure, electrocardiogram, $CHAD_2S$-$VASC_2$ score, and HASBLED score.

Also, the following perioperative data will be collected: date of surgery, nature of the surgical procedure performed, surgical approach: minimally invasive surgery with video thoracoscopy, robot-assisted surgery, conversion to thoracotomy, duration of anesthesia, type of regional anesthesia performed, total dose of phenylephrine, ephedrine, norepinephrine, nicardipine, dobutamine, adrenaline administered, administration of a beta-blocker or amiodarone during surgery. Fluid balance will be considered by taking into account intraoperative fluid management (crystalloids, colloids, and volume in mL), administration of blood products (number and volume in mL), and administration of blood product derivatives (type and volume). Additionally, thoracic drain output and urine output will be recorded.

Postoperative data include duration of orotracheal intubation, duration, type, and total dosage of catecholamines, postoperative VIS score, reoperation, reintubation, MACE

criterion, respiratory, infectious, neurological, and renal complications, duration of stay in continuous care, and duration of hospital stay. Biological data will be recorded (Plasma hemoglobin, serum creatinine, urea, sodium, potassium, calcium, phosphorus, troponin US, leukocytes, CRP, TSH, BNP). During hospitalization, the following clinical parameters will be recorded: general hemodynamic parameters (heart rate, systolic, diastolic, and mean blood pressure, oxygen saturation, oxygen therapy administered) and the MACE criterion.

For the "Smartwatch Monitoring" group: number of single-lead ECGs performed, presence of POAF, duration of smart watch usage, clinical symptoms (EHRA, in appendix), duration of POAF, and treatment provided for POAF. For the "Conventional Monitoring" group: number of 12-lead ECGs performed, presence of POAF, clinical symptoms (EHRA, in appendix), duration of POAF, and treatment provided for POAF. Two months after surgery and 6 months after surgery, the following data will be collected: MACE criterion occurrence, the recurrence of POAF and management of POAF: rhythm status (AF yes/no), treatment for cardioversion (external electrical shock, ablation, pharmacological treatment). The recurrence of AF will be recorded in the hospital by performing an electrocardiogram if the patient is hospitalized. If the patient is not hospitalized, the data will be collected through a phone call to the patient and by reviewing the medical record (consultation for cardioversion, cardiology follow-up, follow-up for other conditions).

Endpoints will be assessed after thoracic surgery. Adverse events will be declared and notified in the eCRFs.

Standard definitions of postoperative outcomes established by the European Society of Anesthesia will be used [11]. Cardiac arrest is defined as the cessation of cardiac mechanical activity, as confirmed by the absence of circulation signs. Stroke is defined as an embolic, thrombotic, or hemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) diagnosed on a neuroimaging. Acute kidney injury is defined according to Kidney Disease Improving Global Outcomes (KDIGO) criteria as an increase in serum creatinine of over 27 µmol/L within 48 h or diuresis lower than 0.5 mL/kg/h [16]. Myocardial injury is diagnosed by the characteristics presentation, serial changes on 12-lead electrocardiographic suggesting infarction, and arise in cardiac troponin, with at least one value above the 99th percentile of the upper reference limit [17]. Mesenteric ischemia will be confirmed by imaging or exploratory

laparotomy, and ischemic colitis will be confirmed by gastrointestinal endoscopy or exploratory laparotomy.

Intention-to-treat analysis

Patients with serious adverse events will be analyzed according to their assigned group following the intention-to-treat principle.

Statistical method and Sample size calculation

In recent studies, the incidence of POAF in the studied population was 20%, with AF predominantly occurring within the first 4 postoperative days. The percentage of POAF at Day 7 is not precisely known, but since most cases occur relatively early, we estimate this percentage to be around 20%. Based on these assumptions, we would need 286 evaluable patients (142 per group) to detect an absolute difference of 12% (20% vs. 8%) in the incidence of AF with a two-sided alpha risk of 5% and a power of 80%. Anticipating 5% of non-evaluable patients, we will randomize 302 patients (151 per group).

Primary Endpoint (incidence of POAF) will be compared between the two groups using either a chi-squared test or Fisher's exact test, with a significance level set at 5%.

Regarding secondary endpoints, the percentage of asymptomatic POAF in the " Smartwatch Monitoring " group will be calculated with a 95% confidence interval. The percentage of major adverse cardiovascular events (MACE) at 6 months among patients diagnosed with asymptomatic POAF in the " Smartwatch Monitoring " group will also be calculated with a 95% confidence interval. In the " Smartwatch Monitoring " group, the duration of MI use will be expressed as mean ± standard deviation or median [range]. The percentage of patients performing a single-lead ECG in the case of POAF will be calculated with a 95% confidence interval. A p value of 0.05 will be considered as significant. No intermediate analysis is planned in the trial. Statistical analyses will be performed using SAS software version 9.4.

Data management and monitoring

Registration

Data will be collected and registered using electronic case report forms (eCRFs) by a dedicated local research technician. A research coordinator will centralize and verify the data.

Record keeping

Consent forms and eCRFs will be retained for 15 years at the University Hospital of Amiens in accordance with French law.

Study organization

The study promotion is performed by the University Hospital of Amiens, France. The Victor Pauchet Clinic is an associated investigator center.

Duration and timeline

Patients from Amiens university hospital and Victor Pauchet clinic can be included during a 2-year period beginning from March 2025.

The processes of developing the protocol, obtaining approval from the ethical committee, obtaining financial support, and developing the eCRFs occurred in 2024. The database should be closed after all participants have been included, followed by data analysis, manuscript writing and submission for publication.

ETHICS AND DISSEMINATION

Ethical approval

The institutional review board (IRB) of the University Hospital of Amiens (*Comité de Protection des Personnes Sud-Ouest et outre-mer 1, 21050 Toulouse, France*) approved the study (Registration number ID RDB: 2022-A02028-27 in November 2024). The THOFAWATCH study will be conducted in accordance with the Declaration of Helsinki and French law on clinical research [18] and was registered on the 05th of December 2024 on the ClinicalTrials.gov website with the trial identification number NCT06724718. THOFAWATCH trial follows CONSORT Statement - CONSORT diagram is given in Figure 1 [19].

Consent to participate

Written informed consent will be obtained from all participants or next of kin.

Patients or public involvement

Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research. Authors will be involved in disseminating research findings (through attending conferences and co-authoring results 'papers).

Access to data

Data sharing is not applicable to this article because no datasets were generated or analyzed during the current study. However, the investigators will provide authorized personnel with access to the necessary documents and individual data for study monitoring, quality control, and auditing in compliance with applicable regulations.

Discussion

The hypothesis suggests that utilizing smartwatches for patients undergoing planned major thoracic surgery may notably enhance the detection of postoperative POAF compared to traditional monitoring methods.

POAF after thoracic surgery arises due to a combination of autonomic imbalance, systemic inflammation, and atrial remodeling. The surgical stress response activates the sympathetic nervous system, which, along with inflammation from tissue injury and oxidative stress, contributes to electrophysiological instability [20–22]. These factors interact dynamically during the perioperative period, leading to the development of transient or sustained atrial fibrillation episodes[23].

Postoperative atrial fibrillation (POAF) is a recurrent issue following major surgery, particularly in thoracic surgery [2]. Smartwatches have demonstrated good diagnostic performance, with high sensitivity and specificity, in non-surgical settings [10]. Several factors influence signal accuracy, including advanced arterial disease or hypothermia. The key challenge lies in detecting arrhythmias and diagnosing asymptomatic or highly transient AF episodes postoperatively. Most arrhythmias are paroxysmal, and a standard 12-lead ECG often fails to identify these episodes. Thus, we designed this study to evaluate the value of continuous smartwatch monitoring to overcome this limitation.

A recent study by Monteiro et al. on 108 patients showed that smartwatches, compared to conventional monitoring, provided improved monitoring, early arrhythmia detection, and better patient outcomes [24].

In non-surgical populations, smartwatches using PPG are effective for AF monitoring, with high detection accuracy. However, heart rate measurements may underestimate

elevated rates. Also, improving diagnostic reliability in older adults may require training for participants and cardiologists, along with sufficient ECG recordings to ensure accuracy [7, 25].

However, no study to date has focused on this topic after thoracic surgery. We hypothesize that continuous smartwatch use can enhance AF detection following thoracic surgery. To limit the scope, smartwatch monitoring is restricted to a maximum of 7 days, as POAF predominantly occurs early in the postoperative period.

This study holds several key strengths. It represents the first exploration of atrial fibrillation detection in the specific context of postoperative thoracic surgery, addressing a critical gap in the existing literature. Furthermore, its multicenter design ensures diverse patient representation and robust data collection, while the inclusion of a significant sample size enhances the reliability and generalizability of its findings.

This study aims to enable early diagnosis of AF, reduce economic and hospitalization burdens, and improve patient outcomes through tailored care and remote monitoring protocols.

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Table 1. Endpoints and definitions

Endpoints	*Definitions*
Primary endpoint	
Occurrence of POAF after major elective thoracic surgery within 7 postoperative days.	POAF is defined according to the 2020 ESC recommendations. - POAF diagnosed by a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >30 seconds recorded by a single-lead ECG or POAF detected via PPG signals and confirmed by a 12-lead ECG. - POAF diagnosed in the standard care group will be confirmed using a 12-lead ECG. - POAF diagnosis will be confirmed through interpretation of single-lead or 12-lead ECGs by a cardiologist.
Secondary endpoints	
Asymptomatic POAF prevalence	- Number of patients presenting with postoperative POAF without symptoms. Symptoms will be evaluated using the EHRA score (Appendix).
Major Cardiovascular and Cerebral Event (MACE)	One of the following criteria (Definitions above): - Stroke - Myocardial infarction - Acute kidney injury - Mesenteric ischemia - Successful resuscitated cardiac arrest
Stroke	An embolic, thrombotic, or hemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) diagnosed on a neuroimaging,
Myocardial infarction	Myocardial infarction was diagnosed by the characteristics presentation, serial changes on 12-lead electrocardiographic suggesting infarction, and arise in cardiac markers, preferably cardiac troponins, with at

	least one value above the 99th percentile of the upper reference limit
Congestive acute heart failure	Clinical syndrome characterized by symptoms and/or signs resulting from a structural and/or functional cardiac abnormality, accompanied by elevated natriuretic peptide levels and objective evidence of pulmonary or systemic congestion. Symptoms can be dyspnoea or fatigue, orthopnoea, paroxysmal nocturnal dyspnoea, increased jugular venous pressure or pulmonary rales on physical examination.
Mesenteric ischemia	Mesenteric ischemia confirmed by imaging or exploratory laparotomy and/or ischemic colitis confirmed by gastrointestinal endoscopy or exploratory laparotomy
Resuscitated cardiac arrest	Cessation of mechanical cardiac activity confirmed by the absence of clinical signs of blood flow.
Feasibility of monitoring POAF using a smartwatch after thoracic surgery	Evaluated based on device wear time and the completion rate of patient-performed single-lead ECGs in case of POAF detection.
Recurrence and management of POAF	Rhythm status (AF yes/no) at 3 and 6 months, treatment for cardioversion (e.g., electrical cardioversion, ablation, or medication).

AF: Atrial Fibrillation**, EHRA:** *European Heart Rythm Association,* **POAF:** Postoperative atrial fibrillation.

Table 2. Collected variables

Collected variables	*Details of collected variables*
Preoperative variables	
Demographic data	Age (years), gender, body mass index (kg m^{-2})
Usual medication	Calcium channel blockers, ACE inhibitors, aldosterone antagonists, beta-blockers, diuretics, statins, sacubitril/valsartan, bronchodilators, oral antidiabetic agents, insulin, antiplatelet agents, anticoagulants, immunosuppressants, antidepressants, antipsychotics, benzodiazepines.
Medical history	Coronary disease, peripheral vascular disease, stroke, smoking, diabetes, dyslipidemia, chronic obstructive pulmonary disease, sleep apnea syndrome, hypertension, chronic kidney disease, surgery type, neurological conditions (stroke, transient ischemic attack, dementia), deep vein thrombosis/pulmonary embolism, heart failure. Baseline electrocardiogram, $CHAD_2S$-$VASC_2$ score and HASBLED score.
Biological data	Blood creatinine levels, creatinine clearance
Perioperative data	
Surgical variables	Date of surgery, nature of the surgical procedure performed (Lobectomy or pneumectomy), surgical approach: minimally invasive surgery with video thoracoscopy, robot-assisted surgery, conversion to thoracotomy.
Medical variables	Duration of anesthesia and type of regional anesthesia performed. Total dose of phenylephrine, ephedrine, norepinephrine, nicardipine, dobutamine or adrenaline administered. Administration of a beta-blocker, amiodarone, magnesium sulfate or dexamethasone during surgery. Intraoperative fluid administration (type of fluid and volume in mL), administration of blood products

	(type of blood product, number and volume in mL), and administration of blood product derivatives (type and volume).
Postoperative data	
Medical variables	Duration of orotracheal intubation and reintubation. Duration, type, and total dosage of catecholamines and postoperative VIS score. Thoracic drain output and urine output. Reoperation. As defined in in Table 1, MACE criterion will be recorded. Also, we will assess respiratory, infectious, neurological, and renal complications. Duration of stay in continuous care and duration of hospital stay.
Biological variables	Plasma hemoglobin, serum creatinine, urea, sodium, potassium, calcium, phosphorus, troponin US and BNP
General hemodynamic variables	heart rate, systolic, diastolic, and mean blood pressure, oxygen saturation and oxygen therapy administered.
Follow up visit	
Smartwatch Monitoring group	Number of single-lead ECGs performed, presence of POAF, duration of smart watch usage, clinical symptoms (EHRA as presented in appendix), duration of POAF, and treatment provided for POAF.
Conventional Monitoring group	Number of 12-lead ECGs performed, presence of POAF, clinical symptoms (EHRA in appendix), duration of POAF, and treatment provided for POAF

Abréviations

ECG: Electrocardiogram**; EHRA:** European Heart Rhythm Association**; MACE:** Major Adverse Cardiovascular Events**; POAF:** Postoperative atrial fibrillation**; VIS:** Vasoactive-inotropic score

Figure legends

Figure 1. Consort diagram. **ECG:** Electrocardiogram

Figure 2. Diagram of the study process**. MACE** Major Adverse Cardiovascular Events, **POAF** Postoperative atrial fibrillation.

Appendix: EHRA score. **European Heart Rhythm Association score:** Evaluation of symptomatology of patients with Atrial Fibrillation.

Trial status

The trial is not yet recruiting.

List of abbreviations

AF: Atrial fibrillation

EACTS: European Association for Cardio-Thoracic Surgery

***ECG:** Electrocardiogram*

EHRA: European Heart Rhythm Association

ESC: European Society of Cardiology

E-crf: electronic case report form

IRB: institutional review board

KDIGO: Kidney Disease: Improving Global Outcomes

LED: Light Emitting Diode

MACE: Major Adverse Cardiovascular Events

***POAF:** Postoperative atrial fibrillation*

TIA: Transient ischemic accident

PPG: photoplethysmography

VIS: Vasoactive-inotropic score

Declarations

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Competing interests

The authors declare that they have no competing interests.

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Author contributions

PH and CB participated in the design of the study and helped to write the manuscript. OAA, AI, GH, MG, TL, HD, and YM participated in the design of the study. MD will perform the statistical analysis. All authors read and approved the final manuscript. PH acted as guarantor.

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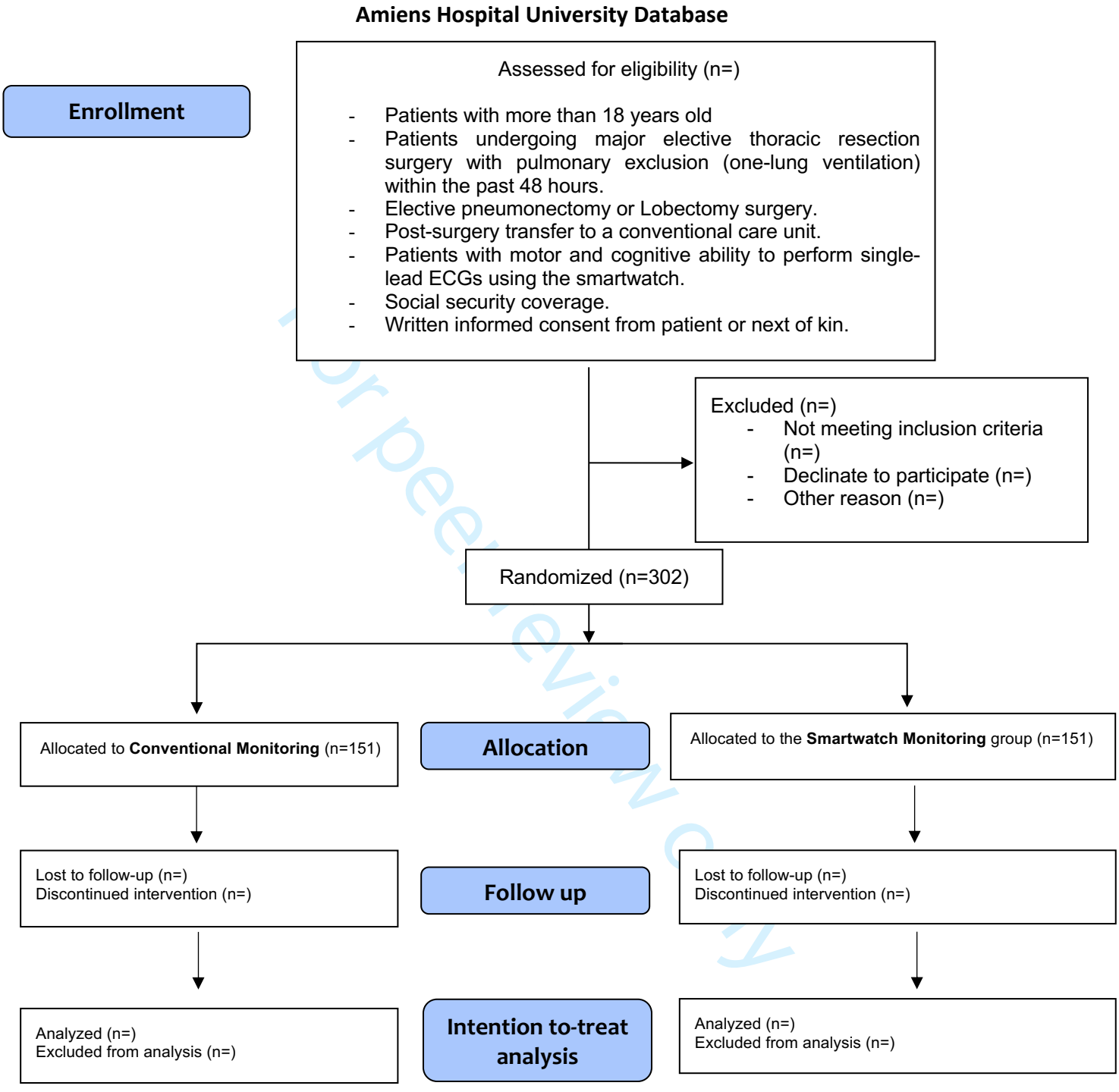
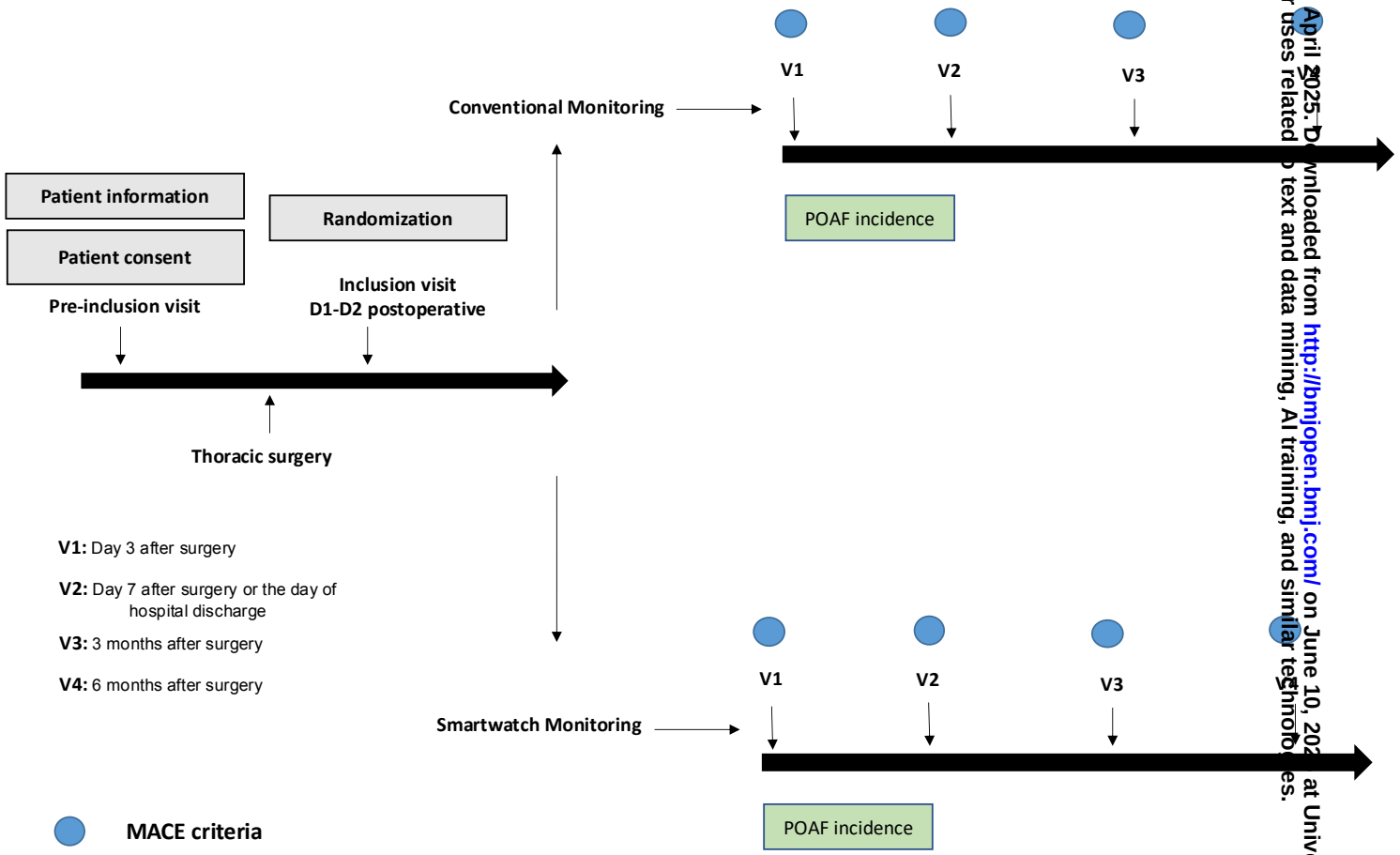
Figure 1. CONSORT diagram



ECG: Electrocardiogram;

Figure 2. Diagram of the study process



EHRA score	Symptoms
EHRA I	None: No symptoms.
EHRA II	**IIa:** Mild: Moderate symptoms not affecting daily life.
	IIb: Intermediate: Moderate symptoms not affecting daily life but causing discomfort for the patient.
EHRA III	Severe: Severe symptoms affecting daily life.
EHRA IV	Disabling: Symptoms necessitating the interruption of daily activities.

European Heart Rhythm Association score: Evaluation of symptomatology of patients with Atrial Fibrillation

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Study protocol: Diagnosis of atrial fibrillation in postoperative thoracic surgery using a smartwatch, an open-label randomized controlled study (THOFAWATCH Trial)

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Introduction

Postoperative atrial fibrillation (POAF) affects approximately 20% of patients undergoing thoracic surgery and is associated with severe complications such as stroke, myocardial infarction, heart failure, and increased mortality. Early diagnosis is critical to mitigate these risks, but conventional monitoring is limited in detecting asymptomatic episodes. Smartwatches equipped with single-lead ECG and atrial fibrillation (AF) detection algorithms offer a novel approach for early POAF detection. This study aims to evaluate the effectiveness of smartwatch-based monitoring compared to standard care in identifying POAF following thoracic surgery.

Methods and Analysis

The THOFAWATCH trial is a randomized, bicentric open-label study enrolling 302 adult patients undergoing major thoracic surgery (pneumonectomy or lobectomy) with one-lung ventilation. Eligible patients will be randomized into two groups: (1) the “Smartwatch Monitoring” group, where participants will undergo rhythm monitoring using a smartwatch, and (2) the “Conventional Monitoring” group, receiving standard care without smartwatch monitoring. In the intervention group, any smartwatch-detected POAF episodes will be confirmed by 12-lead ECG. The primary outcome is the incidence of POAF within seven days post-surgery. Secondary outcomes include the rate of asymptomatic POAF, cardiovascular prognosis evaluated at 2 and 6 months (composite MACE outcome), feasibility of smartwatch usage (device usage time and success rate of single-lead ECGs), and recurrence or management of AF at follow-up. Inclusion criteria include adults (>18 years) undergoing scheduled thoracic surgery and able to use the smartwatch device. Exclusion criteria encompass patients with prior atrial fibrillation, those requiring telemetry, or undergoing reoperations. Statistical analysis will assess the primary outcome using chi-square or Fisher's exact test (α = 5%), while secondary outcomes will include descriptive and inferential statistics, with analysis conducted using SAS version 9.4.

Ethics and Dissemination

Ethical approval for this bicentric study has been granted by the institutional review board (IRB) of the University Hospital of Amiens (Comité de Protection des Personnes sud-ouest et outre-mer 1, 21050 Toulouse, France, registration number ID RDB: 2022-A02028-27 in November 2024). The trial is registered under ClinicalTrials.gov (ID: [NCT06724718]). Results will be disseminated through peer-reviewed publications and

scientific conferences to inform clinical practice regarding POAF detection and management following thoracic surgery.

Trial registration: NCT06724718 (Clinical trial)

Strengths and limitations of this study

- The trial will be a prospective, bicentric, randomized trial and will include adult patients undergoing major thoracic surgery (pneumonectomy or lobectomy).
- The intervention that is being investigated is the use of a smartwatch-based monitoring to detect the occurrence of postoperative atrial fibrillation (POAF) following thoracic surgery.
- No study have yet evaluated the effectiveness of smartwatches in detecting POAF after thoracic surgery.
- The primary endpoint will be the incidence of POAF within seven days post-surgery
- The secondary endpoints will include the rate of asymptomatic POAF, cardiovascular prognosis evaluated at 2 and 6 months (composite MACE outcome), feasibility of smartwatch usage (device usage time and success rate of single-lead ECGs), and recurrence or management of AF at follow-up

INTRODUCTION

In patients undergoing major non-cardiac surgery, postoperative atrial fibrillation (POAF) is a common and significant complication associated with increased risks of heart failure, stroke, myocardial infarction, and death, leading to higher morbidity, prolonged hospital stays, and elevated healthcare costs [1] [2] [3]. POAF episodes are often paroxysmal and asymptomatic, raising the likelihood of developing permanent atrial fibrillation within five years by 4–5 times[2]. Most episodes occur between 2 and 5 days post-surgery, primarily in conventional surgical units without continuous cardiac monitoring, unlike critical care units where rhythm monitoring is routine(2). The absence of monitoring in these settings leaves asymptomatic cases undiagnosed, exposing patients to greater risks of adverse outcomes[5]. Treatment often involves bradycardic agents and, in cases exceeding 48 hours, anticoagulation therapy based on thromboembolic and bleeding risk scores[2].

Smartwatches equipped with single-lead ECG capabilities and algorithms for atrial fibrillation detection provide a promising solution for identifying POAF with high accuracy [6, 7]. These devices utilize photoplethysmography (PPG), a non-invasive optical technique to analyze blood volume changes in superficial tissues, enabling heart rhythm monitoring and oxygen saturation measurement[8, 9]. The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) recommend their use to detect atrial fibrillation, aiming to reduce its economic impact [10]. However, no studies have yet evaluated the effectiveness of smartwatches in detecting POAF after thoracic surgery. Their use could address the unmet need for continuous monitoring in conventional units, enabling early detection and management of POAF.

We hypothesize that the use of smartwatches in patients undergoing elective major thoracic surgery with lung exclusion could significantly enhance the early detection of postoperative atrial fibrillation (POAF) compared to conventional monitoring and improve diagnostic performance during the hospital stay.

METHODS AND ANALYSIS

Trial design

This is a randomized, prospective, multicenter (2 centers), open-label study.

Study population

The inclusion criteria are as follows:

- Patients more than 18 years old
- Patients undergoing major elective thoracic resection surgery with pulmonary exclusion (one-lung ventilation) within the past 48 hours.
- Elective pneumonectomy or Lobectomy surgery.
- Post-surgery transfer to a conventional care unit.
- Patients with motor and cognitive ability to perform single-lead ECGs using the smartwatch.
- Social security coverage.
- Written informed consent from patient or next of kin.

The exclusion criteria are as follows:

- History of atrial fibrillation.
- Need for telemetry monitoring for atrioventricular block and/or rapid supra- or ventricular arrhythmias.
- Unstable condition requiring prolonged hospitalization in a critical care unit with continuous telemetry.
- Dependence on atrial or ventricular pacing from a pacemaker.
- Inclusion in another interventional clinical trial affecting POAF incidence.
- Mediastinal surgery (e.g., mediastinal mass resection or mediastinoscopy).
- Chest wall surgery (e.g., lymph node biopsy or wall repair).
- Pleural surgery (e.g., pneumothorax or pleurisy management).
- Reoperation of the surgical site (early or delayed).
- Surgery conducted >48 hours prior.
- Pregnancy
- Coexisting illness with a high probability of death (inferior to 6 months)

Study protocol

Randomization

The randomization will be performed using a list with fixed-size random blocks. The randomization will be stratified, and the stratification criteria will include: Age > 65 years, Diabetes, Surgical approach via thoracotomy (as opposed to a minimally invasive video thoracoscopy approach). The study is open-label, with an intention-to-treat analysis. Randomization will be conducted using the Ennov Clinical® software implemented by a data manager. Randomization will occur within 48 hours post-surgery (up to the 48th hour) while the patient is hospitalized, provided there are no prior rhythm disturbances or indications for intensive care with telemetry monitoring. The result of randomization will be displayed as “Conventional Monitoring” or “Smartwatch Monitoring” (Figure 1). The diagram of the study process is shown in Figure 2.

Intervention

In the “Smartwatch Monitoring” group, POAF will be identified using a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >20 seconds recorded by a single-lead ECG or POAF detected via PPG signals and/or a 12-lead ECG. More specifically, the smartwatch detects episodes of POAF using its artificial intelligence algorithm. Confirmation is then required, either through a 1-lead ECG recorded by the smartwatch or a 12-lead ECG.

During the second follow-up visit (V2), patients will return the smartwatch on day 7 after surgery or the day of hospital discharge. The main difference in this group is that, in addition to conventional monitoring, the patient can perform a 12-lead ECG independently, either on demand or in the presence of symptoms.

The smartwatch used in this study will be the ScanWatch 42mm, which is CE-marked (CE 1282) for the diagnosis of atrial fibrillation (AF). The smartwatch allows for heart rate monitoring (Continuous monitoring via PPG using three integrated LEDs), Single-lead ECG recordings (The smartwatch allows patients to perform 20-second ECG recordings by placing one hand on the watch's case) and data integration (The device is equipped to record and transmit data and ECG tracings via Bluetooth to the Health Mate app). Data from the smartwatch will be retrieved via the Health Mate app by the investigator during follow-up visits (V1 and V2). The smartwatch will be collected from the patient during the second follow-up visit (V2, Day 7).

"Conventional Monitoring" Group Postoperative Care

In the "Conventional Monitoring" group, patients from both centers (Amiens University Hospital and Clinic Victor Pauchet) will be screened for postoperative atrial fibrillation (POAF) using a 12-lead ECG, according to standard monitoring protocols. Specifically, POAF will be diagnosed using a 12-lead ECG, which will only be performed if clinical symptoms and/or significant heart rate variations are observed by medical or paramedical staff. No routine daily ECG will be conducted in the absence of such symptoms. Additionally, all patients (from both groups) will undergo standardized postoperative monitoring, which includes regular assessments every four hours throughout the hospital stay. These assessments will include the following parameters: non-invasive blood pressure, heart rate, and oxygen saturation (SpO_2).

In both groups, the management of POAF will involve several essential steps:

- Assessment of hemodynamic stability: Evaluate hemodynamic tolerance and perform cardioversion in cases of poor tolerance.
- Correction of coexisting disorders: Address underlying issues such as hypoxemia, postoperative complications, sepsis, or electrolyte imbalances.
- Treatment of atrial fibrillation: Implement rhythm control strategies and initiate antiarrhythmic therapy.
- Decision on curative anticoagulation: In accordance with guidelines, anticoagulation decisions should be based on several factors, primarily the patient's thromboembolic risk as assessed by the CHA2DS2-VASc score and the absence of significant hemorrhagic risk.
- Follow-up consultation: Provide a prescription and schedule a cardiology follow-up appointment after discharge.

Endpoints

Primary endpoint

The endpoints and definitions are presented in Table 1.

The primary outcome measure will be the occurrence of POAF after major elective thoracic surgery within 7 postoperative days.

POAF is defined according to the 2020 ESC recommendations [2].

- POAF diagnosed by a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >20 seconds recorded by a single-lead ECG or POAF detected via PPG signals.
- POAF diagnosed in the standard care group will be confirmed using a 12-lead ECG.
- POAF diagnosis will be confirmed through interpretation of single-lead or 12-lead ECGs by a cardiologist.

Secondary endpoint

The secondary endpoints will be:

- Asymptomatic POAF prevalence, assessed by the number of patients presenting with postoperative POAF without symptoms. Symptoms will be evaluated using the EHRA score (Appendix).
- Cardiovascular prognosis, assessed using a composite endpoint of postoperative cardiovascular complications (MACE criteria) as defined by ESA and ESCIM standards [11]. MACE criteria will be analyzed at 2 months and 6 months and validated in the presence of one of the following:
    - *Stroke:* Hemorrhagic or ischemic stroke, defined by objective criteria including clinical assessment (persistent sensory, motor, or cognitive deficits), neuroimaging, and standardized scales (NIHSS or mRS) [12] [13].
    - *Myocardial infarction:* Elevated cardiac markers (e.g., myoglobin, troponin I) above the 99th percentile per lab standards; ischemic symptoms; ST-segment changes or left bundle branch block on ECG; Q waves; or evidence of coronary thrombus via angiography or autopsy
    - *Congestive acute heart failure:* Clinical syndrome characterized by symptoms and/or signs resulting from a structural and/or functional cardiac abnormality, accompanied by elevated natriuretic peptide levels and objective evidence of pulmonary or systemic congestion [14][15].

- *Mesenteric ischemia*: Mesenteric ischemia confirmed by imaging or exploratory laparotomy, and/or ischemic colitis confirmed by digestive endoscopy or laparotomy.
- *Resuscitated cardiac arrest*: Loss of mechanical cardiac activity confirmed by the absence of clinical signs of circulation.
- *Cardiovascular death.*

- Feasibility of monitoring POAF using a smartwatch after thoracic surgery: Evaluated based on device wear time and the completion rate of patient-performed single-lead ECGs in case of POAF detection.
- Recurrence and management of POAF: Rhythm status (AF yes/no) at 2 and 6 months, treatment for cardioversion (e.g., electrical cardioversion, ablation, or medication).

Data collection and outcome definitions

All collected variables are summarized in Table 2. The following data will be collected: age (years), gender, body mass index (kg m^{-2}), usual medication, medical history (coronary disease, peripheral vascular disease, stroke, smoking, diabetes, dyslipidemia, chronic obstructive pulmonary disease, sleep apnea syndrome, hypertension, chronic kidney disease, creatinine clearance, blood creatinine levels, surgery type, neurological conditions (stroke, transient ischemic attack (TIA), dementia), deep vein thrombosis/pulmonary embolism, heart failure, electrocardiogram, $CHAD_2S$-$VASC_2$ score, and HASBLED score.

Also, the following perioperative data will be collected: date of surgery, nature of the surgical procedure performed, surgical approach: minimally invasive surgery with video thoracoscopy, robot-assisted surgery, conversion to thoracotomy, duration of anesthesia, type of regional anesthesia performed, total dose of phenylephrine, ephedrine, norepinephrine, nicardipine, dobutamine, adrenaline administered, administration of a beta-blocker or amiodarone during surgery. Fluid balance will be considered by taking into account intraoperative fluid management (crystalloids, colloids, and volume in mL), administration of blood products (number and volume in mL), and administration of blood product derivatives (type and volume). Additionally, thoracic drain output and urine output will be recorded.

Postoperative data include duration of orotracheal intubation, duration, type, and total dosage of catecholamines, postoperative VIS score, reoperation, reintubation, MACE

criterion, respiratory, infectious, neurological, and renal complications, duration of stay in continuous care, and duration of hospital stay. Biological data will be recorded (Plasma hemoglobin, serum creatinine, urea, sodium, potassium, calcium, phosphorus, troponin US, leukocytes, CRP, TSH, BNP). During hospitalization, the following clinical parameters will be recorded: general hemodynamic parameters (heart rate, systolic, diastolic, and mean blood pressure, oxygen saturation, oxygen therapy administered) and the MACE criterion.

For the "Smartwatch Monitoring" group: number of single-lead ECGs performed, presence of POAF, duration of smart watch usage, clinical symptoms (EHRA, in appendix), duration of POAF, and treatment provided for POAF. For the "Conventional Monitoring" group: number of 12-lead ECGs performed, presence of POAF, clinical symptoms (EHRA, in appendix), duration of POAF, and treatment provided for POAF. Two months after surgery and 6 months after surgery, the following data will be collected: MACE criterion occurrence, the recurrence of POAF and management of POAF: rhythm status (AF yes/no), treatment for cardioversion (external electrical shock, ablation, pharmacological treatment). The recurrence of AF will be recorded in the hospital by performing an electrocardiogram if the patient is hospitalized. If the patient is not hospitalized, the data will be collected through a phone call to the patient and by reviewing the medical record (consultation for cardioversion, cardiology follow-up, follow-up for other conditions).

Endpoints will be assessed after thoracic surgery. Adverse events will be declared and notified in the eCRFs.

Standard definitions of postoperative outcomes established by the European Society of Anesthesia will be used [11]. Cardiac arrest is defined as the cessation of cardiac mechanical activity, as confirmed by the absence of circulation signs. Stroke is defined as an embolic, thrombotic, or hemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) diagnosed on a neuroimaging. Acute kidney injury is defined according to Kidney Disease Improving Global Outcomes (KDIGO) criteria as an increase in serum creatinine of over 27 µmol/L within 48 h or diuresis lower than 0.5 mL/kg/h [16]. Myocardial injury is diagnosed by the characteristics presentation, serial changes on 12-lead electrocardiographic suggesting infarction, and arise in cardiac troponin, with at least one value above the 99th percentile of the upper reference limit [17]. Mesenteric ischemia will be confirmed by imaging or exploratory

laparotomy, and ischemic colitis will be confirmed by gastrointestinal endoscopy or exploratory laparotomy.

Intention-to-treat analysis

Patients with serious adverse events will be analyzed according to their assigned group following the intention-to-treat principle.

Statistical method and Sample size calculation

In recent studies, the incidence of POAF in the studied population was 20%, with AF predominantly occurring within the first 4 postoperative days[18]. The percentage of POAF at Day 7 is not precisely known, but since most cases occur relatively early, we estimate this percentage to be around 20%. Based on these assumptions, we would need 286 evaluable patients (142 per group) to detect an absolute difference of 12% (20% vs. 8%) in the incidence of AF with a two-sided alpha risk of 5% and a power of 80%. Anticipating 5% of non-evaluable patients, we will randomize 302 patients (151 per group).

Primary Endpoint (incidence of POAF) will be compared between the two groups using either a chi-squared test or Fisher's exact test, with a significance level set at 5%.

Regarding secondary endpoints, the percentage of asymptomatic POAF in the " Smartwatch Monitoring " group will be calculated with a 95% confidence interval. The percentage of major adverse cardiovascular events (MACE) at 6 months among patients diagnosed with asymptomatic POAF in the " Smartwatch Monitoring " group will also be calculated with a 95% confidence interval. In the " Smartwatch Monitoring " group, the duration of MI use will be expressed as mean ± standard deviation or median [range]. The percentage of patients performing a single-lead ECG in the case of POAF will be calculated with a 95% confidence interval. A p value of 0.05 will be considered as significant. No intermediate analysis is planned in the trial. Statistical analyses will be performed using SAS software version 9.4.

Data management and monitoring

Registration

Data will be collected and registered using electronic case report forms (eCRFs) by a dedicated local research technician. A research coordinator will centralize and verify the data.

Record keeping

Consent forms and eCRFs will be retained for 15 years at the University Hospital of Amiens in accordance with French law.

Study organization

The study promotion is performed by the University Hospital of Amiens, France. The Victor Pauchet Clinic is an associated investigator center.

Duration and timeline

Patients from Amiens university hospital and Victor Pauchet clinic can be included during a 2-year period. We plan to begin the study in April 2025 and complete it by 2027.The processes of developing the protocol, obtaining approval from the ethical committee, obtaining financial support, and developing the eCRFs occurred in 2024. The database should be closed after all participants have been included, followed by data analysis, manuscript writing and submission for publication.

ETHICS AND DISSEMINATION

Ethical approval

The institutional review board (IRB) of the University Hospital of Amiens (*Comité de Protection des Personnes Sud-Ouest et outre-mer 1, 21050 Toulouse, France*) approved this bicentric study (Registration number ID RDB: 2022-A02028-27 in November 2024). The THOFAWATCH study will be conducted in accordance with the Declaration of Helsinki and French law on clinical research [19] and was registered on the 05th of December 2024 on the ClinicalTrials.gov website with the trial identification number NCT06724718. THOFAWATCH trial follows CONSORT Statement - CONSORT diagram is given in Figure 1 [20].

Consent to participate

Written informed consent will be obtained from all participants or next of kin (The participant consent form is provided as a supplementary file).

Patients or public involvement

Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research. Authors will be involved in disseminating research findings (through attending conferences and co-authoring results 'papers).

Access to data

Data sharing is not applicable to this article because no datasets were generated or analyzed during the current study. However, the investigators will provide authorized personnel with access to the necessary documents and individual data for study monitoring, quality control, and auditing in compliance with applicable regulations.

Discussion

The hypothesis suggests that utilizing smartwatches for patients undergoing planned major thoracic surgery may notably enhance the detection of postoperative POAF compared to traditional monitoring methods.

POAF after thoracic surgery arises due to a combination of autonomic imbalance, systemic inflammation, and atrial remodeling. The surgical stress response activates the sympathetic nervous system, which, along with inflammation from tissue injury and oxidative stress, contributes to electrophysiological instability [21–23]. These factors interact dynamically during the perioperative period, leading to the development of transient or sustained atrial fibrillation episodes[24].

Postoperative atrial fibrillation (POAF) is a recurrent issue following major surgery, particularly in thoracic surgery [2]. Smartwatches have demonstrated good diagnostic performance, with high sensitivity and specificity, in non-surgical settings [10]. Several factors influence signal accuracy, including advanced arterial disease or hypothermia. The key challenge lies in detecting arrhythmias and diagnosing asymptomatic or highly transient AF episodes postoperatively. Most arrhythmias are paroxysmal, and a standard 12-lead ECG often fails to identify these episodes. Thus, we designed this study to evaluate the value of continuous smartwatch monitoring to overcome this limitation.

A recent study by Monteiro et al. on 108 patients showed that smartwatches, compared to conventional monitoring, provided improved monitoring, early arrhythmia detection, and better patient outcomes [25].

In non-surgical populations, smartwatches using PPG are effective for AF monitoring, with high detection accuracy. However, heart rate measurements may underestimate

elevated rates. Also, improving diagnostic reliability in older adults may require training for participants and cardiologists, along with sufficient ECG recordings to ensure accuracy [7, 26].

However, few studies to date has focused on this topic after thoracic surgery. We hypothesize that continuous smartwatch use can enhance AF detection following thoracic surgery. To limit the scope, smartwatch monitoring is restricted to a maximum of 7 days, as POAF predominantly occurs early in the postoperative period.

This study holds several key strengths. It is the first study, to our knowledge, that explores atrial fibrillation detection in the specific context of postoperative thoracic surgery, filling a crucial gap in the current literature. Furthermore, its multicenter design ensures diverse patient representation and robust data collection, while the inclusion of a significant sample size enhances the reliability and generalizability of its findings.

This study aims to enable early diagnosis of AF, reduce economic and hospitalization burdens, and improve patient outcomes through tailored care and remote monitoring protocols.

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Table 1. Endpoints and definitions

Endpoints	*Definitions*
Primary endpoint	
Occurrence of POAF after major elective thoracic surgery within 7 postoperative days.	POAF is defined according to the 2020 ESC recommendations. - POAF diagnosed by a smartwatch (ScanWatch, Withings Move ECG™, Withings, France), defined as an episode of AF lasting >30 seconds recorded by a single-lead ECG or POAF detected via PPG signals and confirmed by a 12-lead ECG. - POAF diagnosed in the standard care group will be confirmed using a 12-lead ECG. - POAF diagnosis will be confirmed through interpretation of single-lead or 12-lead ECGs by a cardiologist.
Secondary endpoints	
Asymptomatic POAF prevalence	- Number of patients presenting with postoperative POAF without symptoms. Symptoms will be evaluated using the EHRA score (Appendix).
Major Cardiovascular and Cerebral Event (MACE)	One of the following criteria (Definitions above): - Stroke - Myocardial infarction - Acute kidney injury - Mesenteric ischemia - Successful resuscitated cardiac arrest
Stroke	An embolic, thrombotic, or hemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) diagnosed on a neuroimaging,
Myocardial infarction	Myocardial infarction was diagnosed by the characteristics presentation, serial changes on 12-lead electrocardiographic suggesting infarction, and arise in cardiac markers, preferably cardiac troponins, with at

	least one value above the 99th percentile of the upper reference limit
Congestive acute heart failure	Clinical syndrome characterized by symptoms and/or signs resulting from a structural and/or functional cardiac abnormality, accompanied by elevated natriuretic peptide levels and objective evidence of pulmonary or systemic congestion. Symptoms can be dyspnoea or fatigue, orthopnoea, paroxysmal nocturnal dyspnoea, increased jugular venous pressure or pulmonary rales on physical examination.
Mesenteric ischemia	Mesenteric ischemia confirmed by imaging or exploratory laparotomy and/or ischemic colitis confirmed by gastrointestinal endoscopy or exploratory laparotomy
Resuscitated cardiac arrest	Cessation of mechanical cardiac activity confirmed by the absence of clinical signs of blood flow.
Feasibility of monitoring POAF using a smartwatch after thoracic surgery	Evaluated based on device wear time and the completion rate of patient-performed single-lead ECGs in case of POAF detection.
Recurrence and management of POAF	Rhythm status (AF yes/no) at 3 and 6 months, treatment for cardioversion (e.g., electrical cardioversion, ablation, or medication).

AF: Atrial Fibrillation**, EHRA:** *European Heart Rythm Association,* **POAF:** Postoperative atrial fibrillation.

Table 2. Collected variables

Collected variables	*Details of collected variables*
Preoperative variables	
Demographic data	Age (years), gender, body mass index (kg m^{-2})
Usual medication	Calcium channel blockers, ACE inhibitors, aldosterone antagonists, beta-blockers, diuretics, statins, sacubitril/valsartan, bronchodilators, oral antidiabetic agents, insulin, antiplatelet agents, anticoagulants, immunosuppressants, antidepressants, antipsychotics, benzodiazepines.
Medical history	Coronary disease, peripheral vascular disease, stroke, smoking, diabetes, dyslipidemia, chronic obstructive pulmonary disease, sleep apnea syndrome, hypertension, chronic kidney disease, surgery type, neurological conditions (stroke, transient ischemic attack, dementia), deep vein thrombosis/pulmonary embolism, heart failure. Baseline electrocardiogram, $CHAD_2S$-$VASC_2$ score and HASBLED score.
Biological data	Blood creatinine levels, creatinine clearance
Perioperative data	
Surgical variables	Date of surgery, nature of the surgical procedure performed (Lobectomy or pneumectomy), surgical approach: minimally invasive surgery with video thoracoscopy, robot-assisted surgery, conversion to thoracotomy.
Medical variables	Duration of anesthesia and type of regional anesthesia performed. Total dose of phenylephrine, ephedrine, norepinephrine, nicardipine, dobutamine or adrenaline administered. Administration of a beta-blocker, amiodarone, magnesium sulfate or dexamethasone during surgery. Intraoperative fluid administration (type of fluid and volume in mL), administration of blood products

	(type of blood product, number and volume in mL), and administration of blood product derivatives (type and volume).
Postoperative data	
Medical variables	Duration of orotracheal intubation and reintubation. Duration, type, and total dosage of catecholamines and postoperative VIS score. Thoracic drain output and urine output. Reoperation. As defined in in Table 1, MACE criterion will be recorded. Also, we will assess respiratory, infectious, neurological, and renal complications. Duration of stay in continuous care and duration of hospital stay.
Biological variables	Plasma hemoglobin, serum creatinine, urea, sodium, potassium, calcium, phosphorus, troponin US and BNP
General hemodynamic variables	heart rate, systolic, diastolic, and mean blood pressure, oxygen saturation and oxygen therapy administered.
Follow up visit	
Smartwatch Monitoring group	Number of single-lead ECGs performed, presence of POAF, duration of smart watch usage, clinical symptoms (EHRA as presented in appendix), duration of POAF, and treatment provided for POAF.
Conventional Monitoring group	Number of 12-lead ECGs performed, presence of POAF, clinical symptoms (EHRA in appendix), duration of POAF, and treatment provided for POAF

Abréviations

ECG: Electrocardiogram**; EHRA:** European Heart Rhythm Association**; MACE:** Major Adverse Cardiovascular Events**; POAF:** Postoperative atrial fibrillation**; VIS:** Vasoactive-inotropic score

Figure legends

Figure 1. Consort diagram. **ECG:** Electrocardiogram

Figure 2. Diagram of the study process**. MACE** Major Adverse Cardiovascular Events, **POAF** Postoperative atrial fibrillation.

Appendix: EHRA score. **European Heart Rhythm Association score:** Evaluation of symptomatology of patients with Atrial Fibrillation.

Trial status

The trial is not yet recruiting.

List of abbreviations

AF: Atrial fibrillation

EACTS: European Association for Cardio-Thoracic Surgery

***ECG:** Electrocardiogram*

EHRA: European Heart Rhythm Association

ESC: European Society of Cardiology

E-crf: electronic case report form

IRB: institutional review board

KDIGO: Kidney Disease: Improving Global Outcomes

LED: Light Emitting Diode

MACE: Major Adverse Cardiovascular Events

***POAF:** Postoperative atrial fibrillation*

TIA: Transient ischemic accident

PPG: photoplethysmography

VIS: Vasoactive-inotropic score

Declarations

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Competing interests

The authors declare that they have no competing interests.

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Author contributions

PH and CB participated in the design of the study and helped to write the manuscript. OAA, AI, GH, MG, TL, HD, and YM participated in the design of the study. MD will perform the statistical analysis. All authors read and approved the final manuscript. PH acted as guarantor.

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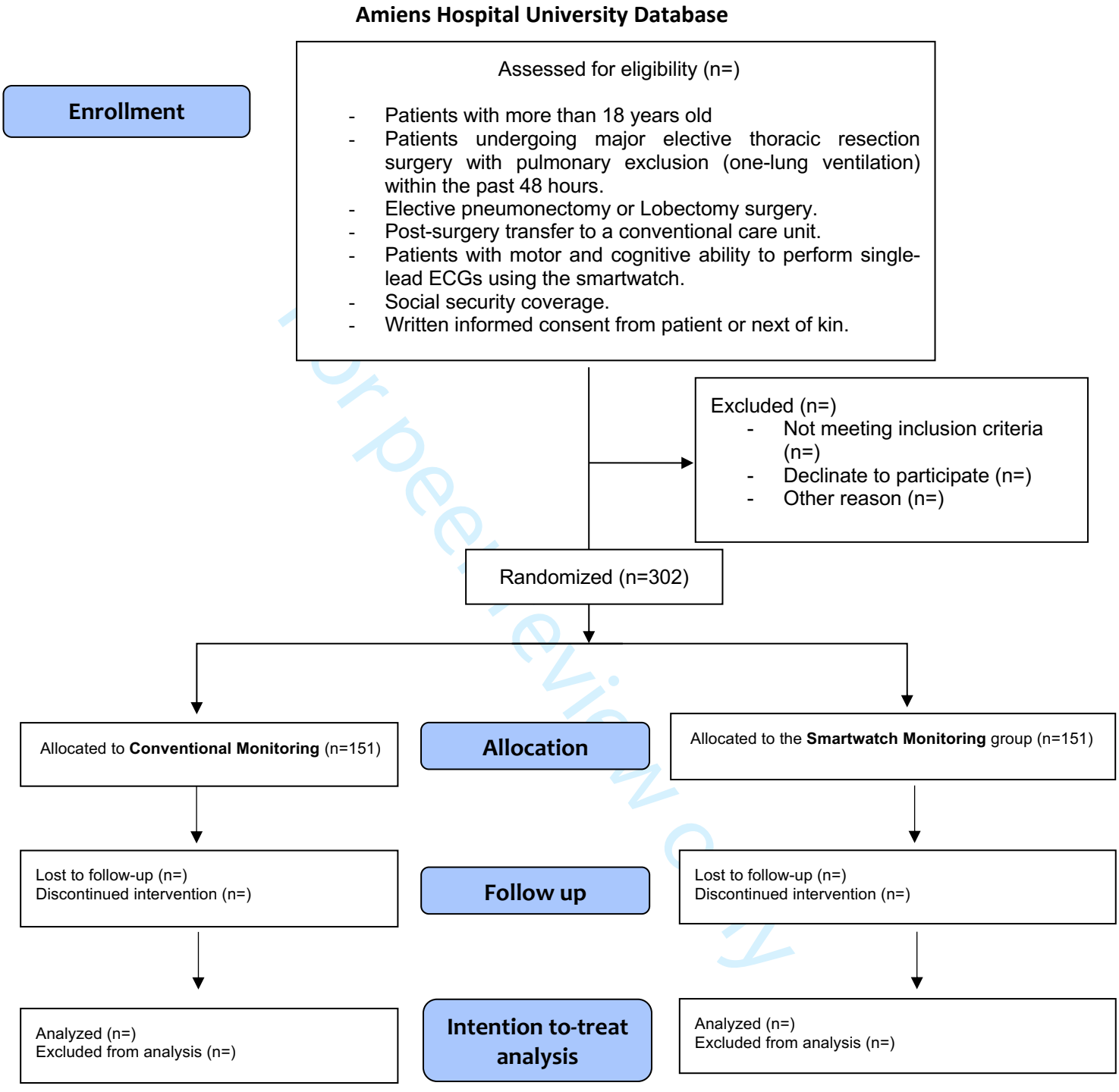
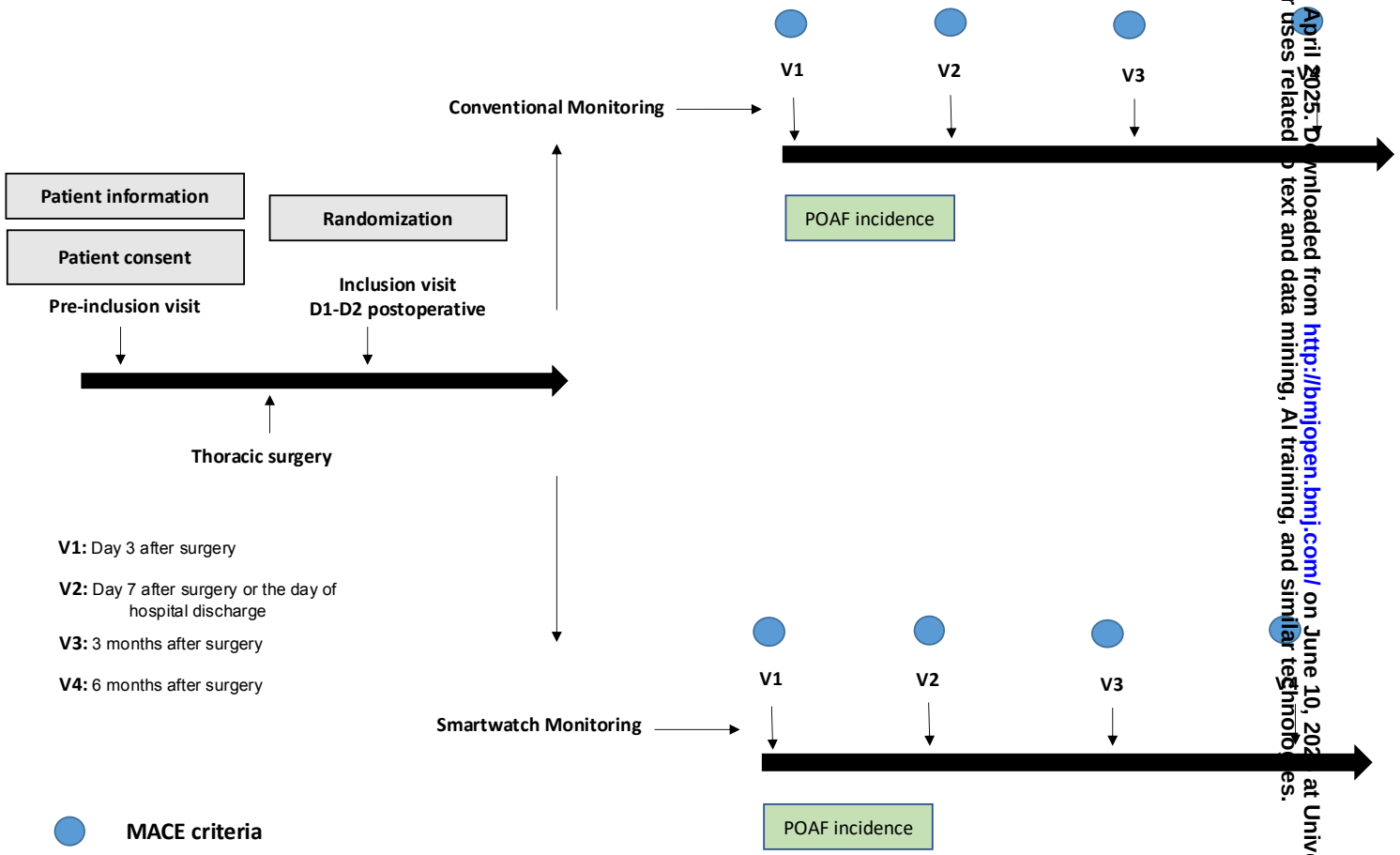
Figure 1. CONSORT diagram



ECG: Electrocardiogram;

Figure 2. Diagram of the study process



EHRA score	Symptoms
EHRA I	None: No symptoms.
EHRA II	**IIa:** Mild: Moderate symptoms not affecting daily life.
	IIb: Intermediate: Moderate symptoms not affecting daily life but causing discomfort for the patient.
EHRA III	Severe: Severe symptoms affecting daily life.
EHRA IV	Disabling: Symptoms necessitating the interruption of daily activities.

European Heart Rhythm Association score: Evaluation of symptomatology of patients with Atrial Fibrillation