Screening and Risk Analysis of Atrial Fibrillation after Radiotherapy for Breast Cancer: Protocol for a Cross-Sectional Cohort Study (Watch Your HeaRT – WATCH study)

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Abstract

Background: Post-radiotherapy atrial fibrillation (AF) in breast cancer (BC) patients is a relatively new and understudied topic. AF can increase the risk of stroke and other serious cardiovascular complications, compromising patients' quality of life and survival. Detection of AF, both asymptomatic and symptomatic forms, is therefore essential for optimal management.

Objective: The aim of the WATCH study is to assess the incidence of AF (symptomatic or asymptomatic) occurring throughout a 5-years follow-up after RT and to investigate whether cardiac radiation exposure is associated with the occurrence of such events.

Methods: WATCH is a cohort study that will include 200 patients over 65 years old, treated with radiotherapy for BC five years before inclusion, without history of AF. Cross-sectional screening for AF at the time of the scheduled five-year post-radiotherapy visit is conducted by recording data from a Withings ScanWatch smartwatch for one month, confirmed by an ECG, and validated by a physician. In addition, a transthoracic echocardiography is performed, providing comprehensive assessment of cardiac structures, and allowing to investigate underlying etiology and assess the risk of complications. Patient's medical record provides retrospective information on the timing and risk factors for the occurrence of AF and other arrhythmias and cardiac diseases during the 5 years following RT. The development of deep learning algorithms for auto-segmentation analysis of potentially critical sub-structures for the occurrence of AF, including cardiac chambers, sinoatrial node, atrioventricular node, coronary arteries, pulmonary veins, will produce dosimetry linked to previous radiotherapy treatment for all contoured structures.

Results: The inclusions started in October 2023 and will continue until mid-2026 to include 200 patients. The results are expected by the end of 2026.

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Keywords: breast cancer, radiotherapy, atrial fibrillation, smartwatches, arrhythmia, cardiac dosimetry

Introduction

Breast cancer (BC) is the most common cancer in women (1). Early detection and advances in treatment, including surgery, chemotherapy, hormone therapy, and targeted therapies, have significantly improved survival rates. Radiotherapy (RT) plays a crucial role in BC management by reducing the risk of local recurrence and improving overall survival, particularly following breast-

conserving surgery (2). Despite its efficacy, RT for BC can induce adverse effects on the heart, particularly when the heart is near the radiation field. Cardiac complications can include coronary artery disease, pericarditis, valvular heart disease, and myocardial infarction (3–5). Emerging evidence also indicates a risk of atrial fibrillation (AF) in BC patients that may manifest months to years after treatment (6,7). AF is a common cardiac arrhythmia characterized by irregular and often rapid heart rate (8,9), that can eventually lead to conditions with significant health impacts (stroke, heart failure, dementia). A challenge for AF detection is compounded by its frequent asymptomatic nature which often go undetected by retrospective non-interventional studies. It is therefore crucial to further investigate the risk of AF in BC patients as it may compromise the quality of life and survival of patients.

Atrial fibrillation in breast cancer patients

It has been shown that cancer patients have an increased risk for developing AF, varying according to cancer type and stage (7), and medical cancer treatments (10). It has been suggested that BC patients may also not be exempt from AF risk but results between studies are conflicting. A recent study based on Medicare database showed that incidence of AF was significantly higher in patients following the year of the diagnosis of BC, compared to a control population without cancer (3.3% vs. 1.6%, $p<0.05$) (6). With longer follow-up, several retrospective studies indicated higher AF rates in BC patients compared to the non-cancer population (11–18), but these results were not confirmed in a Danish cohort (19), a US case-control study (12) and a meta-analysis (16). Impact of age could explain such discrepancies between studies, as illustrated in a large cohort study, using the National Inpatient Sample database in the United States, based on 40,030,380 adults' hospitalizations for cancer where BC patients >80 years had an increased risk of AF (21). Similar results was observed in a systematic review and meta-analysis which found that BC older patients (age ≥65) had a 4.5 higher incidence of AF than BC younger patients (8.6% vs. 1.9%) (15).

Some scarce studies specifically analyzed the link between AF and RT for BC. In two studies, RT

was associated with a significant increased risk of AF when compared to a control population without cancer (RR 1.82 [1.07-3.08]) (22); HR 1.25 [1.05-1.48] (23)). However, in a US cohort study, the risk of AF was not significantly higher in patients with RT compared to general population (24).

Detection of atrial fibrillation: a challenge

Most of afore mentioned studies were retrospective and based on medical records and hospitalizations for identification of AF events, and thus presented the limitation of potential under-capture of events which is a concern for AF as explained below.

AF is the most common arrhythmia which concerns 1% of the general population and about 10 to 20% of subjects aged 80 years and more. The definitive method for diagnosing AF is through visual inspection of an electrocardiogram (ECG). While an irregular pulse might suggest the possibility of AF, an ECG is essential to confirm the diagnosis. Although persistent AF are easily detected, other forms are hard to diagnose, despite patient symptoms. This is due to the paroxysmal nature of many AF that might disappear on the way to the hospital for a 12-lead ECG evaluation. Holter monitoring might fail to detect paroxysmal AF if they do not occur on the day of examination. Moreover, AF may be asymptomatic (25) and the challenge in early detection of AF is compounded by its often asymptomatic nature, as approximately one-third of individuals with this arrhythmia are unaware of its presence (26). This has led to the concept of silent AF, which describes subclinical, asymptomatic episodes of paroxysmal AF.

To overcome these limitations of 12-lead ECG and Holter monitoring, advancements in wearable technology have led to the development of smartwatches with integrated ECG (30 seconds single-lead ECGs (SL-ECG) recording), which allow continuous monitoring of cardiac activity and can help to identify silent AF episodes that might be missed during a single evaluation (27–29). The effectiveness and reliability of ECG smartwatches for the detection of AF has been demonstrated in several studies (sensitivity from 55 to 97.3%, specificity from 60 to 98.2% (27,30–32)), in particular

for silent or paroxysmal AF, by measuring continuous cardiac frequency and SL-ECG (33–35). Moreover, ECGs generated by smartwatches were considered effective and non-inferior to ECG/composite 12 lead ECG/Holter/patch monitoring for AF detection (36,37), even if validation of diagnosis by a manual interpretation of physician is required (35). Regarding adherence rate of the smartwatch wearing in subjects over 65 years, the PulseWatch trial showed a decrease after one month (baseline 73%, day 30 63% $p<0.05$) (38), illustrating the limitations of a long period (> 1 month) of follow-up with smartwatch in the frame of an AF screening campaign.

Recently, the European Heart Rhythm Association published recommendations on the use of digital devices to detect and manage AF (39). It concluded that systematic screening by intermittent ECG may be beneficial to detect AF in individuals aged >65 years with comorbidities increasing the risk of stroke. RT has been shown to increase risk of cardiovascular and cerebrovascular diseases (4,40) in BC patients. It may thus be important to consider AF screening for patients who have undergone RT for BC due to their increased risk of cardiovascular complications. The interest and feasibility of opportunistic screening for AF in women treated with RT for BC were never investigated.

Relationship between cardiac radiation exposure and atrial fibrillation among breast cancer patients

Women treated with RT for BC present clinical characteristics at baseline that may induce higher risk of cardiac event independently of irradiation, and it is consequently crucial to consider cardiac dosimetry to better understand potential association between RT and the occurrence of AF, and then establish causality link. Association between mean heart dose and AF risk was poorly investigated. The NI-HEART study based on lung cancer patients found a dose-response relationship with HR 1.75 [1.03–2.97] (41). For BC, similar association with mean heart dose was observed with HR 1.23 [1.15-1.32] (42). However, radiation exposure of the heart during RT is not homogeneous, and mean heart dose is often not relevant to evaluate cardiac substructures RT doses (43) that may be more relevant to evaluate association with AF. Some studies have begun to explore the dosimetry of

cardiac substructures, and recent data have demonstrated associations between cardiac substructures doses and specific cardiac events and/or mortality in patients. In a cohort that included 238 esophageal cancer patients treated with RT, increasing mean left atrial dose was associated with AF risk (with 30% for every 10 Gray increase) (44). In the field of arrhythmias and conduction disorders, this was observed for right atrium and sinoatrial node and the risk of conduction disorders in patients with BC (45–47). In the case of AF, the arrhythmogenic tissue is often located in the pulmonary veins, but these structures are not yet considered as organs at risk during RT planning, despite potential relevant association as suggested in the NI-HEART study, that investigated pulmonary vein (PV) dose and risk of AF in patients with lung cancer following RT. Dose metrics for both the left (V55) and right (V10) PVs were associated with the incidence of new AF (HR 1.02 [1.00–1.03], p=0.005; and HR 1.01 [1.00–1.02], p=0.033, respectively) (48). Further research remains needed to accurately assess the doses absorbed by some of these substructures and to determine whether the exposure of certain potentially critical structures can better predict the risk of cardiac arrhythmias, particularly AF, in BC patients. Indeed, identifying critical substructures for AF in women undergoing RT for BC, and demonstrating the dose-risk relationship, could thus improve RT delivery protocols to limit the occurrence of these arrhythmias.

Manual contouring in radiation treatment planning is time-consuming, requiring meticulous effort to ensure precise delineation of volumes. In recent years, artificial intelligence, particularly deep learning-based auto segmentation models, has emerged to mitigate this workload. These models are employed for contouring organs at risk, offering significant improvements in consistency and efficiency, and substantially reducing the time required (49). However, such deep learning auto segmentation models are scarce or inexistant for specific sub cardiac structures such as conduction nodes (50) or PV (51), and remain to be developed.

Study rationale

Studies on AF and their potential link with RT for BC are relatively limited and have several limitations: the probable under-capture of AF events, particularly in the case of silent AF; the lack of details on the identification or diagnosis of AF and the lack of precise dose metrics data for cardiac substructures.

In the population of BC patients treated with RT, asymptomatic forms of AF are often missed in retrospective data collection, which typically identifies only symptomatic cases. Our study hypothesizes that at the time of the last follow-up visit, i.e., 5 years post-breast RT by the oncologist, an opportunistic single-timepoint screening combining the use of a smartwatch and a cardiological evaluation including an ECG and an echocardiogram could help to identify these asymptomatic cases. This would facilitate the management and potential treatment of these patients and increase the completeness of identifying incident cases 'potentially associated' with RT.

Cardiac irradiation related to RT for BC can lead to an increased risk of cardiovascular diseases a few months to several years after treatment. However, precise data for AF, to establish a potential dose-response relationship, are sparse. Our study hypothesizes that the risk of AF could be associated with the dose absorbed by critical cardiac substructures.

Objectives

In this context and to explore theses hypotheses, we have implemented the Watch Your HeaRT cohort study combining retrospective design and cross-sectional screening, which aims to investigate AF, including asymptomatic forms, that have occurred in BC patients during the 5 years following RT.

The primary objective of the study is to assess the incidence of symptomatic or asymptomatic AF occurring throughout a 5-years follow-up after RT and to identify non-radiation and radiation risk factors for the occurrence of such events.

The secondary objectives are to

- Perform a dosimetry evaluation of absorbed doses in the heart and cardiac substructures

(chambers, conduction nodes, coronaries, pulmonary veins), based on auto-segmentation models developed with deep learning algorithms.

- Investigate whether the risk of AF is associated with cardiac irradiation characterized by these absorbed doses.
- Assess incidence of other arrythmias or cardiac diseases throughout a 5-years follow-up after RT and analyze these risks according to the level of cardiac irradiation.
- Evaluate BC patient satisfaction and usability of the smartwatch with ECG.

Methods

Study design

WATCH is a cohort study implemented as a retrospective and cross-sectional study (52) that will include female patients with left- and right-sided BC treated with postoperative RT after primary breast-conserving surgery. A cross-sectional collection at least 5 years after RT at the time of the last follow-up visit with the oncologists is performed through smartwatches screening and a cardiology consultation (ECG and echocardiography) for AF detection. The retrospective collection of information is based on questionnaire delivered to the patient completed with medical records. Figure 1 shows the study design.

Ethical considerations

This study is conducted in accordance with the Declaration of Helsinki (amended at the 64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013) and in accordance with the principles of “Good Clinical Practice” and the Medical Research Involving Human Subjects Act (WMO). This project aims to evaluate a medical device, or a device used for non-medical purposes, and is framed by Regulation (EU) 2017/745 on medical devices (MDR). This study has received ethical approval from the French Southwest Committee for Protection of Persons and from National Agency for Medical and Health products Safety (IDRCB number: 2023-A01622-43). Participants enrolled in the study provide their written informed consent.

Study population

In this study, we plan to include 200 female patients with unilateral BC aged over 65 years old at inclusion, treated at least 5 years ago with postoperative modern photon-based RT after surgery. Patients with history of cancer or AF before RT, or with recurrent cancer (breast or other) after RT are excluded. Inclusion and exclusion criteria are summarized in Textbox 1.

Recruitment and study procedures

Patients are enrolled at Clinique Pasteur in Toulouse and at the François Baclesse Center for Cancer Control / Caen University Hospital in Normandy. Until now, the inclusions started only at Clinique Pasteur, Toulouse.

- ***Before inclusion***

Potential participants undergo prescreening by the oncologist during their final post-RT follow-up consultation (approximately 5 years after RT) to ensure eligibility. This is done before any study procedure is conducted. The participants are enrolled formally only after signing the informed consent form at the inclusion visit.

- ***Inclusion visit***

A medical questionnaire is completed by the participants to collect information on the medical history prior to RT, and all treatments and cardiovascular diseases that may have occurred since the end of RT (see details in Data Collection section below). The participants then receive a smartwatch *Withings ScanWatch* (Withings SA) and install on their smartphone the *Withings HeathMate* app to continuously record cardiac activity and register ECG. The watches are purchased by IRSN, the study sponsor. The choice of smartwatch *Withings ScanWatch* was based on several reasons. Many smartwatches with ECG recording currently meet the European Conformity (CE) standards. A recently published study (27) concluded that all evaluated devices have high diagnostic accuracy. An inclusion criterion for the WATCH study specifies that patients must own a smartphone, with no restrictions on the smartphone brand. An analysis of the user manuals of the different watches led us to choose the *Withings ScanWatch*, as it is the only one compatible with all smartphone brands. Moreover, feedback from the cardiologists involved in the study is positive regarding this

smartwatch: accurate ECG recordings, quite simple for patients to use, and good battery life. It should be noted that there is no conflict of interest for the investigators in the choice of the *Withings ScanWatch*.

The subjects are explained how to use the functions of the smartwatch and its application. Participants are required to wear the loaned smartwatch for one month, and record ECG at least once per day and/or when the smartwatch automatically detected abnormal heart rhythm and suggest the patient to record an ECG.

- ***Screening visit***

One month after inclusion visit, all recorded smartwatch-based ECG data (PDF file) are emailed by the patients to the study cardiologists. The patients complete a questionnaire to evaluate satisfaction and usability of the smartwatch with ECG, the smartwatch is reset and returned. The smartwatch is then loaned to another included patient. Finally, a cardiology consultation including 12-lead ECG completed with transthoracic echocardiography (TTE), providing comprehensive assessment of cardiac structures and functions, is performed (see details in Data Collection section below).

Data collection

- ***Cancer and treatment, medical history before and after RT***

Information on cancer and treatment (surgery, chemotherapy, radiotherapy, hormonotherapy) are collected through hospital medical records. The retrospective data collection of information, which aims to identify cardiovascular diseases prior to RT and those that occurred between RT and 5 years post-RT, is based on medical questionnaire fulfilled by the patient, checked with medical records (see Textbox 2).

- ***Cardiac examinations***

The cross-sectional data collection, which aims to identify AF and other cardiac diseases at 5 years post-RT not previously identified in the retrospective data collection, is based on screening for cardiac diseases. This screening is conducted by recording data from *Withings ScanWatch* smartwatch, confirmed by an ECG, and validated by a cardiologist. In addition to AF screening, a

12-lead ECG and a TTE are performed (see Textbox 3). Patient satisfaction and usability of the smartwatch are assessed using a satisfaction survey (53) and the System Usability Scale ('SUS' (54)) score (see Textbox 4).

- ***Cardiac dosimetry***

For cardiac dosimetry, auto-segmentation algorithms are being developed, based on artificial intelligence/deep learning to assess dose to potentially critical substructures for the occurrence of AF (whole heart, cardiac chambers, sinoatrial node, atrioventricular node, coronary arteries, pulmonary veins). For each patient included in the WATCH cohort, computed tomography (CT) images are collected with Digital Imaging and Communications in Medicine (DICOM) data. CT images will be contoured with our deep learning segmentation tool to provide mean doses and dose-volume histograms for all these cardiac structures.

Outcomes Measurement

- ***Primary outcome***

The difference in the occurrence of AF (questionnaire + SL-ECG based) throughout 5-years follow-up after RT according to heart exposure (moderate or low exposure (<75e percentile of dose distribution for whole heart) and high exposure (≥75e percentile of dose distribution)) will be measured as the primary outcome of interest for this study.

- ***Secondary outcomes***

The secondary outcomes are:

- Cardiac substructure dosimetry (including cardiac chambers, conduction nodes, coronary arteries, and pulmonary veins).
- Association between AF occurrence and cardiac substructures dosimetry.
- Occurrence of other arrythmias and conduction disorders (12-lead ECG based) throughout 5-years follow-up after RT.
- Occurrence of other cardiac dysfunctions, cardiomyopathies and valvular heart diseases (TTE-based) throughout 5-years follow-up after RT.

- Association between other arrythmias and conduction disorders, or other cardiac diseases occurrence, and cardiac substructures dosimetry.
- Patient satisfaction score using Lickert scale, and usability score using System Usability Scale (“SUS”).

Sample size calculation

The calculation of the required sample size was conducted within the framework of an exploratory study. The number of 200 patients was based on a statistical power of 80% with a Type I error rate of 5% and theoretical percentages of AF of 10% for the group of patients considered moderately exposed (<75th percentile of the average heart dose distribution) and 25% AF for the group of patients considered highly exposed (>75th percentile of the average heart dose distribution). It is planned to include these 200 patients in approximately 30 months.

Planned Statistical analysis

We will summarize the baseline data (description of the cancer and treatments, history of cardiovascular diseases, cardiac dosimetry) using descriptive statistics: means and standard deviation will be used for continuous data with normal distribution; medians and interquartile range for skewed data, and percentages for categorical data. Continuous data will be compared between control and intervention groups using the *t* -test or the Wilcoxon Mann-Whitney test, and the categorical variables will be compared using the chi-square test. All tests will be bilateral with alpha=5%.

The estimation of the incidence of AF and other cardiovascular pathologies occurring in the 5 years following RT will be carried out based on data collected during the cardiology consultation (SL-ECG screening, 12-lead ECG, and echocardiography) and the medical questionnaire. A univariate analysis using regression models will identify the risk factors associated with the studied cardiovascular pathologies other than cardiac exposure (i.e., individual and medical characteristics). Subsequently, only variables with a p-value <0.20 will be retained for multivariable analyses. Estimations of the risk of AF and other cardiovascular diseases according to cardiac doses will be performed using regression models, adjusted for the risk factors identified

in the univariate analyses. Analysis will be done using the Data Analysis and Statistical Software: SAS, version 9.4.

Results

The study is still in progress. Inclusions began in October 2023 and aim to cover 200 patients until mid-2026. The results are expected by the end of 2026.

Discussion

This study protocol aims to evaluate the risk of AF in BC patients who have undergone RT, addressing a critical gap in understanding cardiovascular complications of BC treatment. AF is a common arrhythmia with potential to cause severe complications, and its risk may be heightened by the incidental cardiac exposure during RT for BC. Given the increasing survival rates in BC patients, assessing long-term cardiovascular outcomes has become essential for optimizing post-treatment care.

Several studies have investigated the association between RT for BC and AF (6,22,55), but these studies did not provide precise dosimetry data for cardiac substructures and it remains unclear whether this association is causative, or whether cancer and AF just share the same pathophysiologic mechanisms. Our study aims to enhance our understanding of how radiation dose distribution across specific cardiac regions correlates with AF incidence. Our study's approach involves detailed dosimetry analysis of cardiac substructures based on deep-learning based auto-segmentation, including the left and right atria, left and right ventricles, coronary arteries, conduction system and pulmonary veins. This precision in quantifying radiation doses received by these areas will allow for a more granular assessment of radiation exposure and its impact on AF risk, distinguishing it from studies that evaluated whole-heart doses (22). Univariate and multivariable regression analyses will be employed to isolate the effects of these localized doses while adjusting for confounding factors such as age, comorbidities, and chemotherapy. This will provide an understanding of the dose-response association and help to identify high-risk cardiac regions.

With retrospective design, previous studies that investigated AF occurrence in BC patients may have under-captured of AF events, particularly in the case of silent AF. Traditional methods, such as standard ECG and echocardiography, have proven efficacy in detecting AF but often lack continuous monitoring capability, essential for capturing transient AF episodes. Smartwatches, equipped with SL-ECG, offer a promising adjunct, providing continuous real-time data on heart rhythm. To investigate AF incidence over five years post-RT, our study is combining retrospective patient-reported outcomes and cross-sectional screening based on smartwatches in addition to traditional diagnostic methods (ECG and echocardiography). Patient questionnaires capture symptoms and medical history, offering a broader context for interpreting cardiovascular health and identifying potential non-cardiac factors influencing AF risk. ECG and echocardiography will provide objective data on cardiac rhythm disturbances, structural and functional cardiac abnormalities. More particularly in patients with AF, echocardiography will allow to investigate underlying etiology and assess the risk of complications, while patient's medical record will provide information on the timing and risk factors for the occurrence of AF and other arrhythmias/conduction disorders during the 5 years following RT. This multimodal approach will allow for a comprehensive understanding of AF development, in the context of radiation exposure and patient-specific factors.

However, this study presents several limitations. First, the sample size is relatively small, which, while suitable for an exploratory analysis, will limit the generalizability of our findings. Future studies should incorporate larger cohorts to enhance the statistical power and validity of the results. Second, the study population is limited to older age categories, potentially overlooking age-related variability in radiation-induced AF risk. Expanding the research to include a broader age range will provide a more comprehensive understanding of the age-dependent effects. Last, the follow-up period is limited to five years and AF screening performed 5 years after RT. This duration and opportunistic single-timepoint screening may not fully capture the long-term incidence of AF or the shorter effects post-RT, suggesting the need for both shorter-term and extended follow-up in future investigations to better understand the timing and progression of AF post-treatment.

To conclude, this study will refine our understanding of radiation-induced AF after RT, a topic almost absent from the ESC guidelines in Cardio-Oncology (56). Given the relatively high incidence rate of AF from a certain age in the general population, identifying an increased AF risk linked to RT could result in a significant number of RT-attributable cases. Detecting silent AF may necessitate medical/preventive management for certain patients to limit the risk of stroke. The use of smartwatches has never been studied in a specific population such as patients treated with RT for BC. This study will evaluate the interest of patients and cardiologists in this type of connected tool within this population. The results of this project could provide recommendations for primary and secondary prevention strategies to limit RT sequelae and improve patients' quality of life.

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Conflict of Interest

None declared

Authors' contributions

Study conception and design: SJ, BP, LP, GJ, YK, JC, DB, MOB, CM, CL, SB, JT. Patient recruitment: BP, LP, GJ, SB. Drafting and revision of manuscript: LSL, SJ. All authors read and approved the final manuscript.

List of abbreviations:

3D CRT: 3D conformal radiation therapy

AF: Atrial fibrillation

BC: Breast cancer

ECG: Electrocardiogram

ESC: European Society of Cardiology

HR: Hazard Ratio

IRSN: Institute of radioprotection and nuclear security

PV: Pulmonary veins

RR: Relative Risk

RT: Radiotherapy

SL-ECG: Single-lead electrocardiogram

TTE: transthoracic electrocardiogram

WATCH: Watch Your HeaRT

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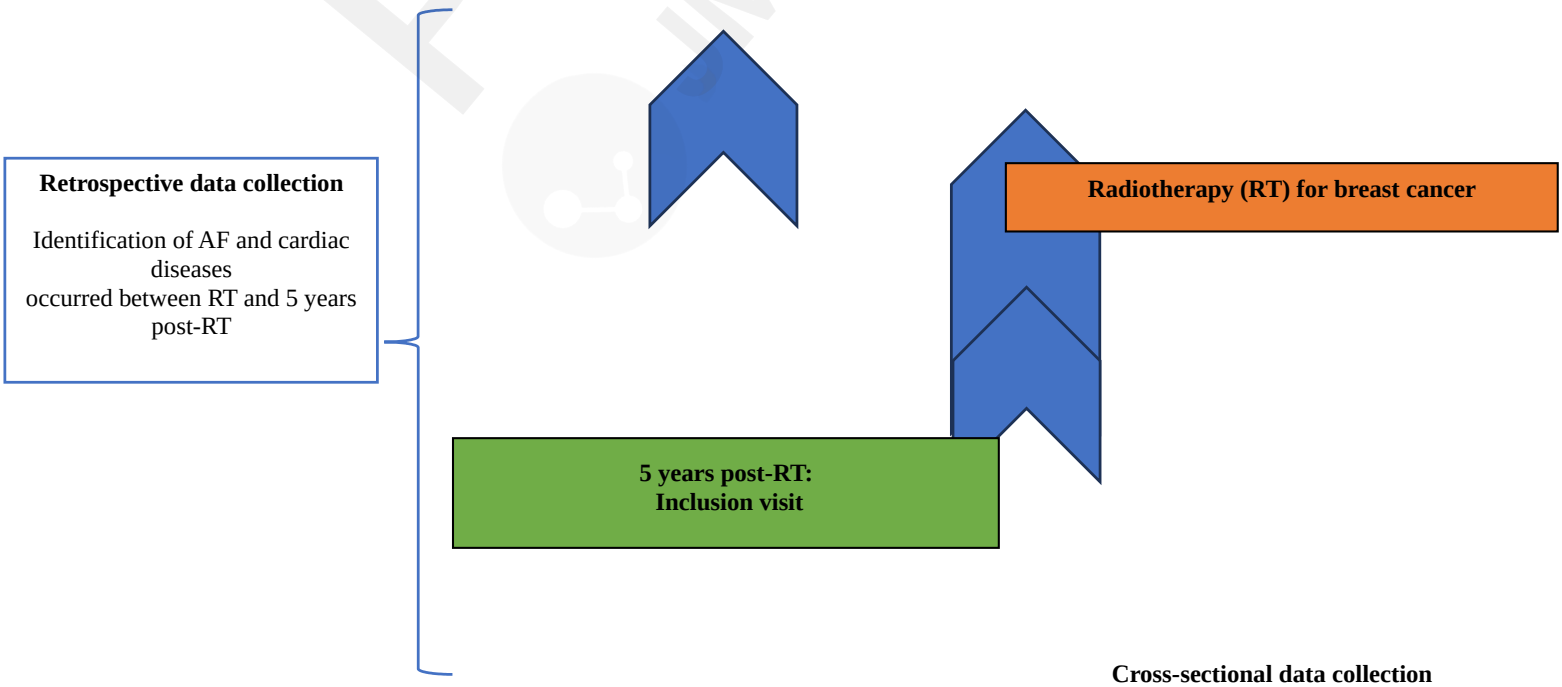

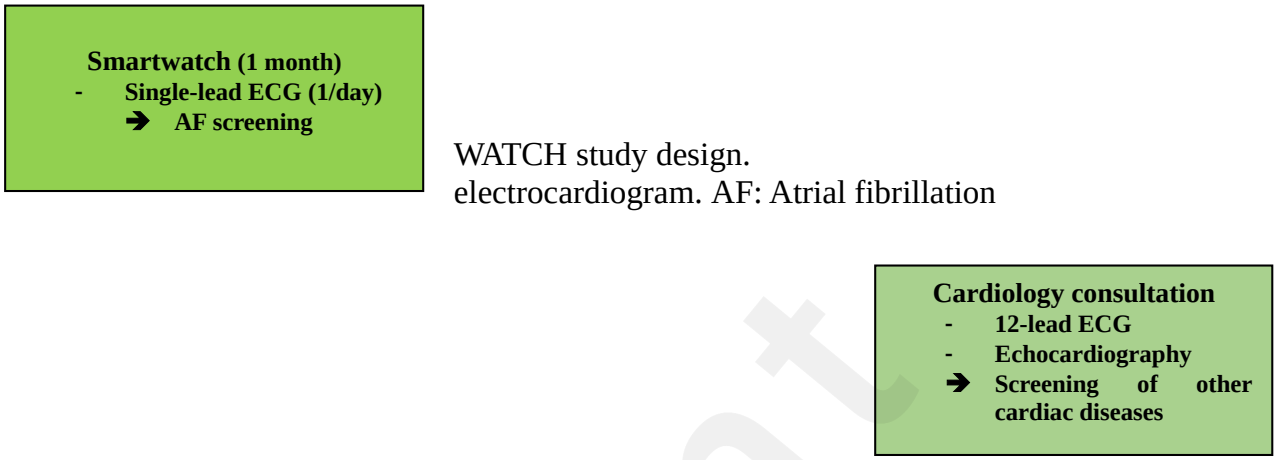

Figure 1: WATCH study design.
ECG: electrocardiogram. AF: Atrial fibrillation

Textbox 1: **Inclusion and exclusion criteria.**

Inclusion criteria	Exclusion criteria
• Women surgically treated for left or right breast cancer (BC), and for whom adjuvant treatment is radiotherapy (RT) with irradiation of the breast or chest wall irradiation and possibly ganglion chains. • Adjuvant RT performed between 5 years before inclusion. • 5-year post-RT follow-up oncologist consultation performed in one of the investigating centers. • Age 65 years and more at inclusion. • Own a smartphone and be able to understand and use digital tools alone and/or with the help of a caregiver. • Consent to a connected follow-up. • Be affiliated with a social security system or equivalent. • Being volunteer to participate in the study and having signed the consent form.	• History of cancer before RT for BC. • History of atrial fibrillation before RT for BC. • Recurrent cancer (breast or other cancer) after RT for BC.

Textbox 2: Medical questionnaire - list of items.

Provide answer for each item: Yes/No, date if yes

Cardiovascular conditions

- Congenital Heart Malformation
- Pulmonary Hypertension
- Carotid Stenosis
- Transient Ischemic Attack
- Stroke
- Intermittent Claudication
- Atherosclerosis
- Aortic Aneurysm
- Deep Vein Thrombosis
- Family History of Myocardial Infarction

Respiratory conditions

- Chronic Obstructive Pulmonary Disease
- Pulmonary Embolism

Endocrine conditions

- Hyperthyroidism
- Hypothyroidism
- Thyroidectomy
- Metabolic Syndrome
-
-

Cardiac diseases

- Acute Myocardial Infarction
- Recurrent Myocardial Infarction
- Coronary Angioplasty +/- Stent
- Coronary Artery Bypass
- Angina Pectoris
- Heart Failure
- Cardiomyopathy
- Endocarditis
- Pericarditis
- Myocarditis
- Valvular Heart Disease
-

Cardiovascular treatments: type, date of start of treatment

Cardiac arrhythmias

- Sinus Node Dysfunction
- First-Degree Atrioventricular (AV) Block
- Second-Degree AV Block
- Complete AV Block
- Left Bundle Branch Block
- Right Bundle Branch Block
- Permanent Atrial Fibrillation and AV Block
- Ventricular Fibrillation (VF)
- Ventricular Tachycardia (VT)
- Polymorphic VT / Torsades de Pointes
- Syncope with Inducible VT or VF
- Prophylactic (Undocumented)
- Supraventricular Tachycardia
- Wolff-Parkinson-White Syndrome
- Atrial Fibrillation
- Atrial Flutter
- Atrial Tachycardias
- Cardiac Arrhythmia, Unspecified

Treatment for cardiac arrhythmia

- Antiarrhythmic Treatments (Amiodarone, Flecainide, Propafenone, Sotalol, Beta-Blockers, Verapamil, Digoxin…)
- Anticoagulant Treatments: VKAs (Fluindione, Acenocoumarol, Warfarine), DOACs (Dabigatran, Rivaroxaban, Apixaban)
- Pacemaker Implantation
- Defibrillator Implantation
- Resynchronization

- Ablative Treatment: Ablations of Flutter, AF, Atrial Tachycardia, AVNRT, Accessory Pathway, VT…

Textbox 3: Cardiology consultation: list of items.

Provide answer for each item: Yes/No, date if yes

- Age; Weight; Height
- Blood Pressure
- Hypertension
- Smoking status
- Dyspnea (NYHA)
- Diabetes
- Cardiovascular Treatments
- Non-cardiovascular Treatments
- Fasting Blood Glucose; Urea; Creatinine; eGFR
- LDL Cholesterol; HDL Cholesterol; Total Cholesterol; Hypercholesterolemia; triglycerides
- CHA2 DS2 VASc score
- HAS-BLED score

Smartwatch ECG

- Number of abnormal heart rhythm alerts
- Number of recorded ECGs
- Number of suspected episode(s) of AF
- Analysis of smartwatch ECG tracings, comments

12-lead ECG

- Sinus Rhythm: Yes / No
- Atrial Fibrillation: Yes / No
- Other Rhythm (please specify)
- PR Interval Duration: …… msec
- AV Block: Yes / No – If yes, please specify: 1st Degree AV Block / 2nd Degree AV Block Mobitz Type 1 / 2nd Degree AV Block Mobitz Type 2 / 3rd Degree AV Block
- QRS Duration
- Bundle Branch Block: Yes / No – If yes, please specify: Right Bundle Branch Block / Left Bundle Branch Block / Other
- QRS Axis
- Premature Atrial Contractions (PAC): Yes / No – If yes, specify the number
- Premature Ventricular Contractions (PVC): Yes / No – If yes, specify the number
- Myocardial Infarction Sequelae: Yes / No – If yes, specify the territory
- Normal ECG: Yes / No

Transthoracic echocardiography
Echogenicity: ……
Aortic Root:

- Sinuses: …… mm;
- Sino-tubular Junction: …… mm;
- Segment I: …… mm.

Pulmonary Valve: Normal, physiological micro-regurgitation

Left Ventricle:

- IVSd: …… mm; LVEDD: …… mm; LVESD: …… mm; LVPWd: …… mm
- LVEF: …… % by biplane Simpson
- Global Longitudinal Strain …… %
- Indexed End-Systolic Volume: …… mL/m²;
- Indexed End-Diastolic Volume: …… mL/m²
- Normal segmental wall motion

Aortic Valve:

- Tricuspid
- LVOT diameter: …… mm; LVOT VTI: …… cm
- Ao VTI: …… cm
- Mean Gradient: …… mmHg; VMax: …… m/s; Velocity Ratio: ……
- Aortic Valve Area: …… cm²
- No regurgitation

Mitral Valve:

- Normal, no regurgitation, no stenotic effect
- Mean Gradient: …….. mmHg; Mitral Valve Area: ……..

Left Atrium: …….. mL/m²

- Reserve strain: …….%
- Systolic strain: ……..%

Right Atrium: …… cm²

Right Ventricle:

- RVEDA: ……. mm²; RVESA: …… mm²; FAC: …… %
- TAPSE: …… mm; S' wave: ……. cm/s; Free Wall Strain (3 segments): …… %
- No RVH

Tricuspid Valve: Normal, physiological micro-regurgitation

Pulmonary Pressures:

- Pulmonary Acceleration Time: …… ms
- sPAP: …….. mmHg
- mPAP: ……. mmHg
- dPAP: …… mmHg

Volumetric Parameters:

- E/A = …….. ; E/E'lat = ……. ; S/D = …….
- IVC: …….

Pericardium Dry ……..

Textbox 4: Questionnaire to evaluate patient satisfaction and usability of the smartwatch with ECG.

For each question, use the five-level scale below to answer:

1- Strongly disagree	2- Disagree	3- Neither agree nor disagree	4- Agree	5- Strongly agree

First set of questions for satisfaction (Lickert scale):

- I understand the benefits of using this smartwatch.
- The smartwatch meets my health and clinical monitoring needs.
- The smartwatch is easy to use and understand.
- The services offered by the smartwatch are useful.
- I did not encounter any malfunctions, unavailability, connection issues, or errors while using the smartwatch.
- I find that the smartwatch integrates well into my medical monitoring and does not disrupt my current medical care.
- The smartwatch improves my current medical care.
- The smartwatch does not require additional time for my current medical care and can potentially also save me time.

Second set of questions for usability (SUS):

- I think that I would like to use this system frequently.
- I found the system unnecessarily complex.
- I thought the system was easy to use.
- I think that I would need the support of a technical person to be able to use this system.
- I found the various functions in this system were well integrated.
- I thought there was too much inconsistency in this system.
- I would imagine that most people would learn to use this system very quickly.
- I found the system very cumbersome to use.
- I felt very confident using the system.
- I needed to learn a lot of things before I could get going with this system.

Supplementary Files

Figures

WATCH Study design.